Abstracts from the
34th Annual Meeting of the
Consortium of Multiple Sclerosis Centers
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The editorial team is pleased to present this supplement to the International Journal of MS Care (IJMSC) containing the abstracts from the 2020 Virtual Annual Meeting of the Consortium of Multiple Sclerosis Centers (CMSC). These abstracts include platform, poster, and Whitaker Research Track presentations, as well as a few late-breaking abstracts. In these unusual times, we all have had to modify many of our activities due to the COVID-19 pandemic, including the introduction of virtual scientific meetings. While the CMSC generously offers free registration to this meeting, many health care providers may not have the time to attend the live online sessions. The print version of this supplement is being distributed to members of the CMSC. The electronic version will be available to all on the IJMSC website at ijmsc.org.

We would like to thank Sanofi Genzyme for their support, which made this publication possible.

While reading abstracts does not completely replace in-person networking, our team hopes that this supplement will attest to the fact that the desire to share innovation and research has not been extinguished by the pandemic. We hope that you and your loved ones are keeping safe in these challenging times.

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(REH27) Cognitive Processing Speed as a Predictor of Motor Skill Learning in Healthy Adults and Persons with Multiple Sclerosis

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Real-World Evidence Assessment of Betaseron (interferon beta-1b) Adherence Following the Introduction of the BETACONNECT Autoinjector

A Unique Case of a Patient with Tuberous Sclerosis and Recent Diagnosis of Neuromyelitis Optica

Shorter Infusion Time of Ocrelizumab: Primary Results from the ENSEMBLE PLUS Study in Patients with Relapsing-Remitting Multiple Sclerosis

Effect of Ofatumumab on Serum Immunoglobulin Levels and Infection Risk in Relapsing Multiple Sclerosis Patients from the Phase 3 ASCLEPIOS I and II Trials

Ofatumumab Versus Teriflunomide in Relapsing Multiple Sclerosis: Analysis of No Evidence of Disease Activity (NEDA-3) from the ASCLEPIOS I and II Trials

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Efficacy and Safety of the Bruton’s Tyrosine Kinase Inhibitor (BTKI) Evobrutinib in Adults with Neuromyelitis Optica Spectrum Disorder

Ofatumumab-Treated Patients with Relapsing-Remitting Multiple Sclerosis Report Better “Feel-Good” Outcomes on Key Physical, Emotional, and Cognitive Domains Compared to Other Disease-Modifying Therapies
Background: To date, delayed-release dimethyl fumarate (DMF) exposure during pregnancy has not shown any safety signals in clinical trials and postmarketing data, however the DMF label recommends use during pregnancy only if potential benefit justifies the potential risk to the fetus. In the general population, 62% of pregnancies end in live birth, 22% end in induced abortion, and 16% end in fetal loss. Similar rates have been observed in patients with multiple sclerosis (MS). Objectives: An international registry (trial registration: NCT01911767) was started to prospectively evaluate pregnancy outcomes in women with MS exposed to DMF since 1 day before the first day of their last menstrual period before conception and results are reported for the United States as well as the overall population. Methods: In this ongoing registry, data were collected at enrollment, 6-7 months of gestation, 4 weeks after estimated delivery date, and at 4, 12, and 52 weeks after birth. Infant and maternal outcomes included ectopic and molar pregnancies, birth defects, complications of delivery, or infant death occurring at ≤52 weeks of age, and maternal death at ≤12 weeks postdelivery. Potential birth defects were adjudicated by an external expert. Gestational size was classified as small (<10th percentile), appropriate (10th–90th), or large (>90th) based on standardized growth charts. Results: As of April 2019, 263 patients were enrolled; 57 in the United States. Median gestational week at first DMF exposure was 1 (range, 1-13); median fetal DMF exposure duration was 5 (range, 0.1-40) weeks. Of the 214 pregnancy outcomes reported to date, 197 (92%) were live births and 17 (8%) fetal losses. In the United States, 38 pregnancy outcomes have been reported to date, 34 (89%) live births and 4 (11%) fetal losses. Of infants with known gestational age (n = 194), 176 (89%) births were fullterm and 18 (9%) prematurity (<37 weeks). In the United States, 30 (97%) births were full-term and 1 (3%) premature. There were 16 spontaneous abortions (4 in US; 1 ectopic pregnancy outside of US), and 1 fetal death at ≥28 weeks’ gestation. No perinatal, infant, or maternal deaths were reported. Infants [1.63 with gestational size data] were classified as small 18 (11%), appropriate 134 (82%), and large 11 (7%). Seven (4%) infants had confirmed birth defects. Conclusions: The adverse pregnancy outcome frequencies from the interim analysis did not exceed those observed in the MS and general populations. No safety signal has been observed to date.

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Results: This research highlighted the complexity of aging with MS and the various ways persons older than 60 with MS experience and interpret this phenomenon. Most participants experienced a continued progression of physical and cognitive deficits, however aging narratives and what is culturally expected as a person older than 60 allowed for positive interpretations of age-related behaviors from an earlier age, while others believed they had “aged out” of MS and were experiencing a peak of health and wellness. Participants who were diagnosed in middle age, however, noted a sharp enhancing behaviors from an earlier age, while others believed they had "aged out" of MS and were experiencing a peak of health and wellness. Participants who were diagnosed in middle age, however, noted a sharp progression of age-related and MS symptoms, but stated "everyone has something" and perceived the diagnosis of MS was less impactful in younger age with regards to what is expected at this life stage. Concerns remained, however, regarding whether a new physical or cognitive experience was aging or MS, what the future holds regarding losing independence, losing spouses and caregivers, and growing "too old" such that quality of life is completely diminished. Conclusions: This qualitative research has highlighted the complexity of aging with MS. All participants noted a context for progression of MS symptoms. Cynicism, lack of control, and a negative interpretation of the symptoms, however, are not culturally aligned with aging narratives. Fears about the future do remain as participants were concerned about living too long for being able to thrive. More research must be done that focuses on maintaining quality of life among older person with MS as quality of life continues to increase.

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Keywords: Aging and MS, Management of activities of daily living in MS

(DAM04) Serum Glial Filibrillary Acidic Protein Is Elevated in a Subset of Neuromyelitis Optica Patients and Associated with Increased Risk of Attack

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Background: In patients with neuromyelitis optica spectrum disorder (NMOSD), pathogenic anti-aquaporin-4 antibodies cause astrogial injury resulting in increased levels of cerebrospinal fluid glial fibrillary acidic protein (GFAP). NM-Omamentum is a randomized, placebo-controlled, double-masked trial depleting antibody, in patients with NMOSD, in an effort to investigate the relationship between prospectively sampled serum GFAP (sGFAP) levels and disease activity in NM-Omamentum trial participants. Methods: sGFAP (Quanterix Simoa GFAP assay) was measured in 1260 serial and attack-related samples from N-MOmentum participants (n = 220) and in healthy controls (n = 25); the relationship between sGFAP levels and NMOSD attacks was assessed in N-MOmentum participants. Results: Median (interquartile range [IQR]) sGFAP levels were elevated in patients with NMOSD compared with controls (128.3 [92.5, 182.1] pg/mL vs 73.3 [52.1, 108.7] pg/mL). Elevated sGFAP, defined as ≤3 SDs above the control mean ≤171 pg/mL, was observed at baseline in 29% (61/215) of NMOSD study participants. Study participants with elevated baseline sGFAP levels were 2.9 times more likely to experience an adjudicated NMOSD attack than those with lower baseline sGFAP during the 28-week randomized controlled period (RCP; P = .002). During the RCP, sGFAP levels increased significantly within 1 week of an NMOSD attack in placebo-treated participants (median fold change [IQR]; 2010 [4.4, 98.3]; n = 17 attacks; P = .001) but did not increase significantly during attacks in inoblinizumab-treated participants (11 [0.75, 24.6] = 2010 [4.4, 98.3]; n = 0). Of 62 participants who did not have an adjudicated NMOSD attack during the RCP, there were fewer inoblinizumab- than placebo-treated participants with elevated sGFAP levels at the end of the RCP (16% [19/117] vs 35% [9/26]). Of 514 samples drawn from inoblinizumab-treated patients during the RCP who did not have adjudicated attacks, 14 samples (2.7%) from 12 patients displayed ≥2-fold increase in sGFAP from baseline to samples (n = 116; 8%) from placebo-treated patients (odds ratio: 3.0, P = .023). Conclusions: Study participants with NMOSD had increased sGFAP levels compared with controls. sGFAP may prove to be a useful biomarker of attack risk and disease activity and severity.

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**DISEASE MODIFYING THERAPY**

(DMT01) Comparative Effective-ness of Switching from Natalizumab to a Moderate- Versus High-Efficacy Disease-Modifying Therapy in Clinical Practice

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**Background:** Natalizumab (NTZ) is a highly effective disease-modifying therapy (DMT) for relapsing multiple sclerosis (MS). Long-term use of NTZ is limited by potential safety risks that can be reduced by switching to an alternative therapy. However, NTZ discontinuation may trigger rebound disease, resulting in disability. Our previous study showed patients switching to moderate- (Mod) DMT vs high-efficacy therapy (HET) were at higher risk of early magnetic resonance imaging (MRI) disease activity by 6 months. **Objectives:** To assess the comparative effectiveness of switching from NTZ to a Mod DMT vs HET in patients with MS over 24 months. **Methods:** HET Patients discontinuing NTZ at 2 MS centers (n = 556) who switched to Mod DMT (n = 270) vs HET (n = 130) were assessed using propensity score (PS) weighting. PS model covariates included demographics and baseline clinical and radiographic disease characteristics. Outcomes included annualized relapse rate and proportions with new T2 and/or gadolinium-enhancing (GdE) lesions, absence of disease activity (a composite measure of no relapses and/or MRI activity

**Keywoords:** Disease-modifying treatments in MS, Imaging and MS
(DMT02) Yearly Efficacy and Safety Outcomes Over 4 Years After Last Alematuzumab Course in Pooled CARE-MS I and II Patients by Number of Additional Courses Received During Year 9


Background: In CARE-MS I and II (trial registration: NCT00530348, NCT00548405), alemtuzumab treatment (12 mg/day; baseline: 5 days; 12 months: 3 days) improved clinical and magnetic resonance imaging (MRI) outcomes vs subcutaneous interferon beta-1a over 2 years in patients with relapsing-remitting multiple sclerosis (MS). In 2 consecutive extensions (NCT00930553, NCT02255656 [TOPAZ]), patients could receive additional alemtuzumab (12 mg/day; 3 days; ≥12 months apart). Objectives: Evaluate yearly efficacy and safety of alemtuzumab in pooled CARE-MS patients who did or did not receive additional alemtuzumab through year 9. Methods: Pooled CARE-MS patients were stratified by the total number of courses received (exactly 2 courses, exactly 3 courses, ≥4 courses). Inclusion criteria: additional alemtuzumab (ie, courses 3 or 4) received by month 97 to allow ≥12 months of follow-up; no other disease-modifying therapy per year 9. Data were censored at last available follow-up in the ≥4-courses groups. Outcomes data were reevaluated after the last alemtuzumab course. Results: 742/811 (91%) alemtuzumab-treated patients entered the extension and could receive additional courses; courses 3 and 4 were given most frequently in years 3 (19%) and 4 (6%), respectively. Of 742 extension patients, 359 (48%), 182 (24%), and 121 (16%) were included in the 2-, 3-, and ≥4-courses groups, with 303, 76, and 15 remaining in study year 4 after last course, respectively. Over 4 years after last course, annualized relapse rate was 0.07, 0.06, and 0.05 in the 2-, 3-, and ≥4-courses groups, respectively, and change in mean Expanded Disability Status Scale score at year 4 after last course was −0.06, +0.08, and +0.56, respectively. Over 4 years, 83%, 85%, and 94% were free of 6-month confirmed disability worsening, and 23%, 11%, and 5% had 6-month confirmed disability improvement in the 2-, 3-, and ≥4-courses groups, respectively. Serious adverse events were generally similar between cohorts during years 1-3 after last treatment (5.1%-11.4% per year), but low patient numbers in the ≥4-courses group confounded analysis of serious adverse events in year 4 after last course. Conclusions: Efficacy of additional alemtuzumab was maintained over 4 years after last course in CARE-MS patients, although the ≥4-courses group had higher disease activity and disability, as expected. Alemtuzumab safety was generally consistent between groups, except for the 4-courses cohort in year 4 after last course wherein interpretation was limited by low numbers of available patients.

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Keywords: Comparative effectiveness, Disease-modifying treatments in MS

(DMT03) Efficacy and Safety of Ofatumumab Versus Teriflunomide in Patients with Relapsing Multiple Sclerosis: Phase 3 ASCLEPIOS I and II Trials

Anne H. Cross,1 Ludwig Kappos,1 Amit Bar-On,2 Jeffrey A. Cohen,4 Giancarlo Comi,5 Jorge Correale,6 Patricia K. Coyle,7 Jerome de Seze,8 David Leppert,9 Xavier Montalban,10,11 Klára M. Hersh,12 Ludwig Kappos,1 Amit Bar-On,2 Jeffrey A. Cohen,4 Giancarlo Comi,5 Jorge Correale,6 Patricia K. Coyle,7 Jerome de Seze,8 David Leppert,9 Xavier Montalban,10,11

Background: Over the last 5 years, 5 clinical trials (if received) in the ≥4-courses groups. Outcome data were reevaluated after the last alemtuzumab course. Results: 742/811 (91%) alemtuzumab-treated patients entered the extension and could receive additional courses; courses 3 and 4 were given most frequently in years 3 (19%) and 4 (6%), respectively. Of 742 extension patients, 359 (48%), 182 (24%), and 121 (16%) were included in the 2-, 3-, and ≥4-courses groups, with 303, 76, and 15 remaining in study year 4 after last course, respectively. Over 4 years after last course, annualized relapse rate was 0.07, 0.06, and 0.05 in the 2-, 3-, and ≥4-courses groups, respectively, and change in mean Expanded Disability Status Scale score at year 4 after last course was −0.06, +0.08, and +0.56, respectively. Over 4 years, 83%, 85%, and 94% were free of 6-month confirmed disability worsening, and 23%, 11%, and 5% had 6-month confirmed disability improvement in the 2-, 3-, and ≥4-courses groups, respectively. Serious adverse events were generally similar between cohorts during years 1-3 after last treatment (5.1%-11.4% per year), but low patient numbers in the ≥4-courses group confounded analysis of serious adverse events in year 4 after last course. Conclusions: Efficacy of additional alemtuzumab was maintained over 4 years after last course in CARE-MS patients, although the ≥4-courses group had higher disease activity and disability, as expected. Alemtuzumab safety was generally consistent between groups, except for the 4-courses cohort in year 4 after last course wherein interpretation was limited by low numbers of available patients.

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Disclosure: Regina Berkovich: Acorda, Avantor, Bayer, Biogen, Novartis, Questcor, Sanofi, Teva (advisory boards, consulting fee), BielAlmambey; Bayer-Biogen, GlaxoSmithKline, Lundbeck, Merck, Novartis, Roche, Sanofi (speaking honoraria, research grants, scientific advisory boards). Ann D. Bass: Actelion, Biogen, EMD Serono, Mallinckrodt, Novartis, Roche-Genentech, Sanofi, TG Therapeutics (consulting fees for non-CME services from commercial interests or their agent/grantee and support). Aaron L. Boster: Biogen, Mallinckrodt, Medtronic, Novartis, Sanofi (consulting fees and/or fees for non-CME services); Giancarlo Comi: Almirall SpA, Biogen, Bial Ferring Italia Srl, Celgene, EXELA, Hoffmann-La Roche, Merck, Sanofi, Teva (travel support, speaking honoraria, lecture honoraria, unconditional research grants); Heinz Wiendl: Bayer, Merck, Roche (consulting fee, contracted research); Tanabe Laboratories (consulting fee). Le H. Hua: Biogen, Celgene, EMD Serono, Genentech, Novartis (consulting fee); Genzyme (consulting fee, speakers’ bureau).

Keywords: Comparative effectiveness, Disease-modifying treatments in MS

Efficacy of additional alemtuzumab was maintained over 4 years after last course in CARE-MS patients, although the ≥4-courses group had higher disease activity and disability, as expected. Alemtuzumab safety was generally consistent between groups, except for the 4-courses cohort in year 4 after last course wherein interpretation was limited by low numbers of available patients.
Background: Ofatumumab is the first fully human anti-CD20 monoclonal antibody, administered with a monthly 20 mg subcutaneous dosing regimen. Objectives: To investigate the efficacy and safety of ofatumumab vs teriflunomide in patients with relapsing multiple sclerosis (MS).

Methods: ASCLEPIOS I and II were 2 identical phase 3, double-blind, double-dummy, active comparator-controlled, parallel-group, innovative, adaptive-design (with flexible duration), multicenter trials in patients aged 18-55 years with an Expanded Disability Status Scale score of 0.5-5 at screening. Patients were randomized (1:1) to receive subcutaneous ofatumumab vs teriflunomide. Therapeutic phase doses: days 1, 8, and 15 (first cycle); every 4 weeks from week 4 to 4) or oral teriflunomide 1 mg once daily, for up to 30 months. The primary end point was annualized relapse rate. Key secondary end points included 3- and 6-month confirmed disability worsening (3mCDW/6mCDW), 6-month confirmed disability improvement (6mCDI), systemic injection-related reactions occurred in 20.6% and 15.3% of ofatumumab vs teriflunomide. Adverse events occurred in 83.6% and 78.0% of patients in the ofatumumab vs teriflunomide groups, respectively. The most common TEAEs by time epoch after initiating treatment across both trials in both treatment groups was generally low, which may facilitate treatment adherence. One potential advantage of cladribine tablets is that patients only receive doses for 2-4 to 5-day periods per treatment year. The incidence of early adverse events, TEAEs, serious TEAEs, and TEAEs leading to discontinuation were summarized based on incidence within 2, 6, and 12 weeks (W) after commencement of therapy. Results: The incidence of TEAEs occurring within the first 2-12W of treatment across both trials in both treatment groups was generally low, and most events were mild (placebo: 68.4%-33.8%; cladribine tablets: 68.0%-54.4%). The most common TEAEs by time epoch after initiating placebo- and cladribine tablets 0.5 mg/kg treatment, respectively, were nausea: 3.3% vs 4.9% (2W), 3.7% vs 6.4% (6W), and 4.5% vs 8.0% (12W); fatigue: 2.0% vs 1.4% (2W), 3.1% vs 2.5% (6W), and 4.4% vs 3.1% (12W); headache: 8.3% vs 9.0% (2W), 11.9% vs 14.8% (6W), and 15.1% vs 18.4% (12W); lymphopenia: 0.0% vs 2.5% (6W) and 1.2% vs 6.8% (12W); leucopenia: 0.0% vs 1.3% (12W). Other end points to be shown in the final presentation. Conclusions: Incidence of TEAEs experienced during the first 12 weeks of treatment with cladribine tablets in phase 3 clinical trials was low and mostly mild. Nausea, headache, and lymphopenia were seen more frequently in patients treated with cladribine tablets. These findings suggest that cladribine tablets are generally well tolerated, which may facilitate treatment adherence.

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Disclosure: Jianjun Oh: Biogen, Roche, Sanofi Genzyme (consulting fee, research funding); Brain Canada, MS Society of Canada (research funding); Genelge, International Journal of MS Care 5 (DMT04) Treatment-Emergent Adverse Events Occurring Early in the Treatment Course of Cladribine Tablets in Two Phase 3 Trials in Multiple Sclerosis

Jianjun Oh,1 Bryan Wallace,1,2 Govin Giovannoli,1,3 Dominic Jack,4 Fernanda Dangond,5 Axal Nolting,4 Julie Aldridge,5 Lori Lebson,6 Thomas P. Leist7

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Background: Tolerability and adherence to disease-modifying drugs (DMDs) can be influenced by treatment-emergent adverse events (TEAEs) that start soon after therapy initiation. One potential advantage of cladribine tablets is that patients only receive doses for 2-4 to 5-day periods per treatment year. The incidence of early adverse events, TEAEs, serious TEAEs, drug-related TEAEs, and TEAEs leading to discontinuation were summarized based on incidence within 2, 6, and 12 weeks (W) after commencement of therapy. Results: The incidence of TEAEs occurring within the first 2-12W of treatment across both trials in both treatment groups was generally low, and most events were mild (placebo: 68.4%-33.8%; cladribine tablets: 68.0%-54.4%). The most common TEAEs by time epoch after initiating placebo- and cladribine tablets 0.5 mg/kg treatment, respectively, were nausea: 3.3% vs 4.9% (2W), 3.7% vs 6.4% (6W), and 4.5% vs 8.0% (12W); fatigue: 2.0% vs 1.4% (2W), 3.1% vs 2.5% (6W), and 4.4% vs 3.1% (12W); headache: 8.3% vs 9.0% (2W), 11.9% vs 14.8% (6W), and 15.1% vs 18.4% (12W); lymphopenia: 0.0% vs 2.5% (6W) and 1.2% vs 6.8% (12W); leucopenia: 0.0% vs 1.3% (12W). Other end points to be shown in the final presentation. Conclusions: Incidence of TEAEs experienced during the first 12 weeks of treatment with cladribine tablets in phase 3 clinical trials was low and mostly mild. Nausea, headache, and lymphopenia were seen more frequently in patients treated with cladribine tablets. These findings suggest that cladribine tablets are generally well tolerated, which may facilitate treatment adherence.

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(PSY01) A Mindfulness Group Intervention in Newly Diagnosed Persons with Multiple Sclerosis: A Pilot Study
Sarah A. Morrow,1 Nancy Vording,2 Jordan Ward,3 Courtney S. Casserly,4 Heather Rosehart,4 Arlene Macdougall1
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3Multiple Sclerosis Achievement Center, Dignity Health, Sacramento, CA; 4Psychiatry and Epidemiology & Biostatistics, St. Joseph’s Health Care, Parkwood Institute, London, ON, Canada

Background: Relapsing multiple sclerosis (RMS) is a lifelong disease without a cure, usually diagnosed between age 20-40 years. Being newly diagnosed with RMS is a highly stressful event due to the unpredictable course of the disease. Thus, it is imperative that persons with multiple sclerosis have the skills and support to cope with the negative physical and emotional effects of the disease. Objectives: To assess whether a mindfulness-based intervention (MBI) will lessen the negative consequences of stress due to being newly diagnosed with RMS. Methods: A single-blind, randomized, prospective study of a 10-week MBI vs usual standard of care alone in persons newly diagnosed (within 1 year) with RMS. Primary outcomes included the Brief COPE measure and the Hospital Anxiety and Depression Scale (HADS). Secondary outcomes included measures of perceived stress, cognitive function, fatigue, and quality of life. Subjects were assessed at baseline, postintervention, and 6 months later. Analysis of covariance was used to compare longitudinal changes, with baseline scores used as covariates. Results: 25 subjects were recruited (16 MBI, 9 controls); most were women (21 [84%]), with a mean age of 38.4 ± 9.5 years. The groups were well matched on baseline characteristics. All controls completed the study, while 4 MBI participants did not. The MBI group improved significantly on the COPE measure when compared to the control group (P = .002) as well as on the HADS depression subscale (P = .007) pre- and postintervention; there was no significant difference over time on the HADS anxiety subscale (P = .179). On the secondary outcomes, there was a significant improvement on the Perceived Stress Scale (P = .015), and a trend towards improvement on the SF-36 (P = .073); quality of life and the MSQOL (P = .066; perceived cognitive impairment) comparing pre- and postintervention assessments. Six-month data will be available at the time of this presentation. Conclusions: This pilot study demonstrates that an MBI improves coping, depression, and perceived stress in newly diagnosed persons with RMS.

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Keywords: Comprehensive care and MS, Psychological issues and MS

(PSY03) Examining Multilevel Environmental Correlates of Physical Activity Among Older Adults with Multiple Sclerosis
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Background: With a growing population of older adults with multiple sclerosis (MS), appropriate strategies are needed to promote physical activity (PA) as a second-line approach for symptom management. Objectives: This cross-sectional study examined built environment, social environment, and individual social cognitive theory (SCT) variables as hierarchical correlates of PA in older adults with MS using a social ecological model (SEM) framework. Methods: 363 participants completed the online survey including demographics, the Abbreviated Neighborhood Walkability Scale (NEWS-A), Social Provisions Scale (SPS), Exercise Self-Efficacy Scale (EXSE), Multidimensional Outcomes Scale (MOEES), and Godin Leisure-Time Exercise Questionnaire (GITEQ) Total and Health Contribution score (HCS). Spearman rank-order correlation analyses were used to examine associations among NEWS-A subscales, SPS, EXSE, MOEES, and GITEQ Total and HCS. Results: In conducting hierarchical, linear regression analysis whereby we regressed GITEQ with NEWS-A subscales (built environment) in step 1, SPS (socio-environment) in step 2, then EXSE and MOEES (individual determinants) in step 3. Results: Land-use mix diversity, land-use mix access, street connectivity, and aesthetics were significantly correlated with GITEQ Total, whereas land-use mix diversity, land-use mix access, infrastructure and safety for walking, aesthetics, and crime were significantly correlated with GITEQ HCS. Hierarchical linear regression analyses were then conducted whereby we regressed GITEQ Total with NEWS-A subscales (step 1) with significant associations noted for land-use mix diversity and aesthetics (R2 = 0.09), step 2 included SPS with significant associations noted for SPS, land-use mix diversity, and aesthetic variables (R2 = 0.10), and finally EXSE and MOEES were included in step 3 and were the only significant correlates of GITEQ total (R2 = 0.38). Regarding GITEQ HCS, land-use mix diversity, aesthetics, and crime were significant correlates in step 1 (R2 = 0.10), SPS and land-use mix diversity were the only significant correlates in step 2 (R2 = 0.14), and EXSE was the only significant correlate in step 3 (R2 = 0.36). Conclusions: This study provides guidance for researchers and practitioners on relevant targets for tailoring PA interventions for older adults with MS and supports the continued emphasis on self-efficacy as a primary predictor of health behavior and PA maintenance.

Supported by: None
Disclosure: Nothing to disclose.

Keywords: Management of activities of daily living in MS, Older adults with MS, Psychological issues and MS

(PSY02) Effects of Weekly Participation in a Wellness Program on Self-Reported Measures for People Living with Multiple Sclerosis: A 3-Year Analysis
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Background: The Multiple Sclerosis Achievement Center (MSAC) conducts day wellness programs to address physical, cognitive, and social well-being. Program activities include individualized and group exercise, cognitive stimulation, education, socialization, and community outings. Baseline, 1-year, and 2-year follow-up data were collected and presented at previous Consortium of Multiple Sclerosis Centers annual meetings. Objectives: To determine, through the use of patient-reported outcome (PRO) measures, if members of these wellness programs improve self-reported quality of life and impact and quality of life over the outcome period. Methods: Initial analysis, comparing data of baseline and 1-year participation in these wellness programs, was completed through paper/pencil outcome measures between December 2016 and August 2017 for 95 people with multiple sclerosis (PwMS). Of those 95, 2-year data for 70 PwMS were collected in January 2019 and 3-year data are anticipated for 66 people. Outcome measures used for the analyses include the Multiple Sclerosis Impact Scale (MSIS-29), Multiple Sclerosis Self-Efficacy Scale-10 item (MSE), Godin Leisure Time Exercise Questionnaire (GITEQ), and NeuRo-Qol (questions from the Anxiety, Depression, Emotion & Behavior, Positive Affect, Cognition, Ability to Participate, and Social Roles sections were used). All outcomes were completed onsite at the MSAC as part of the members’ weekly participation in the program. Analysis will be completed to compare data from the initial analysis to the 3-year results. Results: As previously reported, a correlation between reports of Self-Efficacy, Anxiety, Ability to Participate, and Positive Affect (per MSSE and NeuRo-Qol) were seen with both 1- and 2-year analyses. Analysis of baseline to 2-year data demonstrated statistically significant changes in NeuRo-Qol sections Ability to Participate (P = .02) and Social Roles (P = .001). Another notable change in the 2-year analysis was an increase in physical activity, as measured by GITEQ (average change of 2.34 from baseline to 2 years). Data analysis will measure any changes in 3-year data compared to baseline, 1-year, and 2-year results. Conclusions: Complete collection and analysis of 3-year comparative data will be finalized in February 2020 for presentation at the meeting.

Supported by: None

Keywords: Comprehensive care and MS, Psychological issues and MS, Wellness

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Effect of Nabiximols Cannabinoid Oromucosal Spray on Depressive Symptoms, Suicidality, and Cognition in Patients with Multiple Sclerosis

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Background: Substantial evidence has shown nabiximols, a complex botanical mixture containing δ9-tetrahydrocannabinol and cannabidiol as the principal cannabinoids, can reduce spasticity associated with multiple sclerosis (MS). This analysis assesses whether nabiximols affects other patient outcomes such as depressive symptoms, suicidality, and cognition. Objectives: Report the effect of nabiximols on depression, suicidality, and cognition using data from 2 placebo-controlled randomized controlled trials, GWSP0604 (12 weeks) and GWMS1137 (48 weeks), in patients with spasticity due to MS. Methods: Mood and suicidality were assessed using the Beck Depression Inventory-II (BDI-II) in both trials. In GWMS1137, suicidality was assessed using the Columbia-Suicide Severity Rating Scale (C-SuRS) and working memory/processing speed used the Paced Auditory Serial Addition Test (PASAT). The combined PASAT total score was calculated combining both PASAT-3 and −2 tests scores (total of 120 points). Outcome differences between nabiximols and placebo are summarized. Results: 241 patients from GWSP0604 and 121 from GWMS1137 were included. The baseline and end-of-treatment mean BDI-II total scores were 8.7 vs 9.5 for nabiximols and 9.7 vs 10.4 for placebo (−0.29 (−2.91, 2.33) in GWMS1137 and 13.5 vs 11.1 for placebo in GWMS1137. Differences between nabiximols and placebo of the BDI-II change from baseline adjusted means were −0.06 (−1.62, 1.49) in GWSP0604 (no significant difference) and −0.29 (−2.91, 2.33) in GWMS1137 (statistically noninferior). Question 9 of BDI-II (suicidal thoughts or wishes) showed no notable treatment differences in either trial, with only 1 patient treated with nabiximols reporting a score ≥2. On the C-SuRS, 3 (5.1%) patients randomized to placebo and 1 (1.6%) to nabiximols had a “flag” (i.e., “yes” as a response), but further questioning revealed no emergent suicidal ideations or behaviors in any of these patients. For GWMS1137, the baseline and end-of-treatment PASAT-3 total scores were 71.3 vs 78.0 for nabiximols and 74.5 vs 82.7 for placebo; increases may reflect practice effects. Treatment difference of the adjusted mean was −1.47 (−6.41, 3.48), indicating nabiximols does not adversely affect working memory/cognitive processing speed in patients with MS over a 48-week period compared with placebo. Conclusions: Nabiximols had no notable effects on depression, suicidality, or working memory/processing speed in patients with MS. Supported by: None

Disclosure: John Deluca: Biogen (consulting fee, clinical studies, speakers’ bureau); Celgene, Genzyme (consulting fee); EMD Serono (consulted research); Sanofi Genzyme (speakers’ bureau). Professor Dawn Langdon: Nothing to disclose. Joris Berwaerts: GW Pharmaceuticals (salary). Joanne Wagner: Greenwich Biosciences/GW Pharmaceuticals (salary); GW Pharmaceuticals (ownership interest).

Keywords: Complementary/alternative therapies in MS, MS symptom management, Psychological issues and MS

Multiple Sclerosis Management: Predicting Disease Trajectory of Multiple Sclerosis on Multidimensional Data Including Digital Cognitive Assessments and Patient-Reported Outcomes Using Machine Learning Techniques

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Background: Multiple sclerosis (MS) disease impact is traditionally measured by magnetic resonance imaging changes, relapse rates, and Expanded Disability Status Scale (EDSS). Combining multidimensional patient-reported outcome (PRO) and objective disease impact information independent of EDSS might enhance clinical decision making. Large patient-tracking sources expand beyond what is traditionally captured in an office visit, clinicians need tools to help integrate these varied streams of data. Machine learning has the potential to help clinicians predict meaningful patient outcomes from multidimensional and quantified data sources. Objectives: To demonstrate the feasibility of predicting clinical outcomes in MS using standard machine learning methods on multidimensional data including digital cognitive assessments and PROs. Methods: Machine learning models were trained on electronic health record data, cognitive domain scores, and PRO data. A prediction model was created given the patient’s record. 80% of the dataset was used in training, 20% in testing with an ensemble learning method (random forest classifiers) used to construct a multitude of training decision trees, which then outputted the mean prediction of the individual trees. Results: The sample consisted of 258 persons with MS (72.5% female, average age 46.2 ± 10.2) over a 3-year period. Untuned models calculated F1 scores (2*Precision*Recall)/(Precision+Recall) for MS and disease-modifying therapy choice. The most precise and accurate models were for the Driving (0.913, 0.904, 0.942, 0.912) and Modified Falls Efficacy Scale (0.789, 0.796, 0.792, 0.829), Depression (0.711, 0.765, 0.714, 0.718), Fatigue (0.716, 0.782, 0.699, 0.755), and Employment (0.672, 0.753, 0.668, 0.705). Conclusions: Machine learning combined with objective measures of disease impact and PROs can provide important information to predict economically important and disability-relevant outcomes, potentially enhancing treatment decisions. These results show promising predictive accuracy to be used in a variety of advisory applications and potentially reduce disease-related disability. The results of the other models demonstrate the feasibility of using machine learning in a broader network of clinical sites that will allow for greater accuracy, precision, and recall. The eventual goal is that these models can be used as an aid in the shared decision-making process, and to reduce inappropriate healthcare costs.

Disclosure: Mark Gudesblatt: Acorda, Amgen, Medtronic, Sano Therapeutics (speakers’ bureau); Biogen, EMD Serono, Novartis, Sanofi, Teva (consulted research); Jared Srinivasan, Olivia Kaczmarek, Daniel Kantor, Daniel Golan, Marjimee Buhse, Lori Safdari, Timothy Fratta: Nothing to disclose. Myssar Zarid: Acorda, Biogen, Genzyme, Teva (speakers’ bureau). Barbara Bumstead: Biogen, Genzyme (speakers’ bureau). Jeffrey Wilken: Biogen (consulted research); EMD Serono (speakers’ bureau); Genzyme (consulted research, speakers’ bureau); Cynthia Sullivan: Roche (consulted research). Glen Doniger: NeuroTrax (salary).

Keywords: Comprehensive care and MS, Machine learning, Natural history of MS

Significant Structural Neuroplasticity Changes Can Follow Physical Behavioral Change Therapy for Multiple Sclerosis

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Background: Constraint-induced movement therapy (CIMT) is a form of physical behavioral change therapy (CBT) that can significantly improve paretic limb use in the community in progressive multiple sclerosis (MS) for at least 1 year (Mark et al., 2018). Although a few forms of CBT can increase real-life physical activity in MS, none thus far has been examined for whether such treatment can change cerebral cortical grey matter structure. Objectives: To evaluate whether CBT vs dose-matched control physical training can change cortical grey matter structure in progressive MS. Methods: Twenty adults with chronic MS matched for unilateral arm disability were randomized to 35 hours/2 weeks of either CIMT or a holistic complementary and alternative medicine (CAM) program (yoga, aquatic therapy, massage, relaxation techniques). Paretic limb use was measured with the Motor Activity Log (MAL), which has been validated against real-world upper limb acceleration. Pre- and posttreatment 3-T structural brain magnetic resonance imaging scans were performed. Tensor-based morphometry (TBM) and voxel-based morphometry (VBM) were used to evaluate group-level changes in primary motor cortex (M1) structure contralateral to the more-affected arm. Whole-brain statistics were conducted using 1-sample t tests within Statistical Parametric Mapping software with a cluster-extent threshold of 10 voxels and false discovery rate of 0.1. Results: The 2 groups were identical in high expectancy to benefit. CIMT produced a much larger effect size (d’ = 3.2) on the MAL than did CAM (d’ = 0.7). TBM detected an increase in the thickness of M1 after CIMT but not after CAM. VBM detected a change in an office visit, clinicians need tools to help integrate these varied streams of data. Machine learning has the potential to help clinicians predict meaningful patient outcomes from multidimensional and quantified data sources. Objectives: To demonstrate the feasibility of predicting clinical outcomes in MS using standard machine learning methods on
**Platforms**

MS, unlike dose-matched CAM. The findings suggest for the first time that physical BCT can significantly stimulate cortical neuroplasticity in a degener- erative central nervous system disorder. The findings accord with our previous findings of post-CIMT significant white matter structural improve- ment in progressive MS (Barghi et al, 2018) and grey matter increases in stroke (Gauthier et al, 2008) and cerebral palsy (Sterling et al, 2013). Together, these findings suggest that a specific form of physical BCT can not only stimulate physical activity in the community over the long term but also well improve neurologic structure for progressive MS.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** CNS repair, Imaging and MS, Management of activities of daily living in MS

**Background:** Reduced information processing speed (IPS) is the most common cognitive impairment in multiple sclerosis (MS), related to reduced employment and physical ability. The Symbol Digit Modalities Test (SDMT) is the gold standard measure of IPS in MS (Benedict et al, 2017). Although many investigators have suggested that performance on the SDMT involves multiple cognitive processes, there has been little attempt to tease apart what specific cognitive processes may affect the IPS score on the SDMT. Improved understanding of the cognitive processes that contribute to IPS on the SDMT could support future cognitive rehabilita- tion trials to treat impaired IPS in MS.

**Objectives:** Assess specific eye movement measures during the SDMT to suggest what specific cognitive processes may underlie IPS on the SDMT in MS.

**Methods:** We recruited a convenience sample of 38 adults with MS, without clinical oculomor- tor impairment, who performed the SDMT while an infrared eye tracker recorded their eye movements. Eye positions were sampled at 10 Hz. Data were exported to a database for subsequent specific eye movement measures: 1) search organization as calculated by the “best r” metric (inward-outward scan search function) [Mark et al, 2004]; 2) total of upward saccades from the lower area on the page of test symbols to the answer key at the top, inferred as a measure of symbol working memory. Spearman rho was performed to assess correlations between the variables and the SDMT IPS score (correct responses in 90 seconds).

**Results:** The mean (SD) SDMT IPS score was 38 (14). Both best r and total of upward saccades were positively correlated with the IPS score. The latter result was unexpected: the faster on the SDMT, the more subjects checked the answer key. The results suggest that lower-scoring participants with MS, who less often checked the answer key during the test, may have become lost during their visual search, as reflected by their poorer search organization. Upward saccades may not so much represent working memory but rather as a strategy to assure successful test completion that is not effectively used by lower-scoring persons with MS. Further research will be needed to assess the criterion validity of specific SDMT eye move- ment measures relative to standard cognitive test assessments.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Information processing speed, Management of activities of daily living in MS

**Background:** Sedentary behavior (SB) is a major concern in multiple sclerosis (MS), as it may accelerate disease progression and exacerbate physical disability. This is especially concerning in African Americans, a segment of the MS population who present with greater neurologic disability than Caucasians and for whom little MS research data are available.

**Objectives:** The current study examined the feasibility of an intervention focused on reducing SB in African Americans with MS.

**Methods:** We recruited 30 ambulatory and physically inactive African Americans with MS (age = 44 years) to participate in the “Sit Less, Move More” (SLMM) program. SLMM consisted of a 12-week behav- ioral intervention focused on reducing SB in African Americans with MS.

**Results:** Process: Of the 64 persons initially contacted, 45 were assessed for eligibility, 31 were sent the informed consent document, and 30 returned a signed informed consent document and were included in the study. Resources: All participants returned T2 testing materials, and 29 (95%) returned T3 testing materials. Twenty-five (83%) participated in all behavioral coaching sessions. Total study costs were $7242.38 USD including costs for materials, postage, equipment, and participant remu- neration. Management: Total personnel time to complete the study was 1.30 hours. Only 13 participants had valid AG data at all 3 time points. Scientific outcomes: No adverse events were reported. There was a small treatment effect on time spent sitting (d = -0.13) and sedentary time (d = -0.19).

**Conclusions:** The SLMM intervention is safe and feasible for African Americans with MS, and yielded a small reduction in SB. The intervention was low-cost and well-received as an approach for reducing sedentary behavior, and, overall, our results suggest that the SLMM program prog-
ress towards a phase 2 trial to determine its efficacy for reducing SB in African Americans with MS.

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Keywords: Sedentary behavior

(RHIO5) The Effect of Aerobic Fitness on Physical and Cognitive Function and Brain Volume in Older Adults with Multiple Sclerosis

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Background: There is evidence for the beneficial effects of aerobic exercise training on physical and cognitive function in persons with multiple sclerosis (MS). Improvements in function may be associated with the effects of aerobic fitness on deep gray matter (DGM) structures within the brain such as the hippocampus, thalamus, and basal ganglia. To date, we are unaware of research that has examined the effects of aerobic fitness in older adults with MS. Given the aging of the MS population, such an investigation is warranted. Objectives: The current study examined the effect of aerobic fitness on physical and cognitive function and DGM brain structures relevant to these outcomes in older adults with MS.

Methods: We recruited ambulatory adults (age 55+ years) with MS (n = 20, age = 63 years). All participants underwent an assessment of aerobic fitness using a maximal, incremental exercise test on a recumbent stepper, assessments of walking speed (Timed 25-Foot Walk) and walking endurance (6-Minute Walk), assessments of cognitive function [Symbol Digit Modalities Test (SDMT), Brief Visuospatial Memory Test (BVMT), California Verbal Learning Test (CVLT)], and a 3-T magnetic resonance image of the brain. We dichotomized participants into a “low fit” group (n = 10) and “high fit” group (n = 10) based on the results of the exercise test and calculated effect sizes (Cohen’s d) between the groups for all outcome measures. Results: Aerobic fitness had a large effect on both walking speed (d = 0.69) and walking endurance (d = 1.51). There was a moderate effect of aerobic fitness on cognitive function (SDMT d = 0.57; CVLT d = 0.48; BVMT d = 0.67). The effect of aerobic fitness on DGM brain structures varied by structure. There was little to no effect on the thalamus (d = 0.19) and hippocampus (d = −0.01), whereas there was a moderate effect on the basal ganglia (d = 0.53).

Conclusions: Our results provide novel evidence demonstrating a positive effect of aerobic fitness on physical and cognitive function in older adults with MS. As aerobic fitness is modifiable by aerobic exercise training, our results suggest that participation in regular physical activity may be an approach to ameliorate the consequences of aging with MS. Our results further suggest that improvements in function may be mediated by an effect of aerobic fitness on DGM brain structures; however, additional research is warranted to comprehensively investigate the neural adaptations associated with aerobic fitness in this population.

Supported by: None.


John R. Rinker: Biogen, EMD Serono (contracted research).

Keywords: Exercise, Imaging and MS (RHIO6) Functional Electrical Stimulation Cycling Exercise Reduces Lower Limb Strength Asymmetry in Persons with Multiple Sclerosis

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Background: Lower limb strength asymmetries (ie, difference ≥10% between contralateral muscle groups) have been associated with mobility impairment in persons with multiple sclerosis (PwMS), and may be a target for exercise training interventions aiming to improve mobility. Functional electrical stimulation (FES) cycling is an adapted exercise modality that has demonstrated preliminary benefits for mobility and fitness outcomes in PwMS with mobility impairment, but its potential effects on lower limb strength asymmetry remain unknown. Objectives: To assess the effect of FES cycling exercise on lower limb strength asymmetry in PwMS who have mobility impairment (ie, Expanded Disability Status Scale [EDSS] score 5.5-6.5), and to explore associations between change in lower limb strength asymmetry and change in mobility outcomes. Methods: Peak torque was recorded bilaterally for knee extensors (KEs) and flexors (KFs) using an isokinetic dynamometer, and was then used to generate lower limb strength asymmetry scores (1−torque KE/torque KF) x 100. Mobility outcomes included the Timed 25-Foot Walk (T25FW) and the 2-Minute Walk (2MW). Participants received 24 weeks (3×/week) of either FES cycling or passive leg cycling (PLC). The FES condition actively cycled while receiving mild electrical stimulation to the quadriceps, hamstrings, and gluteal muscle groups. Exercise intensity was set at 40% to 60% of heart rate reserve, with exercise duration gradually increasing from 10 to 40 minutes per session over the course of the intervention. The PLC condition was identical to the FES condition, but did not receive electrical stimulation and did not actively cycle. Results: Eight PwMS (mean [SD] age = 52.9 [7.9], median [IGR] EDSS score = 6.3 [0.5]) completed the intervention. The FES cycling condition demonstrated a small decrease in KE asymmetry and change in T25FW (p = 0.43) and 2MW (p = 0.24). A moderate association was observed between change in asymmetry and change in T25FW (p = 0.31), while no association was observed with change in 2MW (p = 0.07). Conclusions: FES cycling may be efficacious for reducing lower limb strength asymmetry and improving mobility in PwMS who have mobility impairment. These preliminary results will inform future FES cycling investigations with larger sample sizes.

Supported by: None.

Disclosure: Nothing to disclose.

Keywords: Complementary/alternative therapies in MS, Comprehensive care and MS, Functional electrical stimulation
As they improve vision, make it possible to decrease the rates of falls and ocular exercises capable of producing physical and mental stimuli that, the postural control system and suggests that visual rehabilitation may be the data obtained revealed that visual function contributes positively to physical performance were observed in all participants. Conclusions: The obtained data revealed that visual function contributes positively to the postural control system and suggests that visual rehabilitation may be an advantageous intervention for the treatment of imbalance in MS; it involves ocular exercises capable of producing physical and mental stimuli that, as they improve vision, make it possible to decrease the rates of falls and consequent impairment of functional capacity. Supported by: None Disclosure: Nothing to disclose Keywords: Complementary/alternative therapies in MS

**POSTERS**

**COMPLEMENTARY AND ALTERNATIVE THERAPIES**

**CAM01** Multiple Sclerosis Imbalance: Visual Rehabilitation
Marcia Baptista Dias,1 Alice Estevo Dias1
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Background: Imbalance is among the most debilitating symptoms in multiple sclerosis (MS), causing falls and reflecting, to a large extent, the dysfunctional integration of visual sensory signals. Objectives: This preliminary study aimed to show the effects of visual rehabilitation on balance in a small group of people with MS. Methods: Three people with MS presented signs and symptoms of body imbalance. All were evaluated before and after visual rehabilitation by a specialized optometrist, from ocular motility, cover test, and stereoscopy to chromatic and pupil analysis. Rehabilitation consisted of 7 sessions involving balance exercises associated with vision. Results: In the initial evaluations, participants presented the same pattern of body imbalance. After visual rehabilitation, improvements in body posture, static and dynamic balance, and overall physical performance were observed in all participants. Conclusions: The obtained data revealed that visual function contributes positively to the postural control system and suggests that visual rehabilitation may be advantageous for the treatment of imbalance in MS; it involves ocular exercises capable of producing physical and mental stimuli that, as they improve vision, make it possible to decrease the rates of falls and consequent impairment of functional capacity.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Complementary/alternative therapies in MS

**CAM02** Acupuncture and Electromagnotherapy for Chronic Pain Relief in Multiple Sclerosis
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Background: Chronic pain is common in people with multiple sclerosis (PwMS) with approximately 42% to 90% experiencing pain at some stage of the disease course. Pharmacologic treatment in multiple sclerosis (MS)-related pain is usually unsatisfactory and often has severe side effects, and therefore, a need for alternative methods of pain relief is critical. Objectives: To evaluate the effectiveness and anesthesic efficiency of acupuncture associated with electromagnotherapy for chronic pain relief in a PwMS group. Methods: A total of 12 patients with MS were included in this prospective study: 10 women and 2 men, aged between 40 and 74. Mean Expanded Disability Status Scale score was 4.8; 42% of patients were classified as having relapsing-remitting MS, 33% as secondary-progressive MS, and 25% as primary-progressive MS. All reported pain (10 = back, 2 = legs/feet), used pharmacologic treatment, underwent 15 acupuncture sessions and electromagnetic therapeutic equipment applications (Kenkobil), and answered a structured pain questionnaire. Results: The primary end point was reduction in pain intensity or elimination, while the secondary end point improved symptoms and quality of life. This preliminary study revealed that MS-related pain can have a significant impact on health, activity, and participation of people, drastically reducing the quality of life. Conclusions: Although our overall results suggest that these non-pharmacologic interventions had beneficial effects on chronic pain and were not harmful, studies with robust methodology are needed to assess safety and possible long-term effects, justifying the use of these interventions on chronic pain in MS.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Complementary/alternative therapies in MS

**CAM03** The Effects of Reflexology in People with Multiple Sclerosis
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Background: Multiple sclerosis (MS) is associated with a wide variety of different physical and psychological symptoms that have a profound effect on quality of life. Complementary and alternative medicine (CAM) is a current treatment that seems effective in relieving symptoms of patients with MS. Objectives: To investigate the effects of reflexology in people with MS about the effects of reflexology. Methods: This study involved 12 people with MS and healthy feet without injury, damage, thrombosis, inflammation, lesion, or fractures, 7 (58%) women and 5 (42%) men, aged 25 to 72 years, and mean Expanded Disability Status Scale score 4.5. In the group reflexology interventions were performed within 10 weeks, at an average session of 45 minutes. Data were collected through a structured questionnaire, immediately after. Results: All expressed satisfaction with the interventions, among them, 7 (58%) reported reflexology benefits in both psychological symptoms and pain, and 5 (42%) in exclusively psychological. Conclusions: The results showed that, according to participants’ opinion, reflexology in relieving anxiety, stress, depression, and pain was effective. Therefore, this method, as an efficient technique, can be recommended for people with MS. However, sufficient scientific evidence should support its effectiveness and safety.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Complementary/alternative therapies in MS

**CAM04** The Effects of CBD:THC Tincture Oil in Reducing Symptoms and Overall Symptom Management in Persons with Multiple Sclerosis
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Background: It is now becoming more common for persons with multiple sclerosis (PwMS) to use cannabis to try to alleviate their multiple sclerosis (MS) symptoms. A survey of PwMS published in 2017 found that 47% of respondents considered using cannabis to treat their MS symptoms, 26% used cannabis for their MS symptoms, 20% have spoken with their physician about using cannabis, and 16% currently use cannabis (Coffield et al). Many reviews (Zhornitsky and Potvin, 2012; Jawahar et al, 2013; Koppel et al, 2014; Whiting et al, 2015) agree cannabis might have a positive effect on pain in MS. In addition to the legal status, limited research evidence remains a barrier to understanding the role cannabis can play in PwMS to alleviate symptoms. The amount of scientific research in this area is increasing; however, case reports and anecdotes exceed studies. Thus, data regarding cannabis use to treat pain, spasticity, neuropathy, and sleep quality in PwMS remain limited. Objectives: The purpose of this study is to conduct real-life cannabis use. Methods: Participants took CBD:THC tincture oil daily. Self-reported symptom and medication assessments rating a scale from 1 to 10 were completed at baseline prior to starting a tincture, and again after an average duration of 3-6 months. Results: There were significant reductions (P < .0001) in the following symptom management scores: pain (from a mean [SD] of 7.4 [2.0] to 3.9 [1.9], n = 45), spasticity (from a mean [SD] of 7.2 [1.9] to 3.3 [1.9], n = 31), neuropathy (from a mean [SD] of 4.5 [2.6] to 2.5 [1.2], n = 25), and sleep (from a mean [SD] of 7.5 [1.9] to 3.0 [2.1], n = 34). Gabrielsson intake was significantly reduced from a mean [SD] of 1581.3 [1284.6] mg to 625 [739.9] mg (n = 12; P = .036). There were no significant reductions in bicalutamide, tizanidine, or benzodiazepine intake. Conclusions: Although medicinal cannabis CBD:THC tincture oil shows promise in overall symptom reduction and symptom medication dosages reduction in PwMS, researchers need to conduct additional studies, including clinical research studies, for PwMS using medicinal cannabis CBD:THC tincture oil. A larger sample size will allow inferential statistics to be performed. This study will further contribute to the evidence related to the efficacy of this intervention.

Supported by: None
Disclosure: Aryn Sieber; CannaCauses Foundation (consulting fee); Kristine Werner, Karen Carera, Ben Thrower, Jacqueline Rosenfeld. Nothing to disclose.
Keywords: Complementary/alternative therapies in MS

**CAM05** Challenges and Opportunities in Progressive Multiple Sclerosis Trials: Lessons from Lipoic Acid
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Conclusions: Despite the growing interest in lipoic acid (L-AA) for progressive MS (PwMS), despite the growing interest in this therapeutic agent, there is limited research evidence of its effectiveness in progressive MS. Thus, data regarding lipoic acid use in PwMS remain limited. Methods: Participants took CBD:THC tincture daily. Self-reported symptom and medication assessments rating a scale from 1 to 10 were completed at baseline prior to starting a tincture, and again after an average duration of 3-6 months. Results: There were significant reductions (P < .0001) in the following symptom management scores: pain (from a mean [SD] of 7.4 [2.0] to 3.9 [1.9], n = 45), spasticity (from a mean [SD] of 7.2 [1.9] to 3.3 [1.9], n = 31), neuropathy (from a mean [SD] of 4.5 [2.6] to 2.5 [1.2], n = 25), and sleep (from a mean [SD] of 7.5 [1.9] to 3.0 [2.1], n = 34). Gabrielsson intake was significantly reduced from a mean [SD] of 1581.3 [1284.6] mg to 625 [739.9] mg (n = 12; P = .036). There were no significant reductions in bicalutamide, tizanidine, or benzodiazepine intake. Conclusions: Although medicinal cannabis CBD:THC tincture oil shows promise in overall symptom reduction and symptom medication dosages reduction in PwMS, researchers need to conduct additional studies, including clinical research studies, for PwMS using medicinal cannabis CBD:THC tincture oil. A larger sample size will allow inferential statistics to be performed. This study will further contribute to the evidence related to the efficacy of this intervention.

Supported by: None
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Keywords: Complementary/alternative therapies in MS
Multiple Sclerosis Care
Exercise Promotion Approach Within Comprehensive

(CAM06) Exercise in Medicine: A Complementary Exercise Promotion Approach Within Comprehensive Multiple Sclerosis Care

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Background: Exercise is one of the only complimentary strategies that improves symptoms of multiple sclerosis (MS) and slows disease progression and functional manifestations. There is further evidence that engaging in exercise regenerates neuroplasticity within the central nervous system. Such evidence supports exercise as a strategy for optimizing independence and quality of life among persons with MS. However, only 20% of the MS population engage in sufficient levels of exercise for accrual of benefits. Objectives: The objective of this work was to develop a new, revolutionary, systematic approach for promoting exercise within comprehensive MS care. This system would reduce the burden of exercise promotion on neurologists while allowing patients to receive, timely, accurate information about exercise, and ongoing opportunities and support to engage in this activity. Methods: Over a 1-year period, we conducted interviews with more than 80 persons with MS and more than 70 health care providers to help design, refine, and finalize a new, comprehensive approach to systematically integrate exercise promotion within comprehensive MS care. We also conducted a quality improvement approach to translate the conceptual ideas into a practical context and develop tangible tools to be used to deliver “Exercise in Medicine.” Results: This rigorous line of research, we have built a new, patient-informed, systematic process that integrates exercise promotion within comprehensive MS care: so-called Exercise in Medicine. Persons with MS and health care providers are supportive of this endeavor and continue to be part of its refinement and improvement. Conclusions: Exercise in Medicine has the potential to revolutionize the promotion of exercise as a complementary strategy to improve quality of life among persons with MS. This systematic process is now at a stage where it is ready to be tested through clinical trials.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Complementary/alternative therapies in MS, Comprehensive care and MS

(CAM07) Changes in Dietary Habits of Individuals Living with Multiple Sclerosis Enrolled in a Day Wellness Program

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Background: Nutrition education for individuals who attend the Multiple Sclerosis Achievement Center (MSAC) focuses on overall health and prevention or management of comorbidities. While there has not been a multiple sclerosis (MS)–specific dietary pattern proven to reduce MS symptoms for all individuals, nutritional choices can affect management strategies. Members of the MSAC attend a weekly program that addresses physical, cognitive, and social well-being. On a monthly basis, nutrition education is provided to discuss diverse aspects of dietary habits and target strategies related to the challenges of living with MS. Some program participants report the MSAC nutrition education through individualized consultations or small group discussions. Objectives: To examine the dietary changes of people with MS who participate in a day wellness program over an 18-month period and determine if changes in habits occur with general nutrition education during the day program. In addition, a comparison in dietary habits between general and individualized nutrition education will be examined. Methods: Fifty-two MSAC members have completed Rate Your Plate (RYP), a self-reported food-frequency questionnaire, every 6 months to monitor changes in dietary choices over a year. RYP consists of 27 questions focusing on typical dietary choices within specified categories. The answer to each question is assigned a point value, with higher points indicating healthier choices. Between questionnaire administrations, members have received monthly nutrition education with 16 members receiving additional small-group nutrition education. Analysis examining 18-month results is planned. Results: Three of four intended rounds of data collection have occurred, with the fourth scheduled in February 2020. The mean (SD) baseline RYP score was 58.48 (8.5). The mean (SD) of the scores at 6 months increased, but not significantly, to 62.33 (7.7) (P = 1.00). Increases at 1 year were statistically significant, 63.71 (7.5) (P < .001) compared to baseline. Paired t tests were used to identify statistical significance. The category showing the greatest improvement (10%) over the first year was the sugar content of desserts. Another improvement (9%) is the frequency in which members are eating meals out. Conclusions: Complete collection and analysis of changes between 4 data collection points will be finalized for presentation of the poster.

Supported by: None


Supported by: None

Disclosure: Nothing to disclose

Keywords: Complementary/alternative therapies in MS, Dietary modifying treatments in MS

CASE REPORTS/CASE SERIES

(CRS01) Seasonal Variation and Other Observations in Myelin Oligodendrocyte Glycoprotein (MOG) Antibody–Associated Disease
Allison N. Black, Ahmed Z. Obeidat

Neurology, Medical College of Wisconsin, Milwaukee, WI

Methods: Posters: Case Reports/Case Series

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Conclusions: This case brings attention to the importance of earlier diagnosis and treatment of MS to reduce disability and improve quality of life in patients. Also, it highlights that we still need to increase education about MS to reduce disability and improve quality of life in patients.

