2023. EARNEST

RCT/VDZ/Pouchitis/ Induction

Vedolizumab for the treatment of chronic pouchitis

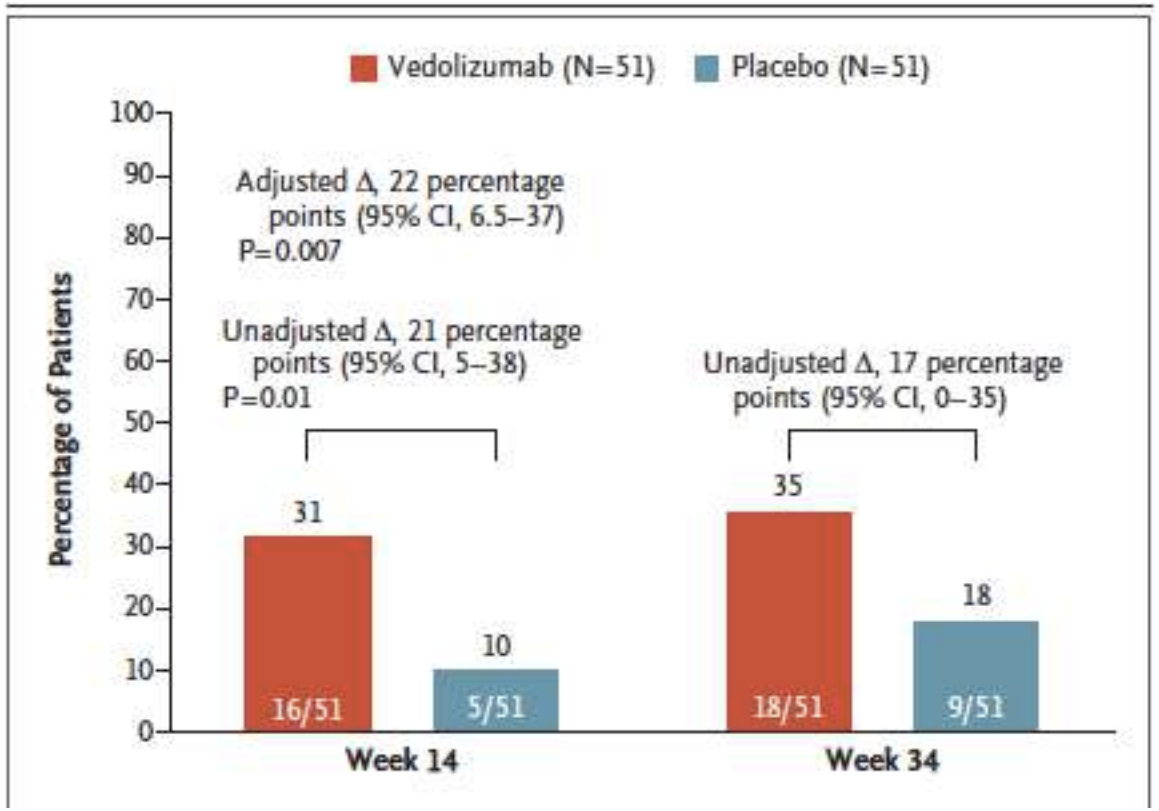
Phase 4, double-blind, placebo controlled trial.
Patients with chronic pouchitis after IPAA for ulcerative colitis were randomized to vedolizumab IV 300mg or placebo at (0,2,,6,14,22 and 30 weeks).
All the patients received concomitant ciprofloxacin from weeks 1-4

Primary endpoints: Modified pouchitis disease activity index (mPDAI) remission defined as <5 and a reduction of >1 point at week 14

Results: N=102

- At week 14 mPDAI remission was 31% VDZ vs 10% placebo, p=0.01
- Bigger number of patients among VDZ group received antibiotic course after randomization (in addition to the ciprofloxacin that all received per protocol) compared to placebo, 59% vs 37%.
- At week 34 mPDAI remission was 35% VDZ vs 18% placebo, Unadjusted , 17 percentage points (95% CI, 0–35)

Conclusion:
Treatment with vedolizumab was more effective than placebo in induction in patients who had chronic pouchitis after undergoing IPAA for ulcerative colitis.



Travis S et al. N Eng J Med. 2023; 388 (13):1191-1200