Results: 169 patients (112 with CD and 57 with UC) were included. At Week 10, a steroid-free remission was achieved in 44 out of 169 patients (26.0%), and a response in 35 (20.7% - overall clinical benefit: 46.7%), while at 52 weeks a steroid-free remission was achieved in 30 out of 128 patients (23.4%), and a response in 18 (14.1% - overall clinical benefit: 37.5%). The median follow-up was 47.0 weeks (148.39 person-years), and the failure-free survival was 60.4% at 1 year. Semi-parametric Cox model showed that patients with CD had a higher risk of treatment failure compared with patients with UC (HR 2.06, 95% CI: 1.05–4.05, $p = 0.036$). After 10 weeks, a response on articular symptoms was reported in 12 out of 39 patients (30.8%) with active SpA at baseline, and in 12 out of 16 patients (75.0%) at Week 52. At Week 10, the only factor that was marginally associated with the articular response was the clinical benefit on intestinal symptoms (OR 5.07, 95% CI: 0.97–31.70, $p = 0.055$), while the coexistence of axial and peripheral SpA was associated with a reduced response rate compared with peripheral manifestations only (OR 0.13, % CI: 0.02–0.64, $p = 0.021$). Overall, 67 adverse events were reported (incidence rate: 45.2 per 100 person-years). Twenty (11.8% of patients) adverse events leading to treatment discontinuation were reported: 11 arthritic flares, 5 subjective perceptions of intolerance, 2 infusion reactions, one pneumonia, and one prostate cancer.

Conclusions: In this large cohort, VDZ provided good effectiveness on intestinal symptoms, particularly in patients with UC. A subset of patients reported improvement also on articular symptoms, especially in cases of peripheral SpA.

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Association between trough levels of vedolizumab and therapy outcome in a cohort of patients with inflammatory bowel disease

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Background: Vedolizumab(VDZ) is an α4β7 integrin antagonist for the treatment of IBD. The role of VDZ therapeutic drug monitoring has not been clearly defined. We aimed to investigate the association between VDZ trough levels and therapy outcome in a cohort of patients with inflammatory bowel disease (IBD) and the association between VDZ trough levels and clinical and biochemical variables.

Methods: IBD patients receiving VDZ were identified in a cross-sectional study where serum samples were not collected at a pre-specified time point. Ulcerative colitis(UC) and Crohn's disease(CD) clinical activity was quantified using Mayo clinical subscore (MCS, remission MCS ≤ 1) and Harvey–Bradshaw Index (HBI, remission HBI < 5). VDZ and antibody-to-vedolizumab (AVA) concentrations determined by Prometheus® Anser® laboratories using non-radiolabelled liquid-phase mobility shift assays. p-values < 0.05 were considered significant.

Results: *N* = 35 IBD patients included (57% UC, 54% male, median age(range) 44.3 years(17.7–76.2), 9% receiving immunomodulators, 83% prior anti-TNF. 34/35 patients had trough VDZ level performed during maintenance therapy. Median(range) trough VDZ concentration 9.5 µg / ml(0 – 25). 0/35 subjects had detectable AVAs. No association between MCS or HBI defined remission and trough VDZ concentrations was observed $p = 0.38$ and $p = 0.83$, respectively. No difference in trough VDZ concentrations observed comparing by IBD phenotype($p = 0.50$); prior biologic exposure($n = 0.37$); or concomitant immunomodulator use($p = 0.68$). CRP and albumin levels were not correlated with trough VDZ concentrations, correlation coefficient –2.2($p = 0.36$) and 0.21($p = 0.36$) respectively.

Conclusions: In a real-world study of IBD patients receiving VDZ no clear association between VDZ trough levels and therapy outcome was observed. Significant immunogenicity was not observed supporting the use of VDZ monotherapy in uncomplicated patients. Further study is required to determine the utility of therapeutic drug monitoring in VDZ-treated patients.

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Incidence and risk factors of micronutrient deficiency in the patients with inflammatory bowel disease in Korea: folate, vitamin B12, 25-OH-vitamin D, ferritin

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Background: Inflammatory bowel disease (IBD) patients are vulnerable to micronutrient deficiencies due to diarrhoea-related gastrointestinal loss and lack of dietary intake from anorexia related to disease activity. According to the European Society for Clinical Nutrition and Metabolism (ESPEN) guideline, patients with IBD should be regularly checked for micronutrient deficiencies and certain defects should be adequately corrected. However, there is still limited number of studies on the incidence and risk factors of micronutrient deficiency.

Methods: We retrospectively analysed 105 IBD patients who underwent micronutrient examination including folate, vitamin B12, 25-OH-vitamin D, ferritin from March 2016 to March 2017. In addition, all of these patients had follow-up blood tests 6 months later at single tertiary university hospital.

Results: In the deficiency group, 76 (72.4%) patients had a deficiency in one of the four micronutrients (folate, vitamin B12, 25-OH-vitamin D, and ferritin), and 29 (27.6%) were in the non-deficient group. Deficiency group showed significantly higher rate of young age (mean ± standard deviation [SD], 38.7 ± 14.5 vs. 54.4 ± 15.0; $p < 0.001$), incidence of deficiency in Crohn's disease (CD) (CD, ulcerative colitis [UC], and intestinal Behcet's disease [BD]; 78.9% vs. 14.5% vs. 6.6%; $p < 0.001$), use of azathioprine (35.5% vs. 10.3%; $p = 0.011$) and anti TNF agents (50.0% vs. 20.7%; $p = 0.006$) compared with non-deficient group. On the multi-variate analysis, CD (Hazard ratio [HR], 3.600; 95% confidence interval [CI], 1.057–12.253; $p = 0.040$) and intestinal BD (HR, 15.469; 95% CI, 1.081–221.359; $p = 0.044$) were determined to be significant independent factors for micro-nutrient deficiency compared with UC.