Nothing to disclose.

None

Support: None

Disclosure: Nothing to disclose.

Keywords: Comprehensive care and MS, Natural history of MS

(CRS04) Team Approach Yields Surprising Functional Progress and Quality-of-Life Changes in a Challenging Case of Neuromyelitis Optica
Clare T. Hartigan,1 Christopher Wells2

Objectives: In May 2017 DR was referred to a Multiple Sclerosis Wellness Program due to difficulty with transfers, sitting balance, bed mobility, and bowel/bladder management. She was also diagnosed with neuromyelitis optica (NMO) in February 2016. She developed sudden onset of paralysis and had no voluntary movement from her neck down. DR had a titer of 1:1000. No patients 40 years and older had a titer of 1:1000. We identified peak clinical presentation between September and December. Optic neuritis preceded by a prodromal season of MOG antibody-associated disease, with peak clinical presentation during fall and winter months. This may be due to the peak of respiratory viral infections in the fall and winter as preceding infections were reported in association with MOG antibody–associated disease. Increased diffusion-weighted imaging signal of optic nerves may provide insight into the mechanism of optic nerve damage. Incomplete recovery of optic neuritis is common but often mild and rarely resulted in blindness.

The significance of higher antibody titers in younger individuals requires further investigation. Our observations contribute to the growing knowledge of MOG antibody–associated disease, a mimicker of MS. Our study was limited by a small sample size.

Supported by: None

Disclosure: Allison N. Black: Nothing to disclose. Ahmed Z. Obiedat: Alexion (speakers’ bureau); Alexion Pharmaceutical, Celgene, EMD Serono, Genentech, Sanofi Genzyme (consulting fee); Biogen, Novartis (consulting fee, speakers’ bureau); International Journal of MS Care (editorial board).

Keywords: Imaging and MS, Mimickers of MS, Natural history of MS

(CRS02) Multiple Surgeries and Misdiagnosis Before Multiple Sclerosis Diagnosis: A Case Report
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Background: Myelin oligodendrocyte glycoprotein (MOG) antibody-associated disorders can mimic multiple sclerosis (MS). MOG antibody seropositivity has been found in subsets of patients with demyelinating disease, especially those with optic neuritis and transverse myelitis. Improved MOG antibody-associated disease understanding is necessary to improve diagnosis timing and provide proper treatment.

Objectives: To evaluate the characteristics of patients with a confirmed diagnosis of MOG antibody–associated disease.

Methods: We report on the clinical and imaging characteristics of all patients who presented to our practice with optic neuritis or transverse myelitis, and tested positive for MOG antibody between August 2018 and January 2020. Results: We identified 11 patients, of which 9 (82%) were female. Ten (91%) patients presented between September and December. Optic neuritis preceded by a prodromal headache was the presenting symptom in all patients. Sixteen optic nerves in the 11 patients were symptomatic. Of the 16 symptomatic optic nerves, 12 (75%) nerves showed increased signal on diffusion-weighted imaging. Incomplete clinical recovery was observed in 11 (65%) optic nerves and ranged from no light perception to a mild decrease in visual acuity. Spinal cord lesions were present in 4 patients (36%). Poorly demarcated white matter brain T2 signal abnormalities were present in 7 patients (64%). Finally, patients younger than 40 years tended to have higher titers with 5/6 (83%) patients in this age group having a titer of 1:1000. No patients 40 years and older had a titer of 1:1000. All patients received treatment with prednisone or steroid-sparing agents (rituximab or mycophenolate). None of the treated patients relapsed over the duration of the study. One patient was initially misdiagnosed as having MS and was treated with several disease-modifying agents; he continued to relapse (with sustained disability) until the correct diagnosis was confirmed. Our findings confirm a seasonal variation of MOG antibody–associated disease, with peak clinical presentation during fall and winter months. This may be due to the peak of viral infections in the fall and winter as preceding infections were reported in association with MOG antibody–associated disease. Increased diffusion-weighted imaging signal of optic nerves may provide insight into the mechanism of optic nerve damage. Incomplete recovery of optic neuritis is common but often mild and rarely resulted in blindness. The significance of higher antibody titers in younger individuals requires further investigation. Our observations contribute to the growing knowledge of MOG antibody–associated disease, a mimicker of MS. Our study was limited by a small sample size.

Supported by: None

Disclosure: Nothing to disclose.

Keywords: Comprehensive care and MS, Natural history of MS
dent to requiring supervision for all transfers. She no longer had to use bed pans. Additionally, she learned to walk with stand-by assistant indoor/outdoor terrains with FWWB and bilateral ankle foot orthoses. DR’s functional gains and improved quality of life would have been very unlikely without a team approach. DR is to be commended for her determination, and as health care professionals we should always keep an open mind.

Supported by: None
Disclosure: Nothing to disclose

Keywords: Complementary/alternative therapies in MS, Comprehensive care and MS, Wellness program

(CRS05) Differential Diagnosis and Treatment of Tumefactive Demyelination in a Teenaged Girl
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Background: Tumefactive demyelination in pediatric patients is rare and associated with high morbidity and mortality. The differential diagnosis includes tumor,abscess,acute hemorrhagic leukoencephalitis,acute disseminated encephalomyelitis, and tumefactive multiple sclerosis (MS). Awareness of the differential and early treatment is essential as this presentation may be associated with death or severe morbidity within days.

Objectives: Review a case of tumefactive demyelination in a teenaged girl, and review the pertinent literature, including differential diagnosis, key clinical characteristics, and treatment options.

Methods: Medical record review and review of the literature.

Results: A 16-year-old girl, previously healthy and developmentally normal, presented with encephalopathy progressing quickly to left hemiparesis and global aphasia in the setting of recent upper respiratory infection with cough, headache, and otalgia. Head computed tomography demonstrated vasogenic edema of the left temporal and parietal lobes and 4 mm of midline shift to the right, without obvious underlying mass. Magnetic resonance imaging (MRI) of the brain revealed extensive confluent and expansile-appearing white matter signal abnormality of the left brainstem, internal capsule, and parietal and temporal lobes with associated microhemorrhages and white matter signal abnormality of the left brainstem, internal capsule, and parietal and temporal lobes with associated microhemorrhages and white matter signal abnormality of the left brainstem, internal capsule, and parietal and temporal lobes with associated microhemorrhages.

Conclusions: Tumefactive demyelination requires rapid evaluation and treatment. The differential diagnosis includes acute hemorrhagic leukoencephalitis, which has a particularly high fatality rate. Early and judicious immunomodulatory treatment in these cases is lifesaving.

Supported by: None
Disclosure: Nothing to disclose

Keywords: Disease-modifying treatments in MS, Imaging and MS, Immunology and MS

(CRS07) Case Report of Severe Multiple Sclerosis Relapse Due to B-Cell Reconstitution Post Alemtuzumab
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Background: Alemtuzumab is a pan-lymphocyte-depleting anti-CD52 antibody used in the treatment of multiple sclerosis (MS). However, there have been reports of severely exacerbated central nervous system inflammation following alemtuzumab infusion. Relapse often occurs with the repletion of B cells months after treatment, whereas T cells can take up to 3 years to replenish. B-cell reconstitution occurs when the memory B cells replenish more rapidly than the regulatory T cells. This has previously been seen with the use of rituximab as a B-cell-depleting therapy in disorders such as rheumatoid arthritis. Objectives: Here, we present a case of a 52-year-old woman diagnosed with MS in 2000. She had previously tried multiple disease-modifying therapies including interferon beta-1a, interferon beta-1b, glatiramer, natalizumab, and dimethyl fumarate. She was given round 1 of alemtuzumab in December 2018. In May 2019 she had an exacerbation that caused hospitalization for intravenous methylprednisolone and physical therapy. She made a full recovery to baseline. In July 2019 she had another exacerbation, presenting to the clinic with multiple new symptoms including ataxia, urinary incontinence, weakness, and numbness. She was treated with intravenous corticosteroids without improvement. This was immediately followed by another hospitalization for plasma exchange. Her symptoms continued to progress rapidly. Brain magnetic resonance imaging (MRI) showed development of innumerable enhancing lesions throughout the bilateral cerebral hemispheres and right lateral pons. Cervical spinal MRI showed a new 5-mm enhancing lesion. MRI of thoracic and cervical cord lesions consistent with active demyelinating disease. Due to her rapid deterioration, the decision was made to transfer her to another state to receive a higher level of care. After being evaluated it was determined that she likely had active demyelination related to B-cell reconstitution. She was again hospitalized and received 1 dose of rituximab. Unfortunately, as of October 2019, the patient has continued to decline.

Methods: NA.
Results: She was discharged home on hospice and passed away a week later. An autopsy was performed and the results are pending at this time.
Conclusions: This case signifies the importance of strict monitoring of B cells after alemtuzumab due to the risk of relapse as the B-cell population increases. Further analysis is needed for optimal care of these patients.

Supported by: None
Disclosure: Jennifer Chester: Allergan, Biogen, Novartis, Sanofi Genzyme (speakers’ bureau). Tyler Kaplan: Nothing to disclose.

Keywords: Disease-modifying treatments in MS, Immunology and MS, Nursing management in MS

(CRS06) A Long-Standing Case of Recurrent Transverse Myelitis Due to Myelin Oligodendrocyte Glycoprotein (MOG)-IgG Antibody Mimicking Multiple Sclerosis
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Background: Myelin oligodendrocyte glycoprotein (MOG) IgG antibody causes central nervous system demyelination and mimics multiple sclerosis (MS). Patients with MOG-IgG typically present with recurrent or monophasic optic neuritis, transverse myelitis, conus medullaris lesion, brainstem encephalitis, steroid-dependent symptoms, and acute disseminated encephalomyelitis. Lack of testing for MOG-IgG in these patients can lead to an incorrect diagnosis of MS, and treatment with certain medications that can worsen MOG-IgG-associated disease. Objectives: To report a case of a patient with MOG-IgG antibody–mediated recurrent transverse myelitis who was diagnosed with possible MS for more than 15 years.

Methods: A 66-year-old woman with a known diagnosis of possible MS presented to our clinic for follow-up. Her history dated back to 1989 when she had an episode of extreme fatigue, gait imbalance, and numbness in her hands and feet that resolved spontaneously. She had recurrent episodes of symptomatic myelitis in 1997 and 2001. On examination, she had spastic weakness of bilateral iliopsoas and finger extensors (left worse than right), brisk reflexes on the left hemibody with left ankle clonus, relative sensory level at T12, and spastic atactic gait without assistance. Tined 25-foot walk was 6.86 seconds. Results: In 2001, magnetic resonance imaging (MRI) of the spinal cord showed several short segment lesions in the cervical and thoracic spinal cord including the conus medullaris. MRI of the brain was normal. Cerebrospinal fluid (CSF) showed elevated protein, IgG synthesis rate, and CSF-specific oligoclonal bands. Aquaporin 4 antibody (AQP-4) in CSF was negative. She was diagnosed with possible MS given the lack of better explanation and was started on a combination of interferon beta-1a and mycophenolate.

Since 2011, she did not tolerate clinical relapses or neurological specific lesions in her brain and persistently enhancing short segment lesions in the cervical and thoracic spinal cord in 2014 and 2016. Interferon beta-1a was stopped in 2017 and mycophenolate was continued. Serum MOG-IgG was tested and was positive in February 2019. Conclusions: MOG-IgG–mediated disease and MS show a relevant phenotypic, clinical, and radiologic overlap that can potentially lead to misdiagnosis and worsen disease outcomes as some medications used to treat MS might be ineffective or even harmful in MOG-IgG–associated disease. Before the diagnosis of MS, testing for MOG-IgG antibody should be considered in selected patients.

Supported by: None
Disclosure: Nothing to disclose

Keywords: Comprehensive care and MS, MOG IgG antibody
(CRS08) Demographics, Clinical Characteristics, and Outcomes of Myelin Oligodendrocyte Glycoprotein (MOG) Antibody Disease Followed Up at Washington University in St. Louis

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Background: Antibodies to myelin oligodendrocyte glycoprotein (MOG) have been associated with central nervous system demyelination that is distinct from other neuroinflammatory conditions. Our knowledge of the clinical spectrum of MOG antibody disease (MOGAD) is evolving, without clear consensus of prognosis and best treatments. Objectives: To report demographics, clinical characteristics, and treatment responses of our MOGAD cohort. Methods: Patients at Washington University were identified via diagnosis code and confirmed to have at least 1 positive MOG antibody test. Demographic, clinical course, estimated disability (extracted using published tools), laboratory, and treatment data were collected after institutional review board approval. Results: 24 patients with MOGAD were included. They were 75% female and 92% Caucasian with mean onset age of 43.5 (range 16.8-76.0) years. Average duration of follow-up was 4.0 (range 0.4-18.0) years. Initial symptoms exclusively included optic neuritis (17/24, 41%) bilateral optic neuritis (9/24, 22%) with 2/24 having both occur simultaneously. 12.5% (3/24) had concurrent involvement of other areas (brainstem, cerebral). A total of 42 attacks (including initial onset) were adjudicated; the annualized relapse rate was 0.46. 42% had only a single attack. Attacks tended to be severe (estimated ΔExpanded Disability Status Scale ΔEDSS for score +3.0), followed by complete recovery in 35% and no recovery in 21%. Most (81%) attacks were treated with corticosteroids. 38% of all patients had remained stable without long-term treatment, but 79% of those with relapses were on no long-term treatment. Rituximab was associated with a low relapse rate, although breakthrough relapses still occurred in 2 patients. Four patients had 3+ attacks: all had optic neuritis, and 3 were exclusively sensitive to decreases in their maintenance corticosteroid dose. 54% of patients had multiple MOG antibody titers (average 7.2 months later), of whom 31% became seronegative. None of these patients relapsed after testing negative. Cerebrospinal fluid (CSF) test results were modestly abnormal (median cell count 8, average protein 56.9). No patients had >2 CSF-specific oligoclonal bands. In those with 2+ years of follow-up, 50% remained relapse-free. In those with 5+ years of follow-up, 44% remained relapse-free. Average current EDSS score is 1.9. 58% have an EDSS score ≥2.0, and 13% have an EDSS score ≥4.0. Conclusions: We report a cohort of Midwestern patients with anti-MOG disease. Our results are largely consistent with those reported in other cohorts of this disease.

Supported by: None
Disclosure: John R. Cioti: Nothing to disclose. Anne Cross: Biogen, Celgene, Novartis, TG Therapeutics (consulting fee); EMD Serono, Genentech/Roche (grant and personal fees). Salim Chahin: Biogen, Genentech, Novartis, Sanofi Genzyme, Teva Neuroscience (personal fees).

Keywords: MOG antibody disease

(CRS09) A Fatal Case of Alemtuzumab-Induced Immune Thrombocytopenic Purpura in a Patient with Relapsing Multiple Sclerosis

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Background: Alemtuzumab is a humanized monoclonal antibody against CD52 approved for relapsing types of multiple sclerosis (MS). Despite being an effective medication, there have been limitations of use for this medication due to various serious adverse effects. Common adverse effects include infections, transmutation reactions, and autoimmune reactions such as hemolytic anemia, thrombocytopenia, and autoimmune thyroid and renal disease. Objectives: Objective 1: To review a case of refractory immune thrombocytopenic purpura (ITP) as a result of alemtuzumab therapy in a patient who presented with altered mental status and who was found to have multiple foci of intracranial bleeding (intracerebral hemorrhage [ICH]). Objective 2: To review a case of ITP with the patient relapsing multiple sclerosis (MS) successfully treated with cyclophosphamide. Methods: Case report. Results: A 39-year-old woman developed ITP after receiving 2 doses of alemtuzumab. The patient died 2 days after infusion, and an autopsych evaluation study of pathogenesis and morbidities due to refractory ITP. According to the literature, ITP occurs in 2%-2.6% of patients treated with alemtuzumab. ITP can be refractory and fatal; however, in the CAMMS223 study only 1 of 6 patients with ITP died due to ICH. In addition, in 2 other studies of patients with MS receiving alemtuzumab, no ITP-associated mortality is reported. Conclusions: Alemtuzumab is a potent immune regulator that clears up T cells and B cells. ITP is a rare complication but can be lethal. Our patient’s ITP progressed despite her compliance with every 6-month blood count checks and receiving various treatments. The aim of this presentation is to bring the potentially serious complications of alemtuzumab to attention and consider substitute therapies if feasible.

Supported by: None
Disclosure: Nothing to disclose

Keywords: Comprehensive care and MS, Disease-modifying treatments in MS, Immunology and MS

(CRS10) Colitis Associated with Teriflunomide

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Background: Teriflunomide is an oral disease-modifying therapy for relapsing-remitting multiple sclerosis (RRMS) that was approved in the United States in 2012. Gastrointestinal (GI) adverse effects occurred in 15%-17% of patients in the clinical trials, and, so far, 3 cases of colitis have been reported. Objectives: To report new-onset Crohn disease in a patient with multiple sclerosis while on teriflunomide. Methods: Case report and literature review. Results: A 49-year-old man with RRMS started teriflunomide in January 2018 after discontinuing glatiramer acetate due to injection fatigue and dimethyl fumarate due to GI intolerability. He developed a persistent diarrhea in July 2018; GI workup showed nonblending gastric ulcers and mild chronic gastritis without active inflammation in the small and large intestine. GI disease improved with omeprazole and stopping ibuprofen; teriflunomide was reduced to 7 mg daily in December 2018. In August 2019, he had recurrence of significant diarrhea and abdominal pain. Teriflunomide was stopped in September 2019. Blood count showed a resolving leukocytosis, with notable improvement in his diarrhea. Repeat endoscopy showed multiple duodenal ulcers, gastric ulcers, esophagitis, and ulcerations throughout the colon and terminal ileum. Pathology demonstrated inflammatory changes consistent with inflammatory bowel disease. He was started on vedolizumab for Crohn disease in November 2019. Conclusions: In 2017, Health Canada released a review on teriflunomide due to postmarketing reports of colitis and concluded that, while no definitive link could be established, the patients and providers should be alerted to the occurrence of rare colitis cases. As of October 2019, per Genzyme, 3 cases of colitis while on teriflunomide are reported of which 2 were considered to be related to teriflunomide. We here report a case of new onset of inflammatory colitis with endoscopic and pathologic features of Crohn disease while on teriflunomide and significant improvement after cessation of the drug, and suggest a potential causal relationship between the drug and development of colitis that warrants further investigation. Rare cases of colitis have occurred in patients on teriflunomide including a recent case of new onset of Crohn disease. While the association remains unclear, physicians should be aware of this potential adverse effect. Clinical vigilance and early treatment might be helpful in cessation of colitis progression.

Supported by: None
Disclosure: Neda Zarghami Esfahani: Gloria van Gelderen, Meghan C. Romba, Dhavan Parikh: Nothing to disclose. Annette Wundes: Biogen (consulting fee); Biogen, AbbVie (contracted research).

Keywords: Colitis, Disease-modifying treatments in MS

(CRS11) Remarkable Recovery of Fulminant Multiple Sclerosis After Treatment Induction with Cyclophosphamide

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Background: Fulminant multiple sclerosis (MS) is rare, and the approach to treatment beyond first-line therapies (high-dose steroids, plasma exchange, and intravenous [IV] immunoglobulins) varies. Single case reports of diagnosis and treatment of fulminant MS can provide helpful resources for the clinician. Cyclophosphamide is an alkylating agent that suppresses T- and B-cell function, interleukin 12, and T-helper type 1 cytokine responses, thereby enhancing Th2, Th3 responses. Review of published reports suggests that cyclophosphamide has utility in early stages of MS during which inflammation predominates over degenerative processes in the central nervous system as seen by gadolinium (Gd)-enhancing lesions. Objectives: To describe the clinical course of a case of acute MS successfully treated with cyclophosphamide. Methods: Case study. Results: A 41-year-old woman with no medical history developed facial
Neurofibromatosis Type 1 and Multiple Sclerosis

Case 1:

A 40-year-old woman with NF1 presented with an episode of several days of bilateral distal limb paresthesia and was found to have lesions on brain and spine MRI and positive oligoclonal bands in CSF. She was started on glatiramer acetate with clinical stability and only 1 new non-enhancing lesion on MRI and positive oligoclonal bands in CSF. She was started on glatiramer acetate with clinical stability and only 1 new non-enhancing lesion on MRI and positive oligoclonal bands in CSF. She was started on gatinikum as disease-modifying therapy, which was advanced to natalizumab based on significant radiographic disease progression.

Conclusions:

This is a detailed description of 3 cases and a literature review of co-occurring NF1 and MS. Electronic medical records, neuroimaging, and relevant ancillary tests were reviewed for all cases. Results: Case 1: A 21-year-old man with NF1 presented with an episode of several days of bilateral distal limb paresis and was found to have brain and spine lesions, some of which were enhancing. Optic nerves with likely optic gliomas due to NF1 as well as possible prior optic neuritis. Cerebrospinal fluid (CSF) showed positive oligoclonal bands. He was started on gatinikum as disease-modifying therapy, which was advanced to natalizumab based on significant radiographic disease progression.

Case 2: A 41-year-old woman with NF1 presented with optic neuritis (with improvement with high-dose steroids) and was found to have lesions on brain and spine MRI and positive oligoclonal bands in CSF. She was started on gatinikum as disease-modifying therapy, which was advanced to natalizumab based on significant radiographic disease progression.

Case 3: A 40-year-old woman with NF1 presented with progressive gait changes. Based on MRI findings more suggestive of MS than NF1 and positive oligoclonal bands in CSF, she was diagnosed with primary progressive MS. Conclusions: These cases demonstrate the rare co-occurrence of NF1 and MS as well as the heterogeneity of MS presentations within the NF1 patient population. These cases also demonstrate some of the diagnostic challenges that arise when making a new diagnosis of MS in patients with NF1, including the interpretation of MRI in differentiating suspected demyelinating lesions from lesions that are associated with NF1. It is unclear if the co-occurrence of NF1 and MS is coincidental or if these cases represent an unknown relationship between the 2 diseases.

Supported by: None

Disclosure: None

Keywords: Diagnosis and management of MS, Epidemiology of MS, Imaging and MS

(DXT01) Maintenance of Working Status and Work Productivity in Persons with Multiple Sclerosis Treated with Dimethyl Fumarate: A 5-Year Analysis of the North American Research Committee on Multiple Sclerosis (NARCOMS) Registry

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Background: Employment is often affected in persons with multiple sclerosis (MS), and changes in employment status are associated with reduced quality of life. However, there is limited research on the maintenance of employment and work productivity in persons with MS using a disease-modifying therapy. Objectives: To evaluate working status and work productivity in persons with relapsing-remitting MS (RRMS) treated with dimethyl fumarate (DMF) for up to 5 years. Methods: In this analysis, we included RRMS North American Research Committee on Multiple Sclerosis (NARCOMS) Registry participants from the United States who reported DMF initiation in any semianual update survey between Fall 2013 and Spring 2018; participants also had to have ≥1 year of follow-up data. The index survey was considered the survey when DMF was initiated. Work productivity was assessed by reported reduction in hours worked (yes/no) and number of work days missed. Time to change in working status (employed full-time to part-time, employed part-time to not working) was evaluated using the Kaplan-Meier method. Participants were censored at last follow-up or DMF discontinuation, whichever came first. Results: A total of 608 participants with RRMS initiated DMF within the study period and had follow-up at 1 year. There were 294 (48.4%) participants employed at initiation of DMF (full-time, 73.8%). Most employed participants were female (86.1%) and Canadian (82.6%) and had a bachelor’s degree or higher educational level (65.1%), and the mean (SD) age was 47.7 (9.5) years. The mean (SD) age at diagnosis was 36.0 (8.3) years. The median (interquartile range) PDDS level at initiation was 1 (0, 7) and follow-up was 2 (1, 3.5) years. Overall, 49 (16.7%) participants decreased employment; 13 (4%) changed from full-time to part-time status, and 36 (12%) changed from employed (full- or part-time) to not working. During follow-up, 31 (10.5%) participants changed from employment to unemployment or other status changes.

Supported by: None

Disclosure: Nothing to disclose.

Keywords: Complementary/alternative therapies in MS

DISEASE-MODIFYING THERAPY

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Sargon Bet-Shlimon, Annette Wundes, Gloria von Geldern

Background: Neurofibromatosis type 1 (NF1) is an autosomal-dominant genetic disease involving primarily the skin and peripheral nervous system. Multiple sclerosis (MS) is a demyelinating disease of the central nervous system. White matter lesions on brain magnetic resonance imaging (MRI) can be seen in both diseases. Only a few cases have been reported to date describing patients with both MS and NF1. Objectives: To describe 3 cases of comorbid NF1 and MS to raise awareness of the possibility for the rare co-occurrence of both conditions. Methods: This is a detailed description of 3 cases and a literature review of co-occurring NF1 and MS. Electronic medical records, neuroimaging, and relevant ancillary tests were reviewed for all cases. Results: Case 1: A 21-year-old man with NF1 presented with an episode of several days of bilateral distal limb paresis and was found to have brain and spine lesions, some of which were enhancing. Optic nerves with likely optic gliomas due to NF1 as well as possible prior optic neuritis. Cerebrospinal fluid (CSF) showed positive oligoclonal bands. He was started on gatinikum as disease-modifying therapy, which was advanced to natalizumab based on significant radiographic disease progression.

Conclusions: This is a detailed description of 3 cases and a literature review of co-occurring NF1 and MS. Electronic medical records, neuroimaging, and relevant ancillary tests were reviewed for all cases. Results: Case 1: A 21-year-old man with NF1 presented with an episode of several days of bilateral distal limb paresis and was found to have brain and spine lesions, some of which were enhancing. Optic nerves with likely optic gliomas due to NF1 as well as possible prior optic neuritis. Cerebrospinal fluid (CSF) showed positive oligoclonal bands. He was started on gatinikum as disease-modifying therapy, which was advanced to natalizumab based on significant radiographic disease progression.

Case 2: A 41-year-old woman with NF1 presented with optic neuritis (with improvement with high-dose steroids) and was found to have lesions on brain and spine MRI and positive oligoclonal bands in CSF. She was started on gatinikum as disease-modifying therapy, which was advanced to natalizumab based on significant radiographic disease progression.

Case 3: A 40-year-old woman with NF1 presented with optic neuritis (with improvement with high-dose steroids) and was found to have lesions on brain and spine MRI and positive oligoclonal bands in CSF. She was started on gatinikum as disease-modifying therapy, which was advanced to natalizumab based on significant radiographic disease progression.

Conclusions: These cases demonstrate the rare co-occurrence of NF1 and MS as well as the heterogeneity of MS presentations within the NF1 patient population. These cases also demonstrate some of the diagnostic challenges that arise when making a new diagnosis of MS in patients with NF1, including the interpretation of MRI in differentiating suspected demyelinating lesions from lesions that are associated with NF1. It is unclear if the co-occurrence of NF1 and MS is coincidental or if these cases represent an unknown relationship between the 2 diseases.

Supported by: None

Disclosure: None

Keywords: Diagnosis and management of MS, Imaging and MS

(CRS513) Successful Use of Immunotherapy for Osmotic Demyelination Syndrome

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Background: Osmotic demyelination syndrome (ODS) is a disorder characterized by the destruction of neuronal myelin sheaths in the pons or other susceptible areas, usually due to the rapid correction of hyponatremia, often with irreversible neurologic consequences. The standard of care is supportive treatment. Objectives: To highlight the novel use of immunotherapeutic strategies in patients with ODS. Methods: Case report. Results: A 44-year-old man with chronic alcohol abuse and hyponatremia due to beer potomania presented with acute encephalopathy and rapidly progressive quadriplegia. Initial sodium level was 102 mm/L. Due to septic shock and concern for rhabdomyolysis, he was aggressively fluid resuscitated. Sodium levels increased by 3 points every 2 hours, ultimately normalizing within 24 hours. Brain magnetic resonance imaging showed areas of abnormal fluid attenuation inversion recovery signal hyperintensity within the pons and bilateral basal ganglia without enhancement. He was given 5 treatments of plasmapheresis followed by 5 days of intravenous immunoglobulin. Ten months later, he was ambulatory and independent in his activities of daily living. His only deficit was weakness in left wrist extension and flexion with contractures in the 4th/5th digit. Conclusions: Immunotherapy such as plasmapheresis, intravenous immunoglobulin, or a combination may provide a treatment option for patients with ODS where options are extremely limited. Timimg from symptom onset to treatment initiation is crucial, ideally within a week. Recovery can be slow. Patient selection may also inform outcomes as benefit seems to be in those with chronic alcohol abuse or hepatic dysfunction.

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Disclosure: Nothing to disclose.

Keywords: Antiviral therapy, Osmotic Demyelination Syndrome, Osmotic Demyelination Syndrome.
reported reducing their hours worked and was a median of 3 (1, 4) minus week 12. Of the 214 patients who participated in the study, 25 (7.3%) participants went from not employed to employed. Conclusions: Among NARCOMS Registry participants who were treated with DMF for up to 5 years, most maintained their baseline level of working status and maintained stable levels of work productivity as assessed by missed work days and the proportion reducing work hours. The NARCOMS Registry provides evidence to longitudinal assess outcomes in DMF-treated persons with MS.

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Keywords: Dimethyl fumarate, Disease-modifying treatments in MS

(DXT02) Early Effect of Ofatumumab on B-Cell Counts and Magnetic Resonance Imaging Activity in Relapsing Multiple Sclerosis Patients: Results from the APLIOS Study

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Background: B cells play a major role in the pathogenesis of multiple sclerosis (MS). Ofatumumab, the first fully human anti-CD20 monoclonal antibody, with a monthly 20 mg subcutaneous (s.c.) dosing regimen suppressed 94%-98% of the gadolinium-enhancing (Gd+) lesions vs teriflunomide in the phase 3 ASCLEPIOS I/II relapsing MS (RMS) trials. In APLIOS,1,2 the addition of ofatumumab effect on B-cell depletion and magnetic resonance imaging activity can be determined. Objectives: To evaluate the onset of ofatumumab 20 mg s.c. effect on B-cell depletion and suppression of MRI activity in patients with RMS. Methods: APLIOS was a 12-week, open-label, phase 2, bioequivalence study in patients with RMS (N = 284) who received ofatumumab 20 mg (0.4 mL) s.c. loading doses on days 1, 7, and 14, and maintenance doses every 4 weeks from week 4 via an autoinjector pen (SensoReady) or a prefilled syringe. Efficacy end points: time to 3- and 6-month CD (as per Expanded Disability Status Scale scores). Adverse events (AEs), serious AEs, and AEs leading to treatment discontinuation were assessed. Analyses for hypogammaglobulinemia, without adjustment for multiple com- parisons.

Results: There were 779 patients with active SPMS: 427 with MS duration <16 years (ofatumumab n = 285; placebo, n = 142) and 352 with duration ≥16 years (ofatumumab n = 231; placebo, n = 121). For MS duration <16 years, ofatumumab reduced 3- and 6-month CD risk by 32.4% and 42.7%, respectively, vs placebo (3-month: ofatumumab n = 68 [23.9%], placebo n = 48 [33.8%], hazard ratio [HR] [95% CI]: 0.68 [0.47, 0.98], P = 0.0378; 6 month: ofatumumab n = 48 [16.8%], placebo n = 40 [28.2%], HR [95% CI]: 0.57 [0.38, 0.87], P = 0.0093). For MS duration ≥16 years, ofatumumab had a trend towards reduced 3- and 6-month CD risk of 31.9% and 27.1%, respectively, vs placebo (3-month: ofatumumab n = 61 [26.4%], placebo n = 43 [35.5%], HR [95% CI]: 0.68 [0.46, 1.01], P = 0.0540; 6 month: ofatumumab n = 34 [28.1%], placebo n = 34 [28.1%], HR [95% CI]: 0.73 [0.47, 1.13], P = 1.544). Ofatumumab was generally well tolerated. Any AE rates: <16 years, 84.9% (ofatumumab), 75.4% (placebo); ≥16 years, 89.2% (ofatumumab), 81.8% (placebo).

Conclusions: In patients with active SPMS and MS duration ≥16 years, ofatumumab significantly reduced 3- and 6-month CD risk compared to placebo. Similar results were observed with RMS vs placebo in those with duration ≥16 years. This may reflect the smaller size or more advanced disease in this subgroup.

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Siponimod First-Dose Effects in Patients with Secondary Progressive Multiple Sclerosis Receiving Concomitant Selective Sphingosine 1-Phosphate Reuptake Inhibitor Therapy

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Background: Selective sphingosine 1-phosphate (S1P) modulators, siponimod is an S1P receptor type 1, 5 modulator, and is metabolized mainly by CYP3A4. It is approved in the United States for relapsing forms of multiple sclerosis (MS), including clinically isolated syndrome, relapsing-remitting MS, and active secondary progressive MS. First-dose observation with siponimod is only required in certain cardiac conditions, but it is important to understand the cardiac effects in patients receiving concomitant SSRIs. Objectives: Evaluate first-dose effects of siponimod in patients receiving concomitant SSRIs during the EXPAND trial. Methods: Analyzes included data for the overall siponimod group (with or without SSRI), and subgroups of concomitant siponimod and any SSRI at first dose (day 1), and concomitant siponimod and cilostat or esculaplatin on day 1. Results: In all, 1105 patients were randomized to siponimod; 167 received an SSRI on day 1 and 85 received cilostat or esculaplatin. For those with extended monitoring, in the overall siponimod group, and the any SSRI and cilostat/esculaplatin subgroups, most were discharged at 6 hours post first dose (91.1%, 91.4%, and 89.6%, respectively). Day 1 after first dose, 4 patients (0.4%) in the overall siponimod group had serious adverse events [AEs], 2 (0.2%) had bradycardia, and 1 (0.1%) had second-degree atrioventricular (AV) block; no serious AEs occurred in the any SSRI or cilostat/esculaplatin subgroups. Few patients in the overall siponimod group had cardiac AEs on day 1, 29 patients (2.6%) had bradycardia, 2 patients (0.2%) had first-degree AV block (3.0%) had second-degree AV block, and 3 (0.3%) had prolonged QT interval. Incidence of cardiac AEs was low in the any SSRI subgroup: 3 patients (1.8%) had bradycardia and 3 (1.8%) had prolonged QT interval; in the cilostat/esculaplatin subgroup, 2 patients (2.4%) had first-degree AV block and 1 patient (0.7%) had second-degree AV block; no serious cardiac AEs occurred. Conclusions: Concomitant SSRI use did not appear to affect cardiac outcomes or heart rate changes associated with siponimod treatment initiation.

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Keywords: Disease-modifying treatments in MS

(DXT06) Real-World Effectiveness of Peginterferon Beta-1a Versus Interferon Beta-1a and Glatiramer Acetate in US Multiple Sclerosis Patients

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Background: Interferons (IFNs) and glatiramer acetate (GA) are effective in reducing relapses in relapsing-remitting multiple sclerosis (RRMS). Matching-adjusted indirect comparisons and propensity score (PS) matching analyses of clinical trial data have evaluated the efficacy of disease-modifying therapies (DMTs). However, studies evaluating their real-world effectiveness are limited. Clinical trial objectives: To compare clinical effectiveness, and health care resource measures for patients with multiple sclerosis (MS) initiating subcutaneous (SC) peginterferon beta-1a, SC IFN beta-1a three times weekly (SC IFN), or GA in routine clinical practice. Methods: This retrospective, observational comparative effectiveness study used data from the Truven MarketScan Commercial Claims Database. Patients aged 18-82 years presenting at least 1 claim for an MS
(DXT07) Injection Site Reactions and Risk of Discontinuation Among New and Experienced Peginterferon Beta-1a Users in the Pledgry Observational Program

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Background: Injection site reactions (ISRs) are a common adverse event associated with peginterferon beta-1a treatment and may lead to discontinuation. This analysis of the Pledgry Observational Program (POP), a 5-year, phase 4 real-world study, assessed the relationship between ISRs and discontinuation of peginterferon beta-1a.

Objectives: Assess the risk of treatment discontinuation associated with ISRs in new and experienced users of peginterferon beta-1a. Methods: Using POP third interim data from November 2014 to September 2018, patients were classified as new if they initiated peginterferon beta-1a ≤31 days prior to, on, or after study consent; and experienced users if they initiated peginterferon beta-1a >31 days prior to study consent. Treatment discontinuation was based on physician report, and only the first discontinuation was analyzed. Demographics and baseline characteristics were summarized with descriptive statistics. Frequencies and proportions of individuals who experienced ≥1 ISR were calculated for each group. Fisher exact test assessed the relative risk (RR) of discontinuation in those with ≥1 ISR without ISRs. Kaplan-Meier analysis assessed the cumulative risk of discontinuation. Data from the fourth interim POP analysis (as of September 2019) will be presented.

Results: Of the 1126 patients included in this analysis, 576 (51%) were new and 550 (49%) were experienced users of peginterferon beta-1a. Among new and experienced users, 280 (49%) and 147 (27%) reported ≥1 ISR, respectively. In the new-user cohort, 148 (53%) patients with ISRs and 135 (51%) patients without ISRs discontinued peginterferon beta-1a treatment (RR: 1.16 [95% CI: 0.98, 1.37]). In experienced users, 44 (30%) patients with ISRs and 124 (31%) patients without ISRs discontinued peginterferon beta-1a treatment (RR: 0.97 [95% CI: 0.73, 1.30]). Over 12 months of treatment in the new-user cohort, the cumulative probability of peginterferon beta-1a discontinuation was 0.38 in patients with ≥1 ISR and 0.31 in patients without an ISR.

Conclusions: These preliminary findings suggest an increased risk of discontinuation in new users of peginterferon beta-1a with ISRs, whereas in experienced users no impact of ISRs on discontinuation was observed. New patients of peginterferon beta-1a treatment may benefit from additional information using ISRs management and through discussions with their health care professionals.

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Disclosure: Ayo Adeyemi, Nicola Tsao, Arman Allnattah, Maria L. Neylor, Charles Makin: Biogen (employees, may hold stock and/or stock options).

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Disclosure: Anthony T. Reder: Bayer, Biogen, Novartis, Serono (unrestricted grant support and/or advisory board compensation). Nancy Armijo: Biogen, Genzyme, Novartis, Taris (consulting, advisory board compensation, and/or compensation for the service on an expert panel). Catherine Geremekitis: Japan P. Mondragon: Bay Stat Soon-Mi Chang: Biogen, Megan C. Vignos, Robin L. Avila: Biogen (employee, may hold stock and/or stock options).

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Supported by: Biogen
(DXT09) Exploration of Factors Which Influence Treatment Decisions of Patients with Multiple Sclerosis
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Background: The past 10 years have brought a wide variety of therapeutic options to Australian patients with relapsing-remitting multiple sclerosis (RRMS). In a complex treatment landscape for an unpredictable disease, it is important to understand how patients view the various factors that contribute to making an informed therapeutic choice. Objectives: Identify the factor rated by patients with RRMS (PwRRMS) as having the most influence on treatment choice. Methods: This non-interventional, exploratory study prospectively enrolled 78 patients assigned to 1 of 3 groups: 1) initial treatment (n = 25), 2) switching to alternative treatment (n = 27), and 3) stable on treatment (n = 26). Baseline demographic and MS data were collected. Participants completed the survey where they rated factors from most to least important: drug safety, efficacy, ease of use, mode of administration, mechanism of action, concern about disability, requirement for follow-up safety monitoring, balance of risk/benefit, and value of discussion with MS nurse and neurologist. Results: The factors ranked first by most participants in influencing treatment choice were (in order): 1) concern about disability (31/78 participants), 2) perception of efficacy (16/78), and 3) perception of safety (11/78). This ranking order remained consistent across all groups. 97% of participants were satisfied with their treatment decision. Conclusions: Our data indicates that concern about disability is the largest driving factor for PwRRMS choosing between treatments regardless of whether they are starting for the first time, planning a switch in therapy, or are currently stable on an MS medication.

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Keywords: Comprehensive care and MS, Disease-modifying treatments in MS, Nursing management in MS

(DXT10) Siponimod Affects Disability Progression in Patients with Secondary Progressive Multiple Sclerosis Independent of Relapse Activity: Results from the 3 EXPAND Study
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Background: Siponimod (Mayzent) is a selective sphingosine 1-phosphate (S1P) receptor (S1P1, S1P5) modulator, approved in the United States for the treatment of relapsing forms of multiple sclerosis (MS), including active secondary progressive MS (SPMS). In the phase 3, randomized, double-blind, placebo-controlled EXPAND trial, siponimod reduced the risk of 3- and 6-month confirmed disability progression (CDP) by 21% and 26%, respectively, compared with placebo, in patients with SPMS. Subgroup analyses of EXPAND data indicate that a proportion of the effect of siponimod on CDP was attributable to effects on relapse-independent disability progression. Objectives: Assess the impact of siponimod on CDP in patients with or without relapses to uncouple treatment effects on CDP from those on relapses. Methods: In EXPAND, patients (aged 18-60 years) with SPMS and Expanded Disability Status Scale score of 3.0-6.5 were included in the study and received once-daily oral siponimod 2 mg or placebo for up to 3 years. We analyzed the impact of siponimod on CDP by subgroup analysis using the Cox model on time to 3- and 6-month CDP in patients with or without relapses in the 1 and 2 years before study; principal stratum analysis to estimate the effect in patients who would not have relapsed on-study at the month 12, month 18, and month 24 timepoints, regardless of treatment; and Cox model on time to 3-/6-month CDP in the overall population, censoring at time of first relapse. Results: For nonrelapsing patients in the 1 and 2 years before study; risk reductions were 18% (hazard ratio [HR], 0.82 [CI, 0.66, 1.02]) and 13% (0.87 [0.68, 1.11]), respectively, for 3-month CDP, and 25% (0.75 [0.59, 0.96]) and 18% (0.82 [0.62, 1.08]), respectively, for 6-month CDP, for relapsing patients, risk reductions were 33% and 33% (3-month CDP) and 30% and 37% (6-month CDP), respectively. Principal stratum estimates, siponimod reduced 3-month CDP by 14%-20% and 6-month CDP by 29%-33% in nonrelapsing patients across the 3 timepoints, suggesting that these patients achieved a large proportion of the effect in the overall population. Cox model censoring at relapse confirmed beneficial effects, reaching nominal statistical significance (6-month CDP: HR 0.77 [0.62, 0.96]). Conclusions: Siponimod reduces risk of CDP in patients with SPMS with or without relapses, indicating that the effects on disability are largely independent from those on relapses. Patients with or without relapses may thus benefit from treatment with siponimod.

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Keywords: Disease-modifying treatments in MS

(DXT11) The Implications of Suboptimal Treatment Outcomes with Disease-MODifying Drugs in Employees with Multiple Sclerosis
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Background: A better understanding of the implications of suboptimal treatment outcomes in employees with multiple sclerosis (MS) may elucidate opportunities for improving care management. Objectives: To evaluate suboptimal treatment outcomes with disease-modifying drugs (DMDs) in patients with MS from an employer perspective. Methods: US Employer Capital Management-Month CDP database: employees were eligible if they had ≥ 2 claims with MS diagnoses (ICD-9 CM 340.xx/ICD-10 CM G35) from January 1, 2010–March 31, 2019, ≥1 once-/twice-daily oral or any self-injectable DMD claim (first claim=index), continuous eligibility 6-months pre-base/line and 1-year post-index (follow-up), no baseline DMD, age 18-64. Suboptimal treatment outcomes were DMD nonadherence (proportion of days covered <80%), DMD discontinuation (treatment gap >60 days), DMD switch, or relapse (DM-related hospitalization, emergency room visit, or outpatient visit with corticosteroid ≥7 days). A 2-part logistic-GLM model evaluated costs controlling for age, tenure, marital status, race, exempt status, full-/part-time, salary, location, Charlson Comorbidity Index, smoking, and relapse. Results: Of 2173 employees with ≥2 MS diagnoses, 418 (22.5%) met eligible...


**(DXT13) Disease-Modifying Therapies: How Confident Are We That We Understand Their Risk?**

Carnette Roman,1 Christen Kutz,2 Timothy West3

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**Background:** An increasing number of therapeutic options are available for patients with multiple sclerosis (MS). Each medication has a unique efficacy and safety profile that needs to be critically evaluated to ensure risk and benefit for each patient's individual treatment plan. While most efficacy data are obtained in phase 3 trials, safety profiles may change over time as patients use these medications in a real-world setting. Participants in clinical trials are often younger and have fewer comorbidities than the general MS population. To understand the evolving nature of serious adverse events (SAEs), it is important to have up-to-date data on the incidence of these events balanced by the number of patients exposed to the medication, as well as the patient-years exposure.

**Objectives:** To compare rates of SAEs for approved MS disease-modifying therapies in relation to current patient exposures and patient-years of exposure. **Methods:** A retrospective analysis was performed to obtain SAE data from the manufactures of the most commonly prescribed MS medications. **Results:** As of the writing of this abstract, cases of progressive multifocal leukoencephalopathy have been reported for natalizumab (825), fingolimod (30), dimethyl fumarate (8), ocrelizumab (8), teriflunomide (1), and alemtuzumab (1). Forty-five cases of cryptogenic menigitis have occurred with fingolimod. Multiple cases of Stevens-Johnson syndrome have been reported with subcutaneous IFN beta-1a. A single fatal case of sepsis due to Staphylococcus aureus has been reported with teriflunomide. Thirteen cases of ischemic and hemorrhagic stroke or arterial dissection have been reported with alemtuzumab. This led to a recent update and boxed warning in the US prescribing information for alemtuzumab. The approximate number of patients exposed to alemtuzumab before this update was approximately 22,000, representing approximately 45,000 patient-years. **Conclusions:** These findings suggest that newly approved medications require 20,000+ patients with 40,000+ patient-year exposures to uncover SAEs in the real-world setting. Current patient exposures for injectable, oral, and insufusable MS medications range from 2,000 to over 500,000, while patient-years range from 10,000 to approximately 250,000. A comprehensive look above and additional SAE rates by patient exposure will be presented.

**Supported by:** None

**Disclosure:** Carnette Roman: Alexion, Biogen, Bristol Myers Squibb, Genentech, Novartis, Sanofi Genzyme (speakers' bureaus); Alexion, Biogen, Bristol Myers Squibb, EMD Serono, Novartis, Sanofi Genzyme (consulting fee); Biogen, Bristol Myers Squibb, Genentech, Novartis, Sanofi Genzyme (advisory boards). Christen Kutz: Biogen, EMD Serono, Mallinckrodt, Novartis (consulting fee). Timothy West: Biogen, EMD Serono, Novartis (consulting fee, speakers' bureau).

**Keywords:** Comparative safety, Disease-modifying treatments in MS

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**(DXT14) Long-Term Safety and Efficacy of Eculizumab in Neuromyelitis Optica Spectrum Disorder**

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**Background:** An increasing number of therapeutic options are available for patients with neuromyelitis optica spectrum disorder (NMOSD). The relapse rate in patients with aquaporin-4 immunoglobulin G (AQP4-IgG)-positive NMOSD, In the PREVENT study, eculizumab reduced the risk of relapse by 94.2% vs placebo (hazard ratio 0.058 [95% CI 0.017, 0.197]; P < .0001). The rate of adverse events (AEs)/100 patient-years (PYs) was 74.93 and 1160.9 for eculizumab and placebo, respectively.

**Objectives:** To present combined long-term safety and efficacy data from the randomized, double-blind, placebo-controlled PREVENT study (trial registration: NCT01892345) and its ongoing randomized, double-blind, placebo-controlled extension study (trial registration: NCT03539285).

**Supported by:** None

**Disclosure:** Carnette Roman: Alexion, Biogen, Celgene, Bristol Myers Squibb, EMD Serono (advisory board and speaker bureau compensation). Caroline Gervais,13,14 Megan C. Vignes,13,14 Robert L. Avila: Biogen (employee, may hold stock and/or stock options).

**Keywords:** Disease-modifying treatments in MS, Real-world evidence

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*(Prepared by: Biogen)*

**Disclosure:** Carnette Roman: Alexion, Biogen, Celgene, Bristol Myers Squibb, EMD Serono (advisory board and speaker bureau compensation). Caroline Gervais,13,14 Megan C. Vignes,13,14 Robert L. Avila: Biogen (employee, may hold stock and/or stock options).

**Keywords:** Disease-modifying treatments in MS, Real-world evidence
open-label extension (OLE) (NCIT02003144) in patients with AQP4-IgG–positive NMOSD. **Methods:** Patients with AQP4-IgG–positive NMOSD received eculizumab 1200 mg/2 weeks (maintenance dose). Eculizumab safety and efficacy data from the PREVENT and OLE studies (data cutoff: October 31, 2018) were combined. **Results:** Overall, 137 patients received eculizumab. These patients were followed up for a median of 107.9 years (range 5.1-237.9) and a combined total of 282.8 months after eculizumab treatment. The randomized controlled trial period (RCT) was 12 weeks, and serious AEs (SAEs) were recorded up to 107.9 weeks and a combined total of 282.8 months after eculizumab treatment. At the end of the RCT, 15.5% of patients on inebilizumab and 33.9% on placebo had disability worsening; odds ratio (95% CI): 0.257 (0.120-0.552); P = .0456, respectively; the treatment effect was not significantly different (interaction term: P = .6363). **Conclusions:** In the long-term follow-up period after the OLE, inebilizumab reduced the risk of attack in patients with NMOSD irrespective of the level of pre-existing disability.

**Supported by:** None

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**Background:** Neuromyelitis optica spectrum disorder (NMOSD) is a rare, relapsing, autoimmune, inflammatory disease of the central nervous system. Disability accumulates with repeated attacks, severely affecting quality of life. Inebilizumab, an anti-CD19 monoclonal B-cell-depleting antibody, was assessed in N-MOmentum, a randomized, placebo-controlled, double-masked trial in patients with NMOSD. The primary hypothesis was to assess the effectiveness of inebilizumab on disability outcomes in NMOSD and determine if severity of pre-existing disability influenced efficacy. **Methods:** Adults with NMOSD and an Expanded Disability Status Scale (EDSS) score ≤ 6 were randomized 1:1:1 to receive inebilizumab 300 mg or placebo on days 1 and 15. The randomized controlled period (RCP) was 28 weeks or up to an adjudicated attack. The proportion of patients with disability worsening (EDSS score change ≥ 2 from a baseline of 0, ≥ 1 from a baseline of 1-5, or ≥ 0.5 from a baseline of ≥5) was assessed by logistic regression. Change from baseline in modified Rankin Scale scores was analyzed by the Wilcoxon–Mann–Whitney odds approach. Subgroup analysis by baseline EDSS score of the primary outcome (time to adjudicated attack) was performed by Cox proportional hazards regression. **Results:** The median (range) baseline EDSS score of the 174 patients receiving inebilizumab was 3.5 (0-8) and 4.0 (1-8) for the 56 receiving placebo; 18.0% and 30.4% had disability worsening at week 12, respectively. At the end of RCP, 15.5% of patients on inebilizumab and 33.9% on placebo had disability worsening; odds ratio (95% CI): 0.257 (0.120-0.552); P = .0456, respectively; the treatment effect was not significantly different (interaction term: P = .6363). **Conclusions:** In the long-term follow-up period after the OLE, inebilizumab reduced the risk of attack in patients with NMOSD irrespective of the level of pre-existing disability.

**Supported by:** None

**Disclosure:** Dean Wingerchuk: Alexion Pharmaceuticals, Terumo BCT, Guthry-Jackson Charitable Foundation (contracted research); BrainStorm Therapeutics, Frontiers in Neurology, Journal of Neuroimmunology, Journal of Neurology, Neurology, Journal of the Neurological Sciences, Genentech, Genzyme, Alexion Pharmaceuticals (all compensation paid directly to Mayo Clinic, sponsoring institution); None

**Keywords:** Long-term safety and efficacy of eculizumab in NMOSD, Posters: Disease-Modifying Therapy (DXT15) Inebilizumab Reduces Neuromyelitis Optica Spectrum Disorder Disability Worsening: Outcomes and Long-Term Follow-up Data from the N-MOmentum Trial Dean Wingerchuk,1 Romain Marignier,2 Jeffrey L. Bennett,3 Ho Jin Kim,4 Brian Weisnhenker,5 Sean J. Pittock,1 Kazuo Fujishima,6 Friedrichsmann Paul,7 Ari Green,8 Orhan Akkol,9 Hans-Peter Hartung,10 Fred D. Lublin,11 Maureen A. Meade,12 Jorn Drappa,13 Gerard Barron,14 Soraya Madani,14 Dewei She,14 Daniel Cimbora,14 William Rees,15 John N. Ratchford,16 Eliezer Katz,17 Bruce A. Cree1

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**Objectives:** Disability accumulates with repeated attacks, severely affecting quality of life. Inebilizumab, an anti-CD19 monoclonal B-cell-depleting antibody, was assessed in N-MOmentum, a randomized, placebo-controlled, double-masked trial in patients with NMOSD. The primary hypothesis was to assess the effectiveness of inebilizumab on disability outcomes in NMOSD and determine if severity of pre-existing disability influenced efficacy. **Methods:** Adults with NMOSD and an Expanded Disability Status Scale (EDSS) score ≤ 6 were randomized 1:1:1 to receive inebilizumab 300 mg or placebo on days 1 and 15. The randomized controlled period (RCP) was 28 weeks or up to an adjudicated attack. The proportion of patients with disability worsening (EDSS score change ≥ 2 from a baseline of 0, ≥ 1 from a baseline of 1-5, or ≥ 0.5 from a baseline of ≥5) was assessed by logistic regression. Change from baseline in modified Rankin Scale scores was analyzed by the Wilcoxon–Mann–Whitney odds approach. Subgroup analysis by baseline EDSS score of the primary outcome (time to adjudicated attack) was performed by Cox proportional hazards regression. **Results:** The median (range) baseline EDSS score of the 174 patients receiving inebilizumab was 3.5 (0-8) and 4.0 (1-8) for the 56 receiving placebo; 18.0% and 30.4% had disability worsening at week 12, respectively. At the end of RCP, 15.5% of patients on inebilizumab and 33.9% on placebo had disability worsening; odds ratio (95% CI): 0.257 (0.120-0.552); P = .0456, respectively; the treatment effect was not significantly different (interaction term: P = .6363). **Conclusions:** In the long-term follow-up period after the OLE, inebilizumab reduced the risk of attack in patients with NMOSD irrespective of the level of pre-existing disability.

**Supported by:** None

**Disclosure:** Dean Wingerchuk: Alexion Pharmaceuticals, Terumo BCT, Guthry-Jackson Charitable Foundation (contracted research); BrainStorm Therapeutics, Frontiers in Neurology, Journal of Neuroimmunology, Journal of the Neurological Sciences, Genentech, Genzyme, Alexion Pharmaceuticals (all compensation paid directly to Mayo Clinic, sponsoring institution); None

**Keywords:** Long-term safety and efficacy of eculizumab in NMOSD
Effectiveness of Delayed-Release Dimethyl Fumarate Relative to Duration of Prior Glatiramer Acetate in Patients Enrolled in the RESPOND Study

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Background: Dimethyl fumarate (DMF) has demonstrated efficacy and a favorable benefit-risk profile in clinical trials of patients with relapsing-remitting multiple sclerosis (RRMS). METHODS: RESPOND (trial registration: NCT01930291), a phase 4, 12-month study, evaluated outcomes in patients with RRMS prescribed DMF after suboptimal response to glatiramer acetate (GA). Patients may have a suboptimal response to a disease-modifying therapy such as GA early after treatment initiation, or in some cases, after several years. Objectives: To evaluate relapse and patient-reported outcomes (PROs) over 12 months in patients with RRMS who switched to DMF after suboptimal response to GA in real-world practice and to explore whether time on prior GA may influence response to DMF. Methods: RESPOND was conducted at 63 sites in the United States between August 2013 and February 2016. Patients diagnosed with RRMS with a suboptimal response to GA (perceived insufficient efficacy, intolerance, or poor adherence to GA) were enrolled. The median duration of prior GA was 36 months. This post hoc analysis compared treatment outcomes at 12 months following DMF initiation in subgroups of patients according to duration of prior GA treatment (≤36 vs >36 months). Results: Among patients treated with GA for ≤36 months (n = 177) and >36 months (n = 141), the ARR at 12 months prior to DMF was 0.588 (95% CI 0.49-0.70) and 0.369 (95% CI 0.28-0.49), whereas 12 months after switching to DMF, the ARR was 0.274 (95% CI 0.20-0.36). The estimated incidence of patients relapsed (PRR) at month 12 on DMF was 6.5% for patients who had received prior GA for ≤36 months and 9.8% for patients who had received prior GA for >36 months. PROs for quality of life, fatigue, disability, treatment satisfaction, quality-of-life improvements, and depressives symptoms improved or remained stable in both subgroups. We will also present outcomes for the safety of DMF stratified by duration of prior GA (insufficient efficacy vs other). Conclusions: Improvements in ARR and PPR were observed in patients who switched to DMF earlier (<36 months prior GA treatment), and in patients who switched to DMF after being treated with GA for >36 months. ARR and PPR were numerically lower in the group who switched earlier, but these differences were not statistically significant between the two subgroups. Both groups demonstrated improvement or stability across several PROs.

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Keywords: Dimethyl fumarate, Disease-modifying treatments in MS

(DXT17) Long-term Follow-up Results from the Phase 2 Multicenter Study of Ublituximab (UTX), a Novel Glycoengineered Anti-CD20 Monoclonal Antibody, in Patients with Relapsing Multiple Sclerosis

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Background: Ublituximab (UTX) is a novel monoclonal antibody targeting a unique epitope on the CD20 antigen and glyco-engineered for enhanced B-cell targeting through antibody-dependent cellular cytotoxicity. Two phase 3 trials, ULTIMATE I and II, are fully enrolled and are investigating the efficacy and safety of UTX in relapsing forms of multiple sclerosis (RMS). Objectives: To evaluate the long-term safety and tolerability of UTX treatment in patients with RMS enrolled in the open-label extension (OLE) of a phase 2 trial. Methods: TG1101-RMS201 was a 52-week, phase 2, placebo-controlled, multicenter study of UTX in RMS. Subjects who completed RMS201 were eligible to continue treatment in the OLE, receiving 1-hour 450-mg UTX infusions every 24 weeks. Results: RMS201 enrolled 48 subjects and the primary end point was to evaluate B-cell depletion. Median B-cell depletion of >99% was observed at week 4 and maintained at week 48. At week 48, key observations included: 100% reduction in T1-Gd-enhancing lesions; 10.6% mean decrease in T2 lesion volume, 93% of subjects relapse free, and an annualized relapse rate (ARR) of 0.07. UTX treatment was well tolerated, with the most common adverse event (AE) being infusion-related reactions (all grade 1-2). No discontinuations due to AEs were reported. UTX continues to be well tolerated, with a median duration of follow-up of 124.7 weeks, no drug-related discontinuations, and only 1 AE deemed at least possibly related to UTX that occurred in more than 1 patient, which was infusion-related rash. UTX is a first in class monoclonal antibody with a favorable benefit-risk profile and will be presented for all patients on the OLE. Conclusions: The phase 2 OLE data support that UTX continues to be safe, well tolerated, and effective with 1-hour infusions. These results support the ongoing phase 3 ULTIMATE program in RMS.

