

Randomized double-blind trial.

Patients with refractory proctitis UC were randomized to once daily tacrolimus suppositories (2 mg) or beclomethasone (3mg) for 4 weeks.

Primary endpoints: Clinical response by decrease in Mayo score of 3 or more

Results:

- Clinical response at week 4, Tacrolimus 63% vs 59% beclomethasone, $p=0.812$
- Clinical remission week 4: 46% Tacrolimus vs 38% beclomet, $p=0.638$
- Endoscopic response week 4: 68% tacrolimus vs 60% beclom, $p=0.092$
- Similar adverse events

Conclusion:

In a 4-week randomized controlled trial, tacrolimus and beclomethasone suppositories induce comparable clinical and endoscopic responses in patients with UP refractory to 5-ASA. There were no significant differences in adverse events rates. Tacrolimus and beclomethasone suppositories are therefore each safe and effective treatment options for 5-ASA refractory disease.

No Superiority of Tacrolimus Suppositories vs Beclomethasone Suppositories in a Randomized Trial of Patients With Refractory Ulcerative Proctitis

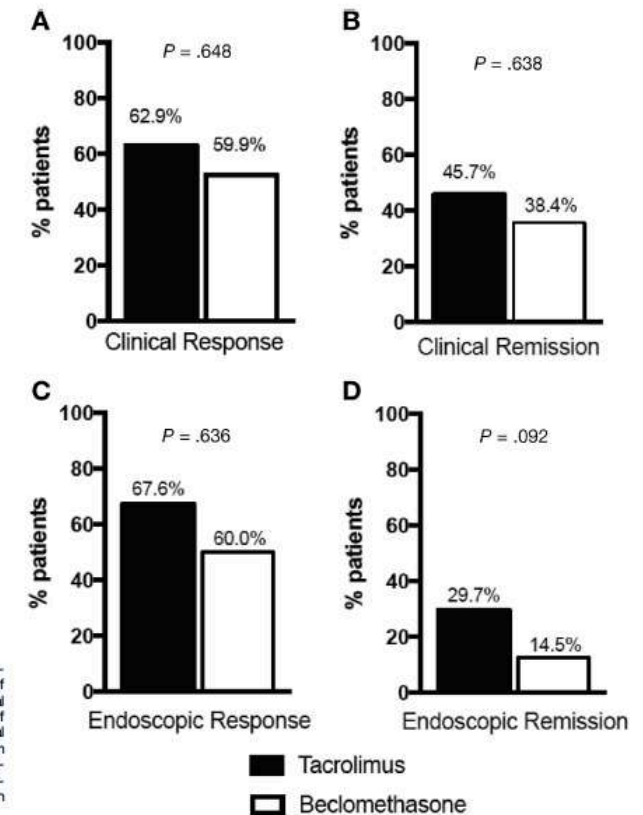


Figure 1. Main study results. (A) Proportion of patients with a clinical response. (B) Proportion of patients with clinical remission. (C) Proportion of patients with endoscopic response. (D) Proportion of patients with endoscopic remission.

