BHPR - research

102. TRANSLATING PATIENT EDUCATION THEORY INTO PRACTICE: DEVELOPING MATERIAL TO ADDRESS THE CARDIOVASCULAR EDUCATION NEEDS OF PEOPLE WITH RHEUMATOID ARTHRITIS

Holly John1,2, Elizabeth Hale1,2, Paul Bennett3, Gareth Treherne1,4, Douglas Carroll5 and George Kitas1,5

1Department of Rheumatology, Dudley Group of Hospitals NHS Trust, Dudley, United Kingdom; 2School of Sport and Exercise Sciences, University of Birmingham, Birmingham, United Kingdom; 3Nursing, Health and Social Care Research Centre, University of Cardiff, Cardiff, United Kingdom; 4Department of Psychology, University of Otago, Dunedin, New Zealand; 5AR-UK Epidemiology Unit, University of Manchester, Manchester, United Kingdom

Background: There is a need to educate people with rheumatoid arthritis (RA) about cardiovascular disease (CVD), in particular aiming to change modifiable CVD risk factors. No educational material designed specifically for people with RA currently exists. Behavioural-style education programmes (which incorporate strategies whereby patients learn and develop skills to enable them to overcome adverse habits), especially interventions grounded in theories of human behaviour, have shown the best outcomes. We describe the rationale and design of a theory-informed patient education programme addressing CVD for people with RA to illustrate how theory can explicitly be translated into practice.

Methods: A literature review was followed by qualitative research with stakeholders (patients and health professionals) to identify both components of the education programme and pertinent psychological models to use in its design and delivery. A steering group oversaw the development of the programme itself, further informed by user involvement. The reading age of the materials was calculated.

Results: A small group 8-week psycho-educational programme was developed (see Table 1) with accompanying manual (reading age equivalent to a 13 year old) and website. A smaller concise booklet was also produced.

Conclusions: The programme aims to change modifiable CVD risk factors (how theory can explicitly be translated into practice). Further evaluation of the programme will be required to assess efficacy in real-world settings.

Disclosure statement: The authors have declared no conflicts of interest.

Table 1. CVD patient education programme for people with RA

<table>
<thead>
<tr>
<th>Week</th>
<th>Topic</th>
<th>Theoretical Model</th>
<th>Behavioural techniques employed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Introduction</td>
<td>CSM</td>
<td>Group discussion</td>
</tr>
<tr>
<td></td>
<td>Current beliefs about CVD</td>
<td>CSM</td>
<td>Information giving</td>
</tr>
<tr>
<td></td>
<td>CVD lifestyle risk factors</td>
<td>CSM</td>
<td>Encourage coping rather than avoidance techniques</td>
</tr>
<tr>
<td></td>
<td>Reaction to learning about CVD</td>
<td>CSM</td>
<td>Personal responsibility for health, self management, patient example</td>
</tr>
<tr>
<td>2</td>
<td>Risk factors for CVD</td>
<td>CSM</td>
<td>Calculating personal risk for CVD</td>
</tr>
<tr>
<td></td>
<td>Consideration of which CVD lifestyle risk factor is most appropriate to modify</td>
<td>TPB</td>
<td>Importance, intention and perceived control over CVD lifestyle factors, readiness to change lifestyle risk factors for CVD, motivational interviewing</td>
</tr>
<tr>
<td>3</td>
<td>Identification of CVD risk factor to be modified</td>
<td>S of C</td>
<td>Target goal identified in writing</td>
</tr>
<tr>
<td></td>
<td>Graded goal setting</td>
<td>S of C</td>
<td>Learning to set SMARTS goals</td>
</tr>
<tr>
<td></td>
<td>Review</td>
<td>S of C</td>
<td>Comparison of performance against initial goal set</td>
</tr>
<tr>
<td></td>
<td>Graded goal setting</td>
<td>S of C</td>
<td>Further SMARTS goals, rewards and contingency plans</td>
</tr>
<tr>
<td></td>
<td>5-7 Graded goal setting and weekly review</td>
<td>S of C</td>
<td>Skills mastery, regular practice, self-monitoring, practicing positive health behaviours</td>
</tr>
<tr>
<td></td>
<td>Review of progress</td>
<td>TPB</td>
<td>Comparing intention and perceived control for lifestyle modifications against week 2 scores</td>
</tr>
</tbody>
</table>