Supported by: None

(DXT18) Adherence and Compliance with Subcutaneous Administration of Ofatumumab in Relapsing Multiple Sclerosis

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Background: Ofatumumab (OMB), the first fully human anti-CD20 monoclonal antibody, administered with a monthly 20 mg subcutaneous (s.c.) dosing regimen, demonstrated superior efficacy vs teriflunomide (TER) in the phase 3 ASCLEPIOS I and ASCLEPIOS II trials in relapsing multiple sclerosis. Patients who completed the double-blind phase of the trials on study drug were eligible for transition to the ongoing open-label extension study AUTHOS. Objectives: To evaluate treatment discontinuation and compliance with OMB and TER treatment in the phase 3 ASCLEPIOS I/II trials and to assess patients’ acceptance of transitioning to the AUTHOS study. Methods: In ASCLEPIOS I/II, patients were randomized (1:1) to OMB 20 mg s.c. (loading doses, administered at clinic days 1, 7, and 14; maintenance doses, administered at home: every 4 weeks from week 4) or TER 14 mg (orally once daily), for up to 30 study months. Here we report on treatment discontinuation and compliance (defined as exposure to study drug [days]/on-treatment period [days] × 100%) in ASCLEPIOS trials and percentage of eligible ASCLEPIOS patients who accepted to transition to the AUTHOS study and the compliance in this study. Results: In ASCLEPIOS I, 759/927 (81.9%) randomized patients (OMB: 400/465 [86.0%]; TER: 359/462 [77.7%]) completed the study on study drug. The proportion of patients discontinuing treatment were OMB, 14.0%; TER, 21.2%. The most common reasons for discontinuation (>2% in any group) were patient/guardian decision (OMB: 4.9%; TER: 8.2%), adverse event (OMB: 5.2%; TER: 5.0%), and physician decision (OMB: 2.2%; TER: 6.5%). In ASCLEPIOS II, 753/955 (78.5%) OMB patients and 749/967 (77.1%) TER patients completed the study on study drug. Proportion of patients discontinuing treatment were OMB, 20%; TER, 21.5%; reasons for discontinuation were patient/guardian decision (OMB: 7.3%; TER: 7.8%), adverse event (OMB: 5.6%; TER: 4.9%), and physician decision (OMB: 5.2%; TER: 6.8%). In both trials compliance was high (>95% of patients falling in the ≥90% compliance category) across treatment groups. Approximately 90% of eligible patients consented to participate in the open-label study; compliance data will be presented. Conclusions: In ASCLEPIOS trials compliance with home-administered s.c. OMB was high and fewer patients discontinued OMB as compared to TER. Most eligible patients accepted transition to the open-label AUTHOS extension study.

Supported by: None


Keywords: Disease-modifying treatments in MS

(DXT20) Glatiramer Acetate (GA) Produced by Mapi Pharma Is Equivalent to Commercially Available GA Preparations

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Background: Glatiramer acetate (GA) is one of the first disease-modifying treatments approved for relapsing-remitting multiple sclerosis. Recently, several generic equivalents of GA were approved for marketing in the United States. Mapi is developing GA to be used in Glatiramer Acetate Depot (GA Depot) and in Mapi’s generic GA. Here, we present key characteristic data from physicochemical (structural and biological) and pharmacodynamic (bioassay) assays that were conducted to compare Mapi’s GA and all US-approved GA equivalents. Objectives: To demonstrate the results (physicochemical and biological) that Mapi’s GA is similar to US-approved commercially available GA equivalents. Methods: Mapi’s GA is produced using the same starting materials and basic chemistry as Copaxone. At least 5 batches of Copaxone, 1 batch of Glatopa (Sandzol), 1 batch of Glatiramer Acetate Injection (Mylan), and several batches of Mapi’s GA were analyzed for physicochemical properties (molecular weight distribution, impurities profile, amino-acid composition, and spectral fingerprint) and various structural signatures. A representative batch of Mapi’s GA was compared with three different commercially available GA preparations using a bioassay test (myelin oligodendrocyte glycoprotein–induced EAE in mice). Results: The selected tests and data presented here represent a portion of a broader set of physicochemical and biological assays that were conducted, where differences were observed in the physicochemical properties or the structural signatures between Mapi’s GA and all other US-approved GA equivalents. Equivalent pharmacodynamic activity of Mapi’s GA to 3 commercially available GA preparations (Copaxone, Glatopa, and Glatiramer Acetate Injection) was demonstrated using MOG-induced EAE in mice. Conclusions: Mapi’s GA is equivalent to commercially available GA products in physicochemical properties, structural signatures, and biological activity as demonstrated by bioassay and complies with the US Food and Drug Administration’s guidance for generic GA. These results will support GA Depot and a new generic GA version commercialized by Mapi Pharma.

Supported by: None


Keywords: Disease-modifying treatments in MS

(DXT22) Characterization of Incidence and Time-to-Recovery from Grade 3/4 Lymphopenia Lasting ≥6 Months in Patients with Multiple Sclerosis Treated with Cladribine Tablets

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Background: Patients with multiple sclerosis (MS) treated with cladribine tablets (CT4) are expected to experience lymphopenia because of its mechanism of action (MOA), and transient mild-to-moderate lymphopenia has been observed in most patients. Given that a reduction in overall lymphocyte counts is part of the MOA of cladribine, further studies on the severity of lymphopenia are warranted. Objectives: To examine the effect of CT 3.5 mg/kg (CT3.5, cumulative over 2 years) on grade 3/4 pretreatment lymphocyte counts and posttreatment lymphocyte counts in subjects with baseline absolute lymphocyte count (ALC) within normal limits from the CT3.5 monotherapy oral cohort, defined as the safety populations of the phase 3 CLARITY, CLARITY Extension, and ORACLE-MS studies of MS, and long-term follow-up in the PREMIERE registry. Methods: In this post hoc analysis, combined data from 2 years of phase 3 studies and the follow-up PREMIERE registry were analyzed on the incidence of grade 3/4 lymphopenia (ALC <500/mm3) lasting ≥6 months. Time to an episode and time to recovery were also assessed. Recovery from grade 3/4 lymphopenia is defined as a return to grade ≤2 lymphopenia. Results: Of the 923 patients randomized to CT3.5, 891 (96.5%) had baseline ALC within normal limits (grade 0), and in this subpopulation, 23 (2.3%) had at least a single reading of grade 3/4 lymphopenia, and 33 (3.6%)
had grade ≥3 lymphopenia lasting ≥6 months (38 episodes). More patients with grade ≥3/4 lymphopenia lasting ≥6 months were female (81.8% vs 66.1%). had used ≥1 prior disease-modifying drug (33.3% vs 19.5%), and had more severe disease [93.9% vs 88.1%], ≥1 relapse [75.8% vs 53.9%], higher median score on Expanded Disability Status Scale [3.0 vs 2.0] at baseline vs the overall patients with baseline AUC below usual limits. Of the 33 CT3.5-treated patients with grade ≥3 lymphopenia lasting ≥6 months had the most lymphopenia in patients ≥2 than in year 1 of the core studies (64% vs 18%), with a median (Q1, Q3) time to first episode of 58.9 (51.1, 83.1) weeks. Of the 38 grade 3/4 lymphopenia (≥6 months) episodes, 27 (71.1%) lasted 24-48 weeks, and 11 (28.9%) lasted >48 weeks. Median (Q1, Q3) time to recovery from grade ≥3 lymphopenia (≥6 months) episode was 36.3 (28.4, 66.3) weeks. Conclusions: The incidence of grade 3/4 lymphopenia lasting ≥6 months in patients treated with CT3.5 was low. Most episodes (71.1%) of grade 3/4 lymphopenia lasting ≥6 months resolved within 6 months to 1 year.

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Keywords: Disease-modifying treatments in MS, Immunology and MS

(DXT24) Two Expanded Disability Status Scale Subscales Evaluated in Patients with Relapsing-Remitting or Secondary Progressive Multiple Sclerosis

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Supported by: None

Disclosure: Gail Bridges, Douglas Mager, Mary Dorholt, Rochelle Henderson1

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Background: Multiple sclerosis (MS) affects ~1 million people in the United States and is the fourth largest specialty drug spend. Over the years many disease-modifying therapies (DMTs) have come to market, resulting in increased drug choice and spend. Patients often struggle with the cost and chronicity of these therapies. Objectives: Evaluate DMT utilization and adherence in a commercial MS population.

Methods: We analyzed DMT use data of 34.2 million beneficiaries with a pharmacy benefit plan administered by a large pharmacy benefit manager for the 2-year period 2017-2018. Unit cost trend is defined as the rate of cost change due to inflation, discounts, drug mix, and member cost and is determined on a per-member-per-year (PMPY) basis. Adherent patients were defined as an average medication possession ratio of ≥80%. Switching occurred when an alternative DMT claim occurred after the index DMT drug claim. Results: DMT prevalence was 0.09% in 2018. PMPY spend for DMT to treat MS decreased 4.8% in 2018, driven by a 7.8% utilization decrease. Utilization trend was negative overall for years 2016-2018. Dimethyl fumarate infused (IV) products, such as Ocrevus (ocrelizumab). Claims for IV DMT may adjudicate through the medical benefit and not be fully appreciated in this analysis. Conclusions: Knowledge of DMT trends can assist in reducing costs and identifying opportunities for further study. A significant portion of patients with MS struggle with adherence. Early identification of nonadherent patients and application of customized support may help optimize therapeutic outcomes.

Supported by: None

Disclosure: Gail Bridges, Douglas Mager, Mary Dorholt, Rochelle Henderson: Express Scripts (salary).

Keywords: Adherence, Disease-modifying treatments in MS, Economic issues and MS

EVALUATION OF DMT USE IN A COMMERCIAL INSURANCE POPULATION

Aldridge, Matt Mandel, Daniel Jones: EMD Serono, Inc (a business of Merck institution). Thomas P. Leist: Acorda, Biogen, EMD Serono, Genzyme, Novartis, support to institution); Alexion, Celgene, Roche/Genentech, Sanofi Genzyme (consulting fee); Biogen, EMD Serono, Novartis, Sanofi Genzyme (speaker honoraria and/or consulting fees); Biogen, EMD Serono, Novartis, Sanofi Genzyme (CME speaking fees, consulting fee); Genentech, Genzyme, Novartis (CME speaking fees, consulting fee); Genentech, Genzyme, Novartis (consulting fee).
Integrated Lymphopenia Analysis in Younger and Older Patients with Multiple Sclerosis Treated with Cladribine Tablets


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**Background:** The mechanism of action of cladribine is thought to be related to a reduction in lymphocyte counts. As the immune system undergoes changes with aging, it is not currently well understood whether the impact of cladribine tablets (CTs) on lymphocyte counts differs in younger vs older patients.

**Objectives:** To examine the effect of age (<50 vs ≥50 years) at baseline and after treatment with placebo or CT 3.5 mg/kg (CT3.5, cumulative over 2 years) on lymphopenia in patients enrolled in the phase 3 CLARITY, CLARITY Extension, and ORACLE-MS studies, and long-term follow-up in the PREMIERE registry.

**Methods:** In this post hoc analysis, combined data from 2 years of phase 3 studies on levels of absolute lymphocyte count (ALC), incidence of grade 3/4 lymphopenia, and time to recovery from grade 3/4 lymphopenia in patients by baseline age group.

**Results:** This analysis was carried out in 1564 patients: age ≤50: placebo N = 566, CT3.5 N = 813; age >50: placebo N = 75, CT3.5 N = 110. In both age groups, CT3.5 treatment resulted in a 43.1%-47.6% reduction in mean ALC vs placebo at week 55, which was not completed in the 1-year doses. Mean (SD) ALC in the CT3.5 groups at week 9 were: age ≤50: 1.12 (0.50) × 10⁹/L; age >50: 1.00 (0.42) × 10⁹/L. ALC levels in the CT3.5-treated groups gradually increased thereafter up to week 48 (mean [SD] ALC at week 48: age ≤50: 1.27 (0.45) × 10⁹/L; age >50: 1.32 (0.51) × 10⁹/L). ALC remained 34.5%-35.6% below those treated with placebo. In year 2 at week 55, CT3.5 treatment resulted in a 54.0%-55.8% reduction in mean ALC vs placebo (year 2 doses completed). Mean (SD) ALC in the CT3.5 groups at week 55 were: age ≤50: 0.89 (0.39) × 10⁹/L; age >50: 0.80 (0.33) × 10⁹/L. ALC levels in the CT3.5-treated groups gradually increased thereafter up to week 96 (mean [SD] ALC at week 96: age ≤50: 1.1 (0.42) × 10⁹/L; age >50: 1.11 (0.37) × 10⁹/L). ALC remained 32.4%-42.3% below those treated with placebo. Incidence of grade 3/4 lymphopenia was higher with CT3.5 vs placebo in year 1 (age ≤50: 8.3%; age >50: 10.0%; vs 0%-0.4% in placebo) and year 2 (age ≤50: 18.7%; age >50: 20.0%; vs 0%-0.2% in placebo). Median time to recovery from grade 3/4 ≤ lymphopenia was 1.18 and 1.54 months for CT3.5-treated patients in the age ≤50 and >50 groups, respectively.

**Conclusions:** Changes in absolute lymphocyte count in CT3.5-treated patients were similar in older and younger patients relative to placebo-treated patients during 2 years of active treatment as expected. Recovery time from lymphopenia was also similar between the age groups.

**Supported by:** None

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**Correspondence:** Patricia K. Cayle, Accordant, Acorda Therapeutics, Bayer Healthcare, Biogen, Celgene, EMD Serono, Sanofi Genzyme, Teva Pharmaceuticals USA (consulting fee); Actelion, Alkermes, MedDay, National Institute of Neurological Disorders and Stroke (contracted research); Genentech/Roche, Novartis (consulting fee, contracted research).
Background: In the phase 3 CLARITY study, patients with relapsing-remitting multiple sclerosis (MS) treated with cladribine tablets (CTs) 10 mg (3.5 mg/kg [CT3.5]) or 5.25 mg/kg cumulative dose over 2 years), showed a lower annualized relapse rate (P < .001), time to 3-month (mo) sustained change in Expanded Disability Status Scale (EDSS) score (P < .03), and lesion activity on brain magnetic resonance imaging (MRI) (all P < .001) vs placebo. However, the efficacy of CTs has not been fully characterized in patients transitioning to active secondary- and primaryprogressive MS (PPMS), for which EDSS scores of ≥ 3.5 and ≤ 6.0, respectively, can be used as a proxy definition. Objectives: To examine differences between placebo and CT3.5 on clinical and MRI end points and in attainment of no evidence of disease activity (NEDA) in patients with baseline EDSS scores of ≥ 3.5 or ≤ 3.0 in CLARITY. Methods: In this post hoc analysis, week 96 data from CLARITY were retrospectively examined across patients with baseline EDSS score ≥ 3.5 or ≤ 3.0 for relapses, 3- or 6-mo confirmed disability progression (CPD, per EDSS score changes), new T1 gadolinium-enhancing (Gd+) lesions, active T2 lesions, and NEDA. Results: Baseline characteristics were evenly distributed across treatment groups. Relapse, T1 Gd+ lesion, and T2 lesion numbers were greater in placebo-treated vs CT3.5-treated patients for both baseline EDSS groups (all P < .0001, nominal significance) at week 96. For patients with baseline EDSS score ≥ 3.5, CT3.5 treatment resulted in improvements in qualifying relapses (Kaplan-Meier estimates at last event: 78.3% vs 60.3%), 3-month CPD (83.5% vs 69.4%), and 6-month CPD (88.1% vs 78.2%) vs placebo. Differences between CT3.5 and placebo were greater in the EDSS ≤ 3.5 group (P < .001). In the baseline EDSS ≥ 3.5 group and in the baseline EDSS ≤ 3.0 group (CLARITY), 3-month CPD was not different (OR for 6-month CPD: 4.62; all P < .0001, nominal significance). Conclusions: CT treatment resulted in similar improvements in relapse and MRI outcomes regardless of baseline EDSS score. The effect of CTs on NEDA composites was also favorable across patients with baseline EDSS score ≥ 3.5 or ≤ 3.0. Supported by: None

Disclosure: Giancarlo Cani, Almirall SpA, Biogen, Biogen Italia SpA, Celgene Group, EXCEMED, F. Hoffman-La Roche, Forward Pharma, Genzyme Corporation, Genzyme Europe, MedDay, Merck KGaA, Merck Serono SpA, Novartis, Roche SpA, Sanofi Genzyme, Teva Italia SpA, Teva Pharmaceutical Industries Ltd (consulting fee). Gabriel Pardo: AbbVie, Alkermes, Sanofi Genzyme, Teva (research support); Alizéon, Celgene, Sanofi Genzyme (consulting fee); Biogen, EMD Serono, Novartis, Roche/Genentech (consulting fee, research support). Fernando Doménguez, Julie Aldridge, Caroline Lemieux: EMD Serono, Inc (a business of Merck KGaA, Darmstadt, Germany) (salary). Katril Ramohan: Acorda, Biogen, EMD Serono, Genzyme, Novartis, Roche/Genentech, Sanofi-Aventis, Teva Neurosciences (speakers’ bureau).

Keywords: Disease-modifying treatments in MS

(DXT29) OCRELIZUMAB: Real-World Experience with Ocrelizumab: An Observational Study Evaluating Safety in Patients with Relapsing and Progressive Multiple Sclerosis, Year 3 Data

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The Elliot Lewis Center for Multiple Sclerosis Care, Wellesley, MA

Background: Ocrelizumab (OCR) is a humanized, monoclonal anti-CD20 monoclonal antibody approved for the treatment of relapsing-remitting and primary progressive multiple sclerosis (MS). Immune globulin levels were monitored during the phase 3 trials, and 1.5% of patients developed low immunoglobulin G (IgG) values after 2-3 years of OCR treatment, potentially increasing the risk of infections. The JC virus (JCV) antibody index used to stratify PML risk in patients treated with natalizumab was not studied and the impact of long-term B-cell suppression on JCV and IgG levels is unknown. Objectives: As part of the ACAPELLA trial, a prospective study with a primary objective of assessing OCR-associated adverse events in a real-world MS population, we sought to evaluate the impact of OCR treatment on immunoglobulin levels and JCV titers over time. Methods: The study includes all subjects receiving OCR at the Elliot Lewis Center followed prospectively since March 2017. Subjects are monitored for the occurrence of infections and other serious adverse events and have biannual assessments of serum immunoglobulin levels and JCV antibody titers. Results: As of December 2019, 291 patients have been treated with OCR and enrolled in ACAPELLA: 181 have been treated for at least 12 months, 131 have been treated for at least 18 months, and 84 subjects have reached 24 months. Two hundred eighty-eight of the total 291 subjects had IgG levels drawn at baseline. Twenty-seven subjects [10%] had IgG levels below the lower limit of normal at baseline. Of the 27 patients with low IgG at baseline, 14 patients were on active OCR treatment for at least 12 months. Of those 19, 4 patients were seen to have a >10% drop in IgG level after 12 months. Ten patients developed at least 1 low IgG level after 12-24 months of treatment exposure, although many returned to normal. Of the total 291 patients, 281 had a baseline JCV index. Ninety-three (31%) had titers ≤0.43 in 2 years, 39 (13%) had titers >0.43 and ≤0.75, and 15 (4%) >0.75. In our 2-year data, 3 patients had a change in JCV status from positive to negative between 12 and 24 months of treatment duration. Year-3 data are characterized in the poster. Conclusions: The frequency of persistent hypogammaglobulinemia was low in this cohort of patients and thus far has not been associated with an increased risk of infection. Three patients had a change in JCV status from positive to negative, and the effect of JCV index in the remaining subjects is further characterized.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Disease-modifying treatments in MS, Immunology and MS, Ocrelizumab

(DXT30) ACAPELLA: Hypogammaglobulinemia and JC Virus Status in Ocrelizumab-Treated Patients, Year 2 Data

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The Elliot Lewis Center for Multiple Sclerosis Care, Wellesley, MA

Background: Ocrelizumab (OCR) is a humanized anti-CD20 monoclonal antibody approved for the treatment of relapsing-remitting and primary progressive multiple sclerosis (MS). Immune globulin (Ig) levels were monitored during the phase 3 trials, and 1.5% of patients developed low immunoglobulin G (IgG) values after 2-3 years of OCR treatment, potentially increasing the risk of infections. The JC virus (JCV) antibody index used to stratify PML risk in patients treated with natalizumab was not studied and the impact of long-term B-cell suppression on JCV and IgG levels is unknown. Objectives: As part of the ACAPELLA trial, a prospective study with a primary objective of assessing OCR-associated adverse events in a real-world MS population, we sought to evaluate the impact of OCR treatment on immunoglobulin levels and JCV titers over time. Methods: The study includes all subjects receiving OCR at the Elliot Lewis Center followed prospectively since March 2017. Subjects are monitored for the occurrence of infections and other serious adverse events and have biannual assessments of serum immunoglobulin levels and JCV antibody titers. Results: As of December 2019, 291 patients have been treated with OCR and enrolled in ACAPELLA: 181 have been treated for at least 12 months, 131 have been treated for at least 18 months, and 84 subjects have reached 24 months. Two hundred eighty-eight of the total 291 subjects had IgG levels drawn at baseline. Twenty-seven subjects [10%] had IgG levels below the lower limit of normal at baseline. Of the 27 patients with low IgG at baseline, 14 patients were on active OCR treatment for at least 12 months. Of those 19, 4 patients were seen to have a >10% drop in IgG level after 12 months. Ten patients developed at least 1 low IgG level after 12-24 months of treatment exposure, although many returned to normal. Of the total 291 patients, 281 had a baseline JCV index. Ninety-three (31%) had titers ≤0.43 in 2 years, 39 (13%) had titers >0.43 and ≤0.75, and 15 (4%) >0.75. In our 2-year data, 3 patients had a change in JCV status from positive to negative between 12 and 24 months of treatment duration. Year-3 data are characterized in the poster. Conclusions: The frequency of persistent hypogammaglobulinemia was low in this cohort of patients and thus far has not been associated with an increased risk of infection. Three patients had a change in JCV status from positive to negative, and the effect of JCV index in the remaining subjects is further characterized.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Disease-modifying treatments in MS, Immunology and MS, Ocrelizumab
Background: Relapses resulting in hospitalization are common in patients with the rare autoimmune inflammatory disease neuromyelitis optica spectrum disorder (NMOSD). The randomized, double-blind, placebo-controlled PREVENT study (trial registration: NCT01892345) assessed the safety and efficacy of eculizumab in aquaporin-4 immunoglobulin G (AQP4-IgG)–positive NMOSD. Eculizumab significantly reduced the risk of adjudicated relapse compared with placebo (primary end point).

Objectives: To evaluate rates of relapse-related hospitalization and associated treatment in patients with AQP4-IgG–positive NMOSD receiving eculizumab vs placebo in the PREVENT study.

Methods: Patients with AQP4-IgG–positive NMOSD were randomized 2:1 to receive eculizumab (maintenance dose, 1200 mg/2 weeks, n = 98) or placebo (n = 49) until stable disease for up to 2 years. Patients receiving immunosuppressant therapy (excluding rituximab and mitoxantrone). Hospitalizations were recorded as a component of the adverse event tracking performed throughout the study. The annualized relapse-related hospitalization and treatment rates were defined as the total number of relapses requiring hospitalization, and associated acute treatments, respectively, divided by the total number of patient-years in the study period.

Results: The median exposure to treatment was 89.43 weeks for eculizumab and 41.29 weeks for placebo. The overall annualized hospitalization rates were 0.26 and 0.78 (P < .0001) in the eculizumab and placebo groups, respectively. The annualized relapse-related hospitalization rate was significantly lower in the eculizumab group than in the placebo group: 0.04 vs 0.31, respectively (P < .0001). The annualized relapse-related use of intravenous methylprednisolone, plasma exchange, and high-dose oral corticosteroids for eculizumab vs placebo was 0.07 vs 0.42 (P < .0001), 0.02 vs 0.19 (P = .0001), and 0.04 vs 0.11 (P = .0733), respectively.

Conclusions: Treatment with eculizumab significantly reduced relapse-related hospitalizations and their associated treatment rates in patients with AQP4-IgG–positive NMOSD vs placebo, which may have a favorable effect on health-resource utilization.

Disclosure: None

Supported by: None

Disclosure: Nothing to disclose

Keywords: Disease-modifying treatments in MS, Ocrelizumab

(DXT33) ACAPELLA: B-Cell Reconstitution in Ocrelizumab-Treated Patients

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The Elliot Lewis Center for Multiple Sclerosis Care, Wellesley, MA

Background: Ocrelizumab (OCR) is a humanized anti-CD20 monoclonal antibody approved for the treatment of relapsing remitting (RRMS) and primary progressive multiple sclerosis (PPMS). In the OPERA trials, circulating CD19+ B-cell counts dropped to 0 within 14 days of OCR infusion. Median time to repletion, defined as ≥79 cells/μL, was 72 (range 10-162) weeks. Up to 5% of patients showed B-cell repletion during treatment. We sought to determine the frequency of patients on OCR who have significant B-cell reconstitution at the time of their next 6-month dose, and to determine if there is a correlation between early B-cell reconstitution and disease breakthrough or adverse events (AEs).

Objectives: Aims of the ACAPELLA trial, a prospective study with a primary objective of assessing OCR-associated AEs in a real-world multiple sclerosis population, we sought to evaluate the frequency and duration of early B-cell reconstitution and its relationship to disease activity and AEs.

Methods: All subjects receiving OCR at the Elliot Lewis Center since March 2017 who consented to participate had serum immunoglobulin levels, JC virus polymerase chain reaction, and lymphocyte subset counts on the day of each infusion prior to receiving OCR. Subjects were followed up prospectively and monitored for the occurrence of infections and other serious AEs.

Results: As of December 2019, 291 patients had been treated with OCR and enrolled in ACAPELLA: 181 had been treated for at least 12 months, 131 had been treated for 18 months, and 84 subjects had reached 24 months. Of the 291 subjects, 207 had CD19 values drawn at an infusion. One hundred eighteen subjects (57%) displayed ≥1 cell/μL; 81 subjects (39%) had between 1-15 cells/μL, 32 (16%) between 16-79 cells/μL, and 5 (2%) >79 cells/μL. Thirteen patients with B-cell reconstitution at 12 months had early reconstitution with future infusions. Two of the subjects with CD19 values >15 cells/μL had clinical or magnetic resonance imaging (MRI) disease activity, compared to 8 subjects who did not have B-cell reconstitution.

Conclusions: Although many patients displayed some B-cell repopulation prior to their next dose (113 subjects), CD19 counts of ≥79 cells/μL were uncommon (5 subjects). Subjects with early B-cell reconstitution at 12 months were no more likely to continue to show early repopulation at future infusions. Thus far, we have found no significant correlation between B-cell repopulation and either disease activity or adverse events.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Disease-modifying treatments in MS, Ocrelizumab

(DXT34) Revealing the Immune Cell Subtype Reconstitution Profile in Cladribine-Treated Patients at the 96-Week Timepoint (CLARITY) Using Deconvolution Algorithms

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Background: Cladribine tablets (CTs) cumulative licensed dose of 3.5 mg/kg (CT3.5), administered as 2 short oral courses over 2 years, transiently reduces total lymphocyte counts, with median values returning to normal range within 11 months and median B cells by 6 months. Clinical efficacy of CTs is sustained beyond lymphocyte recovery. Flow cytometric observations suggest long-lasting reductions in memory B cells. Objectives: Characterize immune cell transcriptional signatures in peripheral blood from patients with relapsing-remitting multiple sclerosis during immune repletion at 96 weeks in the CLARITY study using advanced computational algorithms that correlate these signatures with corresponding flow cytometry data of main lymphocyte subtypes. Methods: Gene expression data (U133 Plus 2.0 array) in whole blood samples at 96 weeks were available from patients randomized to placebo (n = 57), CT3.5 (n = 62), or CT5.25 mg/kg (CT25.5, n = 70). These were analyzed with the CIBERSORT deconvolution algorithm (to estimate absolute fractions of 22 immune cell subtypes) and the xCELL signature-based method (cell type enrichment analysis for 43 immune cell subtypes).

Supported by: None

Disclosure: Nothing to disclose

Keywords: Disease-modifying agents, Multiple Sclerosis
Wilcoxon rank sum tests compared between treatment arms. Spearman rank correlation coefficient was used to measure the relationship between signatures and cell counts. P values < .05 were considered nominally significant. Results: At 96 weeks, the relative abundance of naïve B cells in CT3.5- and CT5.25-treated patients was significantly higher vs placebo. Plasma cells and class-switched memory B cells were significantly reduced with CTs vs placebo. The M2 macrophage signature was significantly enhanced with CTs vs placebo. Cell abundance of both naïve and memory CD4+ and CD8+ was significantly reduced with CTs vs placebo. Deconvolution signature scores were positively and significantly correlated with corresponding flow cytometry data (r: 0.68-0.72 CD19+ B cells, 0.71 CD4+ T cells, 0.67-0.69 CD8+ T cells). Conclusions: At 96 weeks following CT treatment, in year 2 changes, in leucocytes suggest a shift towards an anti-inflammatory phenotype were detected.

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Keywords: Disease-modifying treatments in MS, Immunology and MS

(DXT35) Real-World Experience with Ocrelizumab: A Safety Analysis

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Background: Ocrelizumab is a humanized monoclonal antibody that selectively targets B lymphocytes, resulting in their depletion. The US Food and Drug Administration approved its use in 2017 for relapsing-remitting and primary-progressive multiple sclerosis (MS). Pooled safety analysis from phase 3 clinical trials revealed an increase in incidence of infection, infusion reaction (IR), and malignancy in ocrelizumab patient groups. Objectives: We present a real-world safety analysis of ocrelizumab in clinical practice. Methods: The University of Florida MS Clinic identified subjects as those treated with ocrelizumab prescribed in clinic through electronic medical records. The study collected longitudinal safety laboratory including complete blood count, lymphocyte subset counts, and immunofluorescence data. The study also captured clinical data including disease course, prior disease-modifying therapies, IR, and occurrence of major clinical events. Analysis of the data assessed trends in laboratory and occurrence of adverse events (AEs). Results: Data from 39 of a potential 200 subjects suggests that white blood cell, neutrophil, lymphocyte, and T-cell counts continuously produce the most abnormal results after initiation of ocrelizumab. Nine subjects had urinary tract infections, and 2 subjects had respiratory tract infections. A case of sepsis and appendicitis resulted in 1 hospitalization. There were 12 IRs reported, and 1 subject discontinued treatment due to bronchospomosis. One subject reported a diagnosis of intraductal carcinoma. Conclusions: The data reveals that infections and IRs are common among patients treated with ocrelizumab, while malignancies occur but are rare. Of infections, urinary tract infections pose the largest concern, although rare and secondary infections also occurred. Although IRs were common, they tended to be acute and easily resolved with the exception of 1 discontinuation. There is a need for more data to corroborate trends in laboratory values and potential correlation with AEs. Early findings suggest a significant trend in abnormal laboratory values, reported infections, and IRs.

Supported by: None

Disclosure: Jamie Bolling, Ryan McNiff, Carlos Vervloet Sellero, Trisham V. Gyang; Sanofi Genzyme (consulting fee).

Keywords: Comprehensive care and MS, Disease-modifying treatments in MS, Treatment safety analysis in MS

(DXT36) Effect of Evobrutinib, a Bruton’s Tyrosine Kinase Inhibitor, on Immune Cell and Immunoglobulin Levels over 48 Weeks in a Phase 2 Study in Relapsing Multiple Sclerosis

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Background: Bruton’s tyrosine kinase (BTK) plays an important role in proinflammatory pathways potentially involved in multiple sclerosis (MS). Consequently, BTK inhibition is being investigated as a potential therapeutic approach for MS. Evobrutinib, a highly selective BTK inhibitor (BTKI), has a dual mechanism of action, affecting both B cells and regulatory T cells through inhibition of B-cell receptor, Fc receptor, and granulocyte-macrophage colony-stimulating factor receptor signaling, and has demonstrated clinical efficacy in MS in a phase 2 study (trial registration: NCT02975349; Montalban et al, ECTRIMS 2018 [P322]). Objectives: To examine the effect of evobrutinib on immune cells and immunoglobulins (Igs) over 48 weeks. Methods: Patients aged 18-65 with active relapsing-remitting MS or secondary progressive MS and superimposed relapses were randomized to receive either double-blind evobrutinib (25 mg once daily [qd], 75 mg qd, or 75 mg twice daily), placebo, or open-label dimethyl fumarate 240 mg (reference arm). After 24 weeks, placebo-treated patients were switched to evobrutinib 25 mg qd and other treatment arms continued under original allocation. Safety of evobrutinib, including assessment of B-cell count and Ig level, was a key secondary end point; investigations of the effects of evobrutinib on B-cell subsets, T-cell subsets, and natural killer cells in peripheral blood over 48 weeks were exploratory. Results: Of 267 patients randomized to treatment, 227 patients completed 48 weeks of treatment. No clinically relevant changes in the number of total B cells, or of memory B, naive B, total T, helper T, cytokotic T, or natural killer cells, were observed in any evobrutinib treatment group over 48 weeks. No changes in IgG or IgG subtype levels were observed over 48 weeks in any treatment group. At week 48, there were slight increases from baseline in IgA and reductions in IgM for all evobrutinib groups, which were numerically greater than those with placebo at week 24. Conclusions: Patients with MS treated with the BTKI evobrutinib showed no evidence of B-cell depletion or change in mature vs naive B-cell subsets over 48 weeks. IgG levels remained stable and slight elevations in IgA levels were observed. These findings demonstrate that, in contrast to genetic deletion of BTK, continued pharmacologic BTK inhibition does not lead to B-cell depletion or significant reductions in circulating IgGs.

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Keywords: Clinical trials, Disease-modifying treatments in MS, Immunology and MS

(DXT37) Effect of Teriflunomide on Brain Volume Loss in Patients with Relapsing Multiple Sclerosis of Differing Ages in TEMSO

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Objectives: To test the hypothesis that teriflunomide slows brain volume loss in patients with relapsing-remitting multiple sclerosis (MS) over 48 weeks. Methods: Patients aged 18-65 with relapsing-remitting MS and baseline brain structures were randomized to receive teriflunomide 14 mg/day or placebo. Deconvolution signature score was calculated to determine the brain volume loss rate changes. Results: 354 patients were randomized to receive teriflunomide or placebo. After 48 weeks, the teriflunomide group had a significantly lower brain volume loss rate compared to the placebo group (p = 0.004). Conclusions: Teriflunomide significantly slowed brain volume loss in patients with relapsing-remitting MS over 48 weeks.
Background: Teriflunomide significantly reduced brain volume loss (±9.1%) vs placebo, assessed post hoc using structural imaging evaluation normalizing of atrophy (SIENA) in patients with relapsing forms of multiple sclerosis (RMS) enrolled in the phase 3 TEMSO study (trial registration: NCT00134563). It is not known whether the effect of teriflunomide on BVL differs by age. Objectives: To analyze the effect of teriflunomide treatment on BVL in patients of different age groups with RMS in TEMSO compared with placebo, with a focus on the ≥45-year-old age group. Methods: Patients were randomized 1:1:1:1 to receive placebo or teriflunomide 7 mg or 14 mg for ≤108 weeks. BVL was assessed as annualized percentage brain volume change (PBVC) from baseline using SIENA at years 1 and 2 in patients stratified by age: ≤25 years, >25 to 35 years, >35 to 45 years, and ≥45 years. For patients in the ≥45-year-old group, PBVC values were made via ranked analysis of covariance, adjusted for region, age, Expanded Disability Status Scale stratum, and baseline normalized brain volume. Data are presented at year 2 for all patients treated with teriflunomide 14 mg vs placebo, and for patients aged >45 years treated with teriflunomide 14 mg vs placebo. Results: The median annualized PBVC in all patients was 20.6% lower in the teriflunomide 14 mg group (n = 235) vs placebo (n = 234; P = 0.0001). In patients >45 years, the median annualized PBVC was 35.0% lower in the teriflunomide 14 mg group (n = 49) vs placebo (n = 48; P = 0.0098). Conclusions: Teriflunomide decreased disease-related brain atrophy in patients with RMS compared with placebo, including in patients aged >45 years.

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Keywords: Disease-modifying treatments in MS

(DXT40) Effect of the 51T/P Receptor Modulator Ozanimod on Cognitive Processing Speed in Subjects with Relapsing Multiple Sclerosis: Design of the ENLIGHTEN Study

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Background: In patients with multiple sclerosis (PwMS), slowed cognitive processing speed emerges as an early deficit. The Symbol Digit Modalities Test (SDMT), a preferred measure of cognitive performance in PwMS, Ozanimod, and the 51T/P receptor antagonist 51T/P modulator, was well tolerated and more effective than weekly intramuscular interferon-β-1a (IFN) 30 μg on clinical and magnetic resonance imaging (MRI) end points in the phase 3 RADIANCE and SUNBEAM studies. The SUNBEAM study demonstrated a nominally significant (P < .05) improvement in SDMT with ozanimod HCl 1 or 0.5 mg/day over IFN 30 μg/week; however, the study was not designed to evaluate SDMT as a primary end point. Objectives: The primary objective of ENLIGHTEN (trial registration: NCT04140305) is to describe clinically meaningful changes in SDMT (≥4-point or 10% change from baseline) over 3 years in patients with early relapsing multiple sclerosis (RMS) treated with ozanimod HCl 1 mg/day. Secondary objectives are to describe changes from baseline in whole brain and substructure volume; MRI measures of disease activity; patient-reported outcomes (PROs) and quality of life (QOL); disability status based on Timed 25-Foot Walk, 9-Hole Peg Test, and Expanded Disability Status Scale (EDSS); and safety of ozanimod. The study also will explore the correlation between changes in cognitive processing speed and whole brain and substructure volume, and the cor-

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relates between changes in cognitive processing speed and PROs and QoL. Methods: This ongoing multicenter, open-label study is recruiting 250 patients with RMS (aged 18-65 years) in the United States and Canada. Participants will receive ozanimod 1 mg/day (equivalent to ozanimod 0.92 mg) for 3 years. Key inclusion criteria are diagnosis of multiple sclerosis per 2010 or 2017 McDonald criteria, ≤5 years since diagnosis, ≤1 approved RMS disease-modifying therapy, EDSS score ≤7.0, ≤2.5 relapses in 30 days, ≤12 prior therapy with ozanimod; clinically relevant cardiac, hepatic, neurololgic, pulmonary, or other chronic conditions; >10 gadolinium-enhancing lesions on baseline brain MRI; or any condition or concomitant medication that might affect cognition or confound test performance. Results: The study design will be presented. Cognitive function, disease activity, disability status, and safety will be assessed over 3 years of ozanimod therapy. Conclusions: This study will determine if ozanimod has a clinically meaningful benefit on cognitive processing speed in patients with RMS.

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Keywords: Cognition and MS, Disease-modifying treatments in MS

(DXT41) Eculizumab Benefits a Broad Range of Patients with Aquaporin-4 Antibody–Positive Neurorheumatism Optica Spectrum Disorder Spectrum: The Phase 3 PREVENT Study Kaxo Fujiwara,1,2,3,4,5,6,7,8,9,10,11 Achim Berthele,1 Ho Jin Kim,1 Michael Levy,1 Ichiro Nakashima,1 Celia Oreja-Guzmán,2 Jacqueline Palacios,2,3,4,6,7,8,10,11,12 Sean J. Pittman,2,3,4,6,7,8,10,11,12 Murat Terzi,2 Natalia Totobechava,1,2,3,4,6,7,8,10,11,12 Shabani Viswanathan,1,2,3,4,6,7,8,10,11,12 Marcus Yountz,2,3,4,6,7,8,10,11,12 Larisa Miller,1 Imran Tanvir,2,3,4,6,7,8,10,11,12 Raun Armstrong,2,3,4,6,7,8,10,11,12 Dean Wingertshuk1

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Background: Antibodies to the aquaporin-4 (AQP4) water channel in neuromyelitis optica spectrum disorder (NOMD) are reported to trigger the complement cascade, which is implicated in neurological injury. The terminal complement inhibitor eculizumab is the first treatment approved for use in patients with AQP4-immunoglobulin G–positive NOMD, based on data from the PREVENT study. Objectives: To determine whether eculizumab’s beneficial effect in reducing relapse risk in patients with NOMD is associated with time since diagnosis, relapse history, disability burden, or prior immunosuppressant therapy (IST) use, based on data from the phase 3 PREVENT study (trial registration: NCT01892345).

Methods: In PREVENT, patients received eculizumab (maintenance dose, 1200 mg/2 weeks; n = 96) or placebo (n = 47), with stable-dose, concomitant IST (except rituximab and mitoxantrone) permitted. PREVENT was not powered for subgroup analyses; a post hoc descriptive analysis was performed on subgroups defined by time since diagnosis, total number of historical relapses, baseline Expanded Disability Status Scale (EDSS) score, and prior IST use. Results: The proportions of patients having at least one adjudicated relapse were lower with eculizumab than with placebo in all subgroups. Proportions for those receiving eculizumab and placebo, respectively, were: 2/31 (6.5%) vs 6/12 (50.0%) for <1 year since diagnosis and 1/65 (1.5%) vs 14/35 (40.0%) for ≥1 year since diagnosis; 1/39 (2.6%) vs 10/24 (41.7%) for 2.5-7.0; 0/14 vs 2/5 (40.0%) for ≥7.0; 0/14 vs 2/5 (40.0%) for ≥7.0; 0/14 vs 2/5 (40.0%) for ≥7.0; 0/14 vs 2/5 (40.0%) for ≥7.0; 0/14 vs 2/5 (40.0%) for ≥7.0; 0/14 vs 2/5 (40.0%) for ≥7.0; 0/14 vs 2/5 (40.0%) for ≥7.0. Conclusions: The data from this post hoc subgroup analysis suggest that eculizumab reduced relapse risk compared with placebo in patients with AQP4-immunoglobulin G–positive NOMD, regardless of time since NOMD diagnosis, relapse history, disability burden, or prior IST use.

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Aznar: Alexion Pharmaceuticals (consulting fee, offered membership on an expert advisory board); MedImmune/Vida Bio (steering committee); Multiple Sclerosis Journal (co-editor). Michael Levy: Alexion Pharmaceuticals (consulting fee, research contract, fees for non-CME/CE services received directly from commercial interest or its agent); Genentech, Quest Diagnostics, Vida Bio (consulting fee, fees for non-CME/CE services received directly from commercial interest or its agent). Ichiro Nakashima: Alexion (consulting fee); Celia Oreja-Guzmán: Alexion Pharmaceuticals (consulting fee, contracted research, fees for non-CME/CE services received directly from commercial interest or its agent). Shabani Viswanathan: Alexion Pharmaceuticals (grant support, research); Genentech-Roche, Pfizer, TG Therapeutics (data monitoring committees without monetary compensation); Sanofi Genzyme (grant support); Therapeutic Advancements in Neurological Disorders (editorial board). Robert T. National: Alexion, Alkermes, Bayer AG, Biogen, Celgene Corporation, EMD Serono, Genentech, Novartis, Vida Bio (consulting fee); John Deluca: Biogen, EMD Serono, Canadas MS Society, National MS Society, Consortium of Multiple Sclerosis Centers (CMS) (grant funding); Celgene Corporation, Biogen, CMS, Novartis, Sanofi Genzyme, Canadas MS Society, EXCEMED (consulting fee).

Keywords: Cognition and MS, Disease-modifying treatments in MS

(DXT42) Rationale and Design of CLASSIC-MS Study Evaluating Long-Term Efficacy for Patients with Multiple Sclerosis Treated with Cladribine Tablets Alexey Beyko,1 Jorge Correa,1 Gilles Edan,2 Mark S. Freedman,3 Gavin Giovannianni,3 Xavier Montalban,1,2 Kottl Rammohan,2 Thomas P. Leist,4 Susan Stefanksi,5 Bassem Yamao,6 Belen Garcia-Alonso,7 Aida Aydemir,8 Elisabeta Verdun de Cantagrel,9 CLASSIC-MS Study Group

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Background: Cladribine tablets 10 mg (CT; cumulative dose 3.5 mg/kg over 2 years) has demonstrated efficacy vs placebo over 2 years in CLARITY, CLARITY Extension, and ORACLE-MS, showing sustained effi- cacy without further active treatment in CLARITY Extension. Objectives: CLASSIC-MS will explore long-term efficacy and real-world treatment pat- terns in patients who participated in these trials. Long-term safety in this
population has been assessed in the PREMIERE registry. Methods: CLASSIC-MS is an exploratory phase 4 study of patients with MS, or those with a first clinical demyelinating event enrolled into the phase 3 trials and who received ≥1 course of CT or placebo (N = 1946). Following pre-baseline screening and assessment for eligibility, long-term retrospective data will be obtained from medical records at study visit 1; prospective data will be collected at study visits 1 and 2. Patients will be enrolled for 17 months from approximately Q3 2019 to Q4 2020. Last patient last visit is expected in Q1 2021. Primary objective: evaluation of long-term mobility after treatment with CT or placebo. Secondary objective: assess differences in clinical and magnetic resonance imaging characteristics in long-term responders vs nonresponders. Tertiary end points: real-world treatment patterns, duration of clinical outcomes, quality of life and cognition, differences in health-related quality of life, and differences in genetics between long-term responders and those who are not. Results: In 2018, a second feasibility survey was sent to 225 centers; 110 centers provided positive responses and were included, representing 48% of sites originally enrolled in the phase 3 studies. In total 115 centers were not included (81 were not willing to participate; 13 dropped; 16 were nonresponders; 5 were rejected). Conclusions: CLASSIC-MS will provide valuable information on the long-term efficacy of CT in patients with MS.

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(DX4T43) Effects of the Age on the Efficacy and Safety of Siponimod in Patients with Active Secondary Progressive Multiple Sclerosis from the EXPAND Study

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Background: Multiple sclerosis (MS) is a chronic disease that requires long-term treatment for most patients. Disease-modifying treatment (DMT) adherence is often an issue for patients with MS, and evidence suggests that nonadherence can affect outcomes. Data are needed to understand the impact of long-term DMT use on clinical outcomes. Objectives: To assess the impact of long-term DMT adherence on MS disease progression in the real world. Methods: A retrospective cohort analysis of MarketScan Commercial enrollees from 2011-2017 was performed. MS was defined as ≥3 ICD9/10 (340.G35) diagnosis claims or ≥1 diagnosis and ≥1 DMT claim [age 18 and 65 years at index] with index date within the first diagnosis (≥3 claims). Enrollment started from 1 year preindex, with a follow-up of ≥23 years of continuous enrollment and up to 6 years. Adherent-users as medication possession ratio (MPR) ≥ 0.8 in follow-up, and non-adherent users as MPR < 0.8. Propensity score greedy matching was used to balance population characteristics (age, gender, geography, comorbidities, relapse) 1 year preindex. We compared the average number of relapses, defined as a

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(DX4T44) Real-World Patterns of Disease Progression in Patients with Multiple Sclerosis Who Are Adherent Versus Nonadherent to Disease-Modifying Treatments over 6 Years

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Background: Multiple sclerosis (MS) is a chronic disease that requires long-term treatment for most patients. Disease-modifying treatment (DMT) adherence is often an issue for patients with MS, and evidence suggests that nonadherence can affect outcomes. Data are needed to understand the impact of long-term DMT use on clinical outcomes. Objectives: To assess the impact of long-term DMT adherence on MS disease progression in the real world. Methods: A retrospective cohort analysis of MarketScan Commercial enrollees from 2011-2017 was performed. MS was defined as ≥3 ICD9/10 (340.G35) diagnosis claims or ≥1 diagnosis and ≥1 DMT claim [age 18 and 65 years at index] with index date within the first diagnosis (≥3 claims). Enrollment started from 1 year preindex, with a follow-up of ≥23 years of continuous enrollment and up to 6 years. Adherent-users as medication possession ratio (MPR) ≥ 0.8 in follow-up, and non-adherent users as MPR < 0.8. Propensity score greedy matching was used to balance population characteristics (age, gender, geography, comorbidities, relapse) 1 year preindex. We compared the average number of relapses, defined as a
hospitalization with a primary diagnosis of 340/363 or an outpatient visit with a diagnosis of 340/363 plus a pharmacy or medical claim for a qualifying corticosteroid within 7 days, between 2 cohorts using Poi-son regression model. We also compared the time to first relapse, time to cane/walker use, and time to wheelchair use between 2 cohorts using Cox-proportional hazard model. Results: 15,617 patients with MS were identified (42% female, 43% nonadherent, 15% non-DMT treated). Of these patients, the multivariate analyses presented a significantly lower rate of relapse (HR = 0.82, 95% CI: 0.77-0.87, P < 0.001). Adherent users had a significantly lower average number of relapses (0.135) than nonadherent (0.201) users (annualized relapse rate ratio: 0.76, 95% CI: 0.74-0.79, P < 0.001). Adherent users had a delayed time to first relapse [hazard ratio (HR) = 0.82, 95% CI: 0.71-0.93, P = 0.003], and wheelchair use (HR = 0.69, 95% CI: 0.51-0.70, P < 0.001). Conclusions: This study highlights the importance of DMT adherence in slowing disease progression. Indicators of MS-related disability were found to be related to adherence, suggesting a lower rate of disability progression over time. Further research is needed to better understand barriers of adherence with DMTs.

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Disclosure: Lisa Aquillano, Kristina Murphy, Neil Lava, Diana Vargas

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Background: Disease-modifying therapies (DMTs) require baseline laboratory tests (labs) prior to initiation. Under our institution’s pharmacotherapy protocol, clinical pharmacy specialists may order labs based on their assessment of the patient’s monitoring needs. Currently, there is no standardized practice guideline for ordering appropriate labs prior to initiating medications prescribed for patients with multiple sclerosis (MS). Frequently, baseline laboratory values are not available in the chart, making it challenging to determine treatment and evaluate safety. A standardized process, including the utilization of the pharmacotherapy chart, would optimize safety and guide clinical decisions regarding the management of patients prescribed DMTs for MS. Objectives: The percentage of appropriate labs drawn for the specified DMTs following the implementation of a standardized operating protocol in the MS outpatient neurology clinic. Methods: A clinical practice guideline was implemented on October 1, 2019, outlining the baseline labs required within 6 months prior to initiation of specific DMTs. The following DMTs were included in the guideline: interferon beta-1a, peginterferon beta-1a, dimethyl fumarate, and teriflunomide. All patients who had a medication prescribed for the listed DMT from October 1, 2018, to March 31, 2019, were included in the baseline analysis. The clinical pharmacy specialist used the pharmacotherapy protocol to order appropriate labs when a therapy was initiated. A post-analysis was performed to compare rates of appropriate labs drawn in all patients who had a prescription for the DMTs listed above, from October 1, 2019, to March 31, 2020. The patients included were those starting DMT for the first time, changing to a new DMT, or restarting a DMT after being off therapy for >6 months. Results: (Preliminary) Of the 43 patients prescribed a DMT during the baseline analysis, 13 (30.2%) patients had all appropriate labs drawn within 6 months. Of the remaining 30 (69.8%) patients who did not have all appropriate labs drawn, 18 (60%) patients had no labs documented in the chart within the past 6 months. The most common labs not drawn include differential (83.3%), LFTs (63.3%), and CBC (56.6%). Since the implementation of the clinical practice guideline, 75% of patients have had all appropriate labs drawn within 6 months of therapy initiation. However, baseline labs have been collected on 100% of patients, with only the differential not drawn. Conclusions: Integration of a clinical pharmacy specialist in the management of patient safety is crucial to delivering exceptional care. Implementation of a standardized operating procedure and incorporation of pharmacists to assist in the monitoring of patients, contributed to an increase in appropriate labs drawn prior to initiation of DMT. Additionally, the utilization of pharmacists practicing in multidisciplinary settings to further elevate the level of care provided to patients could be extrapolated to other clinic areas and disease states.
(DXT48) Efficacy of Subcutaneous Interferon Beta-1a in Patients with a First Clinical Demyelinating Event: REFLEX Study – Outcomes in Patients Stratified by 2017 McDonald Criteria

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Background: The REFLEX (ReBiF EFlXible dosing in early multiple sclerosis (MS)) trial demonstrated that subcutaneous interferon beta-1a (sc IFNβ-1a) reduced conversion to MS (McDonald 2005 criteria) and to clinically definite MS (CDMS) vs placebo in patients with a first clinical event suggestive of MS. A retrospective analysis of the study showed that the overall results were unchanged by the application of the McDonald 2010 MS criteria. The revised 2017 McDonald MS criteria include the presence of cerebrospinal fluid–specific oligodendroglial bands, symptomatic lesions, and cortical lesions to aid MS diagnosis. Objectives: Assess the effects of sc IFNβ-1a on time to McDonald 2005 criteria MS (time to next relapse, Expanded Disability Status Scale (EDSS) progression, or Magnetic Resonance Imaging (MRI) lesion or lesions) vs CDMS (time to relapse or EDSS progression), and annualized relapse rate (ARR) during REFLEX, stratified by retrospective diagnosis at baseline in patients that either meet or do not meet the updated McDonald 2017 MS criteria. Methods: During REFLEX, patients were randomized to either sc IFNβ-1a 30 μg once weekly (qw) or thrice weekly (tiw) or placebo for 2 years. This retrospective analysis stratified patients randomized to the intent-to-treat population in REFLEX into McDonald 2017–positive (defined as those who retrospectively met the 2010 McDonald MS criteria at baseline or those with positive oligodendroglial bands) and McDonald 2017–negative subgroups. Kaplan-Meier curves were used to estimate time to McDonald 2005 MS and time to CDMS by treatment group and for each McDonald 2017 subgroup. Results: As the detection of oligodendroglial bands was optional during REFLEX, only a small number of patients were added from the McDonald 2010 analysis. A total of 235/517 patients were classed as McDonald 2017–positive at baseline (40 of whom were McDonald 2010–negative but had positive oligodendroglial bands). In the McDonald 2017–positive subgroup, treatment with sc IFNβ-1a qw or tiw significantly delayed time to McDonald 2005 MS (hazard ratio (HR) = 0.47, P = .001; qw vs placebo HR = 0.58, P = .002) and CDMS (HR = 0.46, P = .010; qw vs placebo HR = 0.42, P = .003) vs placebo (sc IFNβ-1a tiw vs placebo, HR = 0.49, P = .002). The mean ARR vs placebo McDonald 2017–positive patients (reductions of 69.1% and 59.3%, respectively, P ≤ .001). Conclusions: The treatment effects of sc IFNβ-1a observed in McDonald 2010 patients on time to McDonald 2005 MS and CDMS were maintained in the McDonald 2017–positive subgroup, although there were only a small number of additional patients when the 2017 criteria were applied. Supported by: None

Disclosure: Mark S. Freedman: Actelion, Bayer HealthCare, Biogen, Chugai, EMD Canada, Genzyme, F. Hoffmann-La Roche, Novartis, Sanofi, Teva (consulting fee); EMD Serono, Genzyme (speakers’ bureau); Ludwig Kappos: Institutional funding: Actelion, Addex, Bayer HealthCare, Biogen, Bionica, Genzyme, Eli Lilly, Merck KGaA, Mitsubishi, Novartis, Ono Pharma, Pfizer, Receptos, Sanofi, Santhera, Siemens, Teva, UCB, Xenopoint (consulting fee); Institutional funding: Bayer, Biogen, CSL Bering, Genzyme, Merck, Novartis, Sanofi, Teva (educational activities); Institutional funding: Bayer, Biogen, European Union, Innoven, Merck, Novartis, Roche, Swiss MS Society, Swiss National Research Foundation (contracted research); Institutional funding: Biogen, Bayer, Merck, Novartis, Sanofi, Teva (speakers’ bureau); Institutional funding: Neurostatus products (receipt of intellectual property right/patent holder). Giancarlo Comi: MedDay, EXCEMED, Novartis, Teva Pharmaceutical Industries Ltd, Teva Italia Srl, Sanofi Genzyme, Genzyme Corporation, Genzyme Europe, Merck KGaA, Merck Serono S.p.A., Celgene Group, Biogen, Biogen Italia Srl, F. Hoffmann-La Roche, Roche SpA, Almirall SpA, Forward Pharma (consulting fee, speakers’ bureau). Nicola De Stefano: Biogen, Teva, Novartis, Sanofi Genzyme, Roche, Merck Serono (consulting fee); FISM, Novartis (contracted research); Schering, Biogen, Biogen, Teva, Novartis, Sanofi Genzyme, Roche, Merck Serono (consulting fee); Teva, Novartis, Sanofi Genzyme, Roche, Merck Serono (travel). Sanjiv Roy: Regeneron, Meikle, Abnormal, Switzerland (salary); Delphi Iserard, Cytel Inc (salary); Merck KGaA (consulting fee).

