2024. ENTERPRET

RCT/VDZ/ UC/Dose optimization

ENTERPRET: A Randomized Controlled Trial of Vedolizumab Dose Optimization in Patients With Ulcerative Colitis Who Have Early Nonresponse

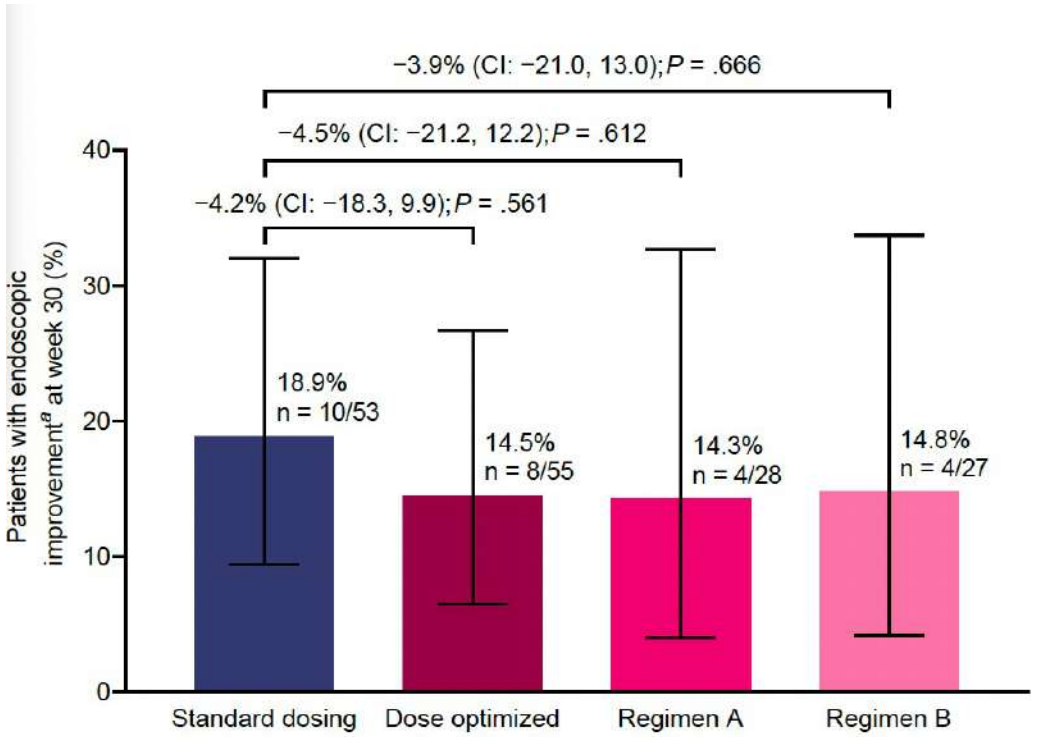
Phase 4, open-label, randomized, controlled trial.
Adult patients with mod-severe UC who had high drug clearance at week 5 (serum concentration <50 μg/mL) and nonresponse to standard vedolizumab treatment at w6, were randomized at w6 to receive either standard 300mg q8w vedolizumab or optimized dose of 600mg at w6 then 300mg q4w or 600mg at w6 and then 600mg q4w depending on their w5 serum concentrations.

Primary endpoint: Endoscopic improvement at w30.

Results: N=106

- At w30, 18.9% standard VDZ vs 14.5% dose-optimized had endoscopic improvement.
- Clinical remission at w30: 9.4% standard vs 9.1% optimized.
- Patients on optimized regimens had higher serum concentrations than standard one.

Conclusion:
In patients with early nonresponse and high drug clearance, vedolizumab dose optimization is probably not required. A proportion of patients benefited from continued treatment irrespective of the dose received.



Jairath V et al. Clin Gastroenterol Hepatol. 2024; 22:1077–1086