

Vedolizumab(VDZ) real world outcomes in ulcerative colitis (UC)

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Introduction In GEMINI 1, UC response to vedolizumab (VDZ) was 47% at week 6 and 42% by week 52. Our aim was to assess real-life outcomes for VDZ in UC

Methods Data collected at 12 Australian (Aus), 1 UK and 2 Hong Kong (HK) centres, assessed response to VDZ at 3, 6 and 12 months using the Mayo Clinic Score (MCS, Aus/HK) or SCCAI and UCEIS (UK).

Results 293 patients (53% male, median age 38yr, 196 Aus, 93 UK, 4 HK) were assessed with similar age, disease location and duration allowing combining of data. Median MCS pre VDZ was 8 (range 2-12, n=152) and Mayo endoscopy subscore 2/3 (Aus, HK). Median SCCAI was 8 (range 0-13, n=87) and UCEIS 5/8 (UK). VDZ was the first biological agent in 170/293 (58%), prior anti-TNF use occurred in 123 [reason for switching: primary non-response (PNR) n=46, loss-of-response (LOR) n=62, side-effects (SE) n=15; 2 patients with side-effects were in remission and not included for analysis]. At VDZ start, 61% taking steroids and 56% immunomodulation (IM)

Response rates at 3 months 220/279 (79%) overall responded, TNF-naïve 134/163 (82%), TNF-exposed 86/116 (74% p=NS).

Remission rates at 3 months 155/279 (55%) in clinical remission, TNF-naïve 110/163 (67%), TNF-exposed 45/116 (39%, p=0.01). 60/132 (45%) patients in remission were on IM and 49/101 (49%) if not (NS).

6 months: Overall 144/235 (61%) in clinical remission, TNF-naïve 97/131 (74%), TNF-exposed 47/104 (45%, p=0.03), and 60/124 (48%) in endoscopic remission (MES = 0 or 1). Steroids were ceased in 61/136 (45%) if in remission and 23/85 (27%) if not (p=0.08). 39% (49/125) patients in remission were on IM and 29% (24/82) if not (NS)

12 months: Overall 117/196 (60%) were in remission, TNF-naïve 72/106 (68%), TNF-exposed 45/90 (50%, NS). No significant difference in remission rates seen between PNR, LOR, or anti-TNF naïve patients. Steroids ceased in 55/110 (50%) if in remission and 6/80 (8%) if not ($p<0.001$). 37/104 (36%) patients in remission were on IM and 13/78 (17%, $p=0.03$) if not. Those in remission at 3 and 6 months, 90% (74/82) and 92% (96/104) respectively maintained remission. Smoking status did not effect response to VDZ. Colectomy occurred in 33/293 (11%). Adverse events occurred in 20/293 (7%); 2 were serious (*Klebsiella* sepsis and hemophagocytic syndrome)

Conclusion VDZ induced remission in 55% at 3 months and 61% at 6 months with >90% maintaining remission at 12 months. VDZ use continued for 12 months in 71% (139/196) with 61% in remission. Steroids were withdrawn in 50% patients in remission at 12 months. IMs might increase remission rates at 12 months. VDZ was initially more effective in anti-TNF naïve patients but differences were lost at 12 months suggesting patience may be needed in anti-TNF-exposed patients.