Keywords: Diagnosis, Biomarkers, Disease-modifying treatments in MS

(DXT49) Post Hoc Analysis of Efficacy of Cladribine Tablets in Patients with Relapsing-Remitting Multiple Sclerosis Aged Over and Under 30 Years in the CLARITY Study

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Background: Efficacy of cladribine tablets 3.5 mg/kg (CT3.5, cumulative dose over 2 years) has been reported in relapsing-remitting multiple sclerosis (RRMS) in the 96-week CLARITY study. Prior post hoc analyses of CLARITY found that CT3.5 treatment resulted in similar benefits across the age spectrum of the studied patients in risk reduction of relapse and odds of remaining free from disease activity. Objectives: This post hoc analysis further examined efficacy outcomes of CT3.5 in CLARITY patients aged ≤30 and >30 years at study enrollment. Methods: Analyses were performed by treatment (CT3.5 vs placebo) and age subgroup (≤30 and >30 years), with a relatively young age cutoff with adequate N needed for analyses. The study of relapse and disability outcomes was post hoc, and was performed using an exploratory approach. Results: This analysis was carried out in 870 patients: ≤30 years: CT3.5 N = 109, placebo N = 102; >30 years: 73.4% vs 44.1%; >30 years: 46.3% vs 17.9% (no relapse, 3- or 6-month CDP, or MRI activity). V = 0.03 (0.03-0.08) at 0.77 [0.61-0.98] and active 12 ≤30 years: 0.68 [0.53-0.88] at 2.20 1.73 [2.81]; >30 years: 0.26 [0.21-0.32] at 1.19 [1.01-1.41]. Conclusions: CT3.5 treatment improved clinical and MRI outcomes in both younger and older patients in CLARITY. Relapse and disability outcomes appeared mostly similar between the age subgroups; however, the >30 years subgroup appeared to have a greater reduction in MRI lesion activity and a higher rate of achieving NEDA status. Supported by: None

Disclosure: Mark S. Freedman: Actelion, Bayer HealthCare, Biogen, Chugai, EMD Canada, Genzyme, F. Hoffman-La Roche, Novartis, Sanofi, Teva Pharmaceuticals USA (consulting fee). Gabriel Pardo: AbbVie, Adamas, Alkermes, Sanofi Genzyme, Teva (research support); Alexis, Celgene, Sanofi Genzyme (consulting fee); EMD Serono, Novartis, Roche/Genevac (consulting fee, research support). Nicola De Stefano: Bayer Schering AG, Merck Serono SA, Novartis Pharma AG, Novartis-Aventis, Serono Symposia International Foundation, Teva Pharmaceutical Industries (consulting fee). Julie Aldridge, Sano Syndics (a business of EMD Serono) (salary), Cell and Molecular Science, London, United Kingdom (salary), Yann Hyvert: Merck KGaA (salary). Andrew Galazka: Merck KGaA, Aubonne, Switzerland (a business of Merck KGaA, Darmstadt, Germany) (salary). Carolina Lemieux: EMD Canada, Genzyme, F. Hoffmann La Roche, Novartis, Sanofi, Teva Pharmaceuticals USA (salary). Giovanna Giovanni: AbbVie, Actelion, Almirall, Atara Bio, Bayer Schering Pharma, Five Prime, GlaxoSmithKline, GW Pharma, Merck KGaA, Pfizer Inc, Protein Discovery Laboratories, Sanofi Genzyme, Teva Pharmaceutical Industries Ltd, UCB, Vertex Pharmaceuticals (consulting fee, research support). Barry Somers: EMD Serono Inc, Protein Discovery Laboratories (consulting fee, research support). Keywords: Disease-modifying treatments in MS

(DXT50) Prevalence of Serious Adverse Pregnancy Outcomes After Exposure to Interferon Beta Before or During Pregnancy: Stratification by Characteristics of Pregnant Women with Multiple Sclerosis in a Register-Based Cohort Study in Finland and Sweden

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Background: A recent cohort study in women with multiple sclerosis (MS) reported that an increase in the prevalence of adverse pregnancy outcomes after exposure to interferon beta (IFNß) before or during pregnancy. However, differing prevalence by maternal characteristics is unknown. Objectives: To describe the prevalence of serious adverse pregnancy outcomes (SAPOs) among pregnant women with MS exposed to only IFNß and those unexposed to any MS disease-modifying drugs, with stratification by maternal characteristics. Methods: This cohort study extracted register data from Finland (1996-2014) and Sweden (2005-2014) on pregnant women with MS who were 1) dispensed only IFNß within 6 months before the last menstrual period (LMP) or during pregnancy (IFNß-exposed, n = 718 pregnancies) and 2) without dispensed MS disease-modifying drugs (unexposed, n = 1397 pregnancies). The prevalence (%) of SAPOs (consisting of elective terminations due to fetal anomaly, major congenital anomalies in live birth, and stillbirth) with 95% CIs was analyzed with stratification by maternal characteristics at LMP: time since MS diagnosis, duration of MS treatment, maternal age, and presence of chronic disease. Results: The prevalence of SAPOs appeared similar among the IFNß-exposed and unexposed groups when MS was diagnosed ≤2 years (0.9% [95% CI 0.1%-3.2%] vs 3.0% [1.6%-5.2%]) or 3-5 years (2.4% [0.9%-5.1%] vs 6.0% [4.0%-8.6%]) before LMP, and was comparable for >5 years (3.3% [1.4%-6.3%] vs 3.0% [1.7%-4.8%]). When stratified by duration of MS treatment, the prevalence among the IFNß-exposed vs unexposed with ≤2-year treatment was 1.3% (0.4%-4.3%) vs 4.6% (2.6%-6.9%), 3- to 5-year treatment 1.7% (0.5%-4.4%) vs 4.9% (2.9%-7.7%), and >5-year treatment 4.3% (1.9%-8.3%) vs 2.7% (1.2%-5.0%). The prevalence was similar among the IFNß-exposed vs unexposed in strata by maternal age ≤20, 21-25, 26-30, 31-35, 36-40, >40 years and presence of chronic disease. Conclusions: In this population-based observational study, the descriptive prevalence of SAPOs appeared similar with IFNß exposure before or during pregnancy, when pregnant women with MS were stratified by maternal characteristics.

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Keywords: Disease-modifying treatments in MS, Medication adherence.

(DXTS5) Efficacy and Safety of Eculizumab in Patients with Neuromyelitis Optica Spectrum Disorder Previously Treated with Rituximab: The Phase 3 PREVENT Study

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Background: In the PREVENT study, eculizumab was associated with a significant reduction in relapse risk vs placebo and was well tolerated. In total, 46 patients (26/96 receiving eculizumab, 20/47 receiving rituximab) had been treated with rituximab antibody rituximab. Objectives: To describe the efficacy and safety of eculizumab in patients in the randomized, double-blind, placebo-controlled, phase 3 PREVENT trial (trial registration: NCT01892345) who had previously received rituximab. Methods: Adults with aquaporin-4 immunoglobulin G–positive neuromyelitis optica spectrum disorder (NMO-SD) received eculizumab (maintenance dose, 1200 mg/2 weeks) or placebo with/
without concomitant immunosuppressive treatment (except rituximab/mitoxantrone). A post hoc descriptive analysis was performed using data from patients with any prior rituximab treatment within the previous year only for review of adverse events [AEs] recorded more than 3 months before randomization. Results: Baseline characteristics of the prior-rituximab subgroup were similar to the total PREVENT population; however, the subgroup included a lower proportion of Asian patients (10.9% vs 36.4% in total PREVENT study population) and greater representation from the Americas (58.7% vs 30.8%). In the subgroup, median times from last dose of rituximab to meningococcal vaccination and to first dose of study treatment were 31.7 and 38.7 weeks, respectively. Adjudicated relapses occurred in 1/26 (3.8%) and 7/20 (35.0%) patients in the eculizumab and placebo arms, respectively (hazard ratio 0.093; 95% CI 0.011–0.755; P = .0055). AE rates in patients receiving eculizumab and placebo within 1 year of previous rituximab use were 1025.8 and 1029.1 events/100 patient-years (both 100% of patients), respectively; rates of serious infections were lower with eculizumab than with placebo. Rates of serious infections were similarly low with eculizumab and placebo.

Supported by: None

Disclosure: None

Conclusions: In patients with aquaporin-4 immunoglobulin G–positive NMO in PREVENT who had previously received rituximab, the risk of adjudicated relapse was significantly lower with eculizumab than with placebo. Serious infections/infections were recorded more than 3 months before randomization.

Conclusions: The Multiple Sclerosis Association of America (MSAA) and the MS Phenotype Group and new guideline recommendations for disease-modifying therapy in MS may help us identify barriers to DMT adherence in veterans with MS. Approximately 20% of patients discontinued the injectable DMT due to inefficacy, compared to 10% for oral DMTs and 4% for infused DMTs. Injectable DMTs were discontinued in 20% of veterans due to adverse drug reactions, compared to 18% for oral DMTs and 4% for infused DMTs. Data collection is ongoing and may help us identify barriers to DMT adherence in veterans with MS. Conclusions: Preliminary results of our study suggest differences in adherence to DMTs and possible reasons for discontinuation of DMTs in veterans with MS.
(DXT55) Herpes Zoster Virus (HZV) Infections Among Multiple Sclerosis Patients Treated with Various Disease-Modifying Therapies
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Background: Disease-modifying therapies (DMTs) for multiple sclerosis (MS) may increase the risk for opportunistic infections, including herpes zoster (HZV). The relative frequency of HZV infection in the treated MS population is unknown. Furthermore, the relative distribution of reported cases per age group and gender is unknown. Objectives: To stratify the frequency of voluntarily reported HZV infections by DMT, age, and gender. Methods: We analyzed Disease Modifying Therapy Adverse Event Reporting System (FAERS) for adverse events (“herpes zoster” and “varicella”) reported in patients with MS from January 1999 and June 2019 receiving interferon beta (INF), glatiramer acetate (GA), natalizumab (NAT), fingolimod (FIN), teriflunomide (TFR), dimethyl fumarate (DMF), alemtuzumab (ALE), and ocrelizumab (OCR). We excluded reports where the “suspect drug” included 2 or more DMTs. We stratified the reports for each DMT, by year of report, age, and gender. Results: 3352 reports met our inclusion criteria. Mean (SD) annual report rates were highest for patients treated with NAT at 4.55 (1.57) and lowest for GA at 2.1 (2.8). Other DMTs: FIN 7.03 (27.3%); DMF 6.34 (3.0%); OCR 5.53 (27.8); ALE 22.8 (15%); INF 22.6 (18%) and TER 10.4 (4.7). Reports were 4.7x more in females (range from 2.3x for ALE to 8.2x for IFNβ). The highest percentage of reports was in the sixth decade of life for all DMTs except ALE (fourth decade). Several reports were in individuals younger than 40 (25.0%).

Conclusions: Reports of HZV infections varied based on the DMT used, patient age and gender. HZV reports were nearly fivefold more frequent in females than males, and reports among patients younger than 40 were higher than expected. Database limitations precluded calculations of incidence. We encourage further investigations of the incidence and risk mitigation strategies (including vaccination practices) of HZV in patients with MS on DMTs regardless of age of the patient.

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Disclosure: Nicola Carlisle, Sam I. Hooshamd, Michelle Maynard, Leah Hoffman: Nothing to disclose. Ahmed Z. Obeidat: Alexion, Biogen (consulting fee, speakers’ bureau); Celgene, EMD Serono, Genentech, Sanofi (consulting fee);
International Journal of MS Care (editorial board); Novartis (speakers’ bureau).

Keywords: Disease-modifying treatments in MS

(DXT56) Potential Weight Changes Among Patients with Multiple Sclerosis Undergoing Treatment with Ocrelizumab (Ocrezulimab)
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Background: Ocrelizumab (OCR) is a humanized monoclonal antibody that has been approved for the treatment of relapsing-remitting multiple sclerosis (RRMS) and primary progressive multiple sclerosis (PPMS). OCR is approved for use in 2017, has quickly become a formidable disease-modifying therapy option for multiple sclerosis (MS). While effective, potential adverse effects from ocrelizumab are still being explored, such as weight changes. Objectives: 1) To examine if patients have had weight changes while receiving ocrelizumab and 2) to explore associations between changes in weight and patients’ demographic and clinical characteristics. Methods: Data were extracted from the medical records of 152 patients who had recorded weight after receiving ocrelizumab (median: 2.36 kg), while nearly 39% (n = 59) lost weight (median: −1.90 kg). In the overall sample (n = 152), there was a significant change from pretreatment weight (z = 2.51, P = 0.012), with a median change of 0.37 kg (range: −7.72 to 17.30 kg). Changes in weight were negatively correlated with EDSS scores (P = −0.18, P = 0.045), with patients having weight gain having a median EDSS score of 3 (range: 0.70) and patients having weight loss having a median EDSS score of 4.0 (range: 1.5-7.5). There were no other significant associations. Conclusions: Findings from this preliminary study suggest that weight changes after ocrelizumab are frequently seen, with most patients either gaining or losing weight. As the EDSS score was the only variable associated with weight changes, further investigation is warranted to understand the underlying phenomenon, as well as the normal distribution of weight changes for persons with MS under more controlled time frames and across all levels of EDSS.

Supported by: None

Keywords: Disease-modifying treatments in MS, Weight changes

(DXT57) FAST: Faster and Safe Administration of Tysabri
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Background: Natalizumab (Tysabri) has been US Food and Drug Administration approved since 2004, and the incidence of infusion reactions is extremely low and has not increased over the 10 years of post-marketing study done to date. Patients sometimes comment on the burden of being infused monthly and being in the infusion center for 2 hours. In fact, many patients refuse the hour of observation after they are comfortable with infusions. Therefore, is it possible to reduce the amount of infusion time for natalizumab safely? Objectives: To determine if natalizumab can safely be given over 30 minutes vs the standard 60-minutes infusion. Methods: Observational study of patients in MS Center of Greater Orlando’s Infusion Center who consented to be infused over 30 minutes. Patients who were recruited for study had been on natalizumab for greater than 6 months. Results: Of 25 patients, 22 (88%) did very well with no effect. The other 3 persons effects were mild, and they did not require any additional treatment. Conclusions: Administering natalizumab over 30 minutes is a reasonable and safe option for most patients. Further studies are suggested to ensure validity.

Supported by: None
Disclosure: Nothing to disclose

Keywords: Disease-modifying treatments in MS, Tolerability

(DXT58) Reduction of Risk of Secondary Progressive Multiple Sclerosis within 2 Years of Treatment with Cladribine Tablets: An Analysis of the CLARITY Study
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1Posters: Disease-Modifying Therapy

Background: Disease-modifying therapies (DMTs) for multiple sclerosis (MS) have evolved over the years, and new treatment options are emerging. Cladribine (DXT56), a novel oral DMT, has been shown to reduce the risk of secondary progressive MS (SPMS) in the CLARITY study. Objectives: Explore [post hoc] the relationship between baseline Expanded Disability Status Scale (EDSS) score and risk of progression to SPMS within 2 years of treatment with cladribine (DXT56) in CLARITY. Methods: As progression to SPMS was not recorded during the trial, a proxy composite definition was used: confirmed disability progression (CDP), CDP within the leading EDSS-defined functional score (FS), EDSS score postbaseline ≥ 4.0, pyramidal FS ≥ 2, all conditions met for at least 3 months (mg) in the absence of a relapse. Patients progressing to EDSS score ≥ 6.0 were defined by having ≥ 1 postbaseline EDSS score ≥ 6.0 with 3-6 month CDP. In this post hoc analysis, odds ratios (ORs) and corresponding CIs are estimated by a logistic regression model with treatment and baseline EDSS score ≤ 3.0 or ≤ 3.5 as fixed effects. Results: Overall, proxy SMPS progression was seen in 6.7% of CT3.5 patients vs 3.5% of placebo (OR 0.46 [95% CI: 0.28; 0.76]; P = 0.0024). In the baseline EDSS ≤ 3.0 subgroup (CT3.5 n = 257; placebo n = 235), proxy SMPS progression occurred in 3.5% vs 7.7% (CT3.5 vs placebo; OR 0.44 [95% CI: 0.19; 0.99]; P = 0.0471). In the baseline EDSS ≤ 3.5 subgroup (CT3.5 n = 148; placebo n = 157), proxy SMPS progression occurred in 12.2% vs 22.4% (CT3.5 vs placebo; OR 0.48 [95% CI: 0.26; 0.9]; P = 0.0212). Similar effects have been observed for each

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proxy SPMS component vs placebo. Proportions of patients with at least 1 EDSS increase ≥1 point were 27.2% vs 31.8% [CT3.5 vs placebo; OR 0.88 [95% CI: 0.75, 1.03]; P = 0.11]; and 44% vs 50% [CT3.5 vs placebo; OR 0.66 [95% CI: 0.55, 0.80]; P = 0.001]. Among patients with prior DMD use, treatment with siponimod for 24 months resulted in a statistically significant treatment effect on the primary endpoint compared to placebo (OR 0.61 [0.45, 0.82]; P = 0.002). A subgroup analysis showed that patients who entered the study with baseline EDSS < 3.5 showed significantly improved outcomes compared to placebo (OR 0.52 [0.35, 0.78]; P = 0.002). The risks of progressing to SPMS (proxy) within 2 years of treatment with siponimod vs placebo, regardless of baseline EDSS score (< 3.5 or ≥ 3.5), were 14.5% vs 20.6% (OR 0.70 [0.47, 1.04]; P = 0.09); 28.9% vs 36.5% (OR 0.79 [0.57, 1.09]; P = 0.15), respectively. In the secondary endpoint analysis of change from baseline in 12-month EDSS score, patients who entered the study with EDSS scores < 3.5 (29.9% vs 34.5% [CT3.5 vs placebo; OR 0.85 [95% CI: 0.74, 0.99]; P = 0.03]) and ≥ 3.5 (38.0% vs 44.1% [CT3.5 vs placebo; OR 0.60 [0.44, 0.83]; P = 0.002) showed a statistically significant improvement in EDSS score change from baseline compared to placebo. Conclusions: The results of this study confirm the results of the phase 3 CLARITY study and further support the efficacy and safety of siponimod in patients with SPMS. The efficacy and safety profile of siponimod was consistent across subgroups, including patients with EDSS ≥ 6.0, and demonstrated a robust long-term safety and efficacy profile, with no new safety signals observed. The results of this study provide additional evidence to support the use of siponimod as a treatment option for patients with SPMS.

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Keywords: Disease-modifying treatments in MS

(DXT59) The CLARITY Study: Efficacy Outcomes Among Patients Who Received Disease-Modifying Drugs Prior to Treatment with Cladribine Tablets

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Background: Cladribine tablets (CTs) 10 mg, [cumulative dose 3.5 mg/kg (CT3.5)] over 2 years showed efficacy vs placebo in patients with relapsing-remitting multiple sclerosis (RRMS) in the pivotal phase 3 D Yazji study. However, patients included in the CLARITY study included patients treated with 2 DMDs prior to study entry (patients treated with ≥ 2 DMDs prior to study entry were excluded). A total of 433 patients were randomized to CT3.5 and 437 patients to placebo. Objectives: To report clinical outcomes and magnetic resonance imaging (MRI) lesion counts in the subgroup of patients from CLARITY who had used a DMD at any time prior to randomization. Methods: Post hoc analysis of efficacy, annualized relapse rate (ARR), relapse-free rate, MRI activity, and time to 3-month and 6-month confirmed EDSS score progression (CDP) stratified by the cohort of patients who had received a prior DMD treatment before entering the CLARITY study. Results: P values less than 0.05 were considered nominally significant. Results: Of those patients who received a prior DMD (interferon beta [IFN]-1b, IFN-1a, glatiramer acetate, or natalizumab), 110 were randomized to CT3.5 and 132 received placebo. Among patients with prior DMD use, CT3.5, compared to placebo, resulted in a nominally significant reduction in ARR (CT3.5, 0.22; placebo, 0.42; P < .005), a higher relapse-free rate (CT3.5, 70.4%; placebo, 55.9%; P < .0004), a numerically lower risk of 3-month endpoint (hazard ratio [HR] = 0.64; P = .1589) and 6-month endpoint (HR = 0.62; P = .2071) CDP, and reductions in the brain lesion counts (P < .001 for each type of lesion). Conclusions: Among patients who were pretreated with either IFN-beta-1a, IFN-1b, glatiramer acetate, or natalizumab, efficacy outcomes were similar to those seen in the full CLARITY active RRMS population, wherein patients who received CT3.5 showed statistically significant improvements in efficacy outcomes compared to placebo.

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Keywords: Disease-modifying treatments in MS
(DXT61) Injection-Related Reactions with Subcutaneous Administration of Ofatumumab in Relapsing Multiple Sclerosis: Pooled Analysis of the Phase 3 ASCLEPIOS I and II Trials

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Background: Ofatumumab, the first fully human anti-CD20 monoclonal antibody, with a monthly 20 mg subcutaneous (s.c.) dosing regimen, dem-onstrated superior efficacy (reductions in clinical relapses by 51%-59%, disability worsening by 33%-34%, and gadolinium-enhancing lesions by 94%-98%) vs teriflunomide in the two phase 3 ASCLEPIOS I/II relapsing multiple sclerosis (RMS) trials. Injection-related reactions (IRRs) were the most common adverse events (AEs) observed.

Methods: In the pooled ASCLEPIOS I/II trials, patients were randomized (1:1) to receive s.c. ofatumumab 20 mg (n = 946) (loading dose: days 1, 7 and 14; maintenance dose: every month) or matching placebo injections. All patients received the first 4 injections at the clinic, and subsequent injections at home. Premedication was recommended, but not mandatory. Both systemic (during and within 24 hours postinjection) and local site IRRs were recorded. Results: 20.6% (n = 193) of the patients in the ofatumumab group and 15.3% (n = 143) in the teriflunomide group had ≥1 systemic IRR. Incidence of systemic IRRs with the first injection was 14.4% with ofatumumab vs 7.5% with terifi-lumide. The incidence of systemic IRRs decreased with subsequent doses and was similar to the matching placebo injections in the teriflunomide group. Most IRRs (99.8%) were grade 1/2 in severity; grade 3 IRRs were observed in 2 patients (0.2%) with ofatumumab at the first injection (1 of which was reported as a serious AE) vs none with teriflumide. One additional IRR (grade 1) was also reported as a serious AE with ofatu-mumab. The serious IRRs (0.2%) were manageable, and patients continued treatment with no recurrences. No life-threatening IRRs were reported during the study. The most frequent (≥2%) IRR symptoms observed with ofatumumab were fever, headache, myalgia, chills, and fatigue. Most local site IRRs (≥2%) were injection-site erythema, induration, pain, itch- ing, and swelling.

Conclusions: Systemic and local IRRs with ofatumumab 20 mg s.c. were mostly mild to moderate in severity. Beyond the first injection, IRRs were no more frequent with ofatumumab vs matching placebo injections.

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Keywords: Disease-modifying treatments in MS, Immunology and MS, Injection-related reactions

(DXT62) Real-world Treatment Patterns in Patients with Multiple Sclerosis Using Disease-modifying Therapies

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Background: Numerous disease-modifying therapies (DMTs) have been approved for the treatment of multiple sclerosis (MS) in the past decade, and few studies have assessed patterns of use among all approved DMTs.

Methods: This study characterized patterns of DMT use in patients with newly diagnosed MS. Patients identified from January 2007 to October 2017 using the IBM MarketScan Commercial and Medicare databases. Patients had at least 12 months of continuous enrollment prior to their initial MS diagnosis and 2 years of follow-up. Up to 3 DMT lines of therapy (LOTs) were reported during a follow-up of 2 to 10.5 years. Discontinuation or switch of therapy was assessed. Results: Of 29,647 patients with at least 2 years of follow-up from MS diagnosis, 14,627 were treated with DMTs. Of these, 49% had 1 DMT LOT during follow-up, 25% had 2 LOTs, and 27% had 3 LOTs. Injectable (subcutaneous or intramuscular) DMTs, comprising increased to State (GA), interferon beta-1a (IFNβ-1a) (pegylated and long-acting interferon β-1a) (IFNβ-1a-p1, and peginterferon beta-1a (pegIFNβ-1a), were used by 87% of patients as first LOT, 68% as second LOT, and 67% as third LOT. Oral DMTs, including dimethyl fumarate, fingolimod, and teriflunomide, were used by 11% of patients as first LOT, but increased to 30% of patients by third LOT. Natalizumab, the only infusion DMT in this analysis, was used by less than 3% as first, second, and third LOTs. The most common pattern after ending the first LOT was discontinuation from all DMTs (51%), while 17% switched DMTs and 26% restarted the same DMT treatment later. Long-term discontinuation increased to 56% of patients with a second LOT treatment and 66% with a third LOT. Patients on GA and IFNβ-1a had the highest rates of discontinuation (52% to 61% for each drug and each LOT) and restarted (18% to 31% for each drug and each LOT). Patients on pegIFNβ-1a had the highest rates of switching to another DMT, ranging from 20% to 29%. Those taking dimethyl fumarate and fingolimod at first LOT were least likely to switch treatments throughout all LOTs. Conclusions: Over 2 to 10.5 years of follow-up, most patients with MS continued different from their first-line DMT, regardless of DMT type. Injectable DMTs were the most commonly used DMTs over this study period, although the rate of oral DMT use increased in later lines of therapy.

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Keywords: Disease-modifying treatments in MS, Treatment patterns

(DXT63) Associations Between Treatment Satisfaction, Medication Beliefs, and Adherence to Disease-modifying Therapies in Patients with Multiple Sclerosis Among Adult Saudis: A Tertiary Care Center Experience

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The objective of this study was to examine the association among chronic diseases, medication beliefs, and adherence to disease-modifying therapies in patients with multiple sclerosis (MS). The study design was a cross-sectional analysis of patient data from a tertiary care center. A total of 100 patients were included in the study. Of these, 90% were females, and 95% had MS. The most common medications among patients were glatiramer acetate and interferon beta-1a. The mean adherence rate for patients was 78%. Adherence was positively associated with treatment satisfaction (β = 0.34, p = 0.001) and negatively associated with medication beliefs (β = -0.23, p = 0.01). The study concluded that adherence to disease-modifying therapies in patients with MS was influenced by treatment satisfaction and medication beliefs.
Background: Multiple sclerosis (MS) is considered one of the most common neuroimmune diseases that leads to major disabilities in an affected patient with a significant burden and consequences to patients and their families. Even though there is no available cure for MS, the past 2 decades witnessed a promising future for MS treatment drugs, specifically disease-modifying therapies (DMTs), to reduce MS relapse and delay disability. Adherence to DMTs has a significant impact on treatment outcomes and is considered a critical factor in therapeutic success. Accordingly, the need to examine this issue in Saudi Arabia stands.

Objectives: To identify the factors associated with adherence to DMT medications among patients with MS in Saudi Arabia. To evaluate the relationship between treatment satisfaction, medication beliefs, and DMT adherence and other factors.

Methods: A survey was conducted in 2019 in neurology clinics in King Fahad Medical City (KFMC) in Riyadh, Saudi Arabia. Patients were sampled from the KFMC’s Data Base with population size of 387 patients. The survey measured self-reported DMT adherence (doses taken divided by doses prescribed during previous 2-week period—adherence ≥ 20.80), DMT satisfaction using the Treatment Satisfaction Questionnaire for Medication version II, medication beliefs using the Beliefs About Medicines Questionnaire, and demographic and clinical covariates. Relationships between variables were examined using multivariate logistic regression.

Results: Final analyses included 239 usable surveys. Mean ± SD participant age was 35.07 ± 9.7 years. Most respondents were female (74.9%), taking an injectable DMT (49%), and adherent to DMT (64.4%). Significant predictors of DMT adherence were DMT experience (naive vs experienced [odds ratio (OR), 3.722; 95% CI, 1.487-9.316; P = .005]), DMT route (oral vs injectable; OR, 0.974; 95% CI, 0.950-0.995; P = .003), and global satisfaction (OR, 0.950; 95% CI, 0.926-0.975; P < .001).

Conclusions: In patients with MS sampled from KFMC’s Data Base, medication beliefs was not significantly associated with DMT adherence while global satisfaction was significantly associated with DMT adherence. Based on significant predictors, patients taking injectable DMTs and patients with previous experience with another DMT(s) are at higher risk for nonadherence. Future research is warranted to assess relationships between variables in more diverse MS populations.

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Disclosure: Rola F. Alarieh: King Fahad Medical City (ownership interest).

Keywords: Adherence to therapy, Disease-modifying treatments in MS

(DX6T56) Longitudinal Disability Follow-up in Patients with 6-Month Confirmed Disability Improvement or Worsening in the CARE-MS and Extension Studies

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Background: Advanced Neuroinflammatory Treatments in Optic Neuritis and Multiple Sclerosis, Ottawa, ON; 1Amir Hospital, Sharq, Kuwait; 2University Hospital Centre of Liège, Liège, Belgium; 3Research Institute and Hospital, National Cancer Center, Goyang, Korea, Republic of (South); 1Institute of Neuroscience and Physiology, University of Gothenburg, Göteborg, Sweden; 2Austin Health, Flinders Medical Institute and Hospital, Adelaide, South Australia, Australia; 3Department of Medicine, University of Münster, Münster, Germany

Background: In the 2-year CARE-MS trials (trial registration: NCT00530348; NCT00548405), alemtuzumab (12 mg/day; baseline: 5 days; 12 months later: 3 days) significantly improved clinical/magnetic resonance imaging outcomes vs placebo in patients relapsing-remitting multiple sclerosis (RRMS). Efficacy of alemtuzumab-treated patients was maintained through year 9 in 2 consecutive extension studies (NCT00930553; NCT02255656 [TOPAZ]).

Objectives: To evaluate the status of disability over 9 years in pooled CARE-MS patients who achieved 12 months of 6-month confirmed disability improvement (CDI) or 6-month confirmed disability worsening (CDW) by years 2 or 9. Methods: Alemtuzumab-treated CARE-MS patients with baseline Expanded Disability Status Scale (EDSS) score ≥ 2 were stratified into 3 subgroups: with CDI, with CDW, or with stable disability. CDI and CDW were defined as ≥ 1-point decrease and increase, respectively, in EDSS score from core study baseline by ≥ 12 weeks and by ≥ 12 months. For each treatment arm, EDSS scores at each time point were compared with baseline using repeated measures ANOVA. Significant predictors were added to the model using forward selection.

Results: Final analyses included 239 patients from each treatment arm. Patients with CDI at any time during the 9-year study; 31 (6%) had both CDI and CDW. Few patients (n = 12) had a CDW event after CDI. Of patients with CDI at any time over 9 years, mean EDSS score change was −0.58 at year 9 vs core study baseline, and 51% had lower EDSS scores at year 9. Similar EDSS outcomes were observed at year 9 in the subset of patients who achieved CDI within the first 2 years of the study. However, patients with CDW any time over 9 years had worsened disability at year 9, with a +1.71 mean change in EDSS score from core study baseline; patients with CDW in the first 2 years of the study had a +2.27 EDSS score change by year 9. EDSS scores remained stable at 9 years (mean change, −0.10) in the 149 (29%) patients who had neither CDI nor CDW. Compared with previous years, no new safety signals were identified in year 9 in CARE-MS extension study patients.

Conclusions: Achievement of CDI at any point in the CARE-MS studies was associated with improved disability at year 9 vs baseline. However, those with CDW had increased disability over 9 years regardless of when worsening occurred. These findings suggest that CDI and CDW are meaningful end points for predicting long-term disability outcomes in patients with RRMS.

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**Results:**
Patients treated with interferon beta (1b or 1a, subcutaneous) (n = 342), glatiramer acetate (GA) (n = 188), or fingolimod (n = 226). Mean age was higher in the fingolimod group (P < .05). Physical disability was assessed with Expanded Disability Status Scale (EDSS), and cognitive status was assessed with Brief International Cognitive Assessment for MS (BICAMS) which included the Symbol Digit Modalities Test (SDMT), the California Verbal Learning Test-1 (CVLT-I), and the Brief Visuospatial Memory Test-Revised (BVMT-R).

**Conclusions:** Assessments were performed at baseline and yearly until the end of fifth year of treatment. **Results:** 85% of patients treated with fingolimod were still having their medication at the end of fifth year (79% for GA and 78.9% for interferon beta, P < .05). Most of the patients treated with DMTs remained stable over the course of 5 years (fingolimod: 70.1%, interferons: 71.9%, GA: 75%, P > .05). Cognition improved in some patients (fingolimod: 11.2%, interferons: 9.6%, GA: 6.8%, P > .05). More than 80% of patients remained stable or improved. The most significant improvement was observed in SDMT, and it was significantly higher than CVLT and BVMT (30.7%, 18.6%, and 17%, respectively, P = .02).

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Disease-modifying treatments in MS, Psychological issues and MS

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**DXT67**

**One-Year Interim Analysis of Real-World Patient-Reported Outcomes in Relapsing-Remitting Multiple Sclerosis Patients Transitioning to Alemtuzumab (PRO-ACT Study)**

**Background:** Clinical trials of alemtuzumab have demonstrated its 9-year efficacy and safety, but real-world data are limited. PRO-ACT assesses patient-reported outcomes (PROs), safety, and treatment sequencing in adults with relapsing-remitting multiple sclerosis (RRMS) transitioning to alemtuzumab.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Disease-modifying treatments in MS, Psychological issues and MS
from prior disease-modifying therapy to alemtuzumab in the United States and Europe. At year 1, ARR was 0.00 (95% CI: 0.00–0.00) resulting from the world PRO-ACT study. Methods: PRO-ACT is an ongoing 24-month, prospective, multicenter, noninterventional, single-arm, observational study. The primary end point evaluates change in overall satisfaction on the Treatment Satisfaction Questionnaire for Medication v1.4 (TSQM; scale 0-100; higher scores indicate greater satisfaction), after transitioning to alemtuzumab. Mean TSQM scores improved from baseline to year (Y) 1 for ≥50 years of age enrolled in POP. Patients transitioned from natalizumab (37%), dimethyl fumarate (14%), fingolimod (13%), teriflunomide (12%), or other therapies (24%) to alemtuzumab. Mean TSQM scores improved from baseline to Y1 for overall satisfaction (50.3 vs 66.5; P < .0001) and effectiveness (49.3 vs 60.7; P < .0001) domains; scores were unchanged for side effects (77.6 vs 76.5) and convenience (70.3 vs 70.7). Mean scores for other PRs showed improvement at Y1 vs baseline: MSIS-29 physical impact scale (52.4 vs 47.8; P < .001), MSIS-29 psychological impact scale (53.4 vs 47.9; P < .001), and MSIS-5 (12.8 vs 11.7; P < .001). Scores remained stable on the PDDS (3.1 vs 3.2). Mean hours of weekly employment productivity lost from 11.4 at baseline to 7.4 at Y1 (P < .05). Incidence of adverse events was 92% and serious adverse events was 11%. Overall adverse events: ≥50 years of age (n = 413), ≥50 years of age (n = 274). Conclusions: PRs improved during the first year of alemtuzumab treatment after transitioning from another therapy. Alemtuzumab safety in Y1 was consistent with the pivotal studies.

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Keywords: Disease-modifying treatments in MS

(DXT71) Efficacy and Safety of Teriflunomide in Patients with Relapsing-Remitting Multiple Sclerosis of Various Disease Duration: Analysis of Pooled Clinical Trials

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Background: Teriflunomide is a once-daily oral immunomodulator approved for the treatment of relapsing forms of multiple sclerosis (MS) or relapsing-remitting MS (RRMS), depending on the local label. Objectives: To evaluate and measure the longitudinal safety profile in patients with RRMS stratified by disease duration. Methods: This was a pooled efficacy and safety analysis using data from the phase 2 study (trial registration: NCT01487096) and the phase 3 TEMSO (NCT00134563, NCT00803049), TOWER (NCT00715881), and TENERE (NCT00883337) core and extension studies. Patients receiving placebo or teriflunomide 14 mg were stratified by disease duration at baseline (≤1 year, >1 to 5 years, >5 to 10 years, and >10 years). Study end points included annualized relapse rate (ARR), Expanded Disability Status Scale (EDSS) score, 6-month confirmed disability worsening (CDW), and safety. Results: In the core period, ARR was lower in patients treated with teriflunomide 14 mg compared with placebo across disease duration subgroups: ≤1 year (0.33 [n = 272] vs 0.56 [n = 251], P = .0013), >1 to 5 years (0.46 [n = 278] vs 0.70 [n = 268], P = .0011), >5 to 10 years (0.39 [n = 191] vs 0.52 [n = 164], P = .0571), and >10 years (0.33 [n = 154] vs 0.58 [n = 129], P = .0005). In the core-extension period (up to year 13), ARRs in teriflunomide-treated patients were similar regardless of disease duration ≤1 year (0.19 [n = 276], ≥1 to 5 years (0.22; n = 669), >5 to 10 years (0.25; n = 393), and >10 years (0.25; n = 325). At year 13, 6-month CDW rates for each group were 48.3% (≤1 year), 37.1% (>1 to 5 years), 52.6% (>5 to 10 years), and 36.8% (>10 years). From core study baseline to year 10 (the last time point at which all groups had at least 10 patients), ARRs were stabilized and remained lower in teriflunomide-treated patients across all disease durations: ≤1 year: 0.07; >1 to 5 years: 1.11; >5 to 10 years; >0.05; and >10 years, >0.7. Overall incidences of adverse events during year 3 were 93.1% (≤1 year), 87.2% (>1 to 5 years), 88.0% (>5 to 10 years), and 88.7% (>10 years); incidences of serious adverse events (SAEs) during this period were 21.2% (≤1 year), 19.6% (>1 to 5 years), 15.5% (>5 to 10 years), and 18.0% (>10 years). Conclusions: Teriflunomide 14 mg reduced relapses across all patients regardless of disease duration vs placebo in the core studies. Over 13 years, ARR remained low and EDSS score increased minimally. Safety outcomes from baseline to year 13 were consistent across disease duration subgroups.

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(DXT71) Efficacy and Safety of Teriflunomide in Patients with Relapsing-Remitting Multiple Sclerosis of Various Disease Duration: Analysis of Pooled Clinical Trials

Posters: Disease-Modifying Therapy

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Background: Malignancy risk was previously characterized in a mono-therapy oral cohort of patients with multiple sclerosis (MS) treated with cladribine tablets (CTs) 10 mg (3.5 mg/kg cumulative dose over 2 years; referred to as CT3.5) including cumulative data up to February 2015. In clinical trials, an imbalance in the number of malignancies observed for cladribine vs placebo was observed, suggesting malignancy risk may be increased.

Objectives: To provide a more detailed assessment of malignancy using safety data integrated from clinical trials and a safety follow-up registry (up to May 2017), to further characterize the malignancy risk of CTs in patients with MS and investigate whether there is a dose-dependent risk.

Methods: Cohorts were monotherapy oral: patients with MS receiving CTs at any dose as a monotherapy; all exposed: patients with MS receiving any formulation of cladribine to provide a larger cohort to identify rare events such as malignancies. Results: In the monotherapy oral cohort, patient numbers (patient-years [PYs]) were: placebo N = 641 (2275 [CT3.5, N = 923, patient-years [PYs]=3936.69, placebo, N = 641, PYs = 2421.47) was derived from the CLARITY, CLARITY Extension, and ORACLE MS trials and the PREMIERE registry. Incidences per 100 PYs were calculated for adverse events, cumulative to the end of PREMIERE. Adverse drug reactions (ADRs) including serious ADRs (SADRs); implied causality from postapproval sources were reported in the Periodic Benefit-Risk Evaluation Report, of which 136 were SADRs; none of which are new safety findings for CT3.5. Conclusions: This integrated analysis of trial data, exclusively focused on the frequency of serious TEAEs with CT3.5 in patients with RMS, further establishes the safety profile of this dose. This profile is consistent with the previously published integrated safety analysis profile. No new major safety findings were identified in this latest dataset which includes final data from the PREMIERE registry. The pattern of postapproval ADRs was consistent with the clinical safety profile for CT3.5.
**Posters: Disease-Modifying Therapy**

**(DXT75) Switches to Established and Recently Approved Oral Disease-Modifying Therapies: Comparison of Patient Clinical Profiles and Therapy Selection Drivers**

Virginia R. Schobel, Jennifer Robinson

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**Background:** With the approval of siponimod (BAF), cladribine (CdA) and dimethyl fumarate (DMF) in the United States, the number of oral disease-modifying therapies (DMTs) for the treatment of multiple sclerosis (MS) has grown. **Objectives:** To describe clinic, treatment history, and switch drivers among patients with MS recently switched to an oral DMT. **Methods:** In February 2019, 209 US neurologists contributed to a cross-sectional, retrospective chart audit of patients with MS (n = 1003 total; n = 718 relapsing-remitting MS (RRMS)) switched to a new DMT in 2018 or 2019. Patients were characterized by likelihood of alternative switch to DMTs in development, if the therapies had been available at switch. Analyses will be updated with February 2020 data. **Results:** Most patients recently switched to an oral DMT were diagnosed with RRMS (87%-92%). Oral DMTs constituted 43% of RRMS patients, with 11% switched to teriflunomide (TFL), 16% to fingolimod (FTY), 15% to dimethyl fumarate (DMF). Oral DMTs were predominantly first switches (85%-89%); such switches were frequently due to efficacy (39%-43%) or tolerability (25%-29%). Patients switched to FTY were more likely to have switched from another oral DMT compared to those switched to DMF (21% vs 7%, P < .05). Desire for a high-efficacy DMT drove more FTY switch selection (60% vs TFL: 32%, DMF: 35%, P < .05). Compared to the established oral DMTs, candidates for alternative BAF, CdA, or DMF switches were less likely to be diagnosed with RRMS and more likely to have had a second or later switch. Patients with RRMS considered CdA candidates were more likely to have switched from an oral DMT compared to noncandidates (22% vs 12%; P < .05); administration type preference (43% vs 26%; P < .05), good tolerability profile (49% vs 38%; P < .05), and long-term safety (34% vs 22%; P < .05) drove more of the switched-to DMT selections among CdA candidates. DMT candidates were more likely to have switched from another DMT compared to noncandidates (34% vs 16%; P < .05). **Conclusions:** Switches to established oral DMTs are typically first switches among patients with RRMS, although FTY may be reserved as a high-efficacy option for patients in whom a prior oral DMT failed. Oral class impact will grow within the switch segment with the availability of new oral options; however, the recently approved therapies will inherit the drawbacks of later line options. 2020 chart audit data will assess early adoption patterns and selection drivers among patients switched to BAF, CdA, or DMF.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Disease-modifying treatments in MS

**(DXT76) First-Line Ocrelizumab Use for Relapsing-Remitting Multiple Sclerosis in the United States: Trend and Comparison to Glatiramer Acetate and Dimethyl Fumarate**

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**Background:** In March 2017, ocrelizumab (OCR) was approved for the treatment of relapsing-remitting and primary progressive multiple sclerosis (MS) in the United States, the number of oral disease-modifying therapies (DMTs) for the treatment of multiple sclerosis (MS) has grown. **Objectives:** To compare clinic, treatment history, and switch drivers among patients with MS recently switched to an oral DMT. **Methods:** In February 2019, 209 US neurologists contributed to a cross-sectional, retrospective chart audit of patients with MS (n = 1003 total; n = 718 relapsing-remitting MS (RRMS)) switched to a new DMT in 2018 or 2019. Patients were characterized by likelihood of alternative switch to DMTs in development, if the therapies had been available at switch. Analyses will be updated with February 2020 data. **Results:** Most patients recently switched to an oral DMT were diagnosed with RRMS (87%-92%). Oral DMTs constituted 43% of RRMS patients, with 11% switched to teriflunomide (TFL), 16% to fingolimod (FTY), 15% to dimethyl fumarate (DMF). Oral DMTs were predominantly first switches (85%-89%); such switches were frequently due to efficacy (39%-43%) or tolerability (25%-29%). Patients switched to FTY were more likely to have switched from another oral DMT compared to those switched to DMF (21% vs 7%, P < .05). Desire for a high-efficacy DMT drove more FTY switch selection (60% vs TFL: 32%, DMF: 35%, P < .05). Compared to the established oral DMTs, candidates for alternative BAF, CdA, or DMF switches were less likely to be diagnosed with RRMS and more likely to have had a second or later switch. Patients with RRMS considered CdA candidates were more likely to have switched from an oral DMT compared to noncandidates (22% vs 12%; P < .05); administration type preference (43% vs 26%; P < .05), good tolerability profile (49% vs 38%; P < .05), and long-term safety (34% vs 22%; P < .05) drove more of the switched-to DMT selections among CdA candidates. DMT candidates were more likely to have switched from another DMT compared to noncandidates (34% vs 16%; P < .05). **Conclusions:** Switches to established oral DMTs are typically first switches among patients with RRMS, although FTY may be reserved as a high-efficacy option for patients in whom a prior oral DMT failed. Oral class impact will grow within the switch segment with the availability of new oral options; however, the recently approved therapies will inherit the drawbacks of later line options. 2020 chart audit data will assess early adoption patterns and selection drivers among patients switched to BAF, CdA, or DMF.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Disease-modifying treatments in MS

**(DXT77) Alemtuzumab Maintains Efficacy on Clinical and Magnetic Resonance Imaging Lesion Outcomes, Including Slowing of Brain Volume Loss, Over 9 Years in Relapsing-Remitting Multiple Sclerosis Patients: CARE-MS II Follow-up (TOPAZ Study)**

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**Background:** In CARE-MS II (trial registration: NCT00548405), alemtuzumab (12 mg/day; baseline: 5 days; 12 months later: 3 days) significantly improved clinical/magnetic resonance imaging (MRI) outcomes vs subcutaneous interferon-beta-1a (SC IFNβ-1a) over 2 years (y) in patients with RRMS with inadequate response to prior therapy. Efficacy was maintained in a 4-year extension study (NCT00930553), wherein patients could receive additional alemtuzumab courses (12 mg/day on 3 days, 12 months apart) as needed for disease activity, or receive other disease-modifying therapy (DMT) per investigator discretion. Further follow-up was available in an additional 5-year extension, TOPAZ (NCT02255656). **Objectives:** Evaluate the efficacy and safety of alemtuzumab in CARE-MS II patients over 9 years. **Methods:** At investigator discretion, patients in TOPAZ can receive additional as-needed alemtuzumab (≥12 months apart, no criteria) or receive other DMT (at any time). **Results:** From core study baseline through year 9, 288/435 (66%) CARE-MS II alemtuzumab-treated patients remained on study; 41% received neither additional alemtuzumab nor another DMT through year 9. Annualized relapse rate was 0.19 in years 3-9. From core study baseline through year 9, 66% of patients had stable/improved Expanded Disability Status Scale (EDSS); EDSS was not worsened over 9 years, and the mean EDSS was 0.32. Over 9 years, 60% of patients were free of 6-month confirmed disability worsening and 49% achieved 6-month confirmed disability improvement. On average, 69% of patients were free of MRI disease activity, 89% were free of new gadolinium-enhancing lesions, and 69% were free of new/enlarging 12 hyperintense lesions, annually from year 3. From core study baseline through year 9, median percent cumulative...
brain volume (BV) change was $-1.22\%$, median percent BV change was $≤-5\%$. Annually over years 3-9, incidence of overall adverse events (AEs) and infections declined through year 9; cumulative thyroid AE incidence was 43.7% and immune thrombocytopenia (ITP) incidence was 3.7% (1 new case of ITP; 14 months after the fourth alemtuzumab course, was observed at year 9). No new cases of nephropathy were reported. Efficacy and safety in SC IFN-1a–treated patients from the core study with at least 1 relapse was characterized in the extension. Efficacy was consistent with that of previous years.

**Conclusions:** Efficacy of alemtuzumab on clinical, MRI, and BV loss outcomes was maintained over 9 years in CARE-MS II patients, with 41% receiving no further treatment through year 9. Safety in year 9 in this study was consistent with that of previous years.

**Supported by:** Sanofi, Bayer HealthCare Pharmaceuticals

**Disclosure:** Barry A. Singer: AbbVie, Biogen, Novartis, Roche, Sanofi (research and speaking; and/or consulting); Acorda, Alexion, Bayer, Celgene, EMD Serono, Genentech, Teva, TG Therapeutics (speaking and/or consulting); Allergan, MedImmune (research support); Rati Alovaghi: Bayer, Biogen, Biologics, Genpharm, GlassSmithKline, Lundbeck, Merck, Novartis, Sanofi (speaker honoraria, scientific advisory boards, research grants). Ann D. Bass: Biogen, EMD Serono, MedImmune, Novartis, Roche–Genentech, Sanofi, TG Therapeutics (consulting fees for non-CME services from commercial interests or their agents and/or grants). Simon Broadley: Bayer Schering, Merck Serono, Novartis, Roche, Sanofi (conference travel sponsorship, honoraria for advisory board participation); Biogen (conference travel sponsorship, honoraria for advisory board participation, speaker honoraria, unencumbered research grant); Genzyme (speaker honoraria). Yang Mao-Dragary: Acorda, Bayer, Biogen, Celgene, Chugai, EMD Serono, Genzyme, Novartis, Quester, Teva Neuroimmunology (consulting fees and/or grant support); NIH National Institute of Allergy and Infectious Diseases (participation in the NIH National Institute of Allergy and Infectious Diseases Neurological Disorders and Stroke R01-NS080821 [grant support]); Hans-Peter Hartung: Bayer, Biogen, CSL Behring, Grifols, Merck Serono, Novartis, Roche (consulting and/or speaking fees); Ewa Kubaha Havrdova: Actelion, Biogen, Merck Serono, Novartis, Receptes, Roche, Sanofi, Teva (honoraria; grant support); Ministry of Education of Czech Republic (PROGRES Q27/1FL1 [support]); He Jin-Kim: Bayer Schering, Biogen, Cellerion, Eisai, HanAll BioPharma, Novartis (consulting and/or speaking fees); Genpharm, GlassSmithKline, Lundbeck, Merck, Novartis, UCB (consulting and speaking fees; research support); Journal of Clinical Neuroscience, Multiple Sclerosis Journal - Experimental, Translational and Clinical (co-editor/associate editor); MedImmune (consulting and speaking fees, steering committee member); Ministry of Science and ICT (research support); Kanio Nakamura: Biogen (royalty fees for licenses, speaking fees, research support); Novartis, Sanofi (speaking fees, research support); Carlos Navia: Bayer Schering, Genzyme, Stendhal (consulting and speaking fees); Merck Serono, Novartis, Roche (consulting and speaking fees); Alexion, Biogen, Genentech, Morgan, Merck–Novartis, OLEA Medical, Roche, Sanofi, SyntheticMR (consulting and speaking fees); Krzysztof W. Selmaj: Bayer Schering, Biogen, Genentech, Novartis, Ono Pharma, Roche, Sanofi Genzyme, Teva Neuroscience, Wyeth (consulting fees); May H. Han: Novartis (consulting fee); Barry A. Singer: AbbVie, Biogen, Novartis, Sanofi Genzyme (consulting fee, contracted research); National Institute of Allergy and Infectious Diseases Autoimmune Center of Excellence, NIH National Institute of Neurological Disorders and Stroke (contracted research). Jeffrey A. Cohen: Consulenda, Polioversal Council (consulting fee); Multiple Sclerosis Journal (editor); Mylan (speakers bureau). Amir Bar-Oz: Atara Biotherapeutics, Bayer, Bayhill Therapeutics, Berlex, Biogen, BoMS, Celgene/Roche, Diogenes, Eci Liddy, F. Hoffman-La Roche, Genentech, GlassSmithKline, Genzyme-Jackson/GFG, Immunx, Initacare/Akela, Mapi, MedImmune, Merck/EMD Serono, Novartis, Ona Pharmaceuticals, Roche, Genentech, Sanofi Genzyme, Teva Neuroscience, Wyeth (consulting fees). Jeong H. Han: Novartis (consulting fee). Barry A. Singer: AbbVie, Biogen, Novartis, Sanofi Genzyme (consulting fee, contracted research); Acorda, Alexion, Celgene, EMD Serono, Genentech, Teva, TG Therapeutics (consulting fee); Alkermes, MedImmune, Roche (consulted research). Ina J. Jastrow: Scott Koehn, Chelsee Elam, Zanette Elam: Novartis Pharmaceuticals Co. (consulting fees). Marinee Girbau: Novartis Pharma AG (salary); Bruce A.C. Cross: Akelis, Alexion, Atara, Biogen, EMD Serono, Novartis, TG Therapeutics (consulting fees).

**Keywords:** Disease-modifying treatments in MS

(DX779) **Efficacy of Ocrelizumab Treatment on Cognitive Functions in Persons with Multiple Sclerosis**

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**Background:** Ocrelizumab is the first treatment which could be used for progressive forms of multiple sclerosis (MS). Generally ocrelizumab trials in MS investigate side effect and safety properties. There are limited studies examining effects of ocrelizumab on cognition in patients with MS (PwMS). **Objectives:** The aim of this study was to evaluate the efficacy of ocrelizumab treatment on cognitive functions in PwMS. **Methods:** In total, 35 PwMS were included in this study. The participants' clinical characteristics such as MS type, disease duration, and Expanded Disability Status Scale (EDSS) scores were recorded. Cognitive function was evaluated with The Brief Cognitive Assessment Battery (BCAB), which consists of the Symbol Digit Modalities Test (SDMT), the California Verbal Learning Test-II (CVLT-II), and the Brief Visuospatial Memory Test-Revised (BVMT-R). The assessment was done at baseline and in months 6 and 12 after the treatment. **Results:** The age range was 26–79 (mean age 56.2 ± 13.7); the disease duration was 16.84 ± 8.19 and EDSS score was 6.23 ± 1.43. Participants’ clinical characteristics of the disease were 11.4% relapsing-remitting (RRMS), 57.1% in n = 20) secondary progressive (SPMS), and 31.4% (n = 11) primary progressive MS (PPMS). BVMT-R and CVLT-II scores were significantly increased from baseline to 12 months in all PwMS groups. **Conclusion:** A larger clinical trial is recommended to investigate the effect of ocrelizumab on cognitive functions in PwMS.
respectively) (P < .05). No significant differences were observed between baseline and month 6 in terms of SDMT scores (34.37 ± 14.95 vs. 34.51 ± 15.67) (P > .05). **Conclusions:** This study has suggested that ocrelizumab treatment could be affected positively on verbal and visual learning/memory. On the other hand, there was no positive or negative effect on information processing speed. In view most of our patients being in progressive form, the protective or positive effect of ocrelizumab on cognitive function is clinically important. Additionally, to better understand the protective effect of ocrelizumab treatment could be affected positively on verbal and visual learning/memory. On the other hand, there was no positive or negative effect on information processing speed. In view most of our patients being in progressive form, the protective or positive effect of ocrelizumab on cognitive function is clinically important.

**Supported by:**

**Disclosure:** Nothing to disclose

**Keywords:** Disease-modifying treatments in MS, Psychological issues and MS

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**EPIO1** Determining the Effect of Early Versus Later Diagnosis of Multiple Sclerosis on Long-Term Prognosis in a Real-World Setting

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**Background:** Early treatment of multiple sclerosis (MS) is recommended based on studies involving patients identified early with clinically isolated syndromes. Although early diagnosis and subsequent early treatment may result in a better outcome (lower Expanded Disability Status Scale score), in a real-world setting outcomes may be different concerning patients presenting (and treated) early after onset of symptoms (EP group) vs later (LP group). Other risk factors for worsening MS (poor recovery from first attack, motor onset, etc) may be more predictive than EP vs LP status.

**Objectives:** To compare characteristics of EP patients (with less than 1 year of symptoms at presentation) vs LP groups.

**Methods:** Newly diagnosed patients with MS seen up to 15 years divided as EP or LP were studied for attack type, frequency, and recovery, and group statistics were applied. **Results:** There were 121 patients in the EP group, and 86 patients in the LP group. More patients with a high attack frequency in years 0-2 were seen in the EP group vs the LP group (45% vs 28%, P = .014). The median time to treatment was shorter in the EP group vs LP group (by 32 months [8.91]), and we found no significant difference in disability long-term outcomes. Other clinical risk factors were evenly divided between EP and LP groups. **Conclusions:** These EP and LP groups were the same in terms of long-term outcome. Earlier treatment and more active disease were seen in the EP group. We suggest a nuanced approach to interpretation of the “early diagnosis and treatment equals better outcome” rule.

**Supported by:**

**Disclosure:** Jikku Zachariah, Rebecca Schorr, Tim Quezado: Nothing to disclose. Thomas F. Scott: Genentech, Biogen, Novartis, Genzyme (consulting fee, contracted research, speakers’ bureau).

**Keywords:** Disease-modifying treatments in MS, Epidemiology of MS, Natural history of MS

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**EPIO2** Motor Impairment in Multiple Sclerosis: Analysis from the North American Registry for Care and Research in Multiple Sclerosis (NARCRMS)

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**Background:** The North American Registry for Care and Research in Multiple Sclerosis (NARCRMS) is a longitudinal registry studying the course of multiple sclerosis (MS) in the disease-modifying era.

**Objectives:** To examine motor performance metrics of upper and lower extremity function in NARCRMS patients at enrollment. **Methods:** Recruitment began in 2016, and by December 31, 2019, 662 patients were enrolled at 23 MS sites across the United States and Canada. People with any subtype of MS within 15 years of disease onset and an Expanded Disability Status Scale (EDSS) score of up to 6.5 are eligible for enrollment. Various clinical metrics are collected including motor performance for upper and lower extremities. Five initial observations about EDSS, 25-foot timed walk, and the Nine-Hole Peg Test (NHP) are reported below.

**Results:** EDSS scores and 25-foot walk times were available in 579 patients and upper extremity function in 571 patients. A mean walking speed of 4.9 seconds was recorded in patients with an EDSS score of 0 (n = 100). 5.0 seconds remained the mean speed until an EDSS score of 3.0 (n = 37), where a mean speed of 5.6 seconds was recorded. Walking truly became affected at an EDSS score of 3.5 (n = 25), where mean speed of 6.1 seconds was recorded. Thereafter, mean speed progressively declined at every EDSS score increase. For an EDSS score of 4.0 (n = 25), mean speed was 7.9 seconds; for an EDSS score of 4.5 (n = 6), mean speed was 9.1 seconds and continued to increase until an EDSS score of 6.5 (n = 10), where mean speed was 16.8 seconds. For the NHP, patients with an EDSS score of 0 (n = 96) had a mean speed of 19.4 seconds in the dominant and 20.7 seconds in the nondominant hand. Hand function remained unimpaired until an EDSS score of 2.0, and significant slowing occurred in patients with EDSS scores ranging from 2.5 to 6.5. For an EDSS score of 2.5 (n = 40), mean speed was 24.7 seconds in the dominant and 24 seconds in the nondominant hand. For an EDSS score of 4.0 (n = 26), mean speed was 26.1 seconds in the dominant and 26.6 seconds in the nondominant hand. For an EDSS score of 6.5 (n = 15), hand function had declined to a mean speed of 39.1 seconds for the dominant and 49.8 seconds for the nondominant hand.

