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Early vedolizumab trough levels are not associated with a short-term response in patients with inflammatory bowel disease

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Background: Therapeutic drug monitoring is useful in anti-TNFa treatment of inflammatory bowel disease (IBD). However, data on vedolizumab therapy are sparse. Our aim was to assess association between early vedolizumab trough levels (VTL) and response to induction therapy in patients with IBD.

Methods: Study population comprised consecutive IBD patients from a prospective cohort of vedolizumab treated patients at our centre who had vedolizumab trough levels (VTL) and anti-vedolizumab antibodies (AVA) measured during induction phase of therapy. Included patients obtained vedolizumab 300 mg at weeks 0, 2, 6 with additional dose at Week 10 in case of inadequate response after third infusion. Clinical response evaluated by physician global assessment (PGA) was assessed 1 month after last induction dose (Week 10 or 14). Measurement of VTL and AVA was performed by ELISA assays (ImmunoGuide®, Tani Medical) with a detection limit for VTL of 1.9 μg/ml and measurement range of 0 to 600 μg/ml, and with AVA cut-off value 3 AU/ml.

Results: We included 87 patients, 31 with Crohn's disease and 56 with ulcerative colitis. At baseline, only 15% of patients were naïve to anti-TNFa therapy; 61% used systemic steroids and 26% thiopurines. Additional dose at Week 10 was needed in 39% of individuals. Clinical response to induction phase assessed by PGA was reported in 77% of IBD patients. Median VTL at Week 6 and Week 10-14 were 30.6 µg/ml (1.1-80.0) and 19.1 (0-80.0) µg/ml, respectively. Seven per cent of patients developed positive AVA until Week 10–14. Comparing patients with and without clinical response to vedolizumab no significant difference in median VTL was found, both at Week 6 (33.5 vs. 28.2 μ g/ml; p = 0.71) and Week 10–14 (16.2 vs. 22.5 μ g/ml; p = 0.27). Patients with previous anti-TNFa therapy had significantly lower trough levels at Week 10-14 compared with naïve ones (median 16.1 vs. 29.1 μ g/ml, p = 0.02). Otherwise, no impact of diagnosis type or concomitant immunosuppressants on VTL was observed.

Conclusions: No association between early VTL and response to induction therapy was found in our study. Further studies have to address clinical utility of therapeutic drug monitoring in long-term vedolizumab treatment. The study was supported by the IBD-Comfort Foundation.

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Perianal Crohn's disease in the biological era

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Background: The purpose of this study was to characterise perianal disease (PD) in a cohort of patients with Crohn's disease (CD) followed prospectively for 10 years.

Methods: We performed a prospective cohort study to analyse data from 298 patients, 96 of whom with PD, over the period of 10 years (2007–2017). The characteristics of patients with PD were compared with controls with CD without PD. Perianal lesions were described in abscess, fistula, abscess and/or fistula, fissure, ulcer, fissure and/or ulcer, and stenosis. The Montreal classification was used to characterise CD.

Results: The analysis of patients with and without PD showed no difference in sex, behaviour (B1, B2, B3) and involvement of the upper gastrointestinal tract (L4). However, the group of patients with PD had a significantly lower age at onset of symptoms (median=25.5 years, IQR 20.5-34.0) vs. patients without PD (median=30.5 years, IQR 22.0–41.0) (p = 0.018), higher colon involvement (L2 + L3 vs. L1) (OR = 2.64, p = 0.001), higher rectal involvement (OR = 5.60, p < 0.001), higher rate of abdominal resection surgery (OR = 1.70, p = 0.046), and higher rate of biological therapy (OR = 2.86, p < 0.001). In patients with PD, 42 (43.8%) had abscess, 62 (64.6%) had fistula, 69 (71.9%) had abscess and/or fistula, 29 (30.2%) had fissure, 4 (4.2%) had ulcer, 33 (34.4%) had fissure and/or ulcer, 8 (8.3%) had anal stenosis; 37 (38.5%) had L1 involvement, 23 (24%) had L2, 36 (37.5%) had L3; 9 (9.4%) had L4 involvement; 38 (39.6%) had rectal involvement; 49 (51%) had B1 behaviour, 29 (30.2%) had B2; 18 (18.8%) had B3; 70 (72.9%) were under biological therapy; 35 (36.5%) had abdominal surgery and 60 (62.5%) had perianal surgery. In this group of patients, patients with abscesses and/or fistula had a higher rate of abdominal (OR = 3.38, p = 0.022) and perianal surgery (OR = 24.77, p < 0.001); patients with fissure and/or ulcer had a lower rate of abdominal (OR = 0.34, p = 0.025) and perianal surgery (OR = 0.11, p < 0.001); patients with anal stenosis had a higher rectal involvement (OR = 12.87; p = 0.006); and patients with fistula had a higher rate of biological therapy (OR = 3.66, p = 0.005). Conclusions: One third of patients with CD had PD, which is more prevalent in patients with colic involvement. The severity of the perianal location can be inferred by the higher rate of abdominal surgery in this group of patients. Of the perianal lesions, abscess and/ or fistula were associated with a worse overall prognosis. These data are in agreement with what is previously described in the literature. Patients with PD had higher rates of biological therapy, with a higher rate in patients with fistula compared with other lesions.

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Defective anti-microbial peptides expression in Crohn's disease mucosa can be reversed by strengthening IL-22 signalling

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Background: The intestinal epithelium can be easily disrupted during gut inflammation as seen in inflammatory bowel diseases (IBD) such as ulcerative colitis (UC) or Crohn's disease (CD). Aetiology of