Digital oral presentations

DOP Session 1: Current understanding efficacy and safety of biologics

DOP001
Effectiveness and safety of vedolizumab in anti-TNF naïve patients with inflammatory bowel disease: a multicentre retrospective European Crohn’s and Colitis Organisation study

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Background: In GEMINI trials, anti-tumour necrosis factor (TNF) naïve CD and UC patients had a superior response compared with anti-TNF-exposed. In real-world experience (RWE) the number of included anti-TNF-naïve patients was low. We aimed to evaluate the effectiveness and safety of VDZ in anti-TNF naïve patients in RWE setting.

Methods: This retrospective multicentre European pooled cohort study included consecutive active anti-TNF-naïve IBD patients treated with VDZ. Clinical response at week 14 was defined as the primary outcome. Patients with follow-up beyond week 14 and those discontinuing VDZ at any time were included for last follow-up analysis. The study protocol was reviewed and approved by ECCO Clinical Committee (Clincom).

Results: Since January 2015, 184 anti-TNF naïve patients from 23 centres initiated VDZ treatment (CD-50, UC-134).

Efficacy of vedolizumab in Crohn’s disease and ulcerative colitis- week 14.

In CD, 42/50 (82%) patients responded by week 14, and 32 (64%) were in clinical remission; 26/50 (52%) achieved corticosteroid-free remission (CSFR). At last follow-up (44 [IQR 30–52] weeks), 27/35 (77.1%) patients with available data responded to treatment; 24/35 (68.6%) were in clinical remission, 21/35 (60%) were in CSFR. For UC, 116/134 (79.1%) responded to treatment and 53 (39.5%) were in remission by week 14; 49/134 (36.6%) achieved CSFR. At last follow-up (42.5 [30–52] weeks), 79/103 (76.7%) patients responded to treatment, 69/103 (67.0%) were in remission and 61/103 (59.2%) in CSFR.
Efficacy of vedolizumab in Crohn’s disease and ulcerative colitis—last follow-up.

Endoscopic improvement was achieved in 8/11 (63.7%) and mucosal healing in 5/11 (45.5%) CD patients with available baseline/follow-up data. In UC, mucosal healing was achieved in 31/55 (58.5%) patients. Secondary loss of response was developed in 9/90 (10%) patients that continued treatment at week 14 after 39 (32–42) weeks of follow-up.

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Adverse effects were reported in 20 (11%) of the patients, leading to treatment discontinuation in 6 (3.3%).

Conclusions: VDZ was effective for induction of clinical remission and response in anti-TNF naïve patients. The response rates were similar in UC and CD. The efficacy is higher than reported in anti-TNF experienced patients and is comparable to that of anti-TNF biologics in this population.