**Conclusions:** A linear correlation of the 25-foot walk speed to EDSS score increases was remarkable, reiterating the commonly held belief that the EDSS is a “walking scale.” Decline in hand function at an EDSS score of 2.5 was unexpected, because hands are often perceived to be unaffected early in MS and seldom observed as impaired by patients. Progressive decline of hand function at every EDSS score increase would suggest that the NHP test is a good marker of declining hand function and should be included in clinical monitoring of patients.

**Supported by:**

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**Keywords:** Epidemiology of MS

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**EPIO3** Increase in Family Recurrence in Patients Diagnosed with Multiple Sclerosis in the Years 2017-2019 in Hispanic Population of Puerto Rico

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**Background:** Multiple sclerosis (MS) is a neurodegenerative disease in which the immune system damages the central nervous system. The cause of MS is not known, but several studies look at environmental, immunologic, geographic, and genetic factors. Thus, MS is not considered hereditary, but rather polygenic. However, there are several cases of patients with family history of MS in several relative degrees. **Objectives:** Evaluate the increase in recurrence of MS with MS in recent years in Puerto Rico (PR), including any type of degree relative. **Methods:** For this data, from the Puerto Rican MS Registry (PRMS Registry) of all patients diagnosed in the years 2017, 2018, and 2019 registered at present in PR were analyzed. **Results:** Overall 11.4% (45/396) of patients had family recurrence of MS. For 2017, 9.7% (14/143) of patients had family history of MS of at least 1 family member. For 2018, 8.3% (14/167) of patients presented family history of MS. Lastly, for 2019 a total of 19.7% (17/86) of patients reported having family history of MS. **Conclusions:** A slight increase in recurrence was observed when compared to the previous study from 2013 to 2016 (10.2%). Further investigations need to be done to elucidate the genetic aspects of family recurrence of MS among the Puerto Rican population. The genetic mix of Caucasian, African, and Taino races could have an influence on genetic risk among this population. Also, it is important to keep this study ongoing to analyze familial risk in the Hispanic population and compare it to other ethnic groups.

**Supported by:**

**Disclosure:** Nothing to disclose.

**Keywords:** Epidemiology of MS, Genetics and MS

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**EPIO4** Diet Quality and Nutritional Adequacy of Micronutrients Among People with Relapsing-Remitting Multiple Sclerosis: An Analysis of Weighed Food Records

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**Background:** A diet that is rich in fruits and vegetables may influence disease course and disability. **Objectives:** To examine the dietary intake of people with relapsing-remitting multiple sclerosis (RRMS) compared to the national data. **Methods:** Dietary data were collected for 14 participants with RRMS and the Canadian Community Health Survey data, 2015-2017 were used for comparison. **Results:** Participants reported consuming a diet with low nutrient profile. The RRMS group had a lower nutrient density and lower fruit intake compared to the national data. **Conclusions:** There is a need for dietary intervention to improve the nutritional status of people with RRMS.

**Supported by:**

**Disclosure:** Nothing to disclose.

**Keywords:** Epidemiology of MS, Genetics and MS

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Background: Multiple sclerosis (MS) is a neurodegenerative disease that affects nearly 1 million in the United States. Poor diet quality and micronutrient deficiencies have been reported in several studies and are associated with more severe disease. However, previous work has relied on diet screeners and questionnaires for data collection. Thus, these findings are unique in that they examined diet quality and micronutrient intake using weighed food records. Objectives: Weighed food records were used to evaluate diet quality and usual intake of micronutrients from people with diagnosed relapsing-remitting MS (RRMS). Methods: As part of a dietary intervention study comparing the Wahls and Swank diets, 3 weighed food records were collected on 2 weekdays and 1 weekend day at a prerandomization run-in visit from (n = 95) participants and again at a baseline visit from the (n = 87) nonexcluded participants. Food records obtained from all participants were analyzed at the University of Minnesota Nutrition Coordinating Center. Diet quality was assessed using the Healthy Eating Index (HEI), which compares food groups and selected nutrient intakes to the Dietary Guidelines for Americans. Mean intake of each micronutrient was calculated for each individual and adjusted using the National Cancer Institute method to estimate usual intake. Usual intake of each micronutrient was then evaluated with the estimated average requirement cutpoint method for each life stage group and combined by weighted means to assess the overall nutritional adequacy of each micronutrient for the group. Results: Preliminary analyses indicate that this cohort has an HEI score of 61 ± 12, which suggests that diet quality needs improvement. Furthermore, this cohort has high prevalence of inadequate intake for vitamins D 92.9%, E 61.4%, C 50.8%, A 35.3%, folate 31.0%, and B12 22.8%, and minerals including calcium 49.8%, magnesium 45.8%, and zinc 19.5%. However, low prevalence of inadequate intake was observed for niacin 0.2%, thiamin 7.5%, riboflavin 3.0%, B6 5.4%, phosphorus 2.0%, copper 6.6%, and selenium 1.0%. Conclusions: Diet quality is low and intake of several micronutrients is inadequate in this cohort with RRMS. These findings confirm observations from previous studies that poor diet quality and inadequate intake of micronutrients is common among those with RRMS. These findings may lead to new dietary strategies to manage symptoms and improve quality of life among those with MS.

Supported by: None

Disclosure: Nothing to disclose.

Keywords: MS, Caregiver/Family

FAMILY AND CAREGIVERS

(FAM01) Characterizing Predictors of Resilience Among Family Caregivers of People with Advanced Multiple Sclerosis Disability: Work in Progress

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Background: Providing ongoing support can adversely affect physical, psychological, and social health of care partners of people with advanced multiple sclerosis (MS). However, some care partners have also reported positive experiences and benefits of MS caregiving (e.g., greater sense of commitment and pride in the role). This variability highlights the importance of understanding protective factors that can buffer against the adverse effects of caregiving. Psychological resilience describes positive adaptations to stressful situations and includes individual, community, and societal level factors. Research in other caregiving contexts has shown that resilience is associated with improved health outcomes and lower quality of life and care provider burden. Unfortunately, there is limited research on resilience in the context of MS caregiving. Generating this knowledge is important to guide the development of interventions to enhance resilience and to identify individuals most likely to benefit from future intervention. Objectives: To examine the relationships between resilience and a comprehensive set of individual, community, and societal level factors in the context of MS caregiving. Methods: A cross-sectional survey design. We are collecting data as part of a pilot randomized controlled trial evaluating the feasibility and efficacy of a dyadic physical activity program for people with advanced MS and their care partners. Eligibility criteria include care partners who: 1) are ≥18 years old, 2) provide ≥1 hour/day of care, 3) are inactive, 4) are asymptomatic, and 5) are able to communicate in English. Care partners will complete demographics and general health questionnaires. The following scales will also be administered: 1) Coping with MS Scale, 2) Connor-Davidson Resilience Scale, 3) Interpersonal Support Evaluation List-12, 4) Coping with MS Caregiving Inventory, 5) Measure of Experiential Aspects of Participation, and 6) Godin Leisure-Time Exercise Questionnaire. We will conduct regression modelling to identify predictors of resilience among care partners.

Results: Data collection is ongoing. Anticipated completion date is March 2020. We will present findings on resilience and associated factors among MS care partners.

Conclusions: Resilience may be an important protective factor against the adverse effects of MS caregiving. We anticipate that the findings from this study may have implications for interventions designed to enhance and sustain resilience among MS care partners.

Supported by: None

Disclosure: Nothing to disclose.

Keywords: MS and the caregiver/family

INTERNET AND INFORMATION SERVICES

(IS01) North American Registry for Care and Research in Multiple Sclerosis (NARCRMS) Model for Implementing OpenClinica Insight for Data Sharing and Visualization

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Background: Fatigue, defined as the difficulty or inability to perform tasks due to a lack of sufficient energy, is one of the key symptoms of multiple sclerosis (MS). The level of fatigue is difficult to quantify and explain to a person without the condition. Interactions between persons with MS (PsWMS) and those without (PsWO) with whom they have interpersonal relationships can be damaged by this lack of understanding. The Roy Adaptation Model (RAM) (Roy C Sr, Andrews HA. The Roy Adaptation Model, 2nd ed. Appleton and Lange; 1999 ) provides a nursing framework through which to assess, intervene, and evaluate the effective communication between PsWMS and PsWO. The RAM views persons as adaptive entities in constant interaction with their environment. The Roy portion of the theory, the interdependence adaptive mode, focuses on the communication between a person and his or her significant other/support group. Clear understanding of the message sent and received and the ensuring healthy adaptions to their interactive communication resulting in behavioral change are the goals. Objectives: By quantifying the amount of energy each activity takes, PsWMS will be able to communicate more clearly their level of energy and, inversely, their level of fatigue. Relational stress will decrease and communication between PsWMS and PsWO will improve.

Methods: A MS support group composed of 23 persons, some with MS and some without, participated in a 2-hour educational, interactive session, which focused on defining units of energy and describing how many may be needed for both activities of daily living and special events. The PsWO “tried on” different symptoms of MS throughout the session to gain a better understanding of the challenges facing the PsWMS. At the same time, the PsWMS focused on self-assessment and became more aware of the frustrations expressed by the PsWO. Both subgroups practiced active listening techniques.

Results: After 2 months, all 23 persons reported improved relationships due to decreased stress and a better understanding of the effects of MS.

Conclusions: Teaching a simple method of communicating MS fatigue greatly improved the quality of life of PsWMS and those with whom they interact. Using units of energy within conversations improved communication and enabled more positive interdependent interactions with caregivers, family members, and their colleagues in the workplace.

Supported by: None

Disclosure: Nothing to disclose.

Keywords: Fatigue, Management of activities of daily living in MS, MS and the caregiver/family
Background: The North American Registry for Care and Research in Multiple Sclerosis (NARCRMS) is a clinician-based longitudinal registry of sites located in the United States and Canada. Active since 2015, the registry aims to improve the care of patients with multiple sclerosis (MS) care and understanding as a database of clinical records and patient-centered outcomes. With enrollment, yearly follow-up and exacerbation-based visits, patients provide demographic, medical history, attack history, and health productivity information supplemented with physician-collected physical and cognitive assessments. In just a few years the registry has generated several hundred thousand points of data on a wide variety of health-related topics from the current 22 participating sites. The registry includes data from standardized interviews and physician evaluations and is adding self-administered patient-reported outcomes in the coming months. Objectives: To develop a model to share aggregated data from individual sites to enable participating sites and industry partners the ability to view and analyze larger, multisite datasets for research and exploration. Methods: OpenClinica is an open-source and software-as-a-service electronic data collection (EDC) system most often used for data collection and data management in a clinical setting. OpenClinica Insight, built on the open-source Metabase platform, is a data reporting and sharing tool available as part of OpenClinica’s Enterprise system that connects directly to the EDC database and allows real-time data access, visualization, and downloading. To implement Insight, the team coordinated with project leadership, industry, and cooperating investigators to develop a process for defining roles and relationships, defining appropriate summary statistics and graphs to summarize collected data, and defining data access parameters and restrictions. Results: OpenClinica Insight provides a platform to leverage limited standardized patient-derived data on a prospective basis. The platform is useful and end-user friendly and allows for efficient information sharing across the pool of geographically diverse clinical research sites to provide insights into local, regional, and continental patterns and standards of MS care. Conclusions: OpenClinica Insight is a powerful tool to report information from OpenClinica Enterprise, and the model developed from NARCRMS should serve as an example for integrating informatics from large databases developed to study natural history of various chronic disorders such as MS.

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Keywords: Epidemiology of MS

IMAGING

(IMGO1) Conformance to CMSC Magnetic Resonance Imaging (MRI) Guidelines in a Real-World Multicenter MRI Dataset

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Background: Acquiring magnetic resonance images (MRIs) in a standardized way allows early and accurate diagnosis of multiple sclerosis (MS) and patient follow-up. The Consortium of Multiple Sclerosis Centers (CMSC) guidelines for magnetic resonance (MR) imaging suggest a standardized protocol to improve the diagnosis and routine follow-up of MS. Objectives: This study evaluates how many MRI acquisitions from a real-world dataset of patients with MS satisfy the CMSC brain MRI guidelines (2018 revision). In particular, for every individual MR sequence, it is assessed how well the guidelines are met. Methods: CMSC brain MRI guidelines of 2018 impose that 4 different scans should be acquired: a 2D T1-weighted sagittal and axial view, a fluid-attenuated inversion recovery (FLAIR), a 2D axial or 3D T2-weighted scan, an axial 2D diffusion-weighted image (DWI), and a 3D inversion-recovery prepared (IR-prep) gradient-echo T1. For every scan, an in-slice pixel resolution ≤ 1 mm x 1 mm, slice thickness ≤ 3 mm with no slice gap, as well as whole-brain coverage are required. These requirements are checked on a multicenter MRI dataset from the United States, consisting of 1233 sessions, acquired in 581 different centers/scanners from 2016 onwards. Results: None of all 1233 MRI sessions fully complied with the guidelines. For the T1 sequence, only 8% satisfied the criteria. For the other data, 23% did not have a T1 sequence, 73% had a too-large slice thickness, 71% had a too-large pixel size, 56% had a slice gap, and 48% did not use an IR-prep gradient echo. For FLAIR, only 18% satisfied the requirements. For the other data, 8% and 21% missed the axial and sagittal FLAIR acquisition, respectively, and 72% had too-large slice thickness, slice gap, or too-large pixel size. For the DWI sequence, only 7% satisfied the criteria. The most important reason for failing was a too-large pixel size (92% of unsatisfying images). 17% of the scans had no DWI, 1% of all scans had a good DWI, the other 81% had a too-large pixel size. If a post-gad T1 was provided, 29% satisfied the guidelines. Of all post-gad T1 sequences that did not comply, 72% had a too-large pixel size. The most common reason for failing was a too-large pixel size (92% of unsatisfying images). Conclusion: In a real-world MRI dataset of patients with MS, the conformance to the CMSC brain MRI guidelines was extremely low. The main reason was the use of too-large pixel size, mostly in combination with a too-large slice thickness and a slice gap, which could be due to speeding up the protocol. Supported by: None

Disclosure: Giulia Longoni,1 Tara Beraembourg,2 Sunil K. Yadav,3,4 Ella M. Kadas,5,6 Michael J. Wan,2 Arun Reginald,1 Donald Mabbott,1 Alexander Brandt,6 E. Ann Yeh1

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Background: Youth with multiple sclerosis (MS) or myelin oligodendrocyte glycoprotein (MOG)–Associated Disorders

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Objectives: Acquiring magnetic resonance imaging (MRI) is a fundamental imaging tool in the diagnosis, follow up, and monitoring of people with multiple sclerosis (MS) and myelin oligodendrocyte glycoprotein (MOG)–associated disorders. It is a powerful tool to report informatics from large databases developed to study natural history of various chronic disorders such as MS. Supported by: None

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Posters: Imaging

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(IMG03) Cerebellar Connectivity Is Associated with Verbal Memory Impairment in Multiple Sclerosis
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Background: Network connectivity is disrupted in multiple sclerosis (MS) and is related to cognitive function. Verbal memory impairment is central to the care of patients with MS. In this study, we investigated the role of cerebellar connectivity in MS-related verbal memory impairment.

Methods: 45 patients with MS and 23 healthy controls completed a verbal memory task (Selective Reminding Task [SRT]) and underwent magnetic resonance imaging (MRI). Resting-state (RS) functional connectivity analysis and diffusion kurtosis imaging were used to assess functional and structural connectivity, respectively.

Results: The MS group performed significantly worse on SRT trial 1 (t(64) = 1.28, P < .033), SRT trial 3 (t(66) = 2.29, P < .031), SRT trial 6 (t(66) = 2.44, P < .017), and SRT Delayed Recall (t(66) = 2.27, P < .026). Resting-state analysis of cerebellar-cortical connectivity revealed significant differences between the cerebellum and several cortical areas. In MS, higher connectivity was observed between the cerebellum and superior frontal gyrus, precuneus, supramarginal gyrus, medial fronto-parietal lobe, cingulate, and parahippocampal gyrus (P < .05, FWE-corrected). Correlation analysis within the MS group revealed significant correlations between SRT Delayed Recall scores and connectivity values between the cerebellum and parahippocampal gyrus, fusiform gyrus, insula, cingulate, inferior frontal gyrus, uncus, middle temporal gyrus, and angular gyrus (P < .05, FWE-corrected). We observed higher cerebellar-cortical connectivity in memory-impaired patients with MS between the cerebellum and the left parahippocampal gyrus compared to memory-preserved patients with MS. Diffusion analysis showed that axonal volume of the middle cerebellar peduncle significantly explained variability in SRT Delayed Recall scores in patients with MS over and above age and education (F(1,32) = 4.62, P = .039, R2 = 0.17, ΔR2 = 0.12).

Conclusions: Abnormal resting-state structural connectivity between the cerebellum and cortical areas, specifically the left parahippocampal gyrus, may contribute to verbal memory impairment observed in MS.

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Keywords: Imaging and MS, Memory, Psychological issues and MS

(IMG04) The Association Between Magnetic Resonance Imaging Brain Volumes and Computed Cognitive Scores of People with Multiple Sclerosis
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Background: Magnetic resonance imaging (MRI) is a noninvasive and powerful tool that can provide detailed information about the brain's structure. MRI is commonly used in the clinical evaluation of multiple sclerosis (MS) patients to assess disease progression and the extent of brain involvement. The relationship between MRI findings and cognitive impairment in MS is of great interest, as it can help in understanding the mechanisms underlying cognitive dysfunction in this disease.

Methods: In this study, we examined the association between brain volumes, measured using MRI, and cognitive scores from a battery of computerized cognitive tests in a group of people with MS (PwMS) and healthy controls (HC). The cognitive scores included measures of attention, processing speed, memory, language, and executive function. MRI was performed using a 3T scanner, and brain volumes were calculated using automated segmentation software. The association between brain volumes and cognitive scores was assessed using linear regression analyses.

Results: The study included 30 PwMS and 30 HC. The average age of the participants was 47 years, and 60% were female. The PwMS group had a mean Expanded Disability Status Scale (EDSS) score of 3.2. The analysis revealed significant associations between brain volumes and cognitive scores. For example, smaller hippocampal volume was associated with lower scores on the Digit Span Forward test, indicating impaired working memory. Similarly, smaller parietal lobe volumes were associated with lower scores on the Tactual Performance Test, suggesting difficulties in spatial cognition.

Conclusions: These findings suggest a strong link between brain structure and cognitive function in MS. MRI can serve as a valuable diagnostic tool in understanding the underlying mechanisms of cognitive impairment in this disease. Further studies are needed to validate these findings and explore potential therapeutic targets for cognitive rehabilitation in MS.
**Background:** People with multiple sclerosis (PwMS) have complex symptoms and different types of needs. These demands include managing physical disability as well as how to organize daily life and restructure social roles in the family and at work. **Objectives:** To identify difficulties and obstacles experienced by PwMS, highlighting the work of social service in promoting physical, psychological, and social well-being. **Methods:** The sample involved 113 PwMS, 82 women and 29 men, aged 17 to 77 years (mean [SD] = 41 [11.38]). They answered the semistructured sociodemographic questionnaire containing 30 questions, developed specifically for this population. **Results:** Despite the highlighted needs, lack of knowledge about treatment, rehabilitation, and maintenance of quality of life was widely identified among the participants. In this sense, specific referrals and specialized guidance pertinent to our country were carried out as follows: n = 117/100% health (high-cost medicines), n = 35/30% social security, retirement), n = 23/20% education (educational institutions), n = 59/50% judicialization (medicines demand in law suits). **Conclusions:** The individual reception procedure was necessary and sensitive for understanding the demands through the questionnaire. The difficulties identified in this study determined social assistance actions directed to the development of joint actions with multidisciplinary and interdisciplinary teams, which directly affected the quality of life of patients with all types of MS.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Management of activities of daily living in MS, MS and the caregiver/family

(MDC02) Is a 2-Week Intensive Day Program an Effective Approach to Provide Outpatient Services for People with Multiple Sclerosis?

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**Background:** A unique 1-week intensive MS day program rehabilitation model was initiated in 2012 and continues to evolve. The goal of the program is to educate and provide patients, families, and caregivers with a structured plan to improve overall health and wellness. Our interdisciplinary team would like to share “lessons learned the hard way” over the past 7 years and to report the most recent patient outcomes. **Objectives:** 1) Identify key factors that may indicate appropriateness for patient enrollment in an intensive day program (DP). 2) Identify “lessons learned” over the past 7 years. 3) Present results of objective patient outcome measures. **Methods:** Patients are evaluated to determine appropriateness for participation in a 2-week intensive DP. To qualify for DP, they must require skilled services for physical therapy (PT), occupational therapy (OT), speech therapy (ST), and wellness. Additionally, they may also receive nursing, counseling, and vocational rehabilitation as appropriate. It is mandatory that a caregiver/family member be present for all sessions. Pre and post outcome measures used to assess change include Modified Fatigue Impact Scale (MFIS), Fatigue Severity Scale (FSS), Symbol Digit Modalities Test (SDMT), Nine-Hole Peg Test (NHPT), and Timed 25 Foot Walk (T25FW). **Results:** Expanded Disability Status Scale (EDSS) scores ranged from 2.5 to 9.0 with 67% of patients having EDSS score 5.0 or greater. Patient and family feedback regarding DP has generally been positive. The most frequent negative comments are that too much information is presented and becomes overwhelming, not enough rest breaks are given, and the days are too long. Despite reports of being too intensive, a large majority of participants have shown progress on outcome measures. Percentage of patients whose scores improved are as follows: MFIS 70%, FSS 90%, SDMT 70%, NHPT 67% (right) 87% (left), and T25FW 75% (note 3 patients went from being nonambulatory to walking with a rollator). A more detailed report of the data will be ready at the time of presentation.

**Conclusions:** Multiple factors need to be considered prior to recommending DP to persons with MS. To achieve success, patients/families must be willing to modify old behaviors and staff must adapt session intensity so as not to overwhelm or overfatigue patients. An interdisciplinary community outing at the end of the first week has proven valuable to our participants. In this sense, specific referrals and specialized guidance pertinent to our country were carried out as follows: n = 117/100% health (high-cost medicines), n = 35/30% social security, retirement), n = 23/20% education (educational institutions), n = 59/50% judicialization (medicines demand in law suits).

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Comprehensive care and MS, Day program outcomes

(MDC03) The Waiting Room: A Successful Experience in the Multiple Sclerosis Care and Treatment Center (CATEM)

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**Background:** The constant waiting of patients for the call for medical consultation is a reality in the Brazilian public service. The National Policy for Humanization (PNH) of the Brazilian Ministry of Health (MH) advocates providing welcoming, strengthening, and wholesome care, with the adoption of measures and communication among multiprofessional teams. One of the practices used by the health team to share experiences, feelings, and knowledge between patients of professionals is the Waiting Room Group. The Multiple Sclerosis Care and Treatment Center (MSCTC), established in 1997 at the Neurology Clinic of Santa Casa de Sao Paulo, attends through the Unified Health System (SUS) every Friday morning and has about 500 registered patients who make use of several therapies for treatment of multiple sclerosis (MS). To minimize the waiting period, the “Waiting Room” project was created in 2013, consisting of patients, family members, caregivers, social worker, nurse, psychotherapist, psychologist, and neuropsychologist, among others, to provide a welcoming space to minimize anxiety and fear, advise on their rights, inform about the disease and its complications, types of treatment, importance of adherence and adherence of exercise routines, and hospital policy and routines, and providing patients, family members, and caregivers with a space of personal interaction in order to generate a relational model in their role in their treatment. **Objectives:** To describe the experience of the Waiting Room Group as part of humanized care for patients with MS, their family members, and caregivers. **Methods:** Welcoming, integration, and interaction are the key words: the earlier patients talk about and share their experiences with others who are starting their treatment, their anxiety and doubts are minimized. The doctor, psychologist, social worker, nurse, and psychotherapist participate in all meetings, as well as other invited professionals. During the meetings, the doubts presented by the participants are clarified and provide topics for discussion in the next meetings.

**Results:** Not applicable. **Conclusions:** This project has been developed for 6 years and has been successful, with an average participation of 50 patients per year.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Comprehensive care and MS, Interdisciplinary team, MS and the caregiver/family

(MDC05) Implementation of a Pharmacist-Led Immunization Program in a Center for Comprehensive Multiple Sclerosis (MS) Care

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**Background:** In 2019, the American Academy of Neurology issued a practice guideline update for vaccinations in patients with multiple sclerosis (MS). In this guideline, they recommend providers “assess and reassess vaccination status of patients with MS before prescribing immunosuppressive or immunomodulating (ISI) therapy and should vaccine these patients.” Also in 2019, eczulizumab was the first US Food and Drug Administration (FDA) treatment approved for neuromyelitis optica spectrum disorder (NMOSD). Prior to starting, the FDA requires patients receive 2 types of meningococcal vaccines (MenACWY plus MenB-4C or MenB-FHbp) at least 2 weeks prior to starting eczulizumab. MS centers need to create an efficient process to ensure patients receive vaccines in a timely fashion to reduce harm from vaccine-preventable diseases and minimize the start of patient’s disease-modifying therapy (DMT). In 2002, Pennsylvania allowed pharmacists to provide immunizations to patients under a collaborative practice agreement or a direct order from a provider. At the Hospital of the University of Pennsylvania, there are 2 clinical pharmacists dedicated full-time to the MS Center. Little information in the literature addresses pharmacists in providing immunizations in patients with multiple sclerosis and prior to starting DMTs, and the utilization of MS clinical pharmacists and a health-system based specialty pharmacy in providing this unmet need. **Objectives:** The purpose of this quantitative pilot study will be to review the results of a pharmacist-led immunization program imbedded in primary and specialty care provider MS clinic. **Methods:** Patients will be identified by provider referrals and pharmacist comprehensive chart reviews of newly diagnosed patients and patients starting ISIM and eczulizumab therapy.

**Results:** Data will be analyzed with descriptive statistics. **Conclusions:** It is anticipated this pilot study will increase rates of vaccination of patients with MS, reduce time to start DMT, and increase awareness of vaccine-preventable diseases.
(MDC06) The African American Experience and Multiple Sclerosis
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Background: Incidence rates of multiple sclerosis (MS) have been found to be higher in both black males and black females vs white males and white females. In particular, black females have a 47% higher risk for MS when compared to white females. Disease progression is significantly faster in black patients with MS in both brain and retinal measures. Magnetic resonance imaging scans show whole brain and gray and white matter atrophy to occur twice as fast in African Americans compared to Caucasians. African American patients also show quicker atrophy of the thalamus, a possible link to cognitive impairment. Furthermore, African Americans are dying from MS at an earlier age, suggesting that MS burden weights disproportionally across race demographics. To fully understand, the Multiple Sclerosis Association of America (MSAA) launched the African American MS Advisory Board. Objectives: The African American Experience & Multiple Sclerosis initiative included 11 MS clinicians and 16 African Americans affected by MS. The meeting's objective was to 1) create a dialogue allowing both groups to share their views on the problems that African Americans with MS are facing; 2) evaluate programmatic initiatives that address the unmet needs; 3) gather from the meeting to aid in the development of an actionable plan, tailored educational offerings, and services provided; and 4) identify next steps to continue building on the work of the African American committee. Methods: Participants attended a half-day meeting, sharing their views on problems African Americans with MS are facing. Sessions included moderated discussions and a brief presentation, emphasizing the need for research and the importance in developing programmatic initiatives. Results: Key findings from the meeting in Atlanta elucidated the aforementioned performance gaps experienced by MS clinicians responsible for treating African Americans with MS. Characteristics of patients with MS less likely to see neurologists include the following: 1) lack of health insurance, 2) lower income, 3) African American, 4) living in rural areas, and 5) illness longer than 15 years. Conversely, patients cared for by a neurologist are more likely to 1) undergo diagnostic tests, 2) undergo treatment-related tests, 3) be treated with disease-modifying therapies, 4) receive medication for symptoms, and 5) report their providers had a treatment plan. The presence of these gaps requires behavioral change on the behalf of MS clinicians that will appropriately address both the adherence and treatment-related needs of their patients. Conclusions: Data from this comprehensive initiative will drive the materials and information for a set of multifaceted interventions to improve the knowledge, competence, and/or performance of MS clinicians who are currently treating, or have the potential to treat, black patients with MS. The anticipated result is to better identify and detect early signs of disease progression and timely therapeutic intervention. Supported by: None Disclosure: Nothing to disclose Keywords: Comprehensive care and MS, Disease-modifying treatments in MS, Preventative health

(MDC08) Late-Onset Multiple Sclerosis: Comorbidity and Disease Progression
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Background: Late-onset multiple sclerosis (LOMS) defined as multiple sclerosis (MS) with clinical onset after the age of 50. Previous studies have demonstrated that late onset is a poor prognostic factor for MS. Moreover, several comorbidities such as hypertension, diabetes, and dyslipidemia were reported in association with poor clinical outcome in patients with MS. Although the prevalence of comorbidity is increased in the aging population, the roles of comorbidity in LOMS has not been explored. Objectives: To evaluate the influence of comorbidities in LOMS. Methods: This retrospective study included 38 patients with MS with clinical onset after the age of 50. Demographic, clinical, radiologic, and laboratory findings were collected. The survival analysis was performed to identify the comorbidities that associated with losing of no evidence of disease activity (NEDA) status. Results: The median follow-up was 26 (IQR 12-45.75) months. Forty-five percent of participants remained on NEDA status until the last follow-up. Hyper tension (HTN) significantly increased the risk of disease progression (HR 7.36, 95% CI 1.39-13.66, P = .01). More interestingly, there was no significant difference in disease progression risk between well-controlled HTN and normotensive patients with LOMS (HR 1.58, 95% CI 0.28-9.01, P = .608). Diabetes, dyslipidemia, coronary artery disease, stroke, obesity, hypothyroidism, depression, and anxiety were not significantly associated with MS progression in the late-onset population. Conclusions: Our cohort study suggests that HTN is a modifiable risk factor of disease progression in LOMS. Previous studies have demonstrated that HTN can potentiate neurodegenerative process. Larger prospective studies are needed to further explore the interaction between HTN and disease-modifying therapy and the effect of antihypertensive agents. Supported by: None Disclosure: Smatham Thakolwiboon, Pavida Pachariyanun, Jie Pan, Amputch Karukote, Gyengmo Saoh: Nothing to disclose. Miria Avila: Biogen, Genentech, Genzyme (education); Celgene (education).

Keywords: Comorbidty, Comprehensive care and MS

(MDC09) Comparing Patient Perceptions on Multiple Sclerosis Management and Care: A Subanalysis of Geographic Differences
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METHODS OF CARE

(MOC01) Understanding the Health Care Provider–Patient Relationship in Treating Multiple Sclerosis

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Background: Health care providers (HCPs) play a critical role in treating patients with multiple sclerosis (MS), especially in helping patients get on treatment to help slow progression. An online survey of patients with MS as well as natural language analysis of organic interactions on a social network provided insight into the relationship between HCPs and their patients with MS. Understanding the HCP-patient dynamic is crucial to improving these interactions as well as identifying tools to help educate and engage MS patients. Objectives: To understand MS patient social network to understand the HCP-patient dynamics, including what is working and any opportunities to improve HCP-patient interactions. Methods: A 2-pronged approach was undertaken. First, an online survey was completed by 658 US members of MyMSTeam in November 2018. Research was also conducted on deidentified organic discussions within MyMSTeam.com, a social network of >127,000 people diagnosed with MS (approximately 1:9 patients with MS in United States). A natural language processing tool (NLPI) analyzed 178,884 verbatim April to September 2019. Survey results showed 71% of patients indicated they rely on HCP for information about disease-modifying treatments (DMTs). 56% of DMTs recommended to get on a specific DMT is most important factor, and 20% indicated decision to get on a DMT would be easier had HCP provided stronger opinion rather than relying on the patient to research and decide. Results: A total of 55 PwMS from Europe and 46 from North America completed the survey. PwMS in Europe listed a lack of time in medical appointments as their biggest challenge at diagnosis (60.0%), whereas PwMS in North America reported understanding disease progression to be their biggest challenge (57.8%). European PwMS reported greater levels of additional patient support available in their clinics (ie, MS nurse [67.3%], information about employment management [21.2%], or psychological support [25.0%]), whereas 26.1% of North American PwMS reported not having additional support. PwMS in Europe reported being less involved in treatment decisions, with 20.5% saying they were not involved, compared with 2.4% in North America. European PwMS placed more importance on the safety of their treatment (57.7%), whereas PwMS in North America placed more importance on the efficacy of their treatment (71.7%). Conclusions: There were distinct geographical variations between PwMS’s perceptions and priorities relating to MS care, education, and treatment decisions. European PwMS reported less time in appointments and lower involvement in treatment decisions than North American PwMS, however they also reported greater levels of support and education outside of their neurologist appointments including greater access to specialist MS nurses.

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Keywords: Comprehensive care and MS, Shared decision making
Background: Timely treatment is important for reducing relapses and risk of disability in people with multiple sclerosis (MS). However, disease-modifying medications entail a complex enrollment process that can delay treatment initiation. Objectives: This pilot study tracked individuals initiating the enrollment process for ocrelizumab and natalizumab at the University of Florida (UF) MS Clinic. Methods: This quality improvement initiative captured all relevant documents, including enrollment forms, insurance communications, referrals, and other documentation. We monitored the dates of completion, signature, fax, and local medical record upload for all forms. Results: Preliminary data from January 1, 2019, to October 1, 2019, captured 19 patients enrolled in either medication. Of these 19 patients, 6 received treatment as of October 2019. On average, enrollment submission to treatment initiation took 56 (range, 5-135) days. Of the remaining 13 awaiting treatment, the average interval from enrollment to October 2019 was 83 (range, 4-175) days. Overall, 11 quantifiable delays were identified, resulting in 17 recorded contacts. Of the 11 delays, 45.5% were insurance related, 34.6% were clerical delays, and 18.1% were patient related. Delays took an average 24.6 days to resolve (30.4, 9.25, and 41 days, respectively). For the 17-recorded contacts, 41% were insurance-related, 47% were clerical errors, and 12% were related to patient compliance. Most delays occurred in patients referred to outside infusion centers for treatment. Five of 13 ocrelizumab patients initiated treatment as of October 2019. Four of the 5 patients were infused at UF. The 8 patients awaiting treatment were referred to outside infusion centers and averaged 101 days without treatment as of October 2019. Two of 4 natalizumab patients have received treatment, both infused at UF. For the 2 awaiting treatment, both were referred to outside infusion centers and have waited an average of 71 days for treatment as of October 2019. Conclusions: Preliminary analysis suggests that insurance-related delays were the largest barrier to treatment initiation. Referring patients to outside centers further impeded the process. The results indicate that revisions to standard operating procedures for insurance inquiries and referrals may be beneficial. Moreover, while clerical errors were common, they were quickly resolved. Patient compliance issues, though rare, had the most enduring effect on treatment initiation.

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Keywords: Comprehensive care and MS, Quality improvement

(MOC05) Pioneering Multiple Sclerosis Center Program with MSHA Certification to Improve Patient Care and Experience

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Background: The OSF HealthCare Illinois Neurological Institute’s Multiple Sclerosis Center is a Certified Comprehensive MS Center located in Peoria, Illinois, serving over 2,100 patients and is focused on providing excellence in multiple sclerosis (MS) care for patients and families in need of assessment, diagnosis, treatment, education, and research. Like many MS Centers we are fortunate to have physicians, nurses, physical therapists, occupational therapists, and a registered dietician who are specialized in MS. However, we came to realize there were opportunities in our level of patient care and experience with the potential to be transformed if we invested in our medical office assistants and our MS patient navigators through MSHA Certification. Certified employees are able to deliver a higher level of care, better connect patients to resources, and also better support our comprehensive care team, which allows our center to ensure all members are working at the height of their licensure. We set a goal in May 2019 to have a mission partner in every job role of our MS Center to be certified in MS. We propose that achieving this level of certification in each and every MS Center around the world is a goal worth aspiring to in our combined fight against MS. Objectives: MSHA certification within our medical office assistant and MS patient navigator job roles in 2019. In addition, lower risks associated with delay of treatment, reducing barriers to care, increasing clinical competency, and employee efficiency in tasks such as prior authorizations for disease-modifying therapies. Methods: Investing in team training and elevating employees through MSHA certification. We also brought our team to Consortium of Multiple Sclerosis Centers (CMSC) for education, networking, and patient resource opportunities. Results: The OSF HealthCare Illinois Neurological Institute’s MS Center has an employee in every job role who is MSHA Certified. MSHA certification has given our team members greater context and compassion through a deeper understanding of MS at a professional level. We increased efficiency and decreased delay in care and also the time it took to obtain prior authorizations. Our certified employees are also better able to communicate with patients and families who have a greater level of Española (Spanish) fluency and communication with patients. MSHA certification has fostered our leaders to develop and drive our patient care care teams as a whole. Conclusions: MS is a complex and lifelong neurologic disease that requires all individuals involved with patient care to have a basic level of knowledge of the disease. The MSHA certification of our employees is a pioneering strategy that has elevated the level of care and experience we provide to our patients with MS by empowering our employees through the education and understanding of MS. MSHA certification is an effective tool for efficient and empathetic health care delivery to those individuals living with MS. Supported by: None

Disclosure: Nothing to disclose.

Keywords: Comprehensive care and MS, MSHA certification

(MOC06) Conceptualizing Access Through the Perspectives of Canadians with Multiple Sclerosis

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Background: Access to health care is vital to the health and well-being of people with chronic conditions like multiple sclerosis (MS). Access is often measured using service utilization as a proxy. Utilization measures of people with chronic conditions like multiple sclerosis (MS) is a complex and lifelong neurologic disease that requires all individuals involved with patient care to have a basic level of knowledge of the disease. The MSHA certification of our employees is a pioneering strategy that has elevated the level of care and experience we provide to our patients with MS by empowering our employees through the education and understanding of MS. MSHA certification is an effective tool for efficient and empathetic health care delivery to those individuals living with MS. Supported by: None

Disclosure: Nothing to disclose.

Keywords: Comprehensive care and MS, MSHA certification

(MOC04) Nurse Telephone Encounters in a Multiple Sclerosis Clinic in 2020

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Background: With the growing treatment landscape in multiple sclerosis (MS), nurses are being challenged with a constantly increasing work load, and more of their time is being spent on telephone encounters. Previous data collected from January to April 2001 at the University of Calgary MS Clinic showed that 50% of nursing time was devoted to telephone encounters, and 30% of those encounters dealt with issues around disease-modifying therapies (DMTs). In 2001 there were 3 Health Canada–approved DMT options as compared to 12 approved DMTs at this time in 2020. Increased patient therapy choice has required more nursing time to educate patients on treatment expectations, potential adverse effects, and adherence to more complex medication protocols. There is a need to understand the type, frequency, and time spent on telephone encounters, which will assist MS Nurses to develop efficient and effective management protocols. Objectives: To determine the frequency, type, and duration of nurse telephone encounters. To compare work previously done in the MS Clinic by Harrison et al. in 2001. Methods: Patient telephone encounters will be analyzed from January 2, 2020, to the end of March 2020. A telephone call log designed based on previous workload analysis at the University of Calgary MS Clinic will be used to capture the type, duration, and frequency of calls. Results: Telephone encounters are ongoing, with data analysis completed April 1, 2020. Conclusions: Analyzing telephone encounters will provide information to assist with the development of work load management strategies.

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Keywords: Comprehensive care and MS
ment to this framework. **Results:** All dimensions of the Candidacy Framework were assessed to the participants. Persons with MS who completed the framework failed to account for important aspects of the participants’ lifelong experience of accessing care. Importantly, participants discussed the process of engaging in help-seeking which was informed by past experiences of seeking and receiving health care services, as well as the accumulated knowledge of living with MS. The most commonly reported past experiences of accessing care to manage illness were those related to health care providers, where negative experiences were described when this approach to care was not taken. Past negative experiences oftentimes made persons with MS hesitant to seek further care. **Conclusions:** The Candidacy Framework alone does not account for the lifelong interaction with health care that individuals with MS experience. For instance, persons with MS who have had negative experiences with their care, may be more prone to experiencing negative experiences, and may be more inclined to seek care from alternative practitioners, such as MS-trained nurses. Future work should further explore the full experience of accessing the framework should consider 3 main extensions: 1) The addition of recursive, which captures the reciprocal nature of interacting with the health care system; 2) inclusion of help-seeking behavior and related decision making; and 3) inclusion of the concepts of patient-centered care.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Access to health care, Comprehensive care and MS

(MOC07) Access to Health Care for Canadians with Multiple Sclerosis: Prioritizing Concerns

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**Background:** Current Canadian literature demonstrates that persons with multiple sclerosis (MS) have high levels of health care services, yet still have multiple unmet needs and low satisfaction with health care services. International studies showing similar results suggest this may be related to issues in access to health care. **Objectives:** We aimed to 1) describe the health care service use of Canadians with MS in managing their condition; 2) identify the most pressing concerns Canadians with MS have in relation to accessing care to manage their illness; 3) to prioritize the concerns regarding the availability of affordable health care services aimed at improving access to health care service in the community. Data were analyzed using descriptive statistics. Access concerns were prioritized by calculating a Needs Index (NI).

**Methods:** The aims were addressed using an online cross-sectional survey guided by Concerns Report Methodology. Inclusion criteria were: older than 18 years, a Canadian citizen, and self-reported diagnosis of MS. Data were collected about health care service use and the importance and satisfaction with access to health care service in the community. Data were analyzed using descriptive statistics. Access concerns were prioritized by calculating a Needs Index (NI). **Results:** To date, 211 persons with MS have completed the survey. Participants were predominantly female (86%), with a mean (SD) age of 46.4 (11.7), living with relapsing remitting MS (77%) for a mean (SD) of 10.4 (8.9) years. Just over half of the participants were living with a partner (54%), with varying levels of disability ranging from 0.7 on the Patient-Determined Disease Steps (median: 2). Preliminary findings indicate that nearly all participants had a regular neurologist (97%), many of whom practice in an MS clinic (83%). Most individuals also had a general practitioner (96%). Participants on average visited their neurologist 5 (SD: 5) times a year (SD: 0.7) and their general practitioner 4.6 times (SD: 1.3) combined. Of the concerns among participants regarding their access to care were: 1) affordability of complementary care (example: massage therapy, yoga, naturopathic care) (NI: 33.8) and physiotherapy and occupational therapy (NI: 29.7), both aimed at improving wellness; 2) availability of health care providers with MS-related knowledge in their communities to guide their care plan (NI: 33.7); and 3) communication between health care providers to ensure coordination of care (NI: 29.2).

**Conclusions:** Preliminary findings suggest that for persons with MS, merely having regular neurologists and general practitioners is not considered satisfactory access to care. Persons with MS identified concerns regarding the availability of affordable health care services aimed at maintaining wellness. They also had concerns regarding the availability of community providers with sufficient MS-related knowledge to guide their referrals and care plans. Targeting policy reform promoting the coverage of health care services aimed at preventative and maintenance care may be a critical step in improving care for this population.

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**Disclosure:** Nothing to disclose

**Keywords:** Access to health care, Comprehensive care and MS

(MOC08) Use of a Clinical Decision Support Tool to Support Monitoring and Care of Patients with Multiple Sclerosis Receiving Disease-Modifying Therapy

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**Background:** As the number of US Food and Drug Administration–approved disease-modifying therapies (DMTs) used to treat various forms of multiple sclerosis (MS) increases, the monitoring requirements for DMTs also increases. The use of the Theradoc software program, a clinical decision support tool (DST), has been shown to improve adherence, quality of care, comply with guidelines of care, optimize cost of care, create efficiencies of care, and minimize adverse drug events. **Objectives:** To compare the delay to treatment and monitoring using manual vs automated surveillance. To compare the time to manually enter data vs automated data for case management. To highlight medication adherence. **Methods:** Theradoc has been used for case management in a variety of medical settings in the VA health care system; it has not been used for the care of patients with MS. A dashboard of patients with MS who are prescribed a DMT was developed with consideration of the VA criteria for use guidelines. Features include automation of laboratory results, flag reports, real time alerts, team communication, ability to export report, and various views.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Access to health care, Comprehensive care and MS, Disease-modifying treatments in MS, Nursing management in MS

(MOC09) Multiple Sclerosis Disease Impact Monitoring: Longitudinal Exploration of the Relationship of Ocular Coherence Tomography to Computerized Cognitive Testing

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**Background:** Disease impact and change in routine care for people with multiple sclerosis (PwMS) is typically measured by combining Expanded Disability Status Scale (EDSS) score, magnetic resonance imaging (MRI) change, and reported relapse. Cognitive impact can be objectively tracked with digital cognitive assessment batteries (CABs) and retinal nerve fiber layer (RNFL) density (ocular coherence tomography [OCT]). Cognitive and RNFL impact are not quantified by traditional care (EDSS, MRI, RNFL, OCT). Enhancing shared decision making to optimize PwMS’s treatment selection could be accomplished by incorporating quantitative measures that provide objective examiner-independent information reflecting disease impact and possibly differentiating relapse from progression. Utilization of the NeuroTrax Cb to measure a global cognitive summary score (GCS) based on 7 tested domains (memory, executive function, visual spatial, verbal function, attention, information processing, motor skills) combined with OCT RNFL measures could lead to earlier detection of disease activity as well as assisting in optimal treatment selection. **Objectives:** To explore the relationship between rate of change in PwMS seen in both a global CAB score and various OCT measurements, and disease impact and change in routine care for people with multiple sclerosis (PwMS) through a longitudinal study. **Methods:** Retrospective chart review of CAB data collected in the process of routine care. Paired sample T-tests were done collected between percent change of 2 visits, 1 year apart, with GCS and the following OCT measurements (right OD and left OS eyes): RNFL (sublayers: global [G], nasal/temporal ratio [N/T], papillomacular bundle [PMB], and macular volume [MV]). **Results:** N = 103 (75% female, average age of first visit 51 ± 10). All regressions run between CAB-GCS and OCT

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Community library and can be implemented without charge at other institutions. A significant difference was not observed (P > .05) in the percent change between visit 1 and 2 when comparing the following OCT measurements with the CAB GCS: G-OD&OS, N/T-OD and PMB-OD. Conclusions: The relationships of global RNFL densities to global OCT sometimes remained the same after a year, which suggests that these measures identify disease change in a synchronous manner in monitoring disease progression of PwMS. Nonsignificance between percent changes suggests that OCT and cognitive scores change at similar rates within at least a year’s period. A longer longitudinal study is suggested to further determine the relationship between OCT and cognitive changes over greater lengths of time.

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Keywords: Comprehensive care and MS, Equipment in MS, Natural history of MS

(MOC11) Improving Understanding of Clinical Phenotype for Patients with Multiple Sclerosis: Design and Implementation of Smarttools in Electronic Health Record Systems
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Background: Patients with multiple sclerosis (MS) frequently require complex clinical care and decision making, including monitoring for relapses, chronic immunosuppressive therapy, and extensive serological and imaging work-up. Modern electronic health record (EHR) systems offer the opportunity to facilitate understanding of each patient’s clinical phenotype by allowing discrete data collection, as well as summarization and presentation of critical information to providers. However, such tools often require custom design and build, for which many institutions do not have assigned resources. Objectives: To implement a comprehensive set of EHR-based Smarttools for patients with MS that can be shared among institutions, support data collection and understanding of patient phenotype. Methods: The Epic EHR system was used to develop several Smarttools. A Smartform was designed to allow discrete data collection on items considered critical by MS experts. Content included date of diagnosis, documentation of relapse characteristics, such as date, duration and therapies, current and past immunosuppressive therapy, critical imaging and results of CSF studies. Longitudinal caption of disease impact was incorporated, including number of falls and ability to walk since last visit. Logic was applied to conditionally display the Smartform for patients with a diagnosis of MS. A synopsis was designed to visualize longitudinal data, and a SmartPhrase was implemented to automate documentation of discrete data in provider notes. Results: Version 1 of the MS Smartform was implemented in August 2017. Over the course of 18 months, data on approximately 1000 unique patients were collected. The Smartform was found to be easily accessible and easy to navigate by providers, and the completion rate was high. Based on the initial experience, version 2 of the Smartform was designed and was recently implemented with minor modifications to minimize erroneous data collection, and a predefined list of immunomodulatory therapies and more detailed information about reasons for starting and stopping therapies was included. Data entry for the full cohort of ~3000 patients is ongoing. With the support of the Epic Neurology Steering Board, all discrete data elements were incorporated into the Epic Foundation system to facilitate implementation of the Smartform at other institutions. A significant difference was not observed (P > .05) in the percent change between visit 1 and 2 when comparing the following OCT measurements with the CAB GCS: G-OD&OS, N/T-OD, PMB-OS, and MV-OD&OS. Significance was observed (P < .05) of N/T-OD and PMB-OD. Conclusions: The relationships of global RNFL densities to global OCT sometimes remained the same after a year, which suggests that these measures identify disease change in a synchronous manner in monitoring disease progression of PwMS. Nonsignificance between percent changes suggests that OCT and cognitive scores change at similar rates within at least a year’s period. A longer longitudinal study is suggested to further determine the relationship between OCT and cognitive changes over greater lengths of time.

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Keywords: Comprehensive care and MS, Equipment in MS, Natural history of MS

(MOC12) Changing Language to Acknowledging Patients’ Perceptions of Treatment in Multiple Sclerosis Care
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Background: The language we use in supporting our patients is crucial in fostering a long-term relationship based on trust and understanding. However, it is important to remember that information does not equal education, and the ability to make the complexities of medicine comprehensible for patients is an important skill. Two recently published papers of almost opposing direction have highlighted the message that “I” can do better. Yeandle et al strongly emphasized the increased role patients and their families have in shared decision making, noting “its success is reliant on effective patient–physician communication.” Burke et al in their paper on management of surplus suffering discuss how health care providers can negatively impact the perception of the disease and recognizing our control of information sharing may “go a long way to improving clinical encounters with patients and ultimately lead to greater satisfaction in care and shared decision making.” Objectives: This presentation will briefly explore the core concepts of recent literature that have resulted in a shift in language used by the author in delivery of both clinical patient care and group educational opportunities, and the qualitative patient responses that emphasize the value of patient centrality in multiple sclerosis care. Methods: None. Results: None. Conclusions: None.

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Keywords: Comprehensive care and MS, Disease-modifying treatments in MS, Nursing management in MS

NEUROIMMUNOLOGY AND DISEASE MODELS

(NDM01) Efficacy of the Influenza Vaccine in Multiple Sclerosis Patients: A Systematic Review and Meta-analysis
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Background: Multiple sclerosis (MS) is a neurodegenerative disease thought to be of autoimmune origin. It leads to the development of neurologic symptoms and increases the risk of infection from communicable diseases. Thus, vaccines are endorsed to mitigate this risk. However, it has not yet been confirmed whether these patients’ dysfunctional immune system combined with taking immunosuppressants can lead to a dampened immune response against the influenza vaccine. Infection with the influenza virus is a concern for patients with MS. Previous research on patients with MS who have received the influenza vaccine focuses on safety and relapse rates. Studies that focus on the immune response mounted against the vaccine in these patients are scant. Objectives: This study serves to corroborate this previous research to provide a comprehensive picture of the efficacy of the influenza vaccine in patients with MS. Methods: This was done through a systematic review and meta-analysis. Results: The results of this study suggest that patients with MS can mount an adequate immune response to the influenza vaccine when compared to healthy controls. Most of the immunotherapies these patients are on do not appear to affect this immune response. Conclusions: Therefore, the influenza vaccine should continue to be recommended to patients with MS.

Supported by: None
Disclosure: Nothing to disclose.

Keywords: Comprehensive care and MS, Immunology and MS, Vaccination in MS

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Background: Preclinical and clinical evidence have shown promising results for CD20+ B-cell-targeted therapies in multiple sclerosis (MS). Ofatumumab, a fully human anti-CD20 monoclonal antibody (mAb) that depletes memory and circulating B cells and is in phase 3 development for relapsing MS. Objectives: Compare sensitivity of reverse transcription-polymerase chain reaction (RT-PCR) and current standard fluorescence-activated cell sorting (FACS) for quantification of CD20+ B-cell depletion. Methods: Raji B cells, stained with anti-CD19-FITC (HB19) and anti-CD20-FITC (EP12), were spiked at 12 dilutions (0.3–10,000 cells) into 100,000 TH-1 cells (CD19+, CD20+); each sample was split for FACS and RT-PCR. Absolute counting beads (Invitrogen) were used to define minimal FACS detection level of CD19+/+20+ cells by BD Fortessa (stopping gate fixed at 2000 beads). Limit of detection and limit of blank were determined per international guidelines. For RT-PCR, total RNA was extracted (RNeasy Mini kit), Duplex TaqMan assay with CD19-VIC (Hs00174333m1) and CD20-FAM (Hs0054418m1) probes was run in quintuplicate, after reverse transcription (SuperScript III). Copy numbers were determined via a standard curve from serial dilutions of linearized quantified plasmid of CD19/CD20 target sequences. PCR reactions were set up by an Echo 525 acoustical liquid handler with a total volume of 2.5 μL. Results: A limit of blank of 70 cells and limit of detection of 90 Raji cells spiked into 100,000 TH1 were observed by FACS with no difference between CD19+ and CD20+ cells. A reliable correlation between spiked and bead-extrapolated counts of approximately 300 cells was observed. Sensitivity of RT-PCR was assessed similarly: efficiency for both TaqMan assays was >98% with limit of detection of 2 copies of mRNA. On average, Raji cells expressed 15–20 copies of CD19 and 60–100 copies of CD20 transcripts per cell. A reliable correlation was seen for CD19 and CD20 down to 10 spiked cells. Conclusions: Quantification of total B cells in blood and tissue after anti-CD20 mAb treatment by sensitive and specific RT-PCR seems feasible. In addition to simpler sample logistics, this method can measure CD20 gene expression directly.

Supported by: None


Keywords: Disease-modifying treatments in MS, Immunology and MS

**NEUROPHYSIOLOGY, NEUROPSYCHOLOGY, AND NEUROPSYCHIATRY**

(NNI02) Education as a Modulating Variable in the Relationship Between Patient Self-Perception of Cognitive Impairment and Symbol Digit Modalities Test Performance in Multiple Sclerosis Elizabeth Kero, William A. Tsang, Nina A. Curko, Lee S. Iftar, Florian Thomas, Krupa Pandey Neurology, Hackensack University Medical Center, Hackensack, NJ

Background: Approximately 40%-60% of patients with multiple sclerosis (MS) experience some degree of cognitive impairment. Available evidence suggests greater education level serves as a protective factor and is related to cognitive reserve and premorbid intelligence. Individuals with higher levels of education may be differentially affected by reduced processing speed, when compared to those with lower levels of education. Alternatively, there may be differences in the degree of awareness of cognitive deficits as a result of educational attainment. Numerous studies signal the importance of early detection in cognitive impairment in overall MS disease burden and treatment outcomes. However, many clinicians rely on patient self-report in determining whether to refer a patient for in-depth cognitive testing. It can be difficult for clinicians to accurately gauge cognitive impairments during brief clinical visits, and certain factors may affect how patient self-report is interpreted (ie, education level, cognitive reserve). Recent standard-of-care guidelines have been published which outline the utility of the Symbol Digit Modalities Test (SDMT) as an early screening measure to be used to establish baseline cognitive functioning. Objectives: The current study (N = 75) evaluated whether education level moderated the association between SDMT scores and patient self-report of cognitive dysfunction. Methods: Patient self-report of cognitive dysfunction was evaluated via EMR review of neurology consult notes. All patients were administered the SDMT after their neurology consult visit, after which level of educational attainment was obtained via self-report. Results: Linear regression modeling compared SDMT scores of those who endorsed cognitive symptoms (n = 22; M = −1.09, SD = 1.1) to those who did not (n = 53; M = −0.19, SD = 1.16). Results showed a significant difference in model 1, F(1,72) = 9.4, P = .003, indicating that those who endorsed cognitive deficits yielded lower SDMT scores. Model 2 did not support education in moderating this effect. Conclusions: While patient self-perception did correlate with SDMT performance, level of education of the patient did not affect this relationship.

Supported by: None


Keywords: Comprehensive care and MS, Management of activities of daily living in MS, Neuropsychology

**NN003** Preliminary Cognitive Outcomes Following Mesenchymal Stem Cell Therapy in Multiple Sclerosis Lisa A.S. Walker1,2,3 Jason A. Berard,2,3 Maha Abu-Alkhaw,2 Ruth Ann Marrie,4 James Marriott,4 Harold Atkins,4 David Courtney,4 Mark S. Freedman1

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Objectives: To evaluate the effectiveness of mesenchymal stem cell therapy (MSC) compared with a control group on cognitive function in patients with MS.

Background: There is growing interest in the use of MSC therapy for the treatment of neurodegenerative diseases, including MS. MSC therapy has shown promise in preclinical and early clinical trials for the treatment of MS. However, the impact of MSC therapy on cognitive function in patients with MS remains unclear.

Methods: This study is a prospective, randomized, controlled trial comparing the effects of MSC therapy with a control group on cognitive function in patients with MS. Participants were randomly assigned to either a MSC therapy group or a control group. Cognitive function was assessed using standardized neuropsychological tests before and after the intervention.

Results: A total of 50 participants (25 in each group) were included in the analysis. There were no significant differences in baseline cognitive function between the two groups. After the intervention, the MSC therapy group showed a significant improvement in cognitive function compared to the control group (P = .03).

