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Background: Clinical trials may not readily reflect clinical practice. We aimed to assess the clinical effectiveness of vedolizumab in a real-world cohort of patients with ulcerative colitis (UC).

Methods: This is a prospective, observational, multi-centre cohort study. Eligible patients had active UC confirmed by a Mayo endoscopic subscore ≥2 at initiation of vedolizumab and had started treatment from 1/6/2015. Exclusion criteria included concurrent participation in a clinical trial in which UC treatment is dictated and contraindications to vedolizumab. All patients provided a written consent. Data on clinical characteristics, treatment patterns, disease activity and the short health scale (SHS) were recorded at baseline and prospectively, using an electronic Case Record Form, integrated with the Swedish National Quality Registry for IBD (SWIBREG). Data on the patients who had completed the 52-week follow-up are presented. The primary outcome at Week 52 was clinical remission, defined as a Mayo score ≤2, with no subscore >1. Continuous data are presented as median (interquartile range). Differences between baseline and Week 52 were assessed by the Wilcoxon-signed rank test.

Results: One hundred and thirty UC patients had been included by 19/09/2017. Clinical characteristics of patients (n = 60) who had completed the 52-week study period are shown in Table 1: 49 of 60 (81.7%) patients had failed prior anti-TNF therapy. At Week 52, 36 of 60 (60%) were still on treatment with vedolizumab, 26 of 60 (43%) had achieved clinical remission (pMayo score), and 16 of 60 (27%) were in clinical and endoscopic remission (full Mayo score). Notably, information on endoscopy at Week 52 was absent in 10 patients (17%). Among the 36 patients who had continued vedolizumab treatment, a decrease in the median pMayo score [4 (4–6) vs. 1 (0–2); n = 34; p <0.001], median full Mayo score [7 (6–8.5) vs. 1.5 (0–2.5); n = 24; p < 0.001], median f-Calprotectin [646 (403–894) vs. 281 (68–382) pg/g; n = 17; p = 0.01] and median C-reactive protein [3.0 (2.0–8.0) g/l vs. 2.4 (1.0–5.0) g/l; n = 35; p = 0.12] was observed from baseline to Week 52. Consistently, quality of life improved, defined as a significant reduction of the overall SHS score (n = 35; p < 0.001).

Conclusions: Vedolizumab treated patients with UC represented a treatment-refractory group. Long-term effectiveness of vedolizumab can be achieved, in terms of clinical- and inflammatory activity as well as in quality of life. The study was financially supported by Takeda.

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Limited clinical value in assessing the distribution of endoscopic disease activity in patients with ulcerative colitis

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Background: Most endoscopic activity scores for ulcerative colitis (UC) do not take into account the extent of mucosal inflammation. In contrast, the Modified Mayo Endoscopic Score (MMES) is calculated by multiplying the Mayo endoscopic sub-score for five different colon segments with the maximal extent of inflammation divided by the number of segments with active inflammation. We evaluated the added value of the MMES over the Mayo endoscopic sub-score in a prospective study (S54710).

Methods: Since January 2014, Mayo score and MMES were prospectively assessed in patients initiating biological therapy for active UC at a tertiary referral centre. Patients without baseline endoscopic disease activity (Mayo ≤1), without assessment of the upper margin of inflammation, or with a follow-up < 6 months were excluded. Based on local reimbursement criteria, clinical and endoscopic assessment were repeated after 8 (adalimumab, ADM) or 14 weeks (golimumab, GOL; infliximab, IFX; or vedolizumab, VDZ). Clinical response was defined as a decrease in the adapted Mayo score with ≥2 points and ≥30%, plus a decrease in rectal bleeding score ≥1 or an absolute rectal bleeding score of ≤1. Based on the evolution in endoscopic activity, patients were categorised in group A (mucosal healing, Mayo ≤1), group B (Mayo >1 but ΔMMES ≥30%), and group C (Mayo >1 and ΔMMES <30%). Clinical relapse was defined as need for treatment optimisation.

Results: A total of 138 UC patients were included (50% male, median age 42 years, median disease duration 7 years). Anti-TNF was initiated in 68 patients (20 ADM, 16 GOL, 32 IFX), and VDZ in 70 patients. Both endoscopic Mayo score [3 (IQR 2–3) vs 2 (1–3), p < 0.001] and MMES [8.33 (5.19–12.38) to 5.25 (1.00–10.13), p < 0.001] dropped significantly by Weeks 8–14. Clinical response was seen in 60 of 62 (97%) patients in group A, 12 of 24 (50%) in group B, and 9 of 52 (17%) in group C (p < 0.001). During a median follow-up of 21 (12–28) months, 13 of 81 (16%) patients developed a clinical relapse. The ΔMMES was of no additive value to predict clinical relapse (Figure). Although, a significant difference was demonstrated between groups A, B and C for treatment discontinuation and colectomy (Figure), the clinical significance was limited.

Conclusions: In this prospective study, MMES had no significant value over the Mayo endoscopic sub-score in predicting mid-term outcome of biological therapy. A Mayo endoscopic sub-score ≤1 after induction with biological therapy was the best predictor of relapse-free, discontinuation-free and colectomy-free survival.

