

Randomized placebo-controlled, double-blind trial. Patients with moderate to severe left side or extensive UC steroid-refractory hospitalized received oral therapy with tacrolimus (1-2.5mg/BD adjusted by trough concentration 10-15 ng/mL) or placebo. Azathioprine, 5ASA at unchanged doses were allowed during the study.

Primary endpoints: Clinical response by DAI score

Results:

- Clinical response at week 2, Tacrolimus 50% vs 13.3% placebo, $p=0.003$
- Mucosal healing 43.8% Tacrolimus vs 13.3% placebo, $p=0.012$
- Clinical remission 9.4% tacrolimus vs 0% placebo, $p=0.238$

Conclusion:

Oral tacrolimus therapy in patients with steroid-refractory UC shortened the acute phase and induced rapid mucosal healing. These results suggest that tacrolimus therapy is useful as an alternative therapy for steroid-refractory UC

Double-Blind, Placebo-Controlled Trial of Oral Tacrolimus (FK506) in the Management of Hospitalized Patients with Steroid-Refractory Ulcerative Colitis

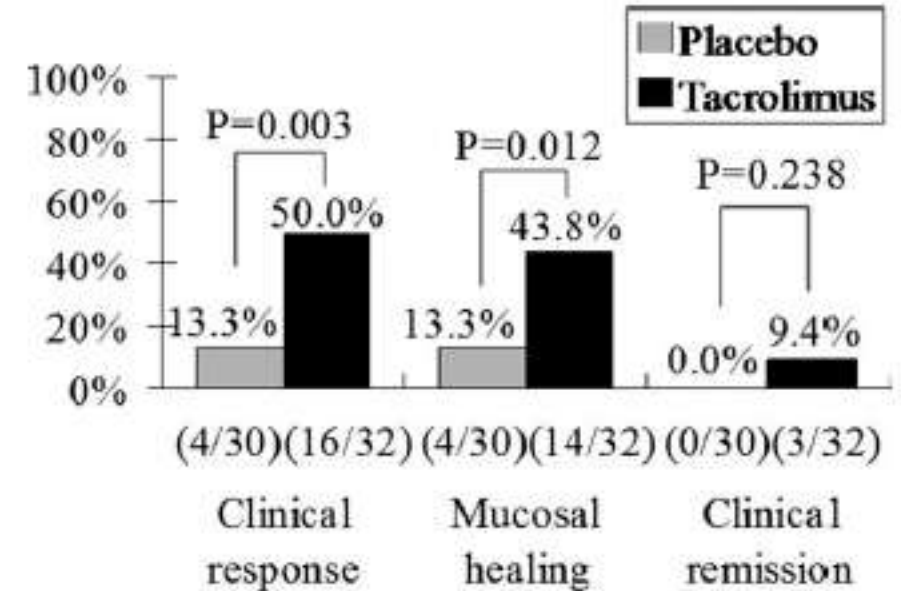


FIGURE 1. Efficacy result.