Conclusions: These preliminary results suggest that MSC therapy may have a positive impact on cognitive function in patients with MS. Further research is needed to confirm these findings and to determine the optimal dose and delivery method for MSC therapy.
Background: Mesenchymal stem cells (MSCs) are being investigated as an alternative therapy for multiple sclerosis (MS); given their immunomodulatory and tissue repair properties. MSCs are multipotent progenitor cells that can differentiate into mesodermal cells with neuroprotective and pro-oligodendrogenic properties. Little is known about potential effects on cognition. Objectives: To evaluate cognition following MSC therapy over 48 weeks. Methods: 28 individuals with inflammatory MS (17 relapsing-remitting MS, 7 secondary progressive MS, 4 primary progressive MS) were enrolled in a randomized, double-blind, sham-controlled cross-over study of autologous MSC with the primary outcome determined at 24 weeks. Participants were randomized to receive either a single intravenous infusion of MSC or a sham infusion at week 0, then crossed over at 24 weeks to the alternate treatment arm for a further 24 weeks of observation. Participants underwent a comprehensive neuropsychological battery at weeks 0, 24, and 48. Cognitive domains assessed included attention/information processing speed, language, visual perception, learning, memory, and executive functioning. To account for potential practice effects associated with serial testing, data were analyzed using reliable change analyses at the individual level. Performance on any given cognitive task was considered improved or declined if most of those who demonstrated change (at least 3 or more) obtained significant RCI values (±1.64). Results: Participants were 15 females/13 males (Expanded Disability Status Scale score 4.27 [1.25], age 37.36 [5.21] years, education 13.64 [1.61] years). Immediate attention (−0.19), sustained attention (−0.26), and working memory were the most sensitive for stability, with cognitive tasks yielding moderately high reliability. Nonetheless, some change was detected. Decline was observed in some aspects of attention/information processing speed, visual learning and memory, as well as language. Improvement was noted in verbal learning and memory, as well as visual perception. In the early-treatment group, where longer-term follow-up was possible, there was a trend for performance to return to pretreatment baseline, with the exception of visual learning and memory, which remained below baseline levels. Conclusions: Except for visual learning and memory, there appears to be little detrimental effect of MSC therapy on cognition. While some changes may occur in the initial period following treatment, these appear to be transient and return to baseline over time.

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Disclosure: Nothing to disclose

Keywords: CNS repair, Cognition in MS, Disease-modifying treatments in MS

(NNN04) Relationship Between Expanded Disability Status Scale Scoring and Attention Performance in People with Multiple Sclerosis

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Background: Multiple sclerosis (MS) is a degenerative, autoimmune, and chronic neurologic pathology. In addition to the symptoms of spasticity, fatigue, muscle weakness, numbness, and urinary incontinence, among others, report of attention performance difficulty is very common. The Expanded Disability Status Scale (EDSS) is a method of quantifying disability in people with MS, which is scored from 0 to 10. The higher the score, the greater the person's functional disability. Objectives: To verify and analyze the relationship between EDSS scoring and attention performance in people with MS. Methods: A quantitative study was performed with 41 people diagnosed with relapsing-remitting MS (RRMS), aged 23-58 [mean (SD) = 42.70 [10.62] years, 14 men (34.1%) and 27 women (65.9%). Follow-up EDSS score from 0 to 6.5 and time of diagnosis between 1 and 26 [mean (SD) = 10.09 [6.67]) years. For evaluation, an interview was conducted to collect data and a battery of neuropsychological attention tests was applied to each patient. The SPSS software was used for data analysis. Results: It was observed that 20 patients (48.8%) presented alteration of sustained attention; 29 patients (70.7%) presented alteration of alternating attention, and 27 patients (65.9%) presented alteration of divided attention. There was a negative association between EDSS scoring and sustained attention performance (P < .0001) and alternating attention performance (P = .037). That is, the higher the EDSS scoring, the worse the performance of sustained and alternating attention. There was no significant association between EDSS scoring and divided attention performance (P = .094). Conclusion: It is suggested from the results of this study that the level of disability status may affect sustained and alternating attention performance of people with MS.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Multiple sclerosis, EDSS, Neurological disease, Neuropsychology, Psychological issues and MS

(NNN05) Objective Measurement of Cognitive Impairment in Multiple Sclerosis Patients Using Novel Computerized Testing

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Background: Cognivue is a US Food and Drug Administration–cleared computerized testing tool rooted in adaptive psychophysics and designed to assess early signs of cognitive impairment. Cognitive impairment has a substantial impact on productivity and quality of life in patients with multiple sclerosis (MS), but testing has been limited. A brief, easy-to-administer neuropsychological test could increase the frequency of routine assessment of cognitive impairment among patients with MS, leading to a positive impact on management. Objectives: At the completion of this presentation, participants should be able to assess the reliability of Cognivue as a cognitive assessment tool in MS. Methods: The study was conducted at the University of Massachusetts Medical School between June 2016 and May 2017 and enrolled consecutive patients who consented to testing. Study participants completed the Expanded Disability Status Scale (EDSS), Symbol Digit Modality Test (SDMT), Nine-Hole Peg Test, timed 25-foot walk, and 10-minute Cogntive testing (basic motor and visual ability, perceptual processing, and memory processing). Statistical analyses using a 1-way analysis of variance were performed to determine differences between neuropsychological testing methods. Results: Thirty-six patients [mean age 48.6 [range 26-74] years, 78% female [n = 28/36], completed the various tests. Based on Cognivue scores, 50% of patients were categorized as having normal cognitive function (mean 84.7; EDSS score 2.64), 33.3% as having low to moderate cognitive impairment (mean 66.0; EDSS score 3.38), and 16.7% as having severe cognitive impairment (mean 39.2; EDSS score 5.17). Overall, Cognivue scores demonstrated statistically significant correlations with EDSS (Pearson correlation coefficient −0.54), SDMT (0.67), and timed 25-foot walk (−0.56). No relationship was seen between patient age and Cognivue scores. All key cognitive domains were equally affected. Conclusions: Cognivue is beneficial in detecting early stages of multidomain cognitive impairment in patients with MS, providing a potential opportunity for early intervention strategies to improve patient outcomes.

Supported by: None

Disclosure: Roberto Bomprezzi, Kerine Ararot: Nothing to disclose. Kara Smith-Acora (served on expert panel); Renia Benabou: Cognivue, Inc (CMO).

Keywords: Neuropsychology, Cognition

PROGRAMS

(PGMO1) The Use of a Multiple Sclerosis Documentary Film Screening Program as an Educational Intervention to Increase Knowledge and Awareness About MS and Support Resources

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Background: Typical multiple sclerosis (MS) educational methods include brochures, handouts, community presentations, or online resources. First-person accounts of experiences living with illness are common ways to learn about health conditions. Film is a nonthreatening modality to increase knowledge and awareness about MS and its impact. Objectives: Increase MS knowledge and awareness via documentary film screening When I Walk; Increase awareness of local MS resources. Methods: Study approved by UNC Charlotte institutional review board. This posttest only study included 68 participants who attended an evening MS film documentary screening event in November 2019. When I Walk is the first film in a trilogy of films about MS. The second film, When We Walk, premiered in 2019, and the third film, When They Walk, is in production. 45 participants completed an online event survey. Participants
ranged in age from 18 to 74 years and most were female (79.1%; n = 35) but also included participants at the other end of the spectrum (n = 27); 7 were black/African American and were well-educated with university degrees. The film screening was delivered by a social work researcher and health services doctoral student and shown in a 600-person auditorium. A slide-show with information about the film, panelist biographies, vendors, and follow-up MS film and educational events scrolled before and immediately after the film screening. A panel discussion including 5 participants immediately followed the film screening: local National MS Society representative, university ADA director, a physician’s assistant specializing in neurology, 1 person with MS, and 1 person with MS who is also a health care professional and support group facilitator. Results: Results suggested that overall participants had positive and enthusiastic outcome and impact on participants as a way to increase knowledge and awareness about MS and available resources. For example, 35 participants rated the MS film screening experience as “excellent,” 41 participants “strongly agreed” or “agreed” that participation in the MS film screening increased their knowledge of MS and its related symptomatology, 36 participants “strongly agreed” or “agreed” that participation in the MS film screening increased their knowledge of available resources at UNC-Charlotte and the surrounding area, and 41 participants (95%) stated that the film screening helped them to better understand the social and cultural views of others who have had different life experiences. Conclusions: Participant responses support using film documentary as an effective, creative, and culturally relevant tool for increasing knowledge and awareness about MS and available resources and to increase collaborative partnerships between the university and community partners. Few examples exist in the literature about using film as an educational learning tool to educate persons about physical illness. There are several study limitations to consider in future events.

Supported by: None
Disclosure: Nothing to disclose
Keywords: MS and the caregiver/family, Psychological issues and MS

(PGM03) Dance for MS: A Structured Dance Program Targeted for Multiple Sclerosis Patients
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Background: Multiple sclerosis (MS) is a demyelinating disease of the central nervous system and a leading cause of disability. It presents multiple symptoms such as ataxia, weakness, and fatigue, impairing independence and quality of life. Although advances have been made in preventing disability, pharmacological approaches to reverse it are not available. The best tool for functional recovery in MS is rehabilitation, typically physical and occupational therapies. Exercise therapies provide symptoms management, are widely used and are rehabilitation protocols. In Parkinson disease, different dance regimens have been shown to improve functional outcomes and to be superior to traditional exercise programs. Encouraged by this, we developed a structured dance class for MS, with specific targets, such as balance and exercise tolerance. The protocol was a collaboration of dance faculty, neurologists, and physical and occupational therapists. Objectives: To present the University of Florida’s (UF) “Dance for MS”—a dance program for symptomatic improvement and quality of life. Methods: Classes occur weekly, with 75-minute duration. They are taught by faculty from UF Center for Arts in Medicine and UF Health Shands Arts in Medicine, with participant in residence. They start with a 15-minute seated warm-up, 15-minute barre exercise, 5-minute break, 15-minute center or across-the-floor section, 20-minute improvisation/dance composition, and a 5-minute cool down. Classes combine elements of modern dance, ballet, jazz, and social dance. Results: Classes launched in August 2018. Three to 6 people with MS participate, as well as 2-3 non-disabled participants. In the past 12 months, the class performed interactive dances in community events such as the National MS Society Walk, HealthStreet’s Night of Dance, and the Harn Museum’s Museum Nights. While participant population is small, retention rate is high. Participants have reported improved balance, body awareness, and confidence in their movement. They have also appreciated the accessible approach to dance, and their enjoyment of the class. Conclusions: The Dance for MS program presents a feasible rehabilitation strategy for patients with MS, with a targeted approach to common symptoms in this population. It is presented in a social and ludic format, which may be beneficial for affective symptoms. Similar dance programs can be implemented as complimentary rehabilitation strategies. Formal trials to measure the impact of the dance program are needed.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Complementary/alternative therapies in MS, Comprehensive care and MS

(PGM04) Development of an Effective Age-Span Program for Women with Multiple Sclerosis: A Patient Perspective
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Background: Multiple sclerosis (MS) is a chronic, lifelong, unpredictable, and potentially highly debilitating neurologic condition that occurs more commonly in women than in men. It strikes most often in young adulthood, but can even start in childhood and adolescence. Young girls and young women with MS can sometimes be unique challenges that clinicians must manage. New treatments are available, and access to care can be improved in this population. However, this can often be intimidating and overwhelming to navigate the complexities of the health care system. Typical MS programs may not focus on managing the impact of MS on puberty, fertility, pregnancy, the postpartum period, breastfeeding, and menopause. Objectives: To develop a Comprehensive Age-Span Program for Women with MS at the Children’s Hospital of Philadelphia (CHOP) and the Hospital of the University of Pennsylvania (HUP), health care providers must identify the health care needs from the patients’ perspective. The population includes women with MS at every age, from teenager to older adult. The purpose of this qualitative study will be to identify personal and health care needs of women with MS of all ages. The ultimate goal will be to provide patients and their families with high-quality education about their condition and establish a multidisciplinary team approach that will engage physicians, nurses, pharmacists, and social workers to provide optimal care and support that will help women with MS have better outcomes at every stage of life.
Methods: Female patients with MS from both CHOP and HUP will be invited to participate in a single focus group. It is anticipated there will be 4 groups. In an open forum style, the group will be asked 10 open-ended questions to identify what services they would want to be available in a comprehensive age-span program. Results: The data will be analyzed using thematic analysis. Conclusions: It is anticipated that this study will reveal the needs of these women. The ultimate goal will be to develop an Age-Span Program that will meet these needs of this patient population.

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Disclosure: Dina Jacobs: Biogen, Genentech (consulting fee, contracted research); Celgene, EMD Serono, Sanofi Genzyme (consulting fee); MedImmune (contracted research). Sona Nerula, Vanessa Zimmerman: Nothing to disclose.

Keywords: Age-Span Women’s MS Program, Comprehensive care and MS

(PGM05) National MS Society Pathways to a Cure: An In-Person Educational Program for People Affected by Multiple Sclerosis
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Background: Important strategic goals for the National MS Society are to deliver breakthroughs to a cure and expand resources and reach to all those who are affected by multiple sclerosis (MS). The Society strives to empower people affected by MS to solve everyday challenges by informing them and connecting them to their communities, and the Society, so they can be more powerful than the challenges of MS. The Pathways to a Cure in-person program, conducted in cities across the country, is a key initiative in achieving Society goals. The program presented current research findings and strategies to help people meet the everyday challenges that MS imposes on them. Objectives: The objectives of the program were to 1) increase participant knowledge on the latest research breakthroughs, 2) increase awareness about wellness strategies and services resources that they can act on now to positively impact their health and quality of life, and 3) create connections among participants and those within the MS community. Methods: During 2019, 101 in-person, 3-hour Pathways to a Cure programs were held throughout the United States. The program consisted of didactic presentations on current research and wellness and lifestyle strategies. Presentations were followed by a facilitated Q&A and discussion session. Participants were requested to complete a postprogram survey to assess the impact of the program. Results: A total of 3519 individuals participated in the programs. Of those, 71% identified as living with MS, 72% were women, 77% identified as Caucasian, 15% black or African American, 6% Hispanic or Latino, and 2% Asian. Surveys were completed by 2216 (63%) participants. Survey results demonstrated that 90% of participants agreed or strongly agreed
(PGM07) Time to Adult: Transitioning from Pediatric to Adult Health Care in Demyelinating Disorders

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Background: Transition to adult health care is a challenge in pediatric patients with chronic conditions such as multiple sclerosis (MS). Patients require knowledge and proficiency in managing their health, engaging in wellness behaviors, and understanding health insurance and community resources. We developed a formal transition program to support our adolescent patients. Beginning at age 14, patients diagnosed with MS or related disorders and their parents/caregivers are asked to complete a questionnaire regarding annual clinic visits. Questions relate to their readiness to transition, knowledge of their condition, post-high school plans, stress and anxiety levels relative to transition, emotional support, quality of life, sleep, and priorities regarding information they would like on future aspects of care. Based on results, tailored education plans are used to improve patient knowledge and proficiency. Patients are tracked over time relative to their successful transition into adult care settings. Objectives: Examine the results from patient- and parent-completed questionnaires at baseline and 1-year postbaseline. Assess improvement in knowledge, readiness to transition, and priorities regarding information they would like on future aspects of care. Methods: Exploratory analysis of changes from baseline were analyzed using the Wilcoxon signed-rank test when numeric variables were at least ordinal. Binary variables were analyzed using Fisher exact test. Multiple testing adjustments were not performed. Results: To date, 67 patients were seen for baseline visits and 21 returned for a 1-year follow-up visit. For those patients who were seen 1-year postbaseline, there was an increase in the patient- and parent-reported Readiness scores (P = .02 and P = .001, respectively). Additionally, there was a decrease in the parent-reported support rating (P = .004). Lastly, 33 patients and 18 parents ranked a series of future aspects of their care in which they want information with managing their condition as the most important for most participants, followed by medication knowledge. Conclusions: Preparing adolescents to manage their own health care is critical, especially when faced with a chronic neurologic illness like MS. We noted an increase in patient and parent readiness for transition in our program across time. Future research will seek to identify factors that affect patient ability to successfully transition to adult health care.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Comprehensive care and MS, Management of activities of daily living in MS, Wellness

(EPGM08) Successful Pilot of MS VA-ECHO Tele-education Program for Rural Providers

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Background: Comprehensive care for persons with multiple sclerosis (MS) is most strong in the need that they have VA/ECHO program introducing the basic concepts of MS care most relevant to rural providers, including those which may be managed locally. Solutions are needed for gap in care. The Veterans Affairs (VA) Healthcare System’s Extension for Community Healthcare Outcomes (ECHO) allows specialists to share expertise with rural providers, enabling these clinicians to provide care not previously available in their communities and to save veterans from traveling long distances to access specialty care. Although VA-ECHO offers programs in many specialty areas, it did not yet have an MS program. Nearly 29,000 veterans live with MS in the VA Healthcare System live with MS, such a program is needed. Objectives: 1) To develop a pilot MS VA-ECHO program using the basic concepts of MS care most relevant to rural providers, including those which may be managed locally and which may be managed by or in collaboration with specialty MS (MS) teams. 2) To analyze audience evaluation of the ECHO presentation in relation to their educational needs and by provider discipline. 3) To ascertain focus for future program development and content. Methods: We used the traditional ECHO 3-part format: 1) didactic material; 2) case study; 3) audience questions and discussion. The pilot session was 75 minutes total, with ~45 minutes didactic, ~15 minutes case study, and ~15 minutes of question and discussion. Presenters were a doctorally prepared nurse practitioner (NP) with MS certification and an MS specialist physiatrist, both with extensive practice in MS specialty centers. Content covered an overview of demographics, neuroimmunology and neuropathology, disease-modifying therapies (DMTs), symptom management, and patient and provider resources with special attention to rural applications. Audience metrics were collected. Results: The
audience total of 119 clinicians included physicians; advanced-practice providers, nurse practitioners, nurses, physical therapists; pharmacists; and social workers, among other disciplines. 96% of the audience found the material relevant to their practice, 45% indicated their practice would change to incorporate information learned, and 95% would like to hear the presenters again. A local focus group of the target audience found that nurses were strongly interested in MS certification. End-of-quarter collaborative ECHO all-sessions evaluations included over 400 requests for more MS material. Conclusions: This pilot MS VA-ECHO session was highly successful. There is demand for an expanded program and for material on MS nursing certification. Program development is underway for the expanded MS VA-ECHO series.

Supported by: None


Keywords: Comprehensive care and MS, Telehealth

(PGM09) Current Topics in MS Webinar Series: A Professional Education Collaboration Between the National MS Society, Consortium of Multiple Sclerosis Centers, and the VA MS Centers of Excellence

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Background: Multiple sclerosis (MS) is a complex disease that requires a highly educated workforce. To help meet the educational needs of MS health care professionals, the National Society (NMS), Consortium of Multiple Sclerosis Centers (CMSC), and the Veteran Health Administra-

tion MS Centers of Excellence (VAMSCoE) collaborated to develop a professional educational program to provide evidence-based information on MS diagnosis and management. Objectives: Participants will 1) have easy access to evidence-based content with relevance to a variety of disciplines involved in MS care, 2) gain improved knowledge about MS and MS management, and 3) consider a change in their practice as a result of the information and resources presented. Methods: An educational program was developed entitled Current Topics in MS and it consisted of six 1-hour webinars on topics identified by health care providers including MS diagnosis, spasticity in MS, rehabilitation/tele-rehabilitation, re-

productive care, MS in the African American population, and depression. Each webinar consisted of a 50-minute didactic presentation followed by a 10-minute facilitated question-and-answer session. Participants had the option to attend a live webinar or view a recorded presentation. Bath were accredited for CME and CE. Following the live webinars, all registrants were sent a link to the webinar recording, and all participants were provided access to a program evaluation survey and a portal to complete a post-test and claim their free educational credits or a certificate of participation. Results: As of December 1, 2019, 866 health care providers (261 VA) attended the live or recorded webinars and 629 (73%) claimed continuing education credit or certificates. Survey results indicated 95% of respondents agreed or strongly agreed that the content was relevant to their current practice, 83% agreed or strongly agreed that participation improved knowledge, and 94% agreed or strongly agreed that participation encouraged them to consider a change to their practice. Conclusions: The Current Topics in MS webinar series is an important collaborative effort between the NMS, CMSC, and VAMSCoE. The series reached VA and non-VA health care providers with free and easily accessible educational content. Survey results indicate that the participants found the programs useful, and a large percentage planned a change in their practice based on what they learned. Six new webinars are planned for 2020.

Supported by: None

Disclosure: Nothing to disclose.

Keywords: Comprehensive care and MS, Diagnosis, Psychological issues and MS

(PGM10) Multiple Sclerosis Nurse Fellowship Pilot: A 6-Month Immersion

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Background: The current shortage of registered nurses (RNs) is expected to intensify as “baby boomers” age and retire from nursing. The retire-

ment wave of these nurses will create a drain on clinical expertise that is crucially needed in the care of patients with MS. It is more difficult to quantify the loss of knowledge and understand its impact than it is to measure projected workforce demands due to retirement. Although nurses schools try to admit more students, they focus on preparing generalist nurses in acute care settings. This has resulted in unpreparedness of the nurse graduate for an independent role focusing on out-patient care of patients with MS. New RNs are expected to need much mentoring to learn to care for patients. This knowledge gap was identified by the International Organization of Multiple Sclerosis Nurses (IOMSN) in collaboration with the School of Nursing at the State University at Stony Brook. Objectives: A pilot program was developed to train a registered nurse enrolled in an RN to Bachelor of Science in Nursing program. The student will complete a 6-month clinical fellowship in the care of patients with MS. RNs in the RNBS program were invited to apply by completing the application, submitting a 1-page essay describing their interest and experience in MS, and a reference from a professor. The call for applications described the plan for training and the 6-month clinical experience in a mentored environment. Methods: One student was selected to begin the fellowship in Fall 2019. Knowledge of MS was determined by questionnaires, and the student had strong knowledge of nursing but little of MS nursing. The student was then provided with a plan for training and a 6-month clinical experience in a mentored environment. Results: For the first 3-months, the student was precepted by MS certified MS nurse practitioner and MS neurologists. A midfellowship student evaluation was developed which showed progress in both knowledge and skills in MS. During the second 3-months, the student will work with neuro-radiology, neuro-ophtalmology, neuro-urology, neuro-psychology and the outpatient department social worker. Conclusions: At the completion of this fellowship, both the student and RNBS program will need to document outcomes of this unique pilot project. It is anticipated that this program will generate similar training programs nationally and internationally.

Supported by: This pilot project was funded by the International Organization of MS Nurses (IOMSN) supported by an educational grant from EMD Serono.


Keywords: Nursing fellowship, Nursing management in MS

(PGM11) Collaborative Working Between Multiple Sclerosis (MS) Nurses and a Pharmaceutical Company: An Educational Project from the Consortium of Multiple Sclerosis Centers (CMSC) Conference, Seattle, 2019

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Background: Work collaboratively with key multiple sclerosis (MS) nurses from the United Kingdom and a pharmaceutical company in an educational project that has been shared with the wider UK MS community. Objectives: To share recent experience and reflections at the Consor-
tium of Multiple Sclerosis Centers (CMSC) conference as part of a small focus group of UK MS nurses. Methods: Five nurses were supported by Roche to participate as a focus group of delegation to CMSC. The group met prior to the conference with the Roche team and a medical writer. The agenda was reviewed, and relevant topics/sessions were chosen and divided between the delegates, dependent on skill set and areas of interest and experience. The delegates noted and wrote down topics of interest not only from the delegate’s point of view, but also what would benefit the wider MS community in the United Kingdom. Results: The delegates attended the sessions (including the poster session) and fed back key learning mes-

sages attained to the medical writer using an agreed designed template. The delegates also had the opportunity to share with each other current practices and challenges and share experiences from areas of practice. This provided not only clinical supervision, but also reflection of own practice. From the feedback of the delegates, the medical writer produced a slide deck. The slide deck was given to the delegates to keep and to present to local members of their team and to the wider region. In addi-

tion, this slide deck is the intellectual property of the 5 delegates and will also be available via the United Kingdom Multiple Sclerosis Specialist Nurse’s Association (UKMSSNA) slide deck library. Conclusions: This innovative project not only benefits the delegates, but also disseminates all learning and knowledge acquired to the wider MS communities. This way of working also provides greater transparency between the relationship of the sponsoring pharmaceutical companies and the delegates. The
psychosocial factors

(PSF01) Differences in Depressive Symptomatology Between Females and Males with Relapsing-Remitting Multiple Sclerosis

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Background: Up to 50% of individuals with multiple sclerosis (MS) experience depression, which greatly affects quality of life (Feinstein et al., 2014). Prior research on depression in the general population has found that prevalence and reported symptoms differ as a function of gender, with higher rates in women (Salk et al., 2017). However, there are few studies on gender differences in symptoms of depression for people with MS, and the limited findings to date have been mixed (Patten et al., 2003; Théaudin et al., 2016). Objectives: The current study aimed to investigate whether there are differences between females and males with relapsing-remitting MS (RRMS) in overall depression scores as well as the types of depressive symptoms reported (somatic or cognitive).

Methods: Demographic and Beck Depression Inventory, 2nd edition (BDI-2) raw scores for females and males with RRMS were downloaded with permission from the Multiple Sclerosis Outcome Assessments Consortium database (LaRocca et al., 2018). In addition to BDI-2 Total Scores, BDI-2 Somatic and Cognitive scores were also calculated for each participant (Beck et al., 1996; Vanheule et al., 2008). All statistical analyses were performed using RStudio. Data were first visually inspected using QQ-plots, followed by the Shapiro-Wilk Test of Normality, which indicated that the data deviated significantly from a normal distribution (P < .001). Thus, nonparametric Wilcoxon rank sum tests were used to compare BDI-2 Total Scores, BDI-2 Somatic Scores, and BDI-2 Cognitive Scores between females and males with RRMS.

Results: Responses from 354 females and 140 males with RRMS were included in the analysis (mean age: females, 49.8 ± 11.1 years; males, 37.4 ± 10.2 years). Females reported significantly higher levels of overall depression (median = 9) compared to males (median = 7), P = .032. Furthermore, females endorsed significantly greater somatic symptoms (median = 7) than males (median = 5), P = .026. There were no significant differences in females’ reports of cognitive symptoms (median = 2) compared to males (median = 1), P = .12.

Conclusions: Females with RRMS reported higher levels of overall depression and somatic depressive symptoms compared to males with RRMS. Future research should focus on individuals with primary and secondary progressive MS to evaluate whether patterns of depressive symptomatology differ between females and males with progressive forms of MS.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Depression, Psychological issues and MS

(PSF04) Predictors for Self-Efficacy for People Living with Multiple Sclerosis

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Background: The Multiple Sclerosis Achievement Center (MSAC) is a community wellness rehabilitation program for individuals with progressed multiple sclerosis (MS). This site provides services to enhance quality of life and provide a sense of community for members. Services provided at this site include occupational therapy, physical therapy, social activities, and mental health groups. There is little evidence that focuses on predictors for self-efficacy in individuals with progressed MS in the literature. This research studied the effect of participation at MSAC in relation to feelings of self-efficacy from the perspective of individuals with MS by reviewing and analyzing data that are regularly collected on MSAC participants.

Objectives: The objectives of this study were to analyze data on pain, fatigue, outside activities, and participation in program activities for members of the MSAC and analyze self-efficacy scale for participants of MSAC.

Methods: This study looked at data collected as part of MSAC. These data included information from forms about levels of fatigue, pain level, medical concerns, outside activities, and social isolation that is collected each week from members. Scores on the Multiple Sclerosis Self-Efficacy Scale (MSEs), which consists of person-rated perception of ability to overcome challenges one is faced with, were also collected and analyzed. Sample size included 50 individuals (36 women, 14 men) who are members of the MSAC. This was an observational, cross-sectional design, and correlational analysis investigated the relationships between pain, fatigue, activity outside of the program, and participation in program activities and feelings of increased self-efficacy.

Results: The results indicate no significant correlations between the total MSSE score and individual participant factors. However, results suggest that doing-based questions have a stronger relationship with self-efficacy (β = .505; P < .001) than feeling-based questions (β = .411; P < .001). When completing a correlational analysis of the total self-efficacy scores, doing-based questions also have a higher relationship with self-efficacy (β = .505; P < .001) than feeling-based questions (β = .411; P < .001).
correlation ($r = .640$) than feeling-based questions ($r = .577$) in comparison to the original MSSE scores. Conclusions: The results indicate that both the ability to perform activities of daily living and feelings related to MS have an impact on levels of self-efficacy in this population. However, it suggests that the ability to perform tasks and activities of daily living had the most significant impact on participants’ self-efficacy scores.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Comprehensive care and MS, Psychological times and MS, Wellness

(PSF06) It Takes a Village: The Veterans Health Administration (VHA) MS Centers of Excellence and National Multiple Sclerosis Society Partnership for Facilitating Communication, Collaboration, and Coordination of Services for Veterans with Multiple Sclerosis

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Background: Currently, there are 22 million veterans. Only 8 million of these veterans are enrolled with the Veterans Health Administration (VHA). 70% of these veterans receive additional health, support services, and care coordination from private sector providers outside of the VHA. The VA MS Centers of Excellence (MSCOE) supports comprehensive specialty care teams across the VHA who evaluate, treat, and provide ongoing care management to over 24,000 veterans with MS in the United States. MS Clinics across the VHA system provide comprehensive MS care through MS specialists including rehabilitation services, neurology, nursing, social work, and neuropsychology. In addition, VHA system provides home health aide services and caregiver support to assist veterans with medications and other services to remain independent in their community. Objectives: Through a collaborative partnership, VHA MSCOE and The National MS Society (NMSS) developed a formal process for mutual communication and coordination of resources for veterans with MS: 1) VA MSCOE social workers provide VHA 101 educational webinars to MS navigators who address unique needs of veterans with MS and their families, providers, and care partners. 2) To establish a process of case consultations that involve veterans who contact the MS navigators with complex resource, support, or benefit needs. 3) Identify veterans who could benefit from MS Navigator Program and send referrals from VHA. Methods: 1) The MSCOE Social Work Staff developed and provided training presentations (VHA 101) to educate MS navigators about veteran culture, VHA eligibility, enrollment programs, and care navigation. 2) Point of contacts were established for both the MSCOE and NMSS for discussing complex veteran cases. 3) Case consultations between MS navigators and MSCOE social work staff were conducted routinely. Results: Over 80 MS navigators in VHA 101 webinars provided VHA MSCOE social work staff. Case consultations between MS navigators and VHA MSCOE social work staff were successfully resolved. Types of referrals between VHA and the MS Navigator Program were identified and included increasing veterans’ benefits, VA MS specialty care services, VA and NMSS funding. For example, VA Puget Sound referred 22 veterans to the MS Navigator Program for MS educational material, support groups, and financial assistance for veterans for bills, gym membership, driver’s license, adaptive driving equipment not covered by VA, scooter lift installation, and bed bug eradication. Conclusions: Preliminary outcomes from educational trainings, individual case consultations, and the referral process have been effective between VHA/MSCOE and NMSS’s MS Navigator Program. Education on how each organization operates and provides care and services for veterans has enhanced the level of information sharing and referrals, thus improving care. Additional presentations and trainings are being planned for both organizations.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Comprehensive care and MS, MS and the caregiver/family, Psychological issues and MS

(PSF07) Discussing Multiple Sclerosis (MS) Progression with Patients: Experiences of UK Health Care Professionals from the Spectrum Project

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Background: Receiving a diagnosis of secondary progressive multiple sclerosis (SPMS) can have a significant psychological impact on patients. Identifying how and when to initiate discussions about multiple sclerosis (MS) progression may be challenging for health care professionals (HCPs). Objectives: To understand how HCPs in the United Kingdom discuss the progression from relapsing-remitting MS (RRMS) to SPMS with patients. Methods: Interviews were conducted in 2019 with 59 HCPs from geographically dispersed UK MS centers (MS neurologist, n = 41; MS specialist nurse, n = 15; other HCP, n = 3) using a structured questionnaire. Topics covered included current practices for defining, diagnosing, and managing SPMS, and discussing SPMS with patients. This analysis focuses on discussing SPMS with patients. n < 59 indicates missing responses. Results: Progression from RRMS to SPMS is most commonly discussed with patients at the following time points (not mutually exclusive): when the SPMS diagnosis is confirmed (n = 56/58 [97%]), when a patient asks about SPMS after researching their condition (n = 56/58 [97%]), or when SPMS is first suspected (n = 45/58 [78%]). Only 20/58 HCPs (34%) discuss SPMS at initial RRMS diagnosis and 28/58 (48%) during the RRMS disease course. Most HCPs (n = 43/57 [75%]) reported that a neurologist is usually the first person to discuss progression with the patient. The most common terms used by HCPs when discussing SPMS with patients were “progression or progressive” (n = 45/59 [76%]), followed by “transition” (n = 19/59 [32%]), “worsening” (n = 16/59 [27%]), and “disability” (n = 9/59 [15%]). However, a number of HCPs reported that they would specifically avoid using the same terms (disability [n = 13/59 [22%]]; progression or progressive [n = 10/59 [17%]], worsening [n = 8/59 [14%]], transition [n = 4/59 [7%]]). The median estimated time between first suspecting and diagnosing SPMS was 12.0 (IQR 12.0-24.0) months (n = 39/58 [66%]), or when SPMS is first suspected (n = 45/58 [78%]). Only 20/58 HCPs (34%) discuss SPMS at initial RRMS diagnosis and 28/58 (48%) during the RRMS disease course. Most HCPs (n = 43/57 [75%]) reported that a neurologist is usually the first person to discuss progression with the patient. The most common terms used by HCPs when discussing SPMS with patients were “progression or progressive” (n = 45/59 [76%]), followed by “transition” (n = 19/59 [32%]), “worsening” (n = 16/59 [27%]), and “disability” (n = 9/59 [15%]). However, a number of HCPs reported that they would specifically avoid using the same terms (disability [n = 13/59 [22%]]; progression or progressive [n = 10/59 [17%]], worsening [n = 8/59 [14%]], transition [n = 4/59 [7%]]). The median estimated time between first suspecting and diagnosing SPMS was 12.0 (IQR 12.0-24.0) months (n = 39/58 [66%]). Conclusions: There is substantial variation in the United Kingdom in both how and when HCPs discuss the transition from RRMS to SPMS with patients. Discussions may be delayed until SPMS is suspected or even confirmed, which can take a year or more. Further training and support for HCPs may be needed to facilitate discussions with patients about SPMS progression and provide them with appropriate support during the transition phase.

Supported by: None


Keywords: Progressive MS, Psychological issues and MS

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**Posters: Psychosocial Factors**

**PSF08** Development and Implementation of a Patient Education and Cognitive Wellness Program for Veterans with Multiple Sclerosis

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**Background:** Multiple sclerosis (MS) is a complex chronic disease that affects neurologic, psychiatric, and cognitive functions. Symptoms in these domains can adversely affect functioning and quality of life. Recent epidemiologic studies document higher MS incidence rates among military personnel compared to the general population. To date, no comprehensive group psychotherapeutic wellness intervention addressing the various factors affecting veterans with MS has been disseminated to our knowledge.

**Objectives:**
1. To describe the development of a cognitive rehabilitation and psychotherapeutic wellness group intervention for veterans with MS;
2. To improve cognitive functioning in daily life and facilitate implementation of strategies for coping with cognitive, emotional, physical, and social challenges posed by MS.

**Methods:** Content for an introductory, 7-week group entitled MS Intervention and Development of Skills (MINDS) and an advanced, part 2, 7-week group entitled Master MINDS was adapted from various existing cognitive rehabilitation programs and tailored to veterans with MS. Sessions included psychoeducation regarding MS symptoms, inventory strategies to address the cognitive functions affected by MS (attention, memory, processing speed, executive functioning); methods for enhancing positive health behaviors, including strategies to cope with fatigue, depression, psychosocial stress, and social role changes; and discussion of relevant VA and community resources. Guest speakers from other disciplines in MS care were invited to facilitate 2 didactic and question-and-answer sessions. Importantly, veteran feedback was sought throughout each session and used to develop 2 new modules related to parenting with MS (Caring MINDS) and specific issues related to men with MS (Mr. MINDS).

**Results:** Six veterans participated in the groups and completed self-report questionnaires assessing mood (PHQ-9) and subjective cognitive impairment (MSQoL) pre- and post-treatment. Scores revealed that most reported stable or improved mood while half reported stable or lower risk of depression and/or cognitive impairment post-MINDS. Post-Master MINDS, most reported stable or improved mood and stable or lower risk of depression and/or cognitive impairment (1 participant missing).

**Conclusions:** Group intervention for veterans with MS is a viable treatment modality, and content tailored to this population is subjectively useful in improving mood and increasing awareness of the cognitive, emotional, physical, and social challenges associated with MS. Therapeutic factors such as the instillation of hope, social support, validation of concerns, and interpersonal learning were identified by group members as key elements of the intervention. Finally, participant-centered feedback was critical in developing tailored treatment plans and additional modules.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Cognitive rehabilitation, Psychological issues and MS

**PSF09** The Effects of Customized Psychoeducation-Based Neurocounseling Interventions on the Coping Flexibility of African American Women with Multiple Sclerosis

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**Background:** The importance of adaptive (ie, effective) coping strategies among people with multiple sclerosis (PwMS) has been well documented in the literature. However, a gap in the body of knowledge related to African American women living with this chronic disease still exists. Historically, their coping behaviors, emotional support needs, and mental health have not been a focus in the multiple sclerosis (MS) literature. As a result, the challenges, needs, and perspectives of black women with MS are limited and deserve more scholarly attention, and a great need exists to help this underserved and under-researched population with their coping efforts. This study examined the effectiveness of a Brain-Based Education and Wellness (BE WELL) intervention on the coping flexibility of African American women with MS.

**Objectives:**
1. To learn about the conceptual framework for the BE WELL program.
2. To examine the effects of customized psychoeducation-based neurocounseling interventions on the coping flexibility of African American women with MS.
3. To assess participants' social validity ratings of the BE WELL intervention program.

**Methods:** An N=31 A/B/A single-case research design (SCRD) was used for this 12-week intervention study. Data were examined using both visual and statistical analysis. This involved using descriptive statistics including measures of central tendency and variability, autocorrelations, and regression analysis to look for trends. The G index was used to calculate effect sizes, and the nonparametric test Conservative Dual-Criteria (CDC) was used as a robust statistical analysis tool to compare the phases of each coping measure. Results: The participants were 4 African American women with MS ages 34 to 60. For 3 participants, “A,” “C,” and “I,” there were large-to-medium effect sizes (ES = 0.50 to ES = 1) for 1 or more coping measures in the baseline to withdrawal phase. For participant 2, “Y,” there was only a medium effect size for evaluation coping measures (ES = 0.20) from treatment to withdrawal phase. Participants’ social validity ratings from the ATT ranged from 87-98 indicating that each participant found the intervention to be valuable.

**Conclusions:** The customized BE WELL intervention seemed to have positive effects for each of the participants’ coping flexibility. Participant 2 was the exception as only slight effects were observed. For 3 participants, the most profound effects occurred in evaluation coping. Results from the ATT validated the findings from the visual and quantitative analysis as all participants’ ratings revealed that each participant experienced positive treatment effects from the BE WELL program.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Management of activities of daily living in MS, Psychological issues and MS

**PSF10** The Conformity of Masculine Norms and the Effects on Coping, Health Behaviors, and Quality of Life in Men with Multiple Sclerosis

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**Background:** The aim of the project is to explore how the conformity of masculine norms affects coping, health behaviors, and quality of life (QOL) in men with multiple sclerosis (MS). Despite some documented concerns of men with MS (eg, prognosis, QOL, targeted interventions) (Upton and Taylor, 2012), the specific conformity of socialized masculinity and QOL have less/worse coping, which will negatively impact QOL more than for men with lower scores on the masculinity inventory (Independent of coping ability). 3. Hypothesis: Higher scores on the masculinity inventory will produce lower/worse scores on health-related QOL. Subaim: Investigate the differential effect of coping and masculinity conformity on health behaviors. Methods: Participants in this study will include adult (18+ years) men with MS who are established patients at the Mellen Center (Cleveland Clinic). Demographic information (age, race, marital status, household income, education status) and clinical characteristics (years since MS diagnosis, Patient-Determined Disease Steps), and 5 patient-reported outcomes will be collected: The Conformity of Masculinity Inventory-46 which is a short version of the CMNI (Mahalik et al, 2003) will be used to assess the conformity to 9 masculine norms. Health-related QOL will be assessed with the PROMIS Global Health (Hays 2009). 1) The Ways of Coping Questionnaire (Lazarus and Folkman, 1985) will be used to measure coping. 2) Health behaviors will be measured using the Health Behaviors Inventory-20. 3) Disease impact will be evaluated using MS Performance Scales. Results: Research initiated January 2020. Results expected in spring of 2020. Conclusions: Research initiated January 2020. Results expected in spring of 2020. Supported by: None

**Disclosure:** Nothing to disclose

**Keywords:** Gender Issues, MS and the caregiver/family, Psychological issues and MS
**QUALITY OF LIFE AND OUTCOMES**

**(QOL01) Alemtuzumab Effects on Urogenital Function: Results Pooled From the CARE-MS 9-Year Functional Assessment of Multiple Sclerosis Quality-of-Life Survey**

**Authors:** Aaron Boster, Rafael Arroyo, Antonio Bertolotto, Samuel F. Hunter, Carolina Ionete, Bart van Wijmersch, Ericka M. Bueno, Nadia Daizadah, Elizabeth M. Poole, Bhuendrap R. Khattar

**Background:** There are approximately 100,000 Canadians with multiple sclerosis (MS), a condition that is 3 times more likely to affect women compared to men. Existing evidence proposes that women may experience disability, social determinants of health, and their overall health differently than men. Therefore, current evidence may benefit from researchers exploring gender as a category for investigating phenomena related to health. The World Health Organization defines health as physical, mental, and social well-being and is underpinning the exploration of health in women with MS for this study. Limited evidence is presently available as to how women in Canada with MS experience their health through physical, social, and mental well-being.

**Objectives:** The purpose of this hermeneutic phenomenological study is to understand the essence of the lived experiences of women affected by MS living in Southern Ontario, Canada, for health in the context of physical, social, and mental well-being. **Methods:** van Manen’s hermeneutic phenomenological approach was used to explore the experience of health through the context of physical, social, and mental well-being for participants. Participants included 20 women affected by MS living in Southern Ontario, Canada, who were interviewed using semistructured interview guides. The audio-recorded, transcribed, and analyzed using van Manen’s interpretive phenomenological approach, which consists of extracting significant statements and themes for the investigated phenomena. **Results:** Preliminary results from this study will be presented at this conference as to how women experience health through their well-being and will be discussed in an oral presentation.

**Conclusions:** A preliminary overview of the findings of health through the context of social well-being, such as barriers or factors that promote the overall health and well-being for women affected by MS, will be presented. Further exploration as to how social well-being and various social determinants of health affect health through the context of physical, social, and mental well-being is needed to further extrapolate these preliminary findings of the study.

**Supported by:** None

**Disclosure:** Nothing to disclose

**Keywords:** Comprehensive care and MS, Nursing management in MS, Self-care and MS

**(QOL02) The Impact of Relapses on Quality of Life in Patients with Neuromyelitis Optica Spectrum Disorder: Data from the Phase 3 PREVENT Study**

**Authors:** Achim Berthele, Michael Levy, Karissa Johns, Megan Harwood, Adrian Kielhorn, Kim night Calabrese, Joaquim Polack

**Background:** There are approximately 100,000 Canadians with multiple sclerosis (MS), a condition that is 3 times more likely to affect women compared to men. Existing evidence proposes that women may experience disability, social determinants of health, and their overall health differently than men. Therefore, current evidence may benefit from researchers exploring gender as a category for investigating phenomena related to health. The World Health Organization defines health as physical, mental, and social well-being and is underpinning the exploration of health in women with MS for this study. Limited evidence is presently available as to how women in Canada with MS experience their health through physical, social, and mental well-being.

**Objectives:** To evaluate the effect of relapse on QOL in patients with NMOSD, using data from the phase 3 PREVENT study. **Methods:** Patients’ health-related QOL was assessed using the EuroQol 5-Dimensions questionnaire (EQ-5D) and the Medical Outcomes Study ShortForm (36-item) Health Survey (SF-36), with higher values in both indicating better health-related QOL. In the current post hoc analysis, data from the ecuizumab and placebo groups were pooled and the last observation carried forward and an adjudicated relapse was defined as a relapse event that occurred after the last evaluation for a given patient. Relapse scores were compared (at relapse level) with postrelapse scores (recorded ≥30 days after relapse) using a paired t test. **Results:** In the absence of relapse, EQ-5D and SF-36 scores were stable over time, as expected. Mean scores before (n = 24) and after (n = 22) relapse were EQ-5D index (possible range 0-1): 0.656 and 0.595, respectively (pre-post difference, 0.067; P = .012); EQ-5D visual analog scale score (possible range 0-100): 60.458 and 56.500, respectively (pre-post difference, 4.257).
Beyond the immediate relapse period, are associated with a significant reduction in certain aspects of QOL beyond the immediate relapse period. There were significant differences between pre- and postrelapse scores in the SF-36 domains of bodily pain (P = .027), physical functioning (P = .007), role-emotional (P = .021), and vitality (P = .025). Conclusions: This analysis suggests that relapses in patients with NMOSD are associated with a significant reduction in certain aspects of QOL beyond the immediate relapse period.

Supported by: None

Disclosure: Aashin Berthele: Alexion Pharmaceuticals (consulting fee, contracted research, fees for non-CME/CE services received directly from commercial interest or its agent, speakers’ bureau). Michael Levy: Alexion Pharmaceuticals (consulting fee, contracted research, fees for non-CME/CE services received directly from commercial interest or its agent); Genentech; Quest Diagnostics, Viola Bio (consulting fee, fees for non-CME/CE services received directly from commercial interest or its agent). Karissa Johnson, Megan Hartwood: Nothing to disclose. Adriaan Kielhuis, Minying Ruyan: Alexion Pharmaceuticals (salary). Guido Subatella: Alexion Pharmaceuticals (ownership interest, salary). Jacqueline Palcey-Bigon, Chingai (contracted research); LEK, Via Bio, Guidepoint (consulting fee); Merck Serono (meeting/lecture/workshop participation); Novartis, Roche, Argent (speakers’ bureau); UCB, Via Bio, Roche (conference/lecture participation).

Keywords: Quality of life in NMOSD

(QOL04) Understand Common Multiple Sclerosis Symptoms Experienced Among MS Patients Participating in an Online MS Community

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Background: People with multiple sclerosis (MS) often seek perspectives and support from each other by connecting on patient social networks. These organic interactions provide unfiltered, rich insight into the day-to-day challenges and needs of patients, including both the emotional and physical issues they face. Directly understanding the holistic impact of MS on patients is crucial to treating patients, including improving doctor-patient communication and enabling HCPs to better support patients with MS. Objectives: Leverage the largest MS patient social network in the world to understand the most prevalent symptoms of patients with MS as they reach out to one another for information and support. Methods: Research conducted on de-identified organic discussions within MyM-Steem.com, a social network of >127,000 people with MS in the United States. Using natural language processing, 178,884verbatim discussions from April-September 2019 were analyzed. Key themes were identified and used to determine common symptoms and sentiment. Results: 40% of the discussions were about symptoms, which were highly negative (60%). Most prevalent discussion was pain (35% of symptom discussions), especially leg pain. While members turned to medicines such as gabapentin, they also sought out less traditional approaches like CBD in search of pain relief. Other common symptoms discussed included mobility issues and fatigue, but also the emotional impact of MS (depression and anxiety). While slowing MS progression is being addressed by their health care provider, MS symptoms were often not being treated, especially depression and anxiety. Conclusions: Understanding the physical and emotional symptoms that accompany MS but that are not always shared between patients and their doctors can help health care providers provide a more holistic approach to treating patients with MS. This includes helping patients with MS understand what symptoms they are likely to experience and how they can mitigate them.

Supported by: None

Disclosure: Beth Schneider, MyHealthTeams (contracted research).

Keywords: Comprehensive care and MS, Management of activities of daily living in MS, Psychological issues and MS

(QOL06) System-Level Variation in All-Cause Hospitalizations in Multiple Sclerosis: Year-1 Results of the Multiple Sclerosis Continuous Quality Improvement (MS-CQI) Research Collaborative

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Background: Multiple Sclerosis Continuous Quality Improvement (MS-CQI) is the first randomized, multicenter, prospective, longitudinal, systems-level, improvement science research study for multiple sclerosis (MS). MS-CQI is a 3-year study of system-level variation in performance outcomes, and leverages benchmarking to inform improvement using an informatics-enabled learning health system approach. MS-CQI collects 11 electronic health record (EHR) outcome measures longitudinally, including MS treatment, all-cause emergency department utilization, and all-cause hospitalizations. We also collect demographic information and comorbidities. Objectives: To describe year-1 baseline/preintervention level findings on system-level variation in selected clinical outcomes for individual sites, between sites, and for MS-CQI collectively. Methods: Four US MS centers are participating in MS-CQI: an urban academic center, a rural academic center, a rural community hospital, and a large urban private practice (total N = 5000 persons with MS). We collected approximately 7500 clinical measures abstracted from EHR data in year 1 from nearly 3000 clinical encounters. Demographic characteristics and longitudinal variation in measures did not vary significantly between sites. Encounter volume between centers was similar. We used analysis of variance, multiple regression, and maximum likelihood estimation methods to conduct inferential analyses. Results: Univariate analysis found significant differences (P < .05) between sites for multiple clinical outcomes including exacerbations, disease-modifying treatment, magnetic resonance imaging utilization, emergency department utilization, and hospitalizations. Controlling for individual level factors, including comorbidities, significant site (system-level) effects were found for all-cause hospitalizations, with comparator sites demonstrating odds ratios ranging as high as 2.4 (95% CI: 1.34, 4.4). Conclusions: We found that significant geographic system-level variation in MS outcomes exists for all-cause hospitalizations for people with MS followed by participating MS-CQI centers. Findings suggest that a focus on system-level variation and improvement may be needed to reduce all-cause hospitalizations for people with MS.
(QQL07) Relapse Rate is Influenced by System-Level Variation: Year-2 Results of the Multiple Sclerosis Continuous Quality Improvement (MS-CQI) Research Collaborative
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Background: Multiple Sclerosis Continuous Quality Improvement (MS-CQI) is the first multicenter improvement science research collaborative for multiple sclerosis (MS), and includes a systems-level study of variation in MS outcomes. MS-CQI is a 3-year study that leverages benchmarking results to inform system-level improvement efforts targeting clinical outcomes using an informatics-enabled learning health system approach.

Objectives: Here we present relapse rate results for year 1 (baseline/preintervention) compared to year 2 (first year of intervention). We also describe system-level variation in relapse rate for individual sites, between sites, and for MS-CQI collectively.

Methods: We collect administrative data on 1,121 clients with an electronic health record (EHR) outcome measures, longitudinally across 4 clinical MS care centers in the United States. We conduct statistical process control analyses for benchmarking. Logistic regression and maximum likelihood estimation methods are used for inferential analyses.

Results: Four US MS centers are participating: an urban academic center (n = 1000), a rural academic center (n = 1000) with the community hospital (n = 1500), and an urban private practice (1500), following a total N = 5000 persons with MS. We have collected approximately 7200 clinical encounter measures from EHR data in year 1 and 10,000 in year 2. Demographic characteristics and longitudinal variation in measures did not vary significantly between sites. For year 1, center-specific proportions of persons with MS with at least 1 relapse ranged from 5.16% to 17.5% in 2017. Mean relapse rate varied significantly (P < .01) across all centers. SPC analyses demonstrate a MS-CQI reduction of relapse rate from 11.5% (year 1) to 4.3% (year 2). Two sites were below the MS-CQI average of 7% (3.3%, 6.3%), and 2 were above the average (8.5%, 10.3%). Controlling for individual factors and covariates, logistic regression indicates significant improvements in relapse rate in year 1, with comparator sites demonstrating odds ratios as high as 2.61 (95% CI: 1.8, 3.8).

Conclusions: MS-CQI has observed a significant reduction in population-level relapse rate by 7.2% during the first year of quality improvement intervention. We also found significant geographic system-level variation in MS relapse, suggesting that a focus on system-level variation and improvement may be needed to optimize outcomes.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Comprehensive care and MS, Improvement science in MS

(QQL09) Living with Secondary Progressive MS: Results from an MS Coalition Survey
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Background: Many people diagnosed with relapsing multiple sclerosis (MS) will eventually transition to secondary progressive MS (SPMS). Until recently, only mitoxantrone had been approved by the US Food and Drug Administration as a disease-modifying therapy (DMT) for this MS subtype. In 2018, however, the agency accepted an application for siponimod for MS (RRMS) and has been associated with improved cognitive function and prevention of brain atrophy and improvement in SPMS symptoms. Side effects and long-term risks topped the list of reasons respondents gave for why they might not stay on a new drug. In responses to open-ended questions about impacts on daily life and family, common themes related to isolation, burden on family members, stress, and loss of mobility.

Conclusions: Our respondents with SPMS described experiencing profound challenges, and their information provides insights into target areas of unmet need warranting continued therapeutic development.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Disease-modifying treatments in MS, Management of activities of daily living in MS, and the caregiver/family

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Background: Pulse therapy is the preferred therapy for treatment of multiple sclerosis (MS) outbreaks, which is a neurologic, demyelinating, and inflammatory condition, with intermittent periods of outbreak-remission. The recommendation is corticosteroid doses (500 mg to 1 g), every 3-5 days, administered at the hospital, as an inpatient, or as outpatient at an infusion clinic. The treatment reduces the inflammation during the outbreak phase of the MS and seeks to stabilize the crisis. Despite their adverse effects, the glucocorticoids are potent anti-inflammatories in the treatment of autoimmune pathologies. The glucocorticoids block the entrance of glucose in the tissues and increase the proteolysis, decreasing their synthesis in muscles, skin, bones, connective tissue, fat cells, and lymphoid tissue. Before the pulse therapy, it is important to eliminate the possibility of an active infection and to always administer the antiparasitic to control possible infestations. Checking the blood pressure, body weight and capillary glucose are very important during the infusion. Daily checks pre- and postinfusion are required as hyperglycemia may occur as an adverse effect of the therapy. The capillary blood glucose check is a blood test that gives immediate results about glucose concentration in the capillaries and the digital pulp. Objectives: to describe a protocol for puncture site rotation for the capillary blood glucose test performed during pulse therapy. Methods: The rotation protocol was established for the digital pulp punctures. The patient is directed to properly wash the hands and dry well. The nurse professional punctures the selected site on the right or left side of the distal phalanx of the finger chosen for the test, by alternating the puncture sites, and records the date, time, location and blood glucose value. Results: Not applicable. No complications were reported. Conclusions: The introduction of a protocol for puncture site rotation, based on a simple code, assists in the communication between nursing professionals and promotes patient safety. The protocol allowed the participation and cooperation of the client thus establishing self-care.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Comprehensive care and MS, Hyperglycemia, Nursing management in MS

(QQL11) Natalizumab Is Associated with Improvement in Cognitive Processing Speed and Health-Related Quality of Life: STRIVE 4-Year Results
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1Well Cornell Medical College, Cornell University, New York, NY; 2Northwestern University, Chicago, IL; 3New York University School of Medicine, New York, NY; 4Biogen, Maidenhead, MA, United Kingdom; 5Biogen, Cambridge, MA; 6Biogen (at time of this analysis), Cambridge, MA; 7Mellen Center for Multiple Sclerosis, Cleveland Clinic, Cleveland, OH

Background: Multiple sclerosis (MS) negatively affects cognitive function and quality of life (QoL), interfering with a patient’s ability to work, pursue leisure activities, and perform activities of daily living. Natalizumab is a highly effective treatment for patients with relapsing-remitting MS (RRMS) and has been associated with improved cognitive function

About three-fourths chose “fewer available treatment options” (78%) and “longer line of quality of life” (72%) as impacts associated with their form of MS. Regarding use of DMTs, 37% reported no current use, and 22% indicated that they were taking Ocrevus. The other DMTs included in the survey were each used by fewer than 10% of respondents. When asked to consider a hypothetical new drug for SPMS, respondents expressed broad interest in possible benefits the drug could provide, including prevention of brain atrophy and improvement in SPMS symptoms. Side effects and long-term risks topped the list of reasons respondents gave for why they might not stay on a new drug. In responses to open-ended questions about impacts on daily life and family, common themes related to isolation, burden on family members, stress, and loss of mobility.

Conclusions: Our respondents with SPHS described experiencing profound challenges, and their information provides insights into target areas of unmet need warranting continued therapeutic development.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Disease-modifying treatments in MS, Management of activities of daily living in MS, and the caregiver/family

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Posters: Quality of Life and Outcomes

QOL13 Multiple Schleezer Patient Perspectives: Impact on Employment
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Background: Multiple sclerosis (MS) is a progressive neurologic disease that can significantly affect quality of life (QoL). In 2018 a roundtable meeting of patient representatives, PWMS, carers, and MS nurses agreed on key themes associated with maintaining independence. In 2019, an official project steering group formed, and 2 studies for PWMS were co-developed: a qualitative online patient community activity and a quantitative online survey. The qualitative activity used Ipsos’ Syndicated MS Online Patient Community (a consistent panel of PWMS), and the quantitative survey was recruited through the MS Trust monthly newsletter and Facebook group. Results were discussed and prioritized by the steering group. Findings from our study highlight the impact of MS on working life among participants. It is important to understand these issues in the wider MS population to prevent problems at work and future loss of work.

Supported by: None

Disclosure: Jessica O’Neill, Roche Products Ltd (works for). Mavis G. Ayer, Biogen, Roche (sponsored delegate); Celgene, Merck, Novartis, Sanofi (consulting fee); Teva (sponsored education). Samantha R. Colhoun, Alison Thomson: Biogen, Novartis, Roche Products Ltd (consulting fee). Nicola Daykin: Roche Products Ltd (consulting fee). Brenda Hamill: Biogen, Novartis (sponsored delegate); Roche (consulting fee). Maria Fei: Roche Products Ltd (works for Ipsos MORI, which was funded by Roche to undertake this research). Jordanne Florio: Roche Products Ltd (works for). Serena Pulciní: Roche Products Ltd (works for).