CSM: Common Sense Model; TPB: Theory of Planned Behaviour; S of C: Stages of Change model

103. A CASE SERIES STUDY TO DEFINE THE CLINICAL CHARACTERISTICS OF FOOT ULCERATION IN PATIENTS WITH RHEUMATOID ARTHRITIS

Heidi J. Siddie1, Jill Firth1, Robin Waxman1, Andrea Nelson2 and Phillip S. Helliwell1

1Section of Musculoskeletal Disease, University of Leeds, Leeds, United Kingdom; 2School of Healthcare, University of Leeds, Leeds, United Kingdom

Background: The overall prevalence of foot ulceration in patients with RA is estimated at 10-13%, with a high rate of recurrence. In contrast with diabetes there has been a lack of research in this area. This study describes the clinical characteristics of affected patients and time to healing.

Methods: Adults with RA, current foot ulceration and no diabetes were recruited. Data collection included: a 36 swollen/tender joint count; measurement of forefoot deformity (Platto’s Structural Index); sensation (10 gm monofilament); peripheral vascular disease (ABPI); plantar pressures (PressureStat); foot pain (VAS) and time to healing. Patients completed the HAQ and Leeds Foot Impact Scale (LFIS).

Results: 32 cases with 52 current ulcers were recruited between April 2009 and June 2010. Patients’ mean age was 72 years (range 45-85); Mean RA disease duration was 22 years (1-48); 75% were female. Mean swollen joint count was 5.48 (0-33) and tender joint count 9.19 (0-34). Median HAQ score was 1.88 (0.13-3.00; IQR 1.25, 2.38); median LFIS impairment/footwear score was 13.00/21 (4-19; IQR 10.00, 16.75); median LFIS activity/participation score was 25.50/30 (5-30; IQR 20.50, 28.00). Mean Platto forefoot index score was 149.05 (95% C.I. 137.43, 160.66).

In ulcerated limbs (n = 37), ABPI was < 0.8 in 2 (5%) patients; 6 (16%) were unable to tolerate measurement. Protective sensation was reduced in 25 (68%) of ulcerated limbs. Peak plantar pressures were high (> 5.0 kg/cm2) in 6 (16%) ulcerated limbs. Median foot pain was 48.5 (0-99; IQR 22.75, 80.25) versus 30.5 (0-98; IQR 11.75, 72.00) in non-ulcerated limbs.

13 patients (41%) had more than one current ulcer (range 1-5, mean 1.63); 5 (16%) had bilateral ulceration and 15 patients (47%) had past ulceration at a current ulcer site. Current ulcers were located over the dorsal aspect of interphalangeal joints (IPJs) (n = 12); plantar aspect of metatarsophalangeal joints (MTPJs) (n = 12); medial aspect of 1st MTPJs (n = 9); dorsal aspect of MTPJs (n = 2); inter-digital aspect of IPJs (n = 7); apex of toes (n = 3); other sites (n = 7). Mean ulcer size was 4.84 mm (range 0.3-13) by 3.29 (0.2-11). Most ulcers (> 42%, 82%) were superficial; 5 (10%) involved deep tissue and 4 (8%) probed to bone. 5 (10%) ulcers were infected. Time to healing was available for 35 ulcers: mean duration was 28 weeks (range 2-71 weeks; 95% C.I. 21.5, 34.6). Four ulcers remain open.

Conclusions: Ulcer patients had evidence of active disease and moderate to severe disability. Patients reported high impact of foot pain, and peak plantar pressures were not. Whilst most ulcers were small and shallow, patients often experience multiple ulcers and recurrent episodes, posing infection risk.

Disclosure statement: The authors have declared no conflicts of interest.

