2014. GEMINI III

Phase 3/ VEDO/CD-failed to TNFi/Induct

Effects of Vedolizumab Induction Therapy for Patients With CD in Whom Tumor Necrosis Factor Antagonist Treatment Failed

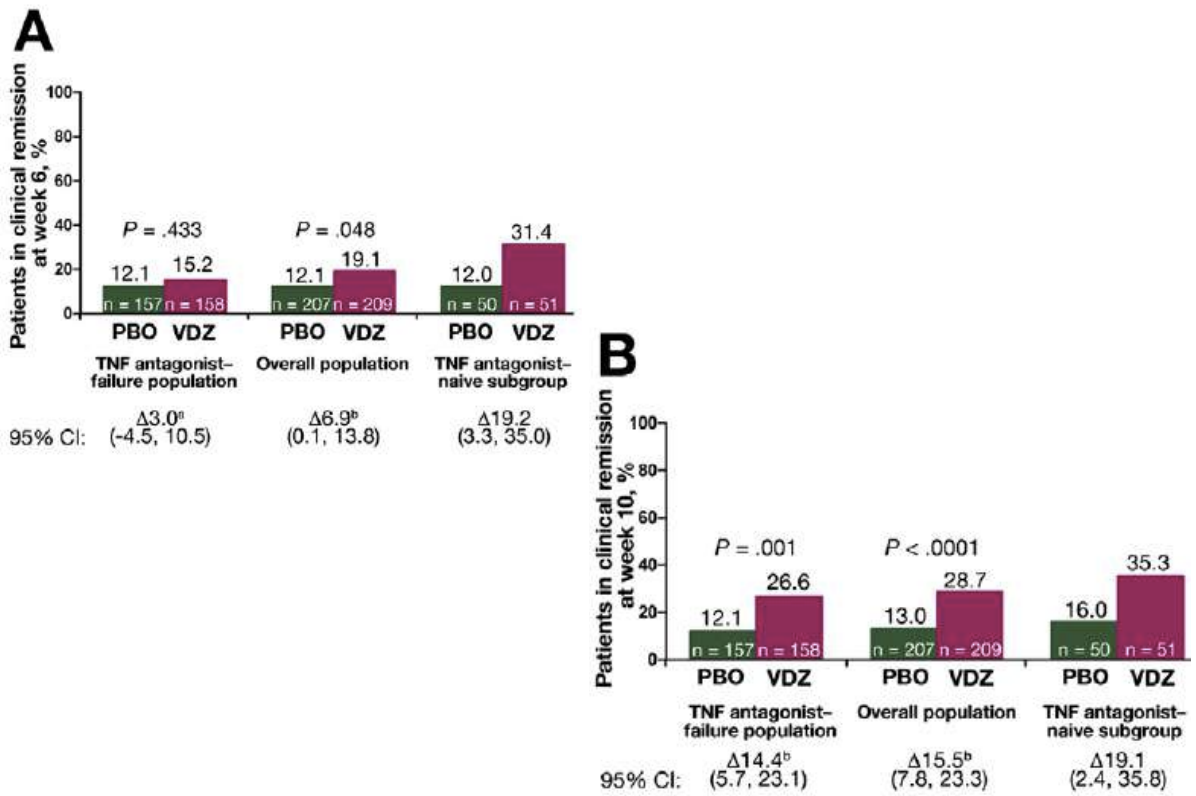
Randomised double-blind, placebo controlled trial.
Moderate-severe CD patients randomised to: VDZ 300mg (0,2,6) or placebo

<u>Primary outcome</u> for induction therapy: clinical response w6
Secondary outcomes: clinical remission w6 and remission w10.

<u>Results:</u>

- Clinical remission w6: antiTNF experienced on VDZ 15.2% vs 12.1% placebo; p=ns
- CDAI response w6: antiTNF experience on VDZ 39.2% vs 22.3 placebo; p=0.001
- Clinical remission w10: 26.6%VEDO vs 12.1% pbo; p=0.001
- CDAI response w10: 48%VEDO vs 24% pbo; p>0.0001

<u>Conclusions:</u>
Vedolizumab not more effective than placebo inducing clinical remission at w6 in patients with CD who failed to antiTNF. The therapeutic benefits of VDZ in these patients were detectable at w10.



Sands BE et al. Gastroenterol 2014; 147: 618-627