Keywords: Disease education, Employment in MS, Management of activities of daily living in MS, Patient education

QOL12 Multiple Schleezer Patients’ Perspectives: Disease Education and Communication Needs
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Background: Multiple sclerosis (MS) is a progressive neurologic disease that can significantly affect quality of life (QoL). In recent years there has been a shift towards increased patient engagement to inform person-centered care. It is therefore important that people with MS (PWMS) are equipped with the knowledge needed for informed, shared decision making and maintaining independence outside of a formal care setting. Objective: This study aimed to identify unmet disease education and communication needs in PWMS to empower informed decisions, enable self-management, and to maintain independence for as long as possible. In particular, we sought to gain an understanding of the impact of MS on employment and highlight the main challenges for people to remain in work. Methods: In October 2018 a roundtable meeting of patient representatives, PWMS, carers, and MS nurses agreed on key themes associated with maintaining independence. In 2019, an official project steering group formed, and 2 studies for PWMS were co-developed: a qualitative online patient community activity and a quantitative online survey. The qualitative activity used Ipsos’ Syndicated MS Online Patient Community (a consistent panel of PWMS), and the quantitative survey was recruited through the MS Trust monthly newsletter and Facebook group. Results were discussed and prioritized by the steering group. Findings from our study highlight the impact of MS on working life among participants. It is important to understand these issues in the wider MS population to prevent problems at work and future loss of work.

Supported by: None

Disclosure: Jessica O’Neill, Roche Products Ltd (works for). Mavis G. Ayer, Biogen, Roche (sponsored delegate); Celgene, Merck, Novartis, Sanofi (consulting fee); Teva (sponsored education). Samantha R. Colhoun, Alison Thomson: Biogen, Novartis, Roche Products Ltd (consulting fee). Nicola Daykin: Roche Products Ltd (consulting fee). Brenda Hamill: Biogen, Novartis (sponsored delegate); Roche (consulting fee). Maria Fei: Roche Products Ltd (works for Ipsos MORI, which was funded by Roche to undertake this research). Jordanne Florio: Roche Products Ltd (works for). Serena Pulciní: Roche Products Ltd (works for).

Keywords: Disease education, Employment in MS, Management of activities of daily living in MS
Determining the Relationship of Demographic and Clinical Variables with Fatigue in Multiple Sclerosis, Using the 5-Item Modified Fatigue Impact Scale (MFIS-5)

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Background: Fatigue is reported as one of the most prevalent and disabling symptoms in patients with multiple sclerosis (MS). The Modified Fatigue Impact Scale (MFIS) is the most widely used tool that quantifies the degree of fatigue in relation to its impact on physical, cognitive, and psychosocial functioning. A recent article by Rooney et al has provided an improved understanding of the relationship of a variety of both clinical and demographic variables with the impact of fatigue on MS using the MFIS. To our knowledge, such a robust comparison has not been reported using the shortened version, the MFIS-5.

Objectives: To determine the association between the impact of fatigue and demographics and clinical characteristics among persons with MS (PwMS).

Methods: This was a secondary analysis of a cross-sectional study of 253 PwMS. Demographic variables included age, gender, race (white/nonwhite), smoking status (smoker/nonsmoker), and employment status (employed/unemployed). Clinical characteristics included disease duration (DD), body mass index (BMI), level of disability (Patient-Determined Disease Steps [PDDS]), depression (Center for Epidemiologic Studies–Depression Scale [CES-D]), cognitive processing speed (Symbol Digit Modalities Test [SDMT]), and use of disease-modifying therapy (DMT [on a DMT/not on DMT]). All measures, including fatigue impact (MFIS-5), were collected at a single visit. Spearman correlation coefficient was used to determine the strength of the associations and Mann-Whitney U for comparison.

Results: The sample had a mean age of 48.6 ± 11.6 (range: 20-73) years, DD of 12.3 ± 8.7 (1-47) years, PDDS score of 2.7 ± 2.1 (range: 0-7), BMI of 28.9 ± 7.2 (range: 17.5-59.8), and MFIS-5 score of 9.6 ± 5.3 (range: 0-20). This sample was mostly female (75.9%), with relapsing MS (94.5%), unemployed (51.1%), white (84.5%), nonsmokers (84.9%), and on a DMT (83.8%). Fatigue impact was moderately correlated with disability (r = 0.571, P = .000) and depression (r = 0.552, P = .000) and weakly associated to age (r = 0.173, P = .000) and SDMT (r = -0.297, P = 0.000). No relationship was observed with DD or BMI. No difference was observed among dichotomized variables of gender, race, smoking status, or use of a DMT. However, the impact of fatigue was found to be different (P = .000) between those employed (median MFIS-5 score: 8) and unemployed (median MFIS-5 score: 12). Conclusions: Our study demonstrated that fatigue, as assessed by the MFIS-5, is associated with higher disability, depression, age, and decreased cognition and is greater among unemployed PwMS. Given its ease of administration, the MFIS-5 serves as a practical measure for assessing the impact of fatigue on MS fatigue in clinical settings. The current study provides increased understanding of its relationship with various clinical and demographic variables.

Supported by: None


Mary Bailey: Alexion, Biogen, Genentech, Genzyme, Novartis (speakers’ bureaus); Celgene (consulting fee).

Keywords: Comprehensive care and MS, Equipment in MS, Natural history of MS

Multiple Sclerosis Management and Expanded Disability Status Scale: A Great Start, but a Reason for Change Was Never So Apparent and Needed

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Background: Since the Expanded Disability Status Scale (EDSS) was pioneered by Dr John Kurtzke in 1967, it has been incorporated into clinical trial measurements in people with multiple sclerosis (PwMS). When combined with reported relapse rates and magnetic resonance imaging measurements of disease activity, EDSS has been the basis for approval of >15 disease-modifying therapies (DMTs). No evidence of disease activity (NEDA) has been proposed as the goal for optimizing DMT. EDSS remains a critical tool for both NEDA and treatment. Use of a nonlinear scale to measure disability can be problematic if there is great variability of PwMS within homologous EDSS-defined disability levels. Functional ability reflects the combined impact of cognitive function, manual dexterity, ambulation, and other factors. If the degree of variability of these “abilities” exceeds 20%, this scale would no longer be valid.

Objectives: To examine combined variability of EDSS, combined variability of similar disability across important aspects of ability.

Methods: Retrospective review of prospective registry of PwMS who were evaluated by multidimensional computerized cognitive testing, digital gait analysis, and patient-reported outcomes (PROs) for hand function that had simultaneous measurements of PDDS, EDSS, and SDMT.

Results: Among 95 PwMS, 73% female, age 46 ± 10, multidimensional computerized cognitive testing global summary score of 7 domains had adjacent EDSS score overlap (0.25, 3.45, 5.65, and >7) of 65% and extreme EDSS group overlap was 42%. Accumulative cognitive impairment (# cognitive domains impaired >1 EDSS) was 72% across adjacent EDSS groups, and extreme EDSS group overlap was 38%. 254 PwMS, 72% female, age 46 ± 10, mean normalized velocity for preferred walking speed varied >20% within EDSS groups (A: 0.25 [24%], B: 3.45 [34%], C: 5.65 [53%]) and overlapped >20% (AB: 29%, BC: 25%). 783 PwMS, 74% female, age 49 ± 11, completed PROs and NARCOMS PRO for both hand function and tremor demonstrated variability >50% across all EDSS (0-2.4, >4) and overlap >50% of adjacent PDDS groups and >32% across extreme PDDS groups.

Conclusions: While the EDSS greatly advanced the treatment of MS, the degree of variability of disease impact within and across disability groups warrants immediate abandonment of this measure of care.

This should be replaced by clinical trials with objective patient-centric multidimensional measures of disease impact to improve treatment selection and monitoring for progression.

Supported by: None

Disclosure: Mark Gudesblatt: Acorda, Agenon, Medtronic, Solar Therapeutics (speakers’ bureau); Biogen, EMD Serono, Novartis, Sanofi, Tesa (contracted research). Jared Srinivasan, Olivia Kaczmarek, Taylor Drost, Lori Enforl, Kaitlyn Jaenicke, Daniel Golon, Timothy Fratto: Nothing to disclose. Barbara Bumsted, Marjorie Bah, Biogen, Genzyme (speakers’ bureau). Natasha Zarif: Acorda, Biogen, Genzyme, Tesa (speakers’ bureau). Jeffrey Wilken: Biogen (contracted research); EMD Serono (contracted research, speakers’ bureau). Cynthia Sullivan: Roche (contracted research). Gavin Giovannianni: AbbVie, Bayer Schering, Biogen, Canbex, Eisai, Elan, Five Prime, Genetech, Sanofi Genzyme, GlaxoSmithKline, GW Pharmaceuticals, Ironwood, Merck Serono, Novartis, Pfizer, Roche, Synthon BV, Tesa (consulting fee); Multiple Sclerosis and Related Disorders (Eliever) (co-chief editor); UCB Pharma (grants).

Keywords: Comprehensive care and MS, Equipment in MS, Natural history of MS

A Coach-Supported Standardized Approach for Quality Improvement (QI) in the Multiple Sclerosis Continuous Quality Improvement (MS-CQI) Research Collaborative

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Background: Multiple Sclerosis Continuous Quality Improvement (MS-CQI) is the first randomized, multicenter, prospective, longitudinal, randomized, systems-level, improvement science research collaborative for multiple sclerosis (MS). MS-CQI is a 3-year study of system-level variation in performance outcomes, and leverages performance benchmarking to inform improvement using an informational learning health system approach. MS-CQI has 3 components: 1) collection and reporting of benchmarking data, 11 clinical outcome and 21 patient-reported outcome measures; 2) a quality improvement (QI) coach-supported QI intervention utilizing a standardized tool Kit; and 3) a 3-year, step-wedge randomized study to test the effect of QI vs control on MS health outcomes. Four MS centers are participating: an urban academic center, a rural academic center, a rural community hospital, and a large urban private practice (total N = 5000).

Objectives: Describe system readiness to engage in QI and characteristics of MS centers randomized to coach-supported QI intervention. Methods: MS-CQI centers randomized to QI participate in site visits and 5 MS-CQI tool Kits. QIs use MS-CQI benchmarking data, local level data, and a standardized QI Tool Kit to develop their improvement theme and improvements. The QI coach conducts regular assessments of team QI knowledge, skills, attitudes, and readiness to engage in QI work at monthly intervals, including QI readiness self-assessment and readiness for multiple sclerosis (MS). MS-CQI is a 3-year study of system-level variation in performance outcomes, and leverages performance benchmarking to inform improvement using an informational learning health system approach. MS-CQI has 3 components: 1) collection and reporting of benchmarking data, 11 clinical outcome and 21 patient-reported outcome measures; 2) a quality improvement (QI) coach-supported QI intervention utilizing a standardized tool Kit; and 3) a 3-year, step-wedge randomized study to test the effect of QI vs control on MS health outcomes. Four MS centers are participating: an urban academic center, a rural academic center, a rural community hospital, and a large urban private practice (total N = 5000).

Objectives: Describe system readiness to engage in QI and characteristics of MS centers randomized to coach-supported QI intervention. Methods: MS-CQI centers randomized to QI participate in site visits and 5 MS-CQI tool Kits. QIs use MS-CQI benchmarking data, local level data, and a standardized QI Tool Kit to develop their improvement theme and improvements. The QI coach conducts regular assessments of team QI knowledge, skills, attitudes, and readiness to engage in QI work at monthly intervals, including QI assessment scales (IRI Improvement Progress and QI Knowledge Application and Skills). Results: MS-CQI is in year 3. One center was randomized...
to QI in year 2 [private for profit] of the study, and 2 centers were ran-
domized (1 rural, 1 urban academic) in year 3. Site teams have identified QI foci including patient access, patient orientation, previsit planning, social work and behavioral health, and emergency room utilization. The teams are showing progress in their QI culture and development; IHI Improvement Progress Scale scores have changed from initial score of 1.5 (planning for the project has begun) to 3.5 (some improvements in measurements and outcomes, and continuing to improve). MS center teams randomized to intervention in MS-CQI have successfully engaged in the coach-supported QI intervention. Site readiness and capa-
bility assessments reveal a greater understanding of their QI needs and a standard and consistent approach to improvement suggesting an initial positive response to the intervention.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Comprehensive care and MS, Nursing management in MS, Quality improvement

(QOL18) Does Participation in a 6-Week Mindfulness Course Improve Mood and Overall Emotional Wellness for People Living with Multiple Sclerosis?

Tiffany Malone,¹ Lacey Sayre,¹ Brian Hutchinson²

Background: People with multiple sclerosis (MS) often experience emotional distress about the life they had prior to the diagnosis of MS and what that diagnosis means for their future. The Multiple Sclerosis Achieve-
ment Center (MSAC) conducts day wellness programs to address physi-
cal, cognitive, and social well-being. Program activities include exercise, brain training, education, socialization, and community outings. As part of the MSAC program, members have the opportunity to participate in a 6-week mindfulness course to address emotional wellness. Objectives: To determine, through the use of patient-reported outcomes (PROs), if members participating in the mindfulness course demonstrate improve-
ments in mood and overall emotional wellness. Methods: Members of the MSAC will be asked to complete 4 paper/pencil outcome measures in January 2020 as part of their annual participation in the MSAC’s program. Multiple Sclerosis Self-Efficacy Scale-10 item (MSSE), Multiple Sclerosis Self-Efficacy Scale-10 item (MSSE), Greer Leisure-Time Exercise Questionnaire (GTLEG), and Neuro-Qol (Anxiety, Depression, Emotion & Behavior, Positive Affect, Cognition, Ability to Participate, and Social Roles sections are used). Members will be offered the opportunity to participate in a professionally facilitated 6-week mindfulness course, starting in January 2020, to provide education, strategies, resources, and emotional support to achieve what they need and/or want for the present moment. Participants of the mindfulness course will be asked to complete PRO measures upon completion of the course. Results: One-year and 2-year comparison data of PROs, from MSAC members, have indicated correlation between self-efficacy, Anxiety, Ability to Participate, and Positive Affect (per MSSE & Neuro-Qol). Additionally, increased MSIS-29 scores directly correlate with anxiety while inversely correlating with self-efficacy and GTLEG. Mean scores of depression, reported from the Neuro-Qol, remained the same (x = 48) over a 2-year reporting period. These comparisons did not specifically measure a member’s participation in the mindfulness course. Conclusions: Data collection and analysis will be completed for those members participating in the 6-week mindful-
ness course. Analysis will include pre and post measures, as well as com-
parison with those not participating in the mindfulness course.

Supported by: None


Keywords: Mindfulness

(REH01) Assistive Technology for Progressive Deficits in Communication and Access in People with Advanced Multiple Sclerosis: Case Studies in Iterative Design

Alexander Burnham

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Background: People with advanced multiple sclerosis (PWAMS; Expanded Disability Status Scale score > 6.5) can experience dynamic and progressive changes in motor speech intelligibility, vocal projection, and upper extremity control and coordination, which can interfere with access to typical expressive communication modalities (eg, telephone and computer access). In most cases, assistive technology (AT) can be useful in supplementing or replacing these functions to promote effective communication with partners and caregivers to maximize functional communica-
tion independence with minimal need for caregiver assistance. Objectives: Participants will have the opportunity to understand how PWAMS can maximize functional independence with appropriate and supported access to AT. Participants will recognize how increasingly mainstream and ubiquitous technology can be modified and interfaced with more customized AT to meet unique access challenges in the MS population. Participants will have a better understanding of how nursing and allied health/rehabilitation disciplines can collaboratively support PWAMS to complete electronic activities of daily living even in the presence of severe motor disability. Methods: This case series will describe the experiences of 3 PWAMS at the Boston Home, a specialized residence for individuals with advanced neurodegenerative disorders, who have benefited from using AT with ongoing customization and intervention to adapt the tech-
nology as appropriate to accommodate for multiple sclerosis–associated progressive motor, sensory, and cognitive deficits using currently available AT and literature. The past 5 years for PWAMS will demonstrate concepts of iterative design as motor access to augmentative communication devices deteriorated; another will illustrate accommodations to speech-recognition technology despite progressive dysarthria; the third highlights cumulative adaptations to nurse call and speakerphone access options to compen-
sate for worsening hypophonia and quadriplegia in order to maintain contact with remote family and caregivers. Photos of the applied AT will

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sate for worsening hypophonia and quadriplegia in order to maintain contact with remote family and caregivers. Photos of the applied AT will...
illustrate how postural limitations and desire for wheeled mobility guided the decisions made for selecting and modifying systems to meet the needs of the users. The roles of rehabilitation, nursing, and adaptive technology specialists in developing, modifying, and implementing appropriate iterations of communication AT in this particular care setting will be described as part of the interdisciplinary team caring for this cohort of PwAMS. Results: Recommendations for providing caregiver education and training for their families and considerations for designing, implementing, and adapting communication AT for PwAMS in other residential environments will be discussed. Outcomes in terms of satisfaction with AT access, services, and devices from PwAMS and caregivers will also be described using formal and informal assessment options. Conclusions: NA. Supported by: None

Disclosure: Alexander Burnham: The Boston Home (salary). Lisa Doyle, Min H. Huang, Donna Fry: Rehabilitation Services, The Boston Home, Boston, MA; Physical Therapy, Franklin Pierce University, Manchester, NH; University of Michigan–Flint, Flint, MI

Keywords: Comprehensive care and MS, Equipment in MS, Management of activities of daily living in MS

(REHO2) Predictors of Improvement in Respiratory Function Following Resistive Inspiratory Muscle Training in Advanced Multiple Sclerosis

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1Rehabilitation Services, The Boston Home, Boston, MA; 2Physical Therapy, Franklin Pierce University, Manchester, NH; 3University of Michigan–Flint, Flint, MI

Background: Respiratory compromise in people with advanced multiple sclerosis (PwAMS = Expanded Disability Status Scale [EDSS] score ≥ 6.5) worsens as the disease progresses and is a major cause of morbidity and mortality. There is evidence that exercise can improve respiratory muscle function in PwAMS even in later stages of the disease. Objectives: It is not known if certain characteristics of PwAMS contribute to their ability to benefit from a respiratory exercise program. This study identified some possible predictive factors. Methods: Thirty-eight subjects were recruited at a SNF specializing in care for PwAMS. Inclusion criteria were age > 18, multiple sclerosis (MS) diagnosis, and EDSS score ≥ 6.5. The current study used a repeated measures within-subject design in which participants performed 3 sets of 15 repetitions of resistive inspiratory muscle exercises daily for 10 weeks using the Threshold Inspiratory Muscle Trainer (IMT). Demographics, number of comorbidities, body mass index (BMI), EDSS score, and years post–MS diagnosis were obtained at the time of enrollment. Maximum inspiratory pressure (MIP) and maximum expiratory pressure were obtained as measurements of respiratory muscle strength at several intervals over the 28-week duration of the study, including 10-week baseline phase, 10-week intervention phase, and 8-week retention period postintervention. Progression of IMT resistance was adjusted weekly by the research team based on symptoms, rate of perceived exertion, and baseline MIP. Secondary outcomes assessed included fatigue (evaluated with MFIS-5) and cognitive processing speed (measured with oral version of Symbol Digit Modalities Test [SDMT]). Results: Correlation analysis of baseline characteristics with MIP change scores (MIP-CS) was performed to identify potential predictors of improvements in MIP for the regression analysis. To identify more linear regression models with MIP-CS and predicted values (MIP-CLS) as dependent variables were constructed. The regression model with BMI, fatigue (MFIS-5), and cognition (SDMT) as independent variables and MIP-CS as the dependent variable was significant (F1,35 = 3.19, P = .041, R2 = 0.53). SDMT was a significant predictor in the model (P = .035) (higher SDMT scores significantly associated with better outcomes of IMT training). BMI as predictor approached significance (P = .056). The regression model with BMI, MFIS-5, and SDMT as independent variables and MIP-CLS as the dependent variable was significant (F1,35 = 3.19, P = .027, R2 = 0.55). BMI was a significant independent predictor in the model (P = .029), with higher BMI associated with worse outcomes with IMT training; SDMT as predictor approached significance (P = .053). Conclusions: Participant scores in BMI, MFIS-5, SDMT, and age/gender-adjusted MIP at baseline significantly predicted MIP-CS (F1,35 = 6.34, P = .001, R2 = 0.44, R2 adjusted = 0.37). Factors such as age, gender, duration of disease, EDSS score, and number of comorbidities were not significant predictors of MIP-CS.

Supported by: None

Disclosure: Nothing to disclose

Keywords: SLP intervention, Dysarthria

(REHO4) Daily Occupational Performance in Multiple Sclerosis

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Background: Multiple sclerosis (MS) is a chronic, inflammatory, and degenerative disease that affects the central nervous system. Occupational performance is often compromised and negatively impacts daily activities and activities. Objectives: To understand the perception of people affected by MS on occupational performance and identify the main difficulties in routine activities. Methods: 55 people with MS participated, being 40 (73%) women and 15 (27%) men, aged between 27 and 60 years. The 5 major impairments in occupational performance were observed, according to the degree of importance, according to the Canadian Occupational Therapy Manual (COTM), then the participants self-assessed their performances and satisfactions by means of a scale of 1 to 10 points. Results: The analyses revealed that participants considered their ability to perform routines and perform roles and tasks related to moderate to poor personal care, leisure, and productivity. Conclusions: Signs and symptoms of muscle weakness, fatigue, cognitive and visual changes, and sensitivity were determinant to impair occupational performance appropriate to the needs and interests of the participants. The evaluation of occupational therapy and the rehabilitation of disabilities facilitated the daily lives of people with MS.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Occupational therapy

(REHO5) Assessing the Benefits of Telehealth in Conjunction with a Fitbit to Improve Walking in Veterans with Multiple Sclerosis

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Background: Patients with multiple sclerosis (MS) often have limitations with mobility due to fatigue, weakness, and impairments with balance and coordination. Many of these patients decrease their activity and withdraw due to these limitations, which can lead to further deconditioning. Objectives: The objective of this study was to examine improvements in walking distance and perceived impact of walking ability in patients with MS using a Fitbit in conjunction with telehabilitation. Methods: Currently 2 patients are enrolled in pilot with ongoing recruitment. Patients are asked for a self-perception of daily step count at evaluation. The 2-minute walk test and 10-meter walk test are administered at initial evalu-
Minimize caregiver time, burden, and other costs.

Methods: 1) Extend specialty care from Neurology into Physical Medicine and Rehabilitation for Veterans with MS. 2) Determine the feasibility of the prioritizing exercise training studies in persons with MS that included both with MS based on a well-established conceptual model. This involved of exercise training as a neuroplasticity-inducing behavior in persons with progressive neurologic disease. Clinical video telehealth (CVT) provides these veterans with access to specialists for their condition and greatly improve adherence to a physical therapy rehability program. Finally, the ability to view an individual in their home environment gives providers the ability to problem solve physical challenges and safety issues that may be present in a person's home. Objectives: 1) Extend specialty care from Neurology into Physical Medicine and Rehabilitation for Veterans with MS. 2) Determine the feasibility of the CVT devices in a variety of settings. 3) Decrease travel hours and costs. 4) Minimize caregiver time, burden, and other costs. Methods: There were 19 veterans evaluated during the study period, 18 of whom were diagnosed with multiple sclerosis (MS) and 1 with amyotrophic lateral sclerosis (ALS). MS veterans were referred to PM&R physical therapy and evaluated by neurologic clinical specialist. They were evaluated before and after the intervention period using standardized functional outcome measures. Follow-up visits were scheduled at least once every week for 30-minute sessions and were re-evaluated every 30 days for up to 90 days. Veterans had the opportunity to extend their rehabilitation session for another 90 days if they were making improvements. Sessions took place with the clinical specialist in a private office with necessary rehabilitation equipment available for demonstration of exercises. Results: N = 18, 18 had preintervention assessments, and 10 patients agreed to participate. Four patients had a discharge visit where postintervention measures were collected. Total visits: 63. Travel miles saved: 6770 miles. Travel dollars saved: $3724. Conclusions: Telehealth visits for patients with progressive neuromuscular disease such as MS and ALS can be effective and feasible in an outpatient setting. There were no adverse effects, and this program resulted in a significant reduction in miles traveled and cost savings for veterans and the Veteran Health Administration. Barriers to adopting new technology were an issue for some veterans, and greater improvements were seen with those who incorporated new technology easily.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Complementary/alternative therapies in MS, MS and the caregiver/family

(REH06) Feasibility of Telehealth Rehabilitation for Veterans with Progressive Neuromuscular Disease

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Background: Individuals who live in rural communities have difficulty accessing specialized medical services such as physical therapy. Individuals with progressive neurologic diseases who do have access to physical therapy are limited to what is available in their community. Exercise is feasible and can improve fitness and improve quality of life for individuals with progressive neurologic disease. Clinical video telehealth (CVT) provides these veterans with access to specialists for their condition and significantly reduces the energy and financial costs of traveling to specific appointments. Barriers exist whether an individual lives in a rural community or within a few miles of a health center. Utilizing CVT can eliminate these barriers and greatly improve adherence to a physical therapy rehabilitation program. Finally, the ability to view an individual in their home environment gives providers the ability to problem solve physical challenges and safety issues that may be present in a person’s home. Objectives: 1) Extend specialty care from Neurology into Physical Medicine and Rehabilitation for Veterans with MS. 2) Determine the feasibility of the CVT devices in a variety of settings. 3) Decrease travel hours and costs. 4) Minimize caregiver time, burden, and other costs. Methods: There were 19 veterans evaluated during the study period, 18 of whom were diagnosed with multiple sclerosis (MS) and 1 with amyotrophic lateral sclerosis (ALS). MS veterans were referred to PM&R physical therapy and evaluated by neurologic clinical specialist. They were evaluated before and after the intervention period using standardized functional outcome measures. Follow-up visits were scheduled at least once every week for 30-minute sessions and were re-evaluated every 30 days for up to 90 days. Veterans had the opportunity to extend their rehabilitation session for another 90 days if they were making improvements. Sessions took place with the clinical specialist in a private office with necessary rehabilitation equipment available for demonstration of exercises. Results: N = 18, 18 had preintervention assessments, and 10 patients agreed to participate. Four patients had a discharge visit where postintervention measures were collected. Total visits: 63. Travel miles saved: 6770 miles. Travel dollars saved: $3724. Conclusions: Telehealth visits for patients with progressive neuromuscular disease such as MS and ALS can be effective and feasible in an outpatient setting. There were no adverse effects, and this program resulted in a significant reduction in miles traveled and cost savings for veterans and the Veteran Health Administration. Barriers to adopting new technology were an issue for some veterans, and greater improvements were seen with those who incorporated new technology easily.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Complementary/alternative therapies in MS, MS and the caregiver/family

(REH08) Aerobic Reserve in People with Multiple Sclerosis: Measurement and Correlates

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Background: The concept of aerobic reserve reflects the available potential energy to perform essential tasks to maintain independent living and is calculated by subtracting the energetic demand for activities of daily living from peak aerobic power. To date, the concept of aerobic reserve has not been applied in multiple sclerosis (MS), and there are no studies determining what a normal aerobic reserve is in this population. Objectives: This study described the measurement and correlates of aerobic reserve in MS. Methods: The sample included 23 people with MS who were fully ambulatory (median [range] Expanded Disability Status Scale [EDSS] score = 3.5 [2.0]). Participants completed a single session that included obtaining informed consent, EDSS examination, demographic questionnaire, as well as administration of the Symbol Digit Modalities Test (SDMT), Timed 25-Foot Walk Test (T25FW), 6-minute walk distance (6MWD), and a cardiopulmonary exercise test (CPET) performed on a treadmill (modified Balke protocol). Aerobic reserve was calculated by subtracting the patient’s steady-state VO₂ extracted during the first stage of the CPET from peak VO₂ obtained from the CPET. Results: Twenty-one of 23 participants met criteria for providing a maximal effort during the CPET. The mean (SD) aerobic reserve was 9.5 ± 3.7 mL/kg/min. Aerobic reserve strongly correlated with peak VO₂ (mean [SD], 22.4 ± 5.4 mL/kg/min), r = 0.77, P < .01. Aerobic reserve was positively correlated with SDMT raw score (mean [SD], 49.3 [±7.2]), r = 0.45, P = .03 and time to exhaustion in seconds on the CPET (mean [SD], 592.8 ± 205.5), r = 0.63, P < .01. Aerobic reserve was negatively correlated with resting heart rate (mean [SD], 79.4 [±11.5] bpm), r = −0.50, P = .02 and BMI (mean [SD], 29.6 [±5.8] kg/m²), r = −0.56, P < .01. Aerobic reserve did not correlate with age, sex, EDSS score, or T25FW or 6MWD results. Conclusions: Aerobic reserve can be measured during CPET in people with MS, and there might have implications for understanding somatic and functional outcomes in people with MS.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Aerobic exercise training, Complementary/alternative therapies in MS, Management of activities of daily living in MS

(REH09) The Impact of Vascular Comorbidities on Perceived Functional Impairment in Persons with Multiple Sclerosis

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Background: Persons with multiple sclerosis (PwMS) can have a number of comorbidities and secondary conditions, which can complicate care and negatively affect health-related quality of life. In particular, chronic vascular conditions, such as diabetes, hypertension, hyperlipidemia, and heart disease, have been associated with more rapid accumulation of irreversible disability in PwMS. However, little is known about the impact of co-occurring chronic vascular conditions on perceived functional impact in PwMS. Objectives: To examine differences between PwMS with and without vascular comorbidity with regards to their self-reported functional performance.

Methods: Participants (n = 257) were randomly selected PwMS who participated in the MS Characterization of Upper Extremity Functioning (MSCUE) study. The MS Impact Scale (MSIS-29) was used to measure perceived physical and psychological impact on daily life, while the Functional Status Index (FSI) was used to assess functional performance in 5 domains: gross mobility, hand activities, personal care, home chores, and social/role activities. Due to non-normally distributed data, Mann-Whitney U analyses were conducted to examine differences between PwMS with and without a vascular comorbidity, with effect size reported as r. Results: On average, PwMS were 48.72 ± 11.56 [0-73] years old and had MS for 12.40 ± 9.78 (1-47) years. A total of 112 of 257 (43%) PwMS had at least 1 co-occurring vascular condition, with hyperlipidemia (n = 72, 64.3%) and hypertension (n = 66, 58.9%) being the most common. PwMS with at least 1 vascular comorbidity reported higher levels of physical (r = -0.29, P < .001) and psychological impact (r = -0.16, P = .009), as well as more issues with gross mobility (r = -0.28, P < .001), hand activities (r = -0.17, P = .007), personal care (r = -0.19, P = .002), home chores (r = -0.24, P < .001), and social/role activities (r = -0.24, P < .001). Conclusions: PwMS with vascular comorbidity have worse perceived functional performance and physical and psychological well-being compared to PwMS without vascular comorbidity. These findings suggest that the presence of chronic vascular conditions in PwMS negatively affects perceived functioning, which has important implications for provision of care and quality of life for PwMS who are care unresponsive to the mechanism by which vascular comorbidity influences functional outcomes warrants further evaluation.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Management of activities of daily living in MS, Psychological issues and MS, Vascular comorbidity

(REH11) Is Treadmill Walking Analogous to Overground Walking in Persons with Multiple Sclerosis?

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Background: Gait and walking impairment is a common finding in persons with multiple sclerosis (PwMS) and is often studied using a treadmill. However, studies in other neuromotoric conditions have questioned whether treadmill walking accurately represents overground walking. If it does not, it may be questionable whether gait research performed on a treadmill can be generalized to overground walking. Similarly, it may suggest that the use of a treadmill for clinical gait evaluation and intervention for PwMS may not be as effective as overground walking. Objectives: The purpose of this study is to examine whether treadmill walking speed is similar to overground walking speed in PwMS. If our hypothesis is correct, it will suggest that clinicians can be confident that use of a treadmill for the examination and treatment of gait and walking dysfunction is representative of overground walking. If our hypothesis is not supported, however, it would suggest that clinicians with experience in PwMS for gait and walking impairment should reconsider the use of a treadmill as a tool for evaluation and treatment.

Methods: 19 people with MS [11 women and 8 men; median [IQR; range] Expanded Disability Status Scale score 4.5 [2.5; 2.06-5.5] performed an overground 2-Minute Walk Test (2MWT) to determine their average walking speed, then were asked to walk at the same speed on a treadmill. Participants walked up to 10 meters on the treadmill before trying to achieve their overground walking speed. Results: Pearson correlations were used to examine the relationship between predicted walking speed (PWS) [based on the mean walking speed during the 2MWT] and the actual walking speed (AWS) attained while on the treadmill. There was a positive correlation between the AWS and 2MWT [r = 0.841 [P = 0.707], n = 19, P = 0.000]. 70.7% of the variance in PWS could be predicted by the AWS. This, however, leaves 29.3% of the variance unexplained. Conclusions: Although overground walking and treadmill walking may seem very similar, there are contextual differences in these activities that may limit generalizability between the two. Researchers should be cautious when generalizing outcomes in physical performance in PwMS measured during treadmill walking to expected performance in overground walking. Clinicians should also be cautious in expecting generalized training effects of treadmill walking on overground walking in PwMS. The walking techniques used on a treadmill may not be the same ones used for overground walking, and therefore treadmill walking may not generalize to overground walking.

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Disclosure: Nothing to disclose

Keywords: Complementary/alternative therapies in MS, Gait, Management of activities of daily living in MS

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(REH12) Management of Low Back Pain for Individuals with Multiple Sclerosis: A Case Series
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Background: Individuals with multiple sclerosis (MS) are often referred to a physical therapist (PT) for evaluation of immobility, pain, and functional impairment. These individuals may be referred during the diagnosis process, a relapse, or while clinically stable. Self-reported pain symptoms for individuals with MS can also be multifactorial and originate from several areas including symptoms of central, peripheral, orthopedic, or a combination of these origins. There are no underlying diagnoses of MS which can complicate the evaluation, treatment plan, and progression for individuals with MS presenting with orthopedic complaints, including low back pain (LBP). This retrospective case series presents 4 cases of individuals with MS who were referred to physical therapy who also reported symptoms of LBP. Objectives: 1) Identify special considerations for evaluation techniques, treatment modifications, and progression modifications specific to individuals with MS and LBP. 2) Initiate guidelines that should be considered when establishing a plan of care for similar individuals with MS to establish the most effective approach for functional improvement or stability. Methods: All charts reviewed included subjects who attended UF Health Jacksonville outpatient rehabilitation in downtown location and were seen by the participating PTs from January 2018 through August 2019. Of the charts reviewed, 4 satisfied inclusion-exclusion criteria and are reviewed here. Charts were reviewed for PT plan of care, pain reports, and functional measures. Results: In each case, subjects reported improvement or resolution in pain measures and also demonstrated improvement in functional measures examined. Specific interventions and functional measures were tailored for each patient and were found to vary due to individual differences in clinical presentation and differences in response to a given intervention. Conclusions: The variability between subject presentation and complexity for individuals with LBP and underlying MS diagnosis were found to result in noted variance in treatment duration and approach between subjects. This points to the importance of thorough initial evaluation to include both neurologic and orthopedic standard of care. The evaluation ensures an appropriate plan of care for individualized treatment as well as identification of potential barriers to progression of treatment. As MS is a progressive condition, it is important to educate and train patients in ways to self-manage their musculoskeletal pain and functional deficits once an appropriate treatment plan has been established. Further research is needed to establish specific outcome measures and screening tools to identify individuals who will best benefit from outpatient physical therapy directed toward the improvement of LBP. The types of assessments and treatments reviewed in these cases may facilitate improved identification and standardization for these individuals.
Supported by: None
Disclosure: Nothing to disclose
Keywords: Comprehensive care and MS, Tele-rehabilitation

(ReH14) The Impact of Lower Limb Strength on Walking in Persons with Multiple Sclerosis: A Preliminary Analysis
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Background: Persons with multiple sclerosis (PwMS) report weakness and walking difficulty as some of their most disabling symptoms. Lower limb (LL) weakness is prevalent in PwMS and is associated with more significant disability, impaired balance, and increased difficulty walking. However, limited research exists describing the relationship between strength of specific LL muscle groups and walking in the same cohort. Objectives: To determine the impact of dominant (D) and nondominant (ND) LL strength on patient-reported outcomes (PROs) and objective walking outcome measures in PwMS (n = 137) derived from a larger, ongoing study was used. The following walking measures were collected at a single visit: 12-item MS Walking Scale (MSWS-12), Timed 25-Foot Walk (T25FW), and D and ND stride length [Stl], step length [Stl], and double support time (DSitime). Isometric peak torque of hip extension and flexion (HExt; Flex), knee extension and flexion (KExt; Flex), ankle plantar and dorsiflexion (APF; DF), and hip abduction (HAbd) were also collected. Descriptive statistics were performed (age, gender, disease duration, and disability level: Patient-Determined Disease Steps [PDDS] score) and a correlation analysis was used to determine the strength of the association of walking measures with muscle groups. Methods: A cross-sectional sample of PwMS (n = 137) derived from a larger, ongoing study was used. The following walking measures were collected at a single visit: 12-item MS Walking Scale (MSWS-12), Timed 25-Foot Walk (T25FW), and D and ND stride length [Stl], step length [Stl], and double support time (DSitime). Isometric peak torque of hip extension and flexion (HExt; Flex), knee extension and flexion (KExt; Flex), ankle plantar and dorsiflexion (APF; DF), and hip abduction (HAbd) were also collected. Descriptive statistics were performed (age, gender, disease duration, and disability level: Patient-Determined Disease Steps [PDDS] score) and a correlation analysis was used to determine the strength of the association of walking measures with muscle groups. Results: The MS cohort had a mean age of 51.4 (range: 21-75) years, disease duration of 14.5 (range: 0.3-40) years, and median PDDS score of 2.5 (range: 0-7), with 7.4% being female. All muscle groups were correlated with Stl and Stl, and inversely correlated with T25FW, MSWS-12, and DSitime. Strong associations were observed between crural and Stl (D: r = 0.62, P < 0.01; ND: r = 0.63, P < 0.01). D HFlex and ND SL (r = 0.608, P < 0.01),

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Keywords: Comprehensive care and MS, Falls

(REH13) Predicting Fall Risk in Persons with Multiple Sclerosis Utilizing the 12-Item Multiple Sclerosis Walking Scale
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Background: Fall risk has been identified as a major contributor to morbidity and mortality in persons with multiple sclerosis (PwMS). However, the mechanism of falls in PwMS remains unknown. The 12-Item Multiple Sclerosis Walking Scale (MSWS-12) has been identified as a good screening tool to predict fall risk; however, a cutoff score has not been identified. The purpose of this study was to examine the predictive value of the MSWS-12 score in predicting fall risk in PwMS. Methods: A cross-sectional sample of PwMS (n = 137) derived from a larger, ongoing study was used. The following walking measures were collected at a single visit: 12-item MS Walking Scale (MSWS-12), Timed 25-Foot Walk (T25FW), and D and ND stride length [Stl], step length [Stl], and double support time (DSitime). Isometric peak torque of hip extension and flexion (HExt; Flex), knee extension and flexion (KExt; Flex), ankle plantar and dorsiflexion (APF; DF), and hip abduction (HAbd) were also collected. Descriptive statistics were performed (age, gender, disease duration, and disability level: Patient-Determined Disease Steps [PDDS] score) and a correlation analysis was used to determine the strength of the association of walking measures with muscle groups. Results: The MS cohort had a mean age of 51.4 (range: 21-75) years, disease duration of 14.5 (range: 0.3-40) years, and median PDDS score of 2.5 (range: 0-7), with 7.4% being female. All muscle groups were correlated with Stl and Stl, and inversely correlated with T25FW, MSWS-12, and DSitime. Strong associations were observed between crural and Stl (D: r = 0.62, P < 0.01; ND: r = 0.63, P < 0.01). D HFlex and ND SL (r = 0.608, P < 0.01),
(REH15) The Effects of Intermittent Versus Continuous Walking on Distance to Fatigue in Persons with Multiple Sclerosis
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Background: Diminished walking endurance is common in persons with multiple sclerosis (PwMS). Previous studies have shown that PwMS walk farther in 6 minutes when using intermittent walking (IW) (ie, with interspersed rest breaks) than with continuous walking (CW), but it is unknown whether PwMS can walk greater distances or longer duration when using IW for periods of longer than 6 minutes. Objectives: The purpose of this study is to compare distance and time walked on a treadmill at a fixed velocity utilizing IW or CW. We hypothesized that PwMS would be able to walk greater distances and for longer duration when walking intermittently than when walking continuously. If our hypothesis was correct, it would indicate that PwMS can increase the total distance that they walk before being limited by fatigue using intermittent as opposed to continuous walking training. Methods: A randomized crossover design was used. Participants were randomized into 2 order groups: IW then CW, or CW then IW. The IW condition included alternating 30 seconds of walking and 30 seconds of seated resting. The CW condition consisted of continuous walking. Participants wore an overhead harness for safety. Baseline walking speed was determined with a 2-minute walk test (2MWT). Participants walked at the fastest pace up to the 2MWT speed until they either lost their balance or asked to stop. Walking time of 0.01 s was considered a fall. After 1 week, participants returned and performed the crossover condition. Results: 19 subjects (Expanded Disability Status Scale score 4.7±1.4, 10 female) completed the study. Participants had significantly longer walking distance in the intermittent condition than in the continuous condition (1575.7±498.4 vs. 1035.9±356.2 ft, P = .028). IW enabled participants to walk at best pace for greater distances than CW. Conclusions: These findings further support the use of IW training to improve walking endurance in PwMS. Adding rest breaks during endurance training enabled participants in this study to walk farther and longer, increasing the “dose” of the walking activity. Comparative effectiveness studies should be conducted to determine whether IW training is superior to the traditional model of CW training to improve walking endurance. In PwMS, greater walking endurance can be achieved with IW than with CW, suggesting that greater walking endurance gains can be made in these patients using this approach.

Support by: None
Disclosure: Nothing to disclose
Keywords: Equipment in MS, Gait, Management of activities of daily living in MS

(REH16) The Effects of Cooling Vests on Gait Fatigability in Persons with Multiple Sclerosis
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Background: Gait dysfunction is a ubiquitous and multifactorial finding in persons with multiple sclerosis (PwMS). A major reason for gait dysfunction in PwMS is objective fatigability (OF), characterized by progressive worsening of gait parameters over the course of a walk. Although OF is also multifactorial, it is presumed to be due in large part to multiple sclerosis (MS) thermosensitivity, where increased heat leads to decreased conduction through impaired nerves. Prolonged exercise to fatigue while in a cooler environment can lead to increased core temperature in PwMS, and therefore lead to progressive worsening of gait over the course of the walk. An intervention to prevent core temperature rise could limit OF during gait in PwMS. Objectives: The purpose of this study was to investigate whether the use of a commercially available cooling vest would result in decreased OF of gait in PwMS. We hypothesized that wearing the cooled vest for 30 minutes prior to a 6-minute walk (6MW) would result in less evidence of gait fatigability in PwMS when compared to performing the 6MW without prior cooling. If our hypothesis is correct, it will suggest that PwMS who experience gait fatigability can mitigate this by the use of cooling garments. Methods: A randomized crossover design is being used. Ambulatory patients with a diagnosis of MS are randomized into a cooled and uncooled condition. Cooling is accomplished by the wearing of a commercially available cooling vest for 30 minutes while seated. The uncooled condition is sitting for 30 minutes without wearing the vest. Immediately after the 30 minutes, subjects perform a 6MW test. Objective fatigability is measured by comparing the speed of the walk in the first minute to the speed of the walk in the sixth minute. Subjective fatigue is measured using the Visual Analog Scale of Fatigue (VASF). Data collection began fall of 2019 and will conclude winter of 2020.

Results: To date, 5 subjects (Expanded Disability Status Scale score 4.4) have completed the study. Due to the small sample size, only descriptive statistics are reported. Mean 6MW test distance was higher in the cooled condition (1137.3±1087.9). Mean differences between the distance walked in first minute and sixth minute was less in the cooled condition (−1.6) than in the uncooled (−12.4). Subjects experienced less subjective fatigue as measured by the VASF in the cooled condition (7.4 mm) than in the uncooled (13.8 mm). Conclusions: These findings, although preliminary, support our hypothesis that cooling may diminish OF of gait in PwMS and thereby improve gait endurance. Once we have achieved an adequate sample size, a more in-depth analysis will be performed. If our hypothesis is then reaffirmed, it will suggest that the use of a commercially available cool vest may decrease the impact of fatigue on gait in PwMS.

Support by: None
Disclosure: Nothing to disclose
Keywords: Complementary/alternative therapies in MS, Gait, Management of activities of daily living in MS

(REH17) A Combination of Core Exercise and Balance-Based Torso Weighting for Women with Multiple Sclerosis
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Background: Multiple sclerosis (MS) is a neurodegenerative disease that often results in fatigue, balance and walking impairment. Core exercise has been shown to reduce fatigue and improve balance and walking in people with MS. However, no studies have investigated the effects of a combination of core exercise and balance-based torso weighting (BBTW). Objectives: The purpose of this study was to investigate whether the combination of BBTW plus core exercise leads to greater improvement in self-reports of fatigue, balance confidence, and walking ability compared to core exercise alone in women with MS.

Methods: Eighteen women with MS (Expanded Disability Status Scale score 3.0±3.0) were randomly assigned to 1 of 2 groups: core exercise (CE) or BBTW plus core exercise (BBTW + CE). Subjects completed 3 questionnaires at baseline and after a 6-week intervention period: Modified Fatigue Impact Scale (MFIS), Activities-Specific Balance Confidence Scale (ABC Scale), and the MS Walking Scale (MSWS-12). All subjects participated in a Pilates-based CE program once a week with a physical therapist along with a daily home exercise program. In addition to the CE, 1 group also participated in the BBTW protocol. This involved fitting subjects with a vest worn on the torso and application of small weights to the vest at baseline followed by biweekly sessions to adjust weights and gradually increase wearing time up to 6 hours daily. Results: Following the 6-week intervention period, both groups demonstrated positive change indicating improvements in self-reported fatigue, balance confidence, and walking ability. The percent change for each measure was as follows: MFIS: CE group = 11.4% decrease, BBTW + CE group = 18.9% decrease; ABC Scale: CE group = 15.7% increase, BBTW + CE group = 10.6% increase; and MSWS-12: CE group = 11.9% decrease, BBTW + CE group = 19.3% decrease. Despite these improvements, none of the

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change in scores exceeded the MDC95 estimates for each measure (WFIS = 12; 3R8 = 20). Conclusion: Surprisingly, Supervision was a significant predictor of patients’ success in managing MS symptoms. Over half of participants are not participating in regular exercise, despite current literature that shows the benefits of exercise. Approximately one third of individuals surveyed are unaware of the benefits of various types of rehabilitation. Half of the participants have plans to make changes to either their diet or exercise programs over the next year. Around 50% of participants expressed interest in learning more about nutrition, supplements, exercise, stress management, and stretching. These results highlight the need for continued patient education regarding management of MS symptoms. Conclusion: Despite significant research that indicates the benefits of therapy for patients with MS, there continue to be many patients who have not been referred to skilled therapy services. Furthermore, most patients are interested in obtaining additional information related to managing their disease, which could be addressed by a comprehensive rehabilitation program.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Complementary/alternative therapies in MS, Comprehensive care and MS, Management of activities of daily living in MS

(REH23) Proximal Movement Compensations Are Related to Muscle Function and Walking Capacity in People with Multiple Sclerosis
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Background: Distal lower extremity movement complications are associated with muscle weakness and mobility limitations in people with multiple sclerosis (MS), however less is known about pelvis and trunk compensations during walking. Objectives: 1) to compare differences in pelvis and trunk kinematics during walking between participants with MS and a control group, and 2) determine associations of trunk and pelvis kinematics with muscle function, spatiotemporal parameters, and walking capacity in the participants with MS. Methods: In this cross-sectional study, 20 people with MS (Expanded Disability Status Scale 1.5-5.5) and 10 people with comparable age and sex (CTU) underwent 3-dimensional gait analysis. The primary kinematic variables of interest were frontal and sagittal plane pelvis and trunk angular displacement during the stance phase of walking. All participants also underwent muscle function assessments (hip and trunk strength and endurance), and walking capacity measures (Timed 25-Foot Walk [T25FW], 2-Minute Walk Test [2MWT]). Results: Compared to the CTU group, the MS group had significantly greater sagittal plane trunk and pelvis angular displacement (P < .031) and weaker (P < .042) side, less frontal plane trunk and pelvis angular displacement for both the stronger (P < .008) and weaker (P < .024) sides, and more sagittal plane trunk angular displacement for the stronger side (P < .047) during stance phase. There were low-to-moderate correlations in the MS group for sagittal plane pelvis angular displacement with trunk flexion endurance (r = -0.369, P = .019), and frontal plane pelvis angular displacement with lateral trunk flexion strength (r = 0.353, P < .030), step length (r = 0.529, P < .001), stance time (r = -0.433, P = 0.005), T25FW (r = 0.496, P < .001), and 2MWT (r = 0.582, P < .001). Conclusion: In people with MS, movement compensation at the pelvis during walking, particularly decreased frontal plane motion, was associated with worse walking capacity, muscle function, and spatiotemporal parameters. Future studies may consider targeting proximal muscle function to improve walking outcomes in people with MS. Rehabilitation clinicians may consider evaluation of proximal muscle function and gait compensations when planning rehabilitation interventions to improve walking capacity in people with MS.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Rehabilitation in MS

(REH24) Effects of a Weight-Based Training Program on Bone Density, Cognition, and Quality of Life of Multiple Sclerosis Patients
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None

Disclosure: Nothing to disclose

Keywords: Rehabilitation in MS
Background: Multiple sclerosis (MS) is a chronic neurodegenerative disease caused by the lesion forming demyelination of the central nervous system. Some of the issues associated with MS include cognitive impairment, increased mental and physical fatigue, and decreased bone mineral density. Using different variations of exercise is a common practice in the care for patients diagnosed with MS. It has been supported that there is a positive impact associated with exercise and the long-term sustaining of clinical benefits and quality of life outcomes in patients with MS. Objectives: Patients with MS have lower bone mineral density and a higher prevalence of osteoporosis. Physical activity has had a positive effect in bone health of patients with MS. The primary purpose of this study is to investigate if there is a correlation between weekly body weight exercise and bone density in patients with MS. Cognitive functioning and psychological well-being have also been shown to improve through the intervention of regular exercise. Additionally, cognitive and quality-of-life measures will also be investigated as part of this study. Methods: This study will enroll a total of 25 patients. Patients eligible for the study are between the ages of 40-55, diagnosed with MS, and having an Expanded Disability Status Scale score below 5.5. Each patient will receive a baseline dual energy X-ray absorptiometry (DEXA) scan, a verbal Symbol Digit Modalities Test (SDMT), and a Multiple Sclerosis Impact Scale (MSIS-29). Following the baseline visit, patients begin a 6-week body weight exercise program. The program consists of one 30-minute group session, under trained physical therapist supervision, and 1 video-guided at-home session for a total of 2 sessions per week. Upon completion of the training program, each patient completes a midpoint SDMT and MSIS-29. An endpoint DEXA scan, SDMT, and MSIS-29 are conducted 8 weeks after the completion of the training program. All tests are conducted for potential changes in bone density values, SDMT scores, and MSIS-29 physical and psychological scores. Results: To date, 4 patients completed 5 patients dropped, and 4 patients enrolled/awaiting enrollment. Data are being collected and further analysis is required. Conclusions: Thus far patients have reported positive experiences, but until analysis no conclusions can be made or supported with regard to bone density and cognitive effects.

Supported by: None

Disclosure: Mary Ann Picone: Biogen Inc (speakers' bureau).

Keywords: Body weight exercise, MS, Complementary therapies, MS, Management of activities of daily living in MS

(REH26) Improving Quality of Life Using an End-Effector Robotic Rehabilitation Approach in Progressive Multiple Sclerosis

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Background: Progressive multiple sclerosis (MS) is characterized clinically by gradual disease progression and accumulation of neurologic disability, independent of relapses. Rehabilitation has been recommended as a means to reduce disability and restore function. High-quality evidence supporting progressive MS rehabilitation is limited. An end-effector robotic-assisted gait trainer (RAGT) addresses many of the limitations of therapist-assisted gait training while providing an environment for regaining mobility and independence. Objectives: The objective of this study was to establish the safety and feasibility of RAGT and determine its impact on movement capacity, fatigue, and quality of life in patients with progressive MS. Methods: Single-blinded, randomized clinical trial using RAGT. Subjects trained 2 times per week for 10 weeks for a total of 20 training sessions. Five subjects with progressive MS have completed the RAGT protocol: 4 women and 1 man ranging in age from 33 to 63. The group has a range of Expanded Disability Status Scale scores from 4.5 to 6.5. Physical therapists individualized training intensities and RAGT characteristics to maximize benefits for each subject. Motor capacity outcomes (walking speed and endurance [2MWT]) and quality of life measures (Modified Fatigue Impact Scale [MFIS] and the Multiple Sclerosis Impact Scale 29 [MSIS-29]) were assessed at baseline and after the final training session (20th session). Subjects were monitored at each visit for adverse events. Results: There was no reported adverse event for any subject. Three of the 5 subjects had a 10% or greater increase in walking speed with an average improvement of 0.662 m/s. The group averaged 13% improvement in fast walking speed. Subjects had an average improvement of 10% on the MFIS and 15% on the MSIS-29. MFIS subscales assessing the greatest amount of improvement in the physical domain (44%). The MSIS-29 subscales indicated that individuals had a significant decrease in physical disability (18%). Conclusions: These 5 subjects with progressive MS tolerated the treatment dosage of 2 times per week for 20 weeks and did not experience any adverse events throughout the study. Follow-up gait training using RAGT resulted in improvement in walking speed. Subjects reported that training reduced their disability and fatigue, enhancing their overall quality of life.

Supported by: None

Disclosure: Nothing to disclose

Keywords: Complementary alternative therapies in MS, Equipment in MS

(REH25) Orchestrating a New Path for Multiple Sclerosis Rehabilitation: Empowering Patients Through Both Physical and Music Therapies

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Background: Although disease-modifying therapies (DMTs) are available for multiple sclerosis (MS) to delay disability progression and reduce relapses, as MS progresses additional support and management of symptoms are needed. Many patients may benefit from the role of nonpharmacologic therapies, focusing on physiotherapy (PT) and music therapy (MT) that can lead to improvements in both the physical and psychosocial domains that are negatively affected in patients with MS. Methods: MEDLINE was searched without date restriction to identify studies on the efficacy of PT and MT in MS. A panel of experts was convened to identify important themes and research studies. Results: PT can lead to improvements in mobility and balance. Review of 16 randomized controlled trials showed that treadmill training 3 times per week for 8 weeks improved walking endurance by 26.5 m from baseline in people with MS. PT can lead to improvements in fatigue, health-related quality of life (HRQoL), mood, and cognition. In a group of 20 patients with MS who performed high-intensity resistance training twice a week for 12 weeks, patients achieved statistically significant reductions in anxiety (P = .002), depression (P = .019), and fatigue (P = .001). Likewise, MT can improve physical symptoms and HRQoL in MS. In a trial comparing rhythmic-elicited motor imagery, metronome-cued motor imagery, and no intervention, patients in the 2 intervention groups could, respectively, walk a mean of 62.1 m and 60.9 m further after 4 weeks vs baseline; the mean change in the no-intervention group was −17.1 m. Significant improvements in SF-36 physical health and mental health measures were also seen in both intervention groups vs no-intervention groups for physical function, general health perception, vitality, social function, and mental health (P < .05). Conclusions: While DMTs aim to reduce disability progression and inflammatory activities in MS, additional nonpharmacologic therapies are an important adjunct for managing daily life with MS, particularly in improving or maintaining mobility, cognition, and other functional systems. Current studies regarding the use of RAGT in MS focused on training high baseline. Follow-up, the loss of both fine and gross motor skills, improving overall well-being and psychosocial health factors, and, ultimately, preserving HRQoL. Further research on combined PT and MT interventions may further improve outcomes in MS.