104. RESTING SPLINT PROVISION: A SURVEY OF PRACTICE AMONG NORTH-WEST RHEUMATOLOGY OCCUPATIONAL THERAPISTS

Charlotte Laver1, Jo-Anne Melson2 and Alison Hammond2

1Rheumatology, Pennine Musculoskeletal Partnership, Oldham, United Kingdom; 2Centre for Health Sport & Rehabilitation Research, University of Salford, Salford, United Kingdom

Background: Resting splints (RS) in rheumatoid arthritis (RA) are commonly provided by OTs for hand pain and inflammation. Recent trials identify effectiveness in established but not early RA. This prompted the North West (NW) COTSS-Rheumatology Group to survey current RS practice; frequency of clinical indicators for RS provision; assessment; joint positioning; wearing regimens; splint instructions; review and costs.

Disclosure statement: The authors have declared no conflicts of interest.
Methods: Survey items were generated by NWCO TSS and reviewed by the group and piloted. Following University of Salford ethics approval, it was sent to 35 NW Rheumatology OTs.

Results: 24 (69%) responded, 19 (79%) of respondents were RTs, 10.5% was not clear; 17 (70.9) made RS, 25% of early (<2y) duration and 22.5% (>2y) duration of established RA patients. For both groups the three most important: a) aims of RS provision were: to reduce night pain, rest weakened joint structures to reduce local inflammation; and correct joint position; b) clinical indications were for: for night-time: high levels of pain; ‘clawing’; strong finger flexion; and to maintain comfortable hand position. All used interview/overt to observe for RS. RS was a standardised measure: eg pain VAS, goniometer, tape measure, DASH and dynamometer. Reasons for non-provision were: psychological (eg patient not yet ready to accept), physical (eg skin integrity, difficulty don/doffing RS at night and recent joint injections. Average RS positioning was: 20° wrist extension (IQR 15-25°), 40° MCP flexion (IQR 30-46.25°) and 20°PIP flexion (IQR 11.5-30°). The most written. All gave some advice on RS wear regimens: gradually.

Conclusions: There was marked variation in care pathways and experiences of care provision that affected the patient journey, indicating a need for improved patient education and better co-ordination of care in some areas. These factors contributed to the impact of foot ulceration on HRQOL for patients with RA.

Disclosure statement: J.F. has received a postdoctoral research fellowship from the Smith & Nephew Foundation. All other authors have declared no conflicts of interest.
Background: Major challenges are faced by the research community in attracting elite minds to biomedical research and retaining them. The graduate research internship programme for podiatrists was conceived in 2003 and has received Arthritis Research UK grant funding since 2006. The concept of the internship relies on two principal ingredients for success: innovation and collaboration. The latter being the Universities of Leeds and Southampton. Our aim was to evaluate the internship programme in terms of interns’ further career pathways and interns’ view of the programme.

Methods: The structure of the internship is an eight week clinical research placement immediately after graduation, followed by a two-year mentorship programme, prior to a return to the host centre to develop a fellowship/PhD studentship application. Data of career pathways was collated from interns who had participated in the Arthritis Research UK internship programme. Eight interns took part in a group evaluation, carried out with the aid of a facilitator and an independent observer. The two interns unable to attend completed their evaluation by telephone at a later date. All evaluations were recorded and transcribed verbatim by an independent transcriber to maintain confidentiality and anonymity. A hermeneutical approach; interpretative phenomenological analysis of the transcripts was undertaken to identify recurring themes. These themes formed the basis of the results.

Results: Ten podiatrists have undertaken the internship and so far, apart from the two 2010 interns who are working in their first clinical posts, seven have gone on to success in obtaining higher degrees, clinical academic posts, externally funded clinical PhD studentships and latterly prestigious NIHR clinical research fellowships. From the interns’ evaluation six main themes were identified. These included (1)perceptions of the internship whilst applying (2)people, place, location (3)personal and professional development (4)psychosocial contributions to being an intern (5)mentorship and networking (6)alternative career pathways. ‘Exposure to research’ was a profound experience for the majority of interns, the desire for each intern reflecting the high levels of motivation to continually learn and achieve. Participating in the internships contributed to being an intern, enhancing self confidence, maturity and clinical knowledge indicated potential sources of uncertainty such as illness trajectory and potentially improve patient management.