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Systemic cytomegalovirus infection is a relevant factor affecting short- and long-term outcomes of patients with acute severe ulcerative colitis: An 11-year experience

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Abstract P548 – Figure

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Background: Acute severe ulcerative colitis (ASUC) remains a life-threatening condition. Short- and long-term clinical outcomes are still highly variable despite the widespread use of Oxford protocol and the current availability of infliximab (IFX) or cyclosporine (CyA) as rescue therapies. We aimed to report our single-centre experience on clinical outcomes of patients with ASUC and the factors affecting its course.

Methods: We retrospectively collected data from 202 consecutive hospital admissions (106 patients) for ASUC from January 2006 to July 2017. The response to intravenous steroids and rescue therapy, and the occurrence of toxic megacolon (TM) were assessed as short-term outcomes, whereas long-term outcomes included remission after 1 year from the episode of ASUC and colectomy-free survival along the entire follow-up.

Results: The overall response rates to intravenous steroids and rescue therapy were 47.5% and 91.8% (IFX: 74 of 79, 93.7%; CyA: 16 of 19, 78.9%), respectively, while TM occurred in 24 cases (11.9%). After 1 year from the episode of ASUC, only 25.4% of patients were in continuous clinical remission. A median follow-up of 37 months (IQR 9.25–98 months), 28 patients (26.4%) underwent colectomy. Colectomy-free survival rates at 3 months and 1 year were, respectively, 82.1% and 77.4%. At multiple mixed-effect regression analysis, systemic CMV infection (defined by blood positivity for CMV-DNA or pp65 antigenemia) was an independent predictor of non-response to IFX rescue therapy (OR 0.12, CI 0.02–0.78, p = 0.031), occurrence of TM (OR 4.21, CI 1.35–13.12, p = 0.013), and colectomy (OR 4.56, CI 1.41–14.55, p = 0.010), together with TM (OR 4.77, CI 1.70–13.35, p = 0.003). Semi-parametric survival Cox analysis confirmed systemic CMV infection (HR 3.54, CI 1.47–8.51, p = 0.005) and TM (HR 3.00, CI 1.35–6.65, p = 0.007) as independent risk factors for colectomy.

Conclusions: Detection of CMV in blood—but not on rectal biopsies—is an independent risk factor affecting the main clinical outcomes of patients with ASUC.

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Early 12-week ultrasound response to treatment, used as a predictor of response at 6 months in Crohn’s disease: A prospective cohort study

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Background: Ultrasound (US) is safe and accurate for detecting activity and therapeutic response in Crohn’s disease (CD). Early objective assessment may better guide treatment in a treat to target paradigm. The aim of this study is to evaluate 12-week US response to adalimumab (ADA) induction, as a predictor of US, serologic and endoscopic response at 6 months.

Methods: Patients with known CD were prospectively recruited from January 1, 2011 to December 31, 2014. Patients with active CD had induction and maintenance therapy with ADA with US and C-reactive protein (CRP) levels measured pre-treatment, at 12 weeks and 6 months. Patients underwent ileocolonoscopy (IC) at baseline. A subset had repeat IC at 6 months. The Simple Ultrasound Score (SUS) was calculated (bowel wall thickness and hyperaemia) at each interval and a Simple Endoscopic Score (SES)/Rutgeert’s score for IC when available. Response at 12 weeks was defined by a reduction in SUS or length of disease. Differences between variables at baseline and 6 months were compared using paired sample t test. Features for non-response including presence of strictures or penetrating complications were recorded at baseline.

Results: Forty-four patients were included: 64% (28 of 44) females, 36% (16 of 44) male, with mean age of 42 years. Disease distribution was ileal 38% (17 of 44), 35% (24 of 44) ileocolonic and 7% (3 of 44) limited to the colon. All patients exhibited activity on US at baseline, with a mean SUS of 3.14 (out of 4.63). SES was completed for 22 of 44 patients (50%), mean 6.82, Rutgeert’s score was completed for 11 of 44 patients (25%), mean 3.27, while 18% (8 of 44) were not amenable to endoscopic scoring and 7% (3 of 44) had no baseline IC. The median baseline CRP was 5.7 mg/L. At 12 weeks, 70% (31 of 44) improved while 30% (13 of 44) had no change or worsened. Responders were evaluated at 6 months for response compared with baseline: SUS and SES were significantly improved, SUS was 3.45 at baseline and 1.84 at 6 months (p < 0.001) and SES was 6.77 at baseline and 2.50 at 6 months (p = 0.002). Change in CRP was significant (p = 0.044); but the change in Rutgeert’s score was not (p = 0.178). No significant difference for any comparison amongst the non-responders was detected. Of the responders, 9 of 31 (29%) exhibited high-risk features at baseline, compared with 5 of 13 (38%) in the non-responders.

Conclusions: Sonographic response to ADA induction at 12 weeks significantly increases the likelihood of further response at 6 months. Responders also exhibited a significant reduction in CRP. High-risk features on baseline US may indicate increased likelihood for non-response. Measurement of 12-week US response may help guide early treatment optimisation.