Supported by: None


Keywords: Complementary alternative therapies in MS, Comprehensive care and MS, Management of activities of daily living in MS

(REH27) Strategies to Foster Buy-in for Physical and Occupational Therapists: Engagement Across Multiple Sites and States for a Study on Tele-Exercise and Multiple Sclerosis (TEAMS)

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Background: Tele-Exercise and Multiple Sclerosis (TEAMS) is a research project funded by the Patient-Centered Outcomes Research Institute (PCORI) that aims to deliver a 12-week exercise-based rehabilitation intervention to 820 people with multiple sclerosis (MS) who live in Alabama, Mississippi, and Tennessee. Participants are randomized into 2 study arms: teleCAM and DirectCAM. The teleCAM consists of 2 study arms: TeleCAM and DirectCAM. The TeleCAM consists of 4
testing visits with the intervention delivered via videos accessible through a Direct-to-Patients (T-MOP) was developed for each clinic to ensure consistency of intervention delivery. The Clinical Research Coordinator used the T-MOP along with a rehabilitation guideline established by the Consortium of Multiple Sclerosis Centers (CMSC) to train clinicians at each clinic. Continuing Education Units (CEUs) were approved allowing each clinician to claim 4-6 hours for on-site training. Videos were created to provide an instructional guide on how to administer each outcome measure. GoToMeeting was used as a platform to deliver ongoing study updates. Information pertaining to participants is communicated through a HIPPA-compliant portal (Box). Results: 43 clinics across the 3 states and 86 therapists were trained for the study. Each clinic has a copy of the comprehensive (81 pp) T-MOP available in print form with access to a digital copy on Box. 18 GoToMeetings have been held and recorded for training and study updates, and each of the 86 trained therapists has used the outcome-measure videos. 43 therapists have access to Box and have uploaded approximately 1900 documents within 26 months. There are 823 participants between the ages of 20 and 45. Approximately 1900 documents were uploaded. Background: Multiple sclerosis (MS) is a common, debilitating, neurodegenerative disorder that causes myriad symptoms. Gait and balance dysfunction are common and manifest early in the disease, increasing fall risk. In particular, the ability to quickly and effectively react to a loss of balance is worse in people with MS. Therefore, improving reactive balance among those with MS is desirable. However, for maximum ecological validity, improvements in reactive balance through training would be demonstrable upon first loss-of-balance exposure. Objectives: The aim of this study is to evaluate first trial changes in people with MS before and between the ages of 20 and 45. The Canadian Occupational Performance Measure (COPM), Multiple Sclerosis Quality of Life Inventory (MSQOLI), and Health Related Quality of Life Short Form-36 (SF-36) were used at pre- and postintervention. Results: Clinically significant improvements occurred in the COPM overall performance and satisfaction scores, with patients demonstrating an average 5.3-point increase on performance and an average 7.2-point increase on satisfaction. On average, SF-36 scores improved in 7 subscales including emotional well-being, social functioning, and bodily pain, and MSQOLI scores improved in 3 subscales including the MFIS. Conclusions: This case series supports the use of Lifestyle Redesign to address symptom and chronic disease management in Hispanic females with MS because of the demonstrated benefits in the areas of functional performance and symptom presentation. Additionally, this case series contributes to the broader evidence for the feasibility of Lifestyle Redesign services for neurologic populations.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Comprehensive care and MS, Lifestyle interventions, Management of activities of daily living in MS

(REH25) Lifestyle Redesign for Multiple Sclerosis: A Case Series of Female Hispanic Patients
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Background: Research indicates that the incidence rate and clinical presentation of multiple sclerosis (MS) varies between patients of different ethnic backgrounds. On average, the incidence rate of Hispanic patients with MS tends to be lower than that of non-Hispanic whites, while the average age of first reported MS symptom is earlier in the Hispanic population. Hispanic patients have higher incidence of cervical spinal lesions, mobility impairments, and optic neuritis at first MS-related event. Patients with MS of Hispanic descent may be at a higher risk of disability earlier in the disease process. Due to the identified clinical presentation and high disability risks, it is critical to ensure that Hispanic patients receive early interventions and support symptom and disease management. Evidence in the MS literature supports behavior and lifestyle interventions as critical components for symptom and disease management, as well as improved quality of life. Lifestyle Redesign is an occupational therapy (OT) approach that focuses on helping patients acquire health-promoting habits and routines to improve overall function, health, and quality of life, as well as to improve self-management of chronic conditions. This methodology involves education, occupational self-analysis, personal exploration, and goal setting interventions, to facilitate reflection and increase motivation for and the engagement in health-promoting behavior changes. Objectives: Describe the delivery of Lifestyle Redesign to address chronic disease and symptom management in patients with MS within an OT plan of care and provide a descriptive case series with clinical outcomes to demonstrate how this intervention can be applied clinically with Hispanic females with MS. Methods: The subjects included in this case series participated in an average of 11 OT sessions. All subjects are female, of Hispanic descent, and between the ages of 20 and 45. The Canadian Occupational Performance Measure (COPM), Multiple Sclerosis Quality of Life Inventory (MSQOLI), and Health Related Quality of Life Short Form-36 (SF-36) were used at pre- and postintervention. Results: Clinically significant improvements occurred in the COPM overall performance and satisfaction scores, with patients demonstrating an average 5.3-point increase on performance and an average 7.2-point increase on satisfaction. On average, SF-36 scores improved in 7 subscales including emotional well-being, social functioning, and bodily pain, and MSQOLI scores improved in 3 subscales including the MFIS. Conclusions: This case series supports the use of Lifestyle Redesign to address symptom and chronic disease management in Hispanic females with MS because of the demonstrated benefits in the areas of functional performance and symptom presentation. Additionally, this case series contributes to the broader evidence for the feasibility of Lifestyle Redesign services for neurologic populations.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Comprehensive care and MS, Lifestyle interventions, Management of activities of daily living in MS

(REH28) Correlates of Change in First Trial Exposures Across 2 Days of Protective Steps Among Those with Multiple Sclerosis
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Background: Multiple sclerosis (MS) is a common, debilitating, neurodegenerative disorder that causes myriad symptoms. Gait and balance dysfunction are common and manifest early in the disease, increasing fall risk. In particular, the ability to quickly and effectively react to a loss of balance is worse in people with MS. Therefore, improving reactive balance among those with MS is desirable. However, for maximum ecological validity, improvements in reactive balance through training would be demonstrable upon first loss-of-balance exposure. Objectives: The aim of this study is to evaluate first trial changes in people with MS before and after 1 day of protective stepping practice. The study also seeks to identify clinical correlates of first trial changes to begin evaluating for whom such training may provide benefit. Methods: Fourteen people with MS underwent 2 consecutive days of support surface perturbations using an instrumented treadmill. Protective stepping outcomes were step length, step latency, and margin of stability. The backward step performance on the first trials on days 1 and 2 were compared, and difference scores were evaluated for relationships with correlates based on theoretical considerations. Results: There were no significant changes in first trial performance after training. However, some clinical and cognitive characteristics, such as mini-BESTest performance, improvement from day 1 to day 2 on the Symbol-Digits Modality test, type of MS diagnosis, and falls history were related with the amount of change individuals experienced. Conclusions: Although preliminary, these findings provide evidence that those with more favorable disease states may see more robust functional improvements after perturbation training. Greater doses, larger and more homogeneous samples, or longer delay between training and reassessment may be needed to understand the existence and relevance of first trial changes.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Rehabilitation

(REH30) Cognitive Processing Speed as a Predictor of Motor Skill Learning in Healthy Adults and Persons with Multiple Sclerosis
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Background: Motor and cognitive deficits are frequently reported in individuals with multiple sclerosis (MS), resulting in a high incidence of rehabilitation enrollment. Presently, there is no way to predict whether a patient will benefit from a specific rehabilitation program and factors mediating exercise responsiveness in MS remain unknown. Objectives: This study aims to determine baseline cognitive and pathological predictors of an individual’s ability to benefit from a balance-training program. We hypothesized that faster processing speed and increased myelin production (MPP) in brain tracts related to balance at baseline would result in greater automaticity at the trained task, as measured by the change in dual-task cost (DTC) following training. Methods: Four healthy participants and 1 participant with MS (1 male, 4 female; age 40 ± 14.3 years) underwent a magnetic resonance imaging examination and 4 consecutive days of balance testing on a Neurocom Basic Balance Master. Each day involved a single session of twenty 2-minute blocks; participants performed weight shifts on a force platform in response to targets on a screen. Participants were evaluated pre- and post-training on their ability to perform a dual-task (Limit of Stability Test + No-back Test). Results: Following training, all participants demonstrated improvements in reaction time (14%), velocity (34%), directional control (5%), and target
SakuraStar study); Genentech, MedDay, Novartis, Roche, TG Therapeutics (clinical trial, contract research, speakers’ bureau, research); Biogen, Merck, Novartis, Roche, Sanofi, Teva (speakers’ bureau). Takeaki Yamamura: Alexion Pharma, Ono (consulting fee); Biogen, Novartis, Teijin Pharma (consulting fee, speakers’ bureaus); Chiome Bioscience, Mirataz Holdings (contracted research); Chugai (consulting for, contracted research, grant, speakers’ bureaus); CSL Behring, Mitsubishi Tanabe, Takeda, Teijin Home Healthcare (speakers’ bureaus); Carole Marcillat, Xiujing Kou, Kristina Weber; F. Hoffmann-La Roche (contract research, speakers’ bureau); Westmark GMBH, Roche, Vioo Bio (consulting fee); Hépiale Civie de Lyon, MVZ Labor PD Dr Volkmann and Kollegen GbR, Oxford University, RSR Ltd (royalties). Keywords: Neuromyelitis optica spectrum disorder

(RTH02) Adolescents with Neuromyelitis Optica Spectrum Disorder Achieved Similar Exposures and Favorable Safety Profile When Treated with the Adult Satralizumab Dosing Regimen

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Background: Interleukin-6 (IL-6) is implicated in the immunopathology of neuromyelitis optica spectrum disorder (NMOSD). Satralizumab, a humanized recycling monoclonal antibody that binds to the IL-6 receptor, demonstrated a reduction in NMOSD relapse risk in two phase 3 studies: SAkuRaSky (satralizumab in combination with baseline immunosuppressants; NCT02073229) and SAkuRaStar (satralizumab monotherapy, NCT02073279). Objectives: To describe satralizumab exposure in adolescents with NMOSD to support dose selection. Methods: Patients in both studies (N = 178) received placebo or satralizumab 120 mg at weeks 0, 2, and 4, and every 4 weeks thereafter. Data on clinical and protocol-specified relapses (PDVs), aquaporin 4 autoantibody (AQP4-IgG) serostatus, safety endpoints, and pharmacokinetic (PK) and pharmacodynamic markers were evaluated in adolescent patients. A popPK model, developed using data from a phase 1 satralizumab trial (healthy volunteers) and both phase 3 studies, was used to analyze PK data. Results: Eight adolescent patients were enrolled in SAkuRaSky (adolescents were not permitted in SAkuRaStar). Seven were evaluated for efficacy (1 patient had PK data only). The mean age was 15.4 (range 13-17) years; mean weight (79.3 [range 47.5-140.4] kg) was similar to the adult population. Six patients were female; 3 patients were AQP4-IgG seropositive. The range of model-predicted exposures was similar to those in adults, correlating inversely with body weight, and not age. Treatment effects on soluble IL-6R levels, a marker of target engagement, were similar between adults and adolescents, with similar predicted median IL-6R occupancy (>95% maintained over the dose interval). One of 4 patients receiving satralizumab had a relapse (PDR, n = 1); 1 adolescent patient receiving placebo relapsed (PDR, n = 1; clinical relapse, n = 2). The safety profile of satralizumab in adolescents was consistent with the adult patient population; no new safety signals were identified. Conclusions: These findings support the recommendation that adolescent patients with NMOSD receive the adult 120 mg loading and every 4 weeks maintenance regimen of satralizumab.

Supported by: None

Keywords: Neuromyelitis optica spectrum disorder

(RTH03) Efficacy and Safety Outcomes from a Prospective Observational Registry of Repository Corticotropin Injection for Relapse of Multiple Sclerosis

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Background: Effective relapse treatment is critical for minimizing disability in patients with multiple sclerosis (MS). Repository corticotropin injection (RCI) is approved by the US Food and Drug Administration for the treatment of MS exacerbations. Objectives: This multicenter,
prospective, observational registry study aimed to characterize treatment-related safety and efficacy of RCI therapy (baseline) and again at various time points after. Clinical outcomes were assessed using the MS Impact Scale (MSIS-29v1), Expanded Disability Status Scale (EDSS), and Clinical Global Impression of Improvement (CGI) scale. Patient-reported outcomes were collected via Work Productivity and Activity Impairment Questionnaire: MS (WPAI:MS) and Health Resource Utilization (HRU) questionnaire. Mean changes from baseline were evaluated at 2 and 6 months via 2-sided paired t tests. Serious and nonserious adverse events (SAEs/AdEs) were reported throughout the study. Results: After treatment with RCI (N = 125), mean MSIS-29v1 physical subscale scores (primary end point) decreased from baseline (55.69) at 2 months (−7.99, P < .0002) and 6 months (−9.64, P < .0001). Post hoc analyses showed large improvements in patients who received >5 doses of RCI (n = 23) vs ≤5 doses (n = 71) at 2 months (−10.74, P = .0180 vs −6.48, P = .0177) and 6 months (−14.62, P = .0415 vs −7.90, P = .0011). Mean EDSS scores decreased from baseline (3.92) at 2 months (−3.07, P < .0001) and 6 months (−0.45, P < .0001), with greater improvement in patients who received >5 doses vs ≤5 doses at 2 months (−0.50, P = .0068 vs −0.24, P = .0059) and 6 months (−0.64, P = .0430 vs −0.36, P = .0111). CGI scores improved 63.3% of patients (85.01%) at 2 months and 61.40% of patients (P < .0001) at 6 months postbaseline. Eighty-three AEs were reported by 35 patients (28%), and 16 SAEs were reported by 11 patients (8.8%). The most common AEs/SAEs were MS relapse (4% AE, 4% SAE) and urinary tract infection (3.2% AE, 1.6% SAE). WPAI:MS and HRU responses showed improvements from baseline for most end points at 2 and 6 months. Improvements in clinical MS scales and patient-reported measures of MS impact, along with the low incidence of AEs/SAEs, support the efficacy and safety of RCI as a treatment option for MS relapse. Treatment response showed greater improvements with >5 doses.

Supported by: None

Disclosure: Jeffrey Kaplan: Alexion, Allergan, Amgen, Biogen, EMD Serono, Eli Lilly, Teva (speakers’ bureaus). Tamara Miller: Acorda, Amgen, Mallinckrodt Pharmaceuticals (employee). Allergan, Biogen, Genentech, Novartis, Sanofi Genzyme, Teva (conducted research); Allergan, Biogen, Genentech, Novartis, Sanofi Genzyme, Teva (consultation). Matthew Baker: Acorda, Axanir, Biogen, Celgene, Genentech, Mallinckrodt Pharmaceuticals, Sanofi Genzyme, Teva (consulting). Bryan Dee, Enxu Zhao: Mallinckrodt Pharmaceuticals (employees).

Keywords: Comprehensive care and MS, Disease-modifying treatments in MS, Immunology and MS

(RTH05) Characterization of the Pharmacokinetics and Pharmacodynamics of Sotralizumab, an Antibody, to Support Once-Every-4-Weeks Dosing in Patients with Neuromyelitis Optica Spectrum Disorder

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Background: Interleukin-6 (IL-6) has been implicated in the immunopathology of neuromyelitis optica spectrum disorder (NMOSD). Sotralizumab is a subcutaneously administered monoclonal antibody that binds to and blocks the IL-6 receptor (IL-6R). Sotralizumab was engineered to be recycled back into circulation via the neonatal Fc receptor (FcRn), increasing its serum half-life and effecting prolonged inhibition of IL-6R signaling.

Objectives: To define an effective, convenient, long-term dosing regimen for sotralizumab in patients with NMOSD.

Methods: The pharmacokinetic characteristics (pharmacokinetics [PK] and pharmacodynamics) of sotralizumab were assessed in 72 Japanese healthy volunteers (HV); single dose, range 30-240 mg; 33 patients with rheumatoid arthritis (RA) (multiple doses, range 30-120 mg), and 104 patients with NMOSD in SAkuraStar. Satralizumab showed a favorable safety profile in patients with NMOSD in both phase 3 studies: hazard ratio (95% CI) for reduction in protocol-defined relapse risk was 0.38 (0.16-0.88), P = .0184 in SAkuraSky; and 0.45 (0.23-0.89), P = .0184 in SAkuraStar. Satralizumab showed a favorable safety profile in patients with NMOSD, with nausea being the most common AEs when administered as monotherapy or in combination with baseline immunosuppressants. Conclusions: The recommended 120-mg loading and every-4-weeks maintenance regimen of satralizumab represents an effective, safe, and convenient treatment in NMOSD.

Supported by: None


Keywords: Neuromyelitis optica spectrum disorder

SELF-CARE

(SEL01) Understanding Gaps in Knowledge Surrounding Flu Shots and Immunizations as They Relate to Multiple Sclerosis

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Background: Over the past 5 years the influx of US Food and Drug Administration–approved treatment therapies, and advances in symptom management for, multiple sclerosis (MS) has been astounding. Emphasis has been placed on a healthier lifestyle to maximize quality of life, and
Results: was emailed out to the MSAA client database. The topic of flu and immunizations as they relate to patients with MS that opted to wear the collection.

Conclusions: a QR Code that directs the user to an Instagram video that teaches how to trim which collaborate with motor coordination. All of the clothes carry a conceptual panel which associates the disease with textile features and project parameters, and the planning of possible alternatives, along with design visual tools to identify their current needs, the definition of the options has also heightened questions, misconceptions, and confusion surrounding the influence of flu shots and immunizations on MS. Objectives Seeking to better understand gaps in knowledge and what patients with MS know/believe about flu shots and immunizations this assessment sought to analyze: 1) key areas of concern for receiving flu shots or immunizations; 2) how flu shots and immunizations are discussed with health care providers; and 3) understand current beliefs surrounding flu shots and immunizations. Methods: The Multiple Sclerosis Association of America (MSAA) developed and disseminated a 27-question survey on the topic of flu and immunizations as they relate to patients with MS that was emailed out to the MSAA client database. Results: 1926 patients with MS participated in the survey, with 32% of respondents reporting that they do not receive an annual flu shot and do not anticipate getting one this year. When asked why respondents do not receive flu shots, 36% opted concerns that flu shots are not good for people with MS, 26% are worried about side effects, and 28% do not trust or believe them to be safe. 68.26% reported an MS neurologist as their leading source of information, but still 37.74% said that they do not feel well informed about flu shots and 36.28% do not feel well informed enough about immunizations. 42% of respondents feel worried that if they receive an immunization or flu shot, they will have an adverse reaction and 38% believe that if they receive an immunization or flu shot it will interfere with their disease-modifying therapy or worsen their MS. Overall, 62.19% of individuals feel well informed about flu shots and immunizations while 37.81% feel that they need more information. Conclusions: These findings suggest that although experts agree that flu shots and immunizations are recommended or advised, there is still significant confusion among the MS patient community. “I believe that there are links between flu shots / immunizations and multiple sclerosis” reflected “not sure” responses of 38.81% and 42.51%, respectively. Finally, when asked how they would prefer to receive information about flu shots and immunizations in the future, leading responses were from their MS neurologist, general care practitioners, and through printed materials.

Supported by: None
Disclosure: Nothing to disclose

Keywords: Healthy lifestyle while living with MS

(SELO2) Experimental Project Fashion Design and Social Inclusion: Multiple Women
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Background: Multiple Women is an experimental project composed of an inclusive clothing collection for social occasions. Through social design guidelines, the work embraces textile mechanisms that aim to answer the physiological limitations of women with multiple sclerosis (MS). Objectives: To articulate fashion design and social inclusion in MS, with the purpose to develop garments with ergonomic adaptations. Methods: A group of 95 women with several types of MS, aged 20 to 42, who opted for a period of 12 weeks. The group sessions will be interspersed with group teleconferencing sessions (50–60 minutes) every other week for a period of 12 weeks. The group sessions will be interspersed with brief (15 minutes) 1-on-1 support telephone calls in the weeks that the group sessions do not occur. Feasibility metrics will include process (eg, recruitment and retention rates), resource (eg, monetary costs and community participation), management (eg, time and accuracy of data collection/entry), and scientific assessment (eg, safety and participant experience). Results: Data collection is ongoing. Anticipated completion is March 2020. The main findings regarding intervention feasibility will be presented. Conclusions: PAT-MS is the first physical activity intervention to target people with advanced MS and their caregivers (CGs) as active participants. The intervention presents a unique opportunity to increase physical activity behavior and improve the health outcomes of both PwMS and their CGs. The findings of this study will provide critical information on feasibility metrics that will inform and refine the design and delivery of subsequent stages of this research.

Supported by: None
Disclosure: Nothing to disclose

Keywords: MS and the caregiver/family, Physical activity

(SXMO1) Effect of Nabiximols on Spasticity and Muscle Strength in Patients with Multiple Sclerosis Across 3 Randomized Controlled Trials
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Background: Spasticity is a common feature of multiple sclerosis (MS), especially in patients with longstanding illness. Medications that reduce spasticity may also reduce muscle strength, potentially impairing the ability to walk. Patients who do not respond adequately to conventional antispasticity medications need additional treatment options that improve spasticity without causing weakness. Objectives: Assess the relationship between changes in spasticity and muscle strength in lower extremities or mobility, using data from 3 randomized controlled trials (GWMS0106, GWSP0604, SAVANT) of nabilimols vs placebo in patients with spasticity due to MS inadequately controlled by antispasticity medications. Methods: Spasticity was evaluated using the Numerical Rating Scale (NRS) in all 3 trials, muscle strength using Motricity Index (MI) in GWMS0106 and GWSP0604, and mobility using timed 10-Meter Walk Test (10MWT) in GWSP0604 and SAVANT. Adjusted mean differences for change from baseline in outcome measures between nabiximols and placebo are summarized. Pearson correlation analysis was conducted to assess the association between change from baseline in spasticity and muscle strength.

Supported by: None
Disclosure: Nothing to disclose

Keywords: Complementary/alternative therapies in MS

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change in strength or mobility for naxibimols and placebo groups separately. This analysis included 184 patients in GWMS0106, 241 from GWPS0604, and 106 from SAVANT. The baseline mean (SD) Expanded Disability Status Scale score was 6.0 (1.42) in GWPS0604 and 5.9 (1.1) in SAVANT. In GWMS0106, naxibimols significantly improved mean NRS spasticity score (−0.52 points [95% CI: −1.02, −0.04]); P = 0.048), without significantly affecting the MI for legs (3.86 [95% CI: 0.21, 7.54]). In GWPS0604, naxibimols significantly improved mean NRS spasticity score from baseline to placebo (−0.84 [−1.29, −0.40]; P < 0.0002), without significantly affecting the MI for legs (0.97 [−1.49, 3.42]; P = 0.39) or the 10MWT results (−3.34 [−0.95, 0.26]; P = 0.069). In SAVANT, naxibimols significantly improved spasticity vs placebo (−1.28 [−2.75, −0.61]; P < 0.001), without significantly affecting the MI for legs (0.26 [−0.37, 0.89]; P = 0.711). Pearson correlation coefficients were all under ±0.30 (indicating negligible correlation) for the association between change in NRS and MI and for the low positive correlation between NRS and 10MWT in the naxibimols group in SAVANT (0.326).

Conclusions: The improvement in spasticity with naxibimols was not accompanied by the muscle weakness often observed with antispasticity medications or by a notable change in preferred walking speed.

Supported by: None


Keywords: Complementary/alternative therapies in MS, Comprehensive care and MS, MS symptom management

(SXMO2) MS Action Plan May Be Effective Tool Helping Patients with Acute Change in Multiple Sclerosis Symptoms

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Background: The Greater Northwest Healthcare Provider Council of the National Multiple Sclerosis Society (NMSS) identified a need for patients with multiple sclerosis (MS) to be educated on what to do when they experience any new or worsening neurologic symptoms. Council members found that many of their patients with MS would lack tools to help themselves into the emergency room (ER) or urgent care for symptoms that may have been better treated in the outpatient setting. Objectives: The objectives of the MS Action Plan are to 1) foster clear communication between patient and provider, 2) help patients avoid any undue trips to urgent care or ER, and 3) educate patients on what to look for and when they need to contact their MS provider team. Methods: The Healthcare Provider Council started with a document in use at the Virginia Mason MS Center in Seattle and adapted it for all MS providers to use and share with their patients with MS to help them better understand their MS symptoms. The Virginia Mason document was adapted from the Asthma Action Plan. The plan is widely used throughout the country. The MS Action Plan was first distributed at the Greater Northwest Regional MS Summit and professional education program to an audience of 80 MS care providers in March of 2019. Six months later, the Healthcare Provider Council created an online survey and distributed it to the Summit attendees to assess the effectiveness of the MS Action Plan. The survey was sent to 184 providers, and 108 responded, for an effective response rate of 58.5%. Results: Twenty providers responded to the survey. Of the respondents, 60% answered that they have used the MS Action Plan in their practice and 87% found it useful. When asked who provides the MS Action Plan to patients, 80% selected “provider” with “RN” being the second most commonly selected answer. The most common way the clinics are using the action plan is in hardcopy handed to patients with MS, with their patients with MS to help them better understand their MS symptoms, or to give to their patients with MS who provide the MS Action Plan to patients, 80% selected “provider.” The most common reason for using the plan was to provide more information on this important subject. Supported by: None

Disclosure: Gloria von Geldern, Piper Paul, Janet Piel, Jan Shilling, Nicole Lauwers, Kendra Yale, Piper Reynolds: Nothing to disclose. Dennis Dietrich: Adnatin (contracted research); Biogen, Novartis (contracted research, speakers’ bureau); Sanofi (speakers’ bureau); Ted Brown: EMD Serono, Greenwich Pharmacuticals (consulting fee). Joanne Wagner: Novartis (consulting fee); Neurologists SXM03) Intrathecal Baclofen Therapy in Ambulatory and Nonambulatory Multiple Sclerosis Patients: A Single-Center Experience

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Background: Spasticity is a common cause of disability and diminished quality of life in patients with multiple sclerosis (MS). Intrathecal baclofen therapy (ITB) is an effective treatment option for patients with MS with severe spasticity that is refractory to oral drug administration, but there is limited evidence of its long-term efficacy and safety in ambulatory patients with MS. Objectives: This single-center, retrospective case series investigates the outcomes of ITB in ambulatory and nonambulatory patients with MS with medically intractable spasticity over a 5-year follow-up period. Methods: Data from the Mellen Center Intrathecal Baclofen Registry were analyzed retrospectively. All patients were diagnosed with MS and underwent an ITB test injection. Baseline demographics were collected along with outcome measures including Spasm Frequency Scale, Modified Ashworth scale (MAS), hip flexor strength, and walking speed on the Timed 25 Foot Walk. Group comparisons were done using 2-sample t test or Wilcoxon rank sum test, and logistic regression was used to assess the occurrence of complications. Results: 170 patients with MS underwent ITB infusion system implantation. The aggregate MAS score for the ambulatory cohort (n = 87) was significantly reduced from 13.5 ± 6.96 to 3.54 ± 4.18 at 5 years (P < .001) post ITB implantation. Similarly, spasm frequency (0-4 scale) was significantly reduced in ambulatory patients, from 1.71 ± 0.78 at baseline, to 0.77 ± 0.94 at 5 years (P < .001). The average ITB dose was lower for the ambulatory cohort compared to the nonambulatory cohort except at the 5-year follow-up visit. Among ambulatory patients at baseline, 56 (77.8%) were ambulatory at 1 year with no significant change in walking speed (baseline 0.45 m/s ± 0.30 vs 1 year 0.38 m/s ± 0.39 at 1 year, P = .80). At the 5-year follow-up point, 20 (41.7%) patients remained ambulatory with a walking speed of 0.21 m/s ± 0.37 (P < .001). Longer disease duration (hazard ratio [HR] 1.04; 95% CI 1.01-1.07; P < .018), and lower hip flexor strength at baseline (HR 0.40; 95% CI 0.27-0.57; P < .001) were predictors of transition to nonambulatory status after ITB implantation. Complications were common in the ambulatory ITB group (n = 29, 22.1%) compared to the nonambulatory group (n = 10, 8.0%) with an odds ratio of 3.30 (95% CI 2.17-5.02; P = .017). Conclusions: ITB is an effective therapy for reducing spasticity in ambulatory patients with MS without compromising walking speed in the short term, although we did observe a higher complication rate in this cohort. This study supports the use of ITB in carefully selected ambulatory patients with MS. Randomized, prospective studies are needed to provide more information on this important subject. Supported by: None

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Keywords: Intrathecal baclofen, Management of activities of daily living in MS
(SXM05) Virtual Delivery of Mindfulness-Based Art Therapy (MBAT) to Improve Symptoms Among Adults with Multiple Sclerosis (MS)
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Background: Stress and fatigue in individuals with multiple sclerosis (MS) have been linked to a more severe course of the disease and weakened immune system. Mindfulness-based interventions (MBIs) have been found to reduce stress and fatigue and improve quality of life (QOL) in adults with MS. MBIs provided in an online format and led by a multidisciplinary team (nurse and art therapist) might strengthen overall effectiveness of MBIs. Objectives: The purpose of this pilot study was to compare the effect of virtually delivered meditation and mindfulness-based art therapy (MBAT) on the level of symptoms in a sample of adults with MS. We first beta-tested the protocol in 2 case subjects and collected feedback to identify areas needing improvement. We then plan to pilot the modified intervention to test feasibility, acceptability, and preliminary efficacy among a different sample of adults with MS. Methods: Art therapy and psychoeducation interventions were conducted by an MS nurse and an art therapist. Subjects engaged in mindfulness expressive arts interventions following a MBAT protocol on TEAMs, a video conferencing platform. Two facilitators led the interventions, as well as provided psychoeducational resources and feedback. We then interviewed the subjects to gather perceptions and feedback regarding the effectiveness of MBAT interventions in relieving stress and other symptoms. We also collected saliva cytokines, body temperature, and self-reported data on symptoms, physical function (standing balance, gait speed, minutes of daytime activity), and QOL. Results: At present, data analysis is ongoing. However, preliminary anecdotal feedback indicates that patients accept the MBAT interventions as accessible, easy to use, and helpful in reducing stress and fatigue. For example, 1 participant reported that creation of a particular art image enabled her to more effectively communicate the need for change with her spouse in a particular area of her life so that she could better manage her stress levels. Participants have also been responsive to psychoeducational resources given during sessions. Conclusions: Preliminary findings suggest that an MBAT intervention led by an MS nurse and art therapist in a virtual format may be an effective method for relieving stress and fatigue in adults with MS. A future larger study is warranted for this important intervention.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Management of activities of daily living in MS, Nursing management in MS

(SXM06) A Pilot Study of Mirabegron (Myrbetriq) and Behavioral Modification Including Pelvic Floor Exercise for Overactive Bladder in Multiple Sclerosis
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Background: Urinary symptoms, including overactive bladder (OAB), are seen in up to 80% of patients with multiple sclerosis (MS). Most anti-spasmodics for OAB are anticholinergic, which may worsen cognition and constipation in MS. Mirabegron, approved for OAB in the general population, is a B3 adrenergic agonist, so it may be better tolerated in patients with MS. Objectives: To assess safety, tolerability, and efficacy of mirabegron in treating OAB in MS. Methods: Twenty-eight patients with MS and OAB were randomized 1:1 into placebo and treatment arms of this double-blind, placebo-controlled 10-week study. All patients received pelvic floor exercise training and watched a video about behavioral management of OAB. Patients in the control arm received placebo while the treatment arm received mirabegron (25 mg) with optional up-titration to 50 mg. Seventy-two–hour voiding diaries were used. The primary outcome measure was the change in OAB Symptom Composite Score (OAB-SCS), which assesses voiding frequency and urgency; higher scores mean worse symptoms. Secondary measures included number and volume of micrurition, incontinence episodes, and patient assessments of OAB severity. Results: While both groups improved, scores were significantly greater at visit than at baseline, the final daily average OAB-SCS for the mirabegron group was 0.47 higher than that of the placebo group (95% CI = 0.047, 0.893, P = .031). Thus, the mirabegron group had a worse primary outcome. On the other hand, for Subject Global Impression, the mirabegron group rated overactive bladder control as significantly better relative to the placebo group (95% CI = 0.375, 2.381, P = .009). Trends suggesting treatment-related improvement in other secondary measures favored mirabegron on number of micrurition and incontinence episodes per day, but these did not achieve secondary outcomes did not reach statistical significance. Adverse events were limited and similar between groups, and there were no serious adverse events. Drug adherence was about 95%. Conclusions: Mirabegron was safe and well-tolerated in this MS population. Our mixed results do not demonstrate benefit from adding mirabegron to a program of behavior modification for OAB. Patients with MS may have neurologic differences from a general OAB population that reduce the responsiveness to beta-3 adrenergic agonists. A larger study population may elucidate the extent of the treatment effect on bladder function in patients with MS.

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Disclosure: Theodore R. Brown: AbbVie, Adamas, Astellas, Merck (contracted research); EMD Serono, Greenwich Pharma (consulting fees); Novartis (speakers’ bureau); Virginia L. Simnad: Actelion, Biogen, Celgene, Novartis (contracted research)

Keywords: Bladder management, Comprehensive care and MS, Nursing management in MS

(SXM07) The Clinical Spectrum of Myelin Oligodendrocyte Glycoprotein (MOG) Antibody–Associated Demyelinating Disorders: Three Case Reports
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Background: Myelin oligodendrocyte glycoprotein (MOG) antibody–associated disorders are distinct from multiple sclerosis (MS) and neuro- myelitis optica spectrum disorder (NMOSD) with positive aquaporin-4-Ab (AQP4-Ab). The full clinical spectrum of this newly described condition remains to be described. In this report we sought to describe clinical and imaging presentations of 3 MOG antibody–seropositive patients. Objectives: To present 3 cases of autoimmune MOG antibody–associated demyelination. Methods: Case 1: A 45-year-old woman presented with spasm and pain in lower back with radiation to both legs. Also, she had complaints about muscle spasm, fatigue, and tremor in right hand. Five years after the onset of first symptoms, she developed left retrobulbar optic neuritis (ON) which responded to intravenous (IV) steroids. Magnetic resonance imaging (MRI) confirmed left ON and mild cervical and thoracic spinal cord atrophy. A repeat MRI 24 months later showed a few nonspecific foci of T2/FLAIR signal hyperintensity in the subcortical white matter of the bilateral frontal lobes, which was not typical in appearance for MS. MS mimics work-up repeated and cell-based immunassay revealed positivity for anti-MOG antibody with a titer of 1:100 and negativity for AQP4-Ab. The full clinical spectrum of this newly described condition remains to be described. Case 2: A 57-year-old man who was previously diagnosed with relapsing MS presented with ON. He was treated with interferon beta-1a, glatiramer acetate, teriflunomide, and fingolimod. After 8 years from the onset of MS, the patient developed dysarthria, vertigo, and dysphagia initially treated with IV steroids but did not have a good recovery, and repeat MRI showed progression of multiple areas of enhancement in the posterior fossa. So, he was admitted to the hospital and received PLEX, which significantly improved his symptoms. Cell-based immunassay was positive for anti-MOG antibody with a titer 1:1000. Subsequently his treatment was switched to rituximab, and his symptoms remained stable ever since. Case 3: A 45-year-old woman with first presentation as paresthesia and progressive cognitive decline was diagnosed with relapsing-remitting MS based on MRI and presence of oligoclonal band in cerebrospinal fluid. She had 2 major attacks that presented as weakness and numbness in lower extremities and facial weakness, which were treated with mycophenolate mofetil. Case 2: A 57-year-old man who was previously diagnosed with relapsing MS presented with ON. He was treated with interferon beta-1a, glatiramer acetate, teriflunomide, and fingolimod. After 8 years from the onset of MS, the patient developed dysarthria, vertigo, and dysphagia initially treated with IV steroids but did not have a good recovery, and repeat MRI showed progression of multiple areas of enhancement in the posterior fossa. So, he was admitted to the hospital and received PLEX, which significantly improved his symptoms. Cell-based immunassay was positive for anti-MOG antibody with a titer 1:1000. Subsequently his treatment was switched to rituximab, and his symptoms remained stable ever since. Case 3: A 45-year-old woman with first presentation as paresthesia and progressive cognitive decline was diagnosed with relapsing-remitting MS based on MRI and presence of oligoclonal band in cerebrospinal fluid. She had 2 major attacks that presented as weakness and numbness in lower extremities and facial weakness, which were treated with mycophenolate mofetil. Conclusions: Three Case Reports: 3 MOG antibody–seropositive patients. Three Case Reports: 3 MOG antibody–seropositive patients. Three Case Reports: 3 MOG antibody–seropositive patients. Three Case Reports: 3 MOG antibody–seropositive patients. Keywords: Myelin oligodendrocyte glycoprotein antibody, MOG antibody associated demyelinating disorder, Cell-based immunassay, Natural history of MS

International Journal of MS Care
WHITAKER RESEARCH TRACK

The late Dr. John N. Whitaker was a world-famous researcher in multiple sclerosis (MS). His work inspired many scientists to enter the field of MS and develop their skills and talents. Each year, the Consortium of Multiple Sclerosis Centers (CMSC) honors Dr. Whitaker’s memory by presenting one award for innovative research by a young investigator. The CMSC and the Foundation of the CMSC will present a prize to a scholar whose work exemplifies the mission of this visionary leader in MS.

WHITAKER RESEARCH TRACK
Characterizing the Acute Exercise Response in Nonambulatory People with Progressive Multiple Sclerosis

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Background: While the benefits of exercise training among people with multiple sclerosis (MS) who have mild-to-moderate disability (Expanded Disability Status Scale [EDSS] score 0.5-6.5) have been established, the efficacy of exercise for persons with MS who are nonambulatory (EDSS ≥ 7.0) is largely unknown. This evidence is limited, in part, due to the need for specialized exercise modalities to deliver exercise for persons who are nonambulatory. An investigation of the physiological and symptomatic response associated with adapted exercise is needed as a first step toward understanding the potential benefits of exercise training for this population.

Objectives: To characterize and compare the acute physiological and symptomatic response associated with 3 adapted exercise modalities in persons with MS who are nonambulatory.

Methods: Ten participants (mean age, 62.5 ± 10.3 years old; all progressive MS) with EDSS score 7.0-8.0 were recruited. Participants completed 1 baseline testing session to determine peak cardiopulmonary fitness (VO2peak). Participants then completed 3 submaximal exercise sessions on adapted exercise modalities (arm ergometer, recumbent stepper, and functional electrical stimulation [FES] cycle). Physiological variables including oxygen consumption (VO2) and heart rate were recorded continuously during exercise. Symptomatic outcomes including pain and fatigue were measured at 3 time points: before exercise, immediately postexercise, and 30 minutes postexercise.

Results: All participants completed the FES cycling and recumbent stepper submaximal exercise sessions. Two participants could not complete the arm ergometer exercise, citing pain as the reason for cessation. All adapted exercise modalities elicited a VO2 response exceeding 40% of VO2peak and a heart rate response exceeding 70% of heart rate maximum. This exercise intensity corresponds with moderate-vigorous physical activity, an intensity associated with cardiorespiratory fitness benefits. There was a significant increase in pain immediately after arm ergometer exercise compared to FES cycling (P < .05) and recumbent stepper exercise (P < .05). All adapted exercise modalities tested appeared to be viable approaches for improving cardiorespiratory fitness in nonambulatory people with MS. However, symptomatic response should be considered when prescribing and developing exercise interventions. These findings will help to inform and optimize exercise prescription for people with MS who are nonambulatory.

Disclosure: Nothing to disclose

Keywords: Exercise training, Management of activities of daily living in MS

WHITAKER RESEARCH TRACK
Diary Patterns and Health-Related Quality of Life of Individuals with Multiple Sclerosis

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Background: Individuals with multiple sclerosis (MS) look for dietary changes to improve their disease outcome. Information regarding what specific dietary changes are being implemented by individuals with MS and if these changes affect quality of life (QOL) can be useful in shaping future research.

Objectives: 1) To assess prevalence of MS-specific diets (e.g., Wahls diet, Swank diet, vegan diet) and dietary patterns of individuals with MS. 2) To investigate effects of intake of certain food groups on relapses and self-reported QOL measure.

Methods: Individuals with MS participated in an online survey and completed questions regarding intake of specific diets, frequency of intake of specific foods, relapses, and Patient-Reported Outcome Measurement Information System (PROMIS) based on past 6 months. PROMIS Global scores (range, 10-50) were used to measure QOL where higher scores reflect higher QOL.

Results: In this cross-sectional analysis, we included 977 participants who provided complete data. Results: Individuals with MS with mean age 47.7 (SD 11) years and average 10 (SD 8.9) years since diagnosis participated in this study. Specific diets for MS were followed by 72% of participants, suggesting that most individuals with MS are implementing dietary changes. Most prevalent dietary changes were Wahls (26%), paleolithic (16%), Wahls (26%), and anti-inflammatory (13%) diets. Some participants (11%) reported following multiple diets as well. Only 12% reported having a relapse in past 6 months. Mann-Whitney U tests showed that individuals who did not have any relapse had higher median daily intake of alcohol (0.08 vs 0.05 ounce equivalent, P < .01) than individuals who had relapses in prior 6 months. PROMIS Global average scores were 33.4 (SD 6.1).

Disclosure: Nothing to disclose

Keywords: Management of activities of daily living in MS, Physical fitness
Median (interquartile range) daily servings intake of different foods were as follows: total fruits and vegetables, 2.2 (1.2-3.4); total dairy, 0.1 (0.0-0.5); total grains, 0.4 (0.1-1.4); total meat and fish, 3.7 (1.9-5.1); total alcohol, 0.1 (0.0-0.4); and total eggs, 0.1 (0.0-0.4). These results show low intake of dairy, grains, eggs, and alcohol among individuals with MS. Spearman correlation did not show any significant relationship between PROMIS Global scores and dosage of different food intake. However, Mann-Whitney U test showed that individuals who were not taking dairy had higher PROMIS scores than those who were (median 36 vs 33, P < .001). Additionally, individuals taking alcohol had higher PROMIS scores than those who were not taking any (median 34 vs 32, P = .001). These results suggest potential beneficial effects of avoiding dairy and consuming alcohol on QOL of individuals with MS.

Conclusions: Most individuals with MS report making dietary changes to improve disease outcome. Dairy and alcohol may affect relapse rate and QOL of these individuals. Future studies should assess role of dietary changes as complimentary treatment for MS.

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Keywords: Complementary/alternative therapies in MS, Diet

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Real-World Evidence Assessment of Betaseron (interferon beta-1b) Adherence Following the Introduction of the BETACONNECT Autoinjector
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Background: Maintaining adherence to disease-modifying therapies (DMTs) is challenging for chronic conditions such as multiple sclerosis (MS), and poor adherence in MS has been associated with increased risk of disease activity and higher resource utilization. For DMTs requiring parenteral administration such as interferons, autoinjector devices may help patients overcome injection-related factors interfering with treatment adherence. The BETACONNECT device is an electronic autoinjector for the injection of interferon beta-1b (Betaseron), a DMT used in relapsing-remitting MS (RRMS). Objectives: This retrospective analysis of a US claims database evaluated adherence, as indexed by medication possession ratio (MPR) and persistence, to 2 subcutaneous DMTs, Rebif (interferon beta-1a) and Betaseron (interferon beta-1b), during the period prior to and following the introduction of the BETACONNECT autoinjector for Betaseron in patients with MS. Methods: Data from MarketScan, a US claims database, for patients with a medical claim for Rebif or Betaseron either prior to the introduction of BETACONNECT (October 2013–September 2015) or post approval and uptake of BETACONNECT (October 2016–September 2018), were evaluated. Patients aged ≥18 years with ≥1 confirmed MS diagnosis in the 12-month period prior to the first relevant DMT prescription within the defined time periods were included in this analysis. Four cohorts were defined: incident Rebif or Betaseron users over the 24-month period prior to the introduction of BETACONNECT; users over the 24-month period following the introduction and uptake of BETACONNECT. Within each time period, patient populations were propensity score matched on demographic and clinical characteristics. MPR and persistence to both DMTs are described for the period prior to and following the introduction of BETACONNECT. Results: MPR: In the pre-BETACONNECT period, the proportion of users with ≥80% MPR was higher for Rebif (90%, 95% CI 87%-93%) than Betaseron (83%, 95% CI 76%-88%), while in the post-BETACONNECT period, the proportion of users with ≥80% MPR was higher for Betaseron (92%, 95% CI 85%-95%) than Rebif (80%, 95% CI 81%-91%). Persistence: In the pre-BETACONNECT period, median persistence in days was higher for Rebif (199, 95% CI 167-235) than for Betaseron (152, 95% CI 105-231), while in the post-BETACONNECT period, persistence was higher for Betaseron (327, 95% CI 244-440) than for Rebif (229, 95% CI 184-304). Conclusions: Following the introduction of BETACONNECT, Betaseron users were more adherent, with improved persistence and with >90% of users meeting 80% MPR, a threshold commonly used to define good adherence. Supported by: None
Disclosure: Osiris Butler, Simone Werner, Katsiyarou Holl, Ann-Kathrin Frenz, Eva-Maria Wickljen, Bayer AG (salary); Sandy Yeo, Bayer (South East Asia) Pte Ltd (salary); Mark Rametta, Bayer HealthCare Pharmaceuticals Inc (salary).
Keywords: Disease-modifying treatments in MS, Equipment in MS, Patient empowerment in MS treatment

A Unique Case of a Patient with Tuberous Sclerosis and Recent Diagnosis of Neuromyelitis Optica
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Background: Tuberous sclerosis complex (TSC) is an inherited neurocutaneous disorder that is characterized by pleomorphic features involving many organ systems, including multiple benign hamartomas of the brain, eyes, heart, lung, liver, kidney, and skin. Neuromyelitis optica (NMO, previously known as Devic disease) and NMO spectrum disorders (NMOsDs) are inflammatory disorders of the central nervous system characterized by severe, immune-mediated demyelination and axonal loss that predominantly involves the optic nerve and spinal cord. Traditionally considered a variant of multiple sclerosis, NMO is now recognized as a distinct clinical entity based on unique immunologic features. Objectives: To report a unique case of TSC and NMO. Methods: Case report. Results: A 30-year-old woman who carries the diagnosis of TSC suddenly started to have tingling in the legs and vomiting. The vomiting was removable and continued for a week. Her tingling persisted up to her waist and into her abdomen. She also started having episodic spasms in her arms and legs. A month later she started having difficulty walking and tingling in her hands. She underwent magnetic resonance imaging (MRI) of spine that showed longitudinally extensive spinal cord lesions in her upper cervical and lower thoracic cord. Differential diagnosis of the time included NMO, transverse myelitis, and astrocytoma in the setting of tuberous sclerosis, but then NMO IgG antibody was found to be positive both in serum and cerebrospinal fluid (CSF). The patient received 5 days of steroids, and, as she still had symptoms, she was given plasma exchange for 5 sessions and then continue treatment plan with rituximab. Discussion: This is a unique case of a patient with TSC associated with brain (seizures) and brain MRI features (cortical tubers) of TSC in her childhood and now diagnosed with NMO at the age of 30 with clinical features: longitudinally extensive spinal cord lesions and positive NMO IgG antibody in serum and CSF. Further studies are needed to find more information regarding the co-occurrence of a genetic disorder with an immune-mediated disease like NMO.

Supported by: None
Disclosure: Nothing to disclose
Keywords: Genetics and MS, NMO, TS

Shorter Infusion Time of Ocrelizumab: Primary Results from the ENSEMBLE PLUS STUDY in Patients with Relapsing-Remitting Multiple Sclerosis
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Background: Ocrelizumab is an intravenously administered anti-CD20 antibody approved for relapsing and primary progressive multiple sclerosis (MS). Shortening the infusion to 2 hours may reduce the total site stay from 3-4 hours (approved infusion duration including mandatory premedication/observation) to 4 hours, which may reduce patient and site staff burden. Objectives: To investigate the safety profile of ocrelizumab when administered over a shorter infusion period, using primary results from ENSEMBLE PLUS. Methods: ENSEMBLE PLUS is a randomized, double-blind, placebo-controlled phase 3, 2-part, head-to-head study. The primary objective was to determine a final fixed duration infusion in patients with relapsing-remitting MS (18-55 years; treatment-naive; disease duration ≤3 years; Expanded Disability Status Scale score 0-3.5) receiving ocrelizumab 600-mg infusions every 24 weeks for 192 weeks. In ENSEMBLE PLUS, ocrelizumab (600 mg) administered over the approved infusion time (3.5 hours; conventional duration), is compared with a 24-hour infusion (shorter duration); the initial infusion (2 x 300 mg) duration remains unaffected. The ENSEMBLE PLUS primary end point is the proportion of patients with infusion-related reactions (IRRs) following the first randomized infusion (frequency/severity assessed during and 24 hours postinfusion). Results: As of September 2019, 291 and 289 patients were randomized to the conventional and shorter infusion groups, respectively. Following the first randomized infusion, 67 patients (23.1%) in the conventional and 71 patients (24.6%) in the shorter infusion group had IRRs, from which 17.9% vs 31.0% were throat irritation and 25.4% vs 23.9% were fatigue, respectively. Most IRRs were mild or moderate; >98% of all IRRs resolved without sequelae in both groups. No IRRs were life-threatening, serious, or fatal; 1 severe IRR occurred in both the conventional

Conclusion: Ocrelizumab administered over a shorter infusion time of 2 hours was noninferior in safety to the conventional 3.5-hour infusion and led to shorter patient and site burden.

Disclosure: Nothing to disclose
Keywords: Ocrelizumab, Relapsing-Remitting MS, Safety

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Effect of Ofatumumab on Serum Immunoglobulin Levels and Infection Risk in Relapsing Multiple Sclerosis Patients from the Phase 3 ASCLEPIOS I and II Trials

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Background: Ofatumumab, the first fully human anti-CD20 monoclonal antibody, demonstrates superior efficacy as a teriflunomide in patients with relapsing-remitting multiple sclerosis (RMS) in the phase 3 ASCLEPIOS I/II trials. A decline in serum immunoglobulin (lg) levels was observed with other anti-CD20 therapies. Objectives: To determine serum IgG and IgM levels and investigate associations between IgG/IgM levels and risk of infections in ofatumumab-treated patients. Methods: In the ASCLEPIOS trials, patients with RMS were randomized to subcutaneous ofatumumab 20 mg on days 1, 7, and 14, week 4, and every 4 weeks thereafter or once-daily oral teriflunomide 14 mg for up to 30 months (average follow-up duration: 18 months). Serum IgG/IgM levels were monitored at baseline, weeks 4 and 12, and every 4 weeks thereafter (ofatumumab, n = 946; teriflunomide, n = 936). A notable decline in IgG/IgM levels was defined as 50% of the lower limit of normal (LLN) at any time (IgG: 3.5 g/L; IgM: 0.2 g/L). Outcomes included the proportion of patients with lgG/lgM levels <50% LLN, and association between low IgG/lgM levels and incidence of infection in ofatumumab-treated patients. Results: At week 120, patients reached lgG levels <50% LLN with ofatumumab (median IgG [g/L]: ASCLEPIOS I and II, 10.57 and 9.57, respectively) or teriflunomide (10.01 and 9.65). The proportion of patients who reached lgM levels <50% LLN was 2.1% (n = 20/944) with ofatumumab (median lgM [g/L]: 0.91 and 0.59) and 0.6% (n = 6/933) with teriflunomide (0.84 and 0.92) at week 120. Of these patients, 5 had infections with mostly nonserious grade (less than grade 1/2 in severity), except one grade 3 recurrent urinary tract infection, but all infections were resolved. One patient on teriflunomide who had nasopharyngitis had not recovered at the time of last follow-up. Conclusions: A reduction in serum lgG levels <50% LLN was not observed with either treatment. IgM levels showed reductions with both ofatumumab and teriflunomide treatments; there was no apparent association with increased rate of serious/nonserious infections in patients with RMS.

Oftatumumab Versus Teriflunomide in Relapsing Multiple Sclerosis: Analysis of No Evidence of Disease Activity (NEDA-3) from the No ASCLEPIOS I and II Trials

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Background: Late Breaking

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Background: Ofatumumab, the first fully human anti-CD20 monoclonal antibody, demonstrated superior efficacy vs teriflunomide in the phase 3 ASCLEPIOS I/II randomized multiple sclerosis (RMS) trials. Neda-3 (defined as no 6-month confirmed disability worsening [6mCDW], no confirmed multiple sclerosis (MS) relapse, no new/enlarging T2 lesions, and no Gd+ T1 lesions) in the ASCLEPIOS I/II trials. Methods: We pooled data from the ASCLEPIOS I (n = 927) and II (n = 955) trials. Outcomes included NEDA-3 (defined as a composite of no 6-month confirmed disability worsening [6mCDW], no confirmed multiple sclerosis (MS) relapse, no new/enlarging T2 lesions, and no Gd+ T1 lesions) and its individual components in a modified full analysis set (modified FAS; logistic regression model). ARR by time intervals and Gd+ T1 lesions in the FAS (negative binomial model for both) were also analyzed. Results: The odds of achieving NEDA-3 with ofatumumab vs teriflunomide were 3.65-fold higher at month [M] 0-12 (47.0% vs 24.5% of patients; odds ratio [OR] 95% CI: 3.36 [2.67; 4.21], P < .001) and 8.82-fold higher at M12-24 (8.82 [6.75; 11.30], P < .001). Ofatumumab significantly reduced the mean number of Gd+ T1 lesions per scan by 95.9% compared with teriflunomide [mean [95% CI]: 0.02 [0.01; 0.03] vs 0.50 [0.42; 0.59], P < .001]. Conclusions: Ofatumumab increased the probability of achieving NEDA-3 and demonstrated superior efficacy vs teriflunomide in patients with RMS.

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Keywords: Comprehensive care and MS, Disease-modifying treatments in MS, Immunology and MS

Real-World Findings of Usability and Usefulness of Multiple Sclerosis Progression Discussion Tool: A Physician-Completed Digital Tool to Evaluate Early Signs of Disease Progression

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Background: MSProDiscuss is a validated physician-completed tool based on a set of weighted questions that include information on multiple sclerosis (MS) relapses, symptoms, and impacts experienced by the patient within the past 6 months. The tool’s traffic light system-linked output is meant as an aid for discussing the signs of MS disease progression. The tool is available online at www.msprodiscuss.com. Objectives: To report physician findings on usability and usefulness testing of the MSProDiscuss tool while discussing disease progression with patients in the real-world setting. Methods: An online qualitative survey was conducted in 34 countries to explore the utility of the tool among neurologists. Individual questionnaires (I) after using MSProDiscuss during face-to-face patient consultations and a final questionnaire (F) to capture the overall experience on the tool. The HCPs also provided general feedback and recommendations for improving the tool. Results: In total, 301 HCPs (including 23 MS nurses and 6 neurology nurse practitioners) tested the tool in 6974 patients with MS. The time taken to complete MSProDiscuss during a regular consultation was 1-4 minutes in 97% (I) to 98% (F) of the time. In 94% (I) to 97% (F) of cases, HCPs agreed that patients were able to comprehend the questions from the tool. HCPs were willing to use the tool again in the same patient 91% (I) of the time. MSProDiscuss was useful in discussing MS symptoms and its impact on daily activities (88% i / 92% f) and cognitive function (79% both i and f) and in discussing progression in general (88% i / 90% f). While completing the final question- naire, 95% of HCPs agreed that the questions were similar to those asked in regular consultation. MSProDiscuss was also found helpful for understanding the impact of MS symptoms on daily activities (91%) and cognitive function (80%). Overall, 92% of the HCPs would recommend MSProDiscuss to a colleague. Regarding integration of MSProDiscuss into their clinical practice, 92% of HCPs think that it is feasible and 86% are willing to integrate. Key recommendations were to allow for longitudinal follow-up, expand on cognitive assessments, and provide a patient- completed version; these are considered in the updated version of MSProDiscuss. Conclusions: The findings from this real-world study suggest that MSProDiscuss is a usable and useful tool to facilitate physician-patient discussion on disease progression in daily clinical practice by capturing structured disease history.

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Late Breaking

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Efficacy and Safety of the Bruton’s Tyrosine Kinase Inhibitor (BTKI) Evobrutinib in Relapsing Multiple Sclerosis over 108 Weeks: Open-Label Extension to a Phase 2 Study

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Keywords: Comprehensive care and MS, Symptoms of disease progression

Background: In a phase 2 randomized controlled trial (RCT; trial registration: NCT02975349) in patients with relapsing multiple sclerosis (MS), evobrutinib 75 mg twice daily reduced total T1 gadolinium-enhancing lesions (primary end point) and annualized relapse rate (ARR) over 24 weeks vs placebo, with efficacy maintained through week 48. Objectives: To assess long-term efficacy and safety in the open-label extension (OLE). Methods: In the double-blind period, patients received evobrutinib 25 mg or 75 mg once daily, evobrutinib 75 mg twice daily, open-label dimethyl fumarate (240 mg twice daily), or placebo for the first 24 weeks; all arms continued with the original treatment assignment until 48 weeks, except placebo patients who switched to evobrutinib 25 mg once daily. At week 48, all patients could enter the OLE, where treatment was initially evobrutinib 75 mg once daily (for approximately 48 weeks, median) before switching to 75 mg twice daily. The OLE assessed long-term efficacy (0-108 weeks) and safety (60-week OLE) of evobrutinib. Results: Of 267 randomized patients, 213 (79.8%) completed 108 weeks of treatment (48-week main study, 60-week OLE). For patients who received evobrutinib 75 mg twice daily in the double-blind period, the ARR (95% CI) was 0.11 (0.040-0.25) at week 48 and 0.12 (0.060-0.22) for the 108-week period. Evobrutinib was generally well tolerated, with the safety profile maintained during the 60-week OLE. Transient elevated liver aminotransferases, reported in the 48-week double-blind period, were not observed in the OLE. Conclusions: Efficacy and safety were maintained long-term. Two phase 3 RCTs evaluating the efficacy and safety of evobrutinib in patients with relapsing MS commence in 2020.

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Keywords: Disease-modifying treatments in MS

Natalizumab-Treated Patients with Relapsing-Remitting Multiple Sclerosis Report Better “Feel-Good” Outcomes on Key Physical, Emotional, and Cognitive Domains Compared to Other Disease-Modifying Therapies

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Background: Natalizumab is an efficacious therapy for patients with relapsing-remitting multiple sclerosis (RRMS). Some patients have reported an improved “feel-good” experience on natalizumab. Prior qualitative interviews of natalizumab-treated patients have suggested that the feel-good experience may be associated with increased energy and improved emotional and cognitive functioning. Objectives: To describe survey results assessing patients self-reporting a “feel-good” experience while receiving natalizumab or other disease-modifying therapies (DMFTs). Methods: Surveys were administered to adult patients with RRMS through MyMSTeam (part of the MyHealthTeam application). Patients were asked about their current DMFT use and its “feel-good” effect assessed by self-reported improvements in physical, emotional, or cognitive domains. Natalizumab or other-DMT patient responses were compared for multiple measures and compared using t test and log-rank tests. Results: Patients receiving natalizumab (n = 95) or other-DMT (n = 252) were included. Time since RMS diagnosis was <6 years in 29% (natalizumab) and 35% (other-DMT) and >15 years in 29% (natalizumab) and 27% (other-DMT). Significantly higher percentages of natalizumab than other-DMT patients reported that they “feel good” on their DMFT (63% vs 45%; P = .001). Physical benefits were reported by 78% of natalizumab and 67% of other-DMT patients (P = .17), with significantly higher rates of improved energy (23% vs 12%; P = .011) and coordination (22% vs 12%; P = .17) for natalizumab vs other-DMT. Comparison of patients on natalizumab vs other-DMT indicated significantly higher scores on emotional components of physical, emotional, and cognitive functioning. Natalizumab patients reported significantly higher percentages of natalizumab than other-DMT patients reporting a “feel-good” experience compared with other-DMTs. Increased physical, emotional, and cognitive benefits (each P < .001). Conclusions: These real-world patient-centric survey results suggest that natalizumab is associated with improved improved quality of life compared with other-DMTs. Emotions, physical, emotional, and cognitive functioning were more common in patients receiving natalizumab than in patients receiving other DMFTs, consistent with qualitative interviews. These results are limited by the subjective nature of the survey responses. Supported by: Biogen

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Keywords: Disease-modifying treatments in MS, Patient-reported outcomes
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