Conclusions: Study findings confirm the significant role of uncertainty in these rheumatic conditions. Both HCPs and patients portray uncertainty as a multidimensional concept involving all areas of life and arising from a variety of sources that can further hinder patients’ quality of life. Future directions for evidence management of this important concept include: targeting specific patient management strategies including patient support, information and education.

This work will form the basis for the development of a reported outcome measure that will further allow us to quantify uncertainty and potentially improve patient management.

Disclosure statement: The authors have declared no conflicts of interest.

References:

visual analogue or numerical rating scales (BRAF VAS,NRS). This study examined their test-retest reliability.

**Methods:** RA patients attending clinics were invited to participate. On arrival patients completed the BRAF scales, 4-cm VAS, and the fatigue measures (Functional Assessment of Chronic Illness Therapy: Fatigue Scale (FACT-F); Multi-dimensional Assessment of Fatigue (MAF); Profile of Mood States (POMS); Short Form 36 Health Survey Vitality Subscale (SF-36 V); VAS pain, VAS patient global opinion of disease and the Health Assessment Questionnaire (HAQ)). Two questionnaires were completed in 2 random orders. A test-retest interval of 50-60 minutes (T2) ensured that both time points related to the same day and avoided capturing fluctuations in fatigue. The Bland and Altman method compared the two measurements (mean of T1 & T2 scores compared to their difference) and Pearson correlation coefficient was calculated for test-retest.

**Results:** 50 patients (36 female, 14 male; mean disease duration 13.5 years; age 56.2 years and HAQ 1.56) completed the questionnaires. Mean (SD) BRAF-MDQ global score was 37.4 (17.1), Physical 14.9 (5.2), Living with fatigue 9.6 (6.0), Cognitive 6.8 (4.5) and Emotional 6.0 (3.8). Mean (SD) VAS and NRS were: Severity 59.1 (22.0), 6.3 (2.3) and Effect 56.5 (25.1), 6.1 (2.6); and Coping 50.4 (27.5), 5.4 (2.9). Bland and Altman limits of agreement were good for all BRAF-MDQ dimensions (within 5 points on the scale) and the global score (within 11 points) and there were no biases related to overall score. Test-retest correlations (r) were: Physical: 0.94; Living with fatigue: 0.89; Cognitive: 0.89; Emotion: 0.92; Global: 0.95. BRAF short scales also showed good agreement with test-retest correlations (r) for VAS and NRS were: Effect 0.88 and 0.92; Physical 0.78 and 0.85; and Coping 0.82. The NRS Coping scores did not show such good agreement (r = 0.62).

**Conclusions:** The test-retest reliability of the BRAF-MDQ and the BRAF short scales is satisfactory for general use. The Coping short scale NRS performed less well than the Coping VAS and inspection of additional data from a third time point (at 1 week) suggests a few respondents may have inadvertently reversed scored the scale and therefore the wording of the stem question and anchors have been reviewed. The BRAF's are being examined for sensitivity to change as the ability to measure different components of fatigue may guide interventions and management.

**Disclosure statement:** The authors have declared no conflicts of interest.

110. **VALIDITY AND RELIABILITY OF THE SICONOLFI STEP TEST FOR ESTIMATING CARDIORESPIRATORY FITNESS IN RHEUMATOID ARTHRITIS PATIENTS**

Jennifer K. Cooney1, Yaseem A. Ahmad2, Jonathan P. Moore3, Andrew B. Lemmy1, Jeremy G. Jones2, Peter J. Madisson2 and Jeanette M. Thom1

1School of Sport, Health and Exercise Sciences, Bangor University, Bangor, United Kingdom; 2The Department of Rheumatology, Betsi Cadwaladr University Health Board (West), Bangor, United Kingdom

**Background:** Rheumatoid arthritis (RA) is associated with increased morbidity and mortality from cardiovascular disease (CVD). CVD accounts for up to 50% of deaths in RA. However, traditional CVD risk factors do not fully explain this increased risk. Reduced cardiorespiratory fitness is an acknowledged risk factor for CVD and RA patients have poor cardiorespiratory fitness compared to healthy age matched controls. The need for early identification of poor cardiorespiratory fitness in RA patients is essential in order to prescribe exercise interventions that aim to reduce patients’ risk of CVD. The ‘gold standard’ for assessing fitness is a VO2max test which cannot be done in a routine clinical setting due to the requirement of specialised equipment and maximal exertion by the patient. The aim of the present study was to assess the validity and reliability of a simple step test that could be used in the routine assessment of cardiorespiratory fitness in clinical practice.

**Methods:** Thirty patients (24 female, 6 male) with RA were recruited (mean ± SD age 52.7 ± 12.2 years, disease duration 12.9 ± 6.7 years). Patients completed the Siconolfi Step Test on two occasions to assess its reliability and also completed a VO2max test (cycle test with increasing workload every 2 minutes until volitional exhaustion) to assess validity. The step test involved stepping up and down a 10-inch step for 3 minutes in time with a metronome (68 bpm); heart rate was recorded at the end of each 3 minute stage. Reliability and validity was determined using Bland and Altman 95% limits of agreement, Pearson’s correlation and intraclass correlation coefficient (ICC).

**Results:** Twenty two patients completed all aspects of the study. Correlation between predicted (step test) and measured VO2max (22.03 ± 4.48 ml.kg⁻¹.min⁻¹ versus 19.91 ± 4.16 ml.kg⁻¹.min⁻¹) was high (r = 0.790, p < 0.001). Bland and Altman revealed a negative mean bias (-2.12 ml.kg⁻¹.min⁻¹) and the 95% limits of agreement were ± 5.70 ml.kg⁻¹.min⁻¹. There was a very high ICC (0.954, p < 0.01) between VO2max predicted by the step test on visits one and two (22.79 ± 4.60 ml.kg⁻¹.min⁻¹ versus 22.03 ± 4.48 ml.kg⁻¹.min⁻¹), with a negative mean bias (-1.75 ml.kg⁻¹.min⁻¹). The 95% limits of agreement were ± 2.70 ml.kg⁻¹.min⁻¹.

**Conclusions:** The Siconolfi Step Test is well tolerated and is a valid and reliable measure of cardiorespiratory fitness in RA patients. The submaximal test is very easy to perform and could be performed by any member of the rheumatology team. This investigation demonstrates that this group of RA patients have very poor cardiorespiratory fitness and with RA patients being at high risk of developing CVD, this test could be used as an early indicator of CVD risk and provide information necessary for exercise prescription.

**Disclosure statement:** The authors have declared no conflicts of interest.

111. **PATIENT-RELATED BARRIERS TO THE EFFECTIVE MANAGEMENT AND TREATMENT OF GOUT**

Karen T. Spencer1, Alison Carr1 and Michael Doherty1

1Academic Rheumatology, University of Nottingham, Nottingham, United Kingdom

**Background:** Gout affects 1-2% of UK adults and is the most common inflammatory arthritis in men and older women. Although effective treatments are available evidence suggests that gout is not always treated as well as it could be within the primary care setting. Even if healthcare professionals followed evidence-based guidelines, it is not at all clear that patients would adhere to long-term medication regimens. This study was designed to identify potential patient barriers to adherence to medication and lifestyle advice in gout. These data would then be incorporated into strategies to improve the management of gout in primary care.

**Methods:** Individual semi-structured face-to-face interviews were conducted with 20 gout patients recruited from Phase (I) of the Nottingham gout treatment trial. Patients were sampled to reflect differences across gender, age and length of diagnosis. Patients’ experiences of gout, their beliefs and expectations about treatment and the factors influencing how they accessed treatment or adopted lifestyle changes were explored. Interviews were transcribed and data were analysed using the software (QSR NVivo 8).

**Results:** Of the 20 patients interviewed 15 were men and 5 were women. Ages ranged from 35 - 81 years (mean age 61 yrs, standard deviation 10.2). The mean duration of disease was 12 years (standard deviation 11.1, min-max 2-42 years). A number of key themes/barriers emerged from the data suggesting there were several factors impacting on patients’ access to recommended treatments. The main barriers that emerged from the analysis related to patients’ lay beliefs and lay beliefs of their condition which affected adherence to treatment advice from their G.Ps. There was a universal lack of knowledge and understanding about the cause and consequence of gout and the importance of adherence to lifelong urate lowering therapies (ULT) alongside making adequate lifestyle changes.

All participants associated their gout with the negative stereotypical experiences of gout, their beliefs and expectations about treatment would then be incorporated into strategies to improve the management of gout in primary care.

**Conclusions:** Patient education and information giving will be an important factor in improving outcomes in gout. Health professionals need to have a clear understanding of patients’ lay beliefs and attitudes to their illness and treatment in order to help promote patient adherence through shared clinical communication.

**Disclosure statement:** The authors have declared no conflicts of interest.
<table>
<thead>
<tr>
<th>Component</th>
<th>General US populationa</th>
<th>Canakinumab 150 mg s.c.</th>
<th>Triamcinolone acetonide 40 mg l.m.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline N = 27</td>
<td>7 days post-dose N = 26b</td>
<td>Baseline N = 56</td>
</tr>
<tr>
<td>SF-36® scores (0-100)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical Component Summary Score (PCS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50.0 (10.0)</td>
<td>36.4 (8.2)</td>
<td>48.3 (8.6)</td>
<td>12.0 (10.0)</td>
</tr>
<tr>
<td>Mental Component Summary Score (MCS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>50.0 (10.0)</td>
<td>46.7 (13.6)</td>
<td>50.7 (11.2d)</td>
<td>3.4 (11.0)</td>
</tr>
</tbody>
</table>

SF-36® subscale scores:
- Physical functioning: 41.5 (30.2) vs. 40.0 (30.5), p = 0.50
- Role-physical: 50.0 (32.5) vs. 53.0 (29.0), p = 0.17
- Bodily pain: 71.2 (18.5) vs. 71.2 (18.5), p = 0.90
- Mental health: 81.3 (33.0) vs. 63.9 (32.6), p = 0.0005
- Role-emotional: 80.8 (25.0) vs. 80.8 (25.0), p = 0.90
- General health: 61.6 (31.5) vs. 66.5 (31.5), p = 0.01
- Bodily pain: 72.2 (22.0) vs. 72.2 (22.0), p = 0.90
- Role-physical: 53.0 (32.5) vs. 53.0 (32.5), p = 0.90
- Mental health: 61.6 (31.5) vs. 66.5 (31.5), p = 0.01

Mean (S.D.) values are presented throughout; *some scores evaluations were missing for up to 3 patients of the group; **normalized scores representing an average US person with no chronic disease; *reached general population levels; NA: not available. Reference: A Adapted from Ware J et al. SF-36® Physical and Mental Health Summary Scales: A User’s Manual, Boston, MA: The Health Institute. 1994

**Table 1. Comparison of HRQoL scores of gouty arthritis patients treated with canakinumab and triamcinolone acetonide**

---

**Metabolic and crystal arthropathies**

**112. RAPID IMPROVEMENT IN HEALTH-RELATED QUALITY OF LIFE IN GOUTY ARTHRITIS PATIENTS TREATED WITH CANAKINUMAB (ACZ885) COMPARED TO TRIAMCINOLONE ACETONIDE**

Alexander So1, M. De Meulemeester2, A. Pikhlak3, A. E. Yücel4, B. Bodalia5, J. Kerrane6, U. Arulmani7, D. Richard7, K. Stricker7, A. Ferreira7, V. Murphy7, P. Sallstig7 and N. Schlesinger8

**Background:** Canakinumab, a fully human anti-IL-1β antibody has been shown to control inflammation in gouty arthritis. This study evaluated changes in health-related quality of life (HRQoL) in patients treated with canakinumab or triamcinolone acetonide (TA).

**Methods:** An 8-wk, dose-ranging, active controlled, single-blind study in patients (> 18 to < 80 years) with acute gouty arthritis flare, refractory to or contraindicated to NSAIDs and/or colchicine, were randomized to canakinumab 10, 25, 50, 90, 150 mg sc or TA 40 mg im. HRQoL was assessed using patient reported outcomes evaluating PCS and MCS, and subscale scores of SF-36® (acute version 2) and functional disability (HAQ-DI).**

**Results:** In canakinumab 150 mg group, the most severe impairment at baseline was reported for physical functioning and bodily pain; levels of 41.5 and 36.0, respectively, which improved in 7 days to 80.0 and 72.2 (mean increases of 44.6 and 50.6); these were higher than levels seen in the general US population. TA group, showed less improvement in 7 days (mean increases of 23.3 and 21.3 for physical function and bodily pain). Functional disability scores, measured by the HAQ-DI®, decreased in both treatment groups (Table 1).

**Conclusions:** Gouty arthritis patients treated with canakinumab showed a rapid improvement in physical and mental well-being based on SF-36® scores. In contrast to the TA group, patients treated with canakinumab showed improvement in 7 days in physical function and bodily pain approaching levels of the general population.

**Disclosure statement:** U.A., A.F., V.M., D.R., P.S. and K.S. are employees and shareholders of Novartis Pharmaceuticals Corporation, has served on advisory boards for Novartis, Takeda, Savient, URL Pharma and EnzymeRx, and is/has been a member of a speakers’ bureau for Takeda. A.S. has received consultation fees from Novartis Pharma AG, Abbott, Bristol-Myers Squibb, Essex, Pfizer, MSD, Roche, UCB and Wyeth. All other authors have declared no conflicts of interest.

**113. EFFICACY OF CANAKINUMAB (ACZ885), A FULLY HUMAN ANTI-INTERLEUKIN -1BETA MONOCLONAL ANTIBODY, IN THE PREVENTION OF FLARES IN GOUT PATIENTS INITIATING ALLOPURINOL THERAPY**


**Background:** Gout patients initiating urate lowering therapy have an increased risk of flares. Inflammation in gouty arthritis is induced by interleukin (IL)-1β. Canakinumab inhibits IL-1β effectively in clinical studies. This study compared different doses of canakinumab vs colchicine in preventing flares in gout patients initiating allopurinol therapy.

**Methods:** In this 24 wk double blind study, gout patients (20-79 years) initiating allopurinol were randomized (1:1:1:1:1:1:2) to canakinumab s.c. single doses of 25, 50, 100, 200, 300 mg, or 150 mg divided in doses every 4 wks (50 + 50 + 25 + 25 mg q4wk) or colchicine 0.5 mg p.o. daily for 16 wks. Primary outcome was to determine the canakinumab dose giving comparable efficacy to colchicine with respect to number of flares occurring during first 16 wks. Secondary outcomes included number of patients with flares and C-reactive protein (CRP) levels during the first 16 wks.

**Results:** 432 patients were randomized and 391 (91%) completed the study. All canakinumab doses were better than colchicine in preventing flares and therefore, a canakinumab dose comparable to colchicine couldn’t be determined. Based on a negative binomial model, all canakinumab groups, except 25 mg, reduced the flare rate ratio per patient significantly compared to colchicine group (rate ratio estimates 25 mg 0.60, 50 mg 0.34, 100 mg 0.28, 200 mg 0.37, 300 mg 0.29, q4wk 0.38; p < 0.05). Percentage of patients with flares was lower for all canakinumab groups (25 mg 27.3%, 50 mg 16.7%, 100 mg 14.8%, 200 mg 18.5%, 300 mg 15.1%, q4wk 16.7%) compared to colchicine group (44.4%). All patients taking canakinumab were significantly less likely to experience at least one gout flare than patients taking colchicine (odds ratio range [0.22 – 0.47; p < 0.05 for all]). Median baseline CRP levels were 2.56 mg/L for 25 mg, 3.42 mg/L for 50 mg, 1.76 mg/L for 100 mg, 3.66 mg/L for 200 mg, 3.21 mg/L for 300 mg.