

Randomized, double-blind multicenter trial.
 Ulcerative proctitis patients in clinical and endoscopic remission were randomized to a single 500mg rectal suppository vs placebo. 5ASA orally was not allowed.
 Endoscopy done every 3 months and at time of relapse.

Primary endpoints: Time to relapse.

Results:

- Mean time to relapse 453.4 days (5ASA) vs 158 days in placebo, $p < 0.001$
- At 12 and 24 months patients who relapsed: 32% and 46% in 5ASA group vs 86% and 89% in placebo respectively, $p < 0.001$
- No differences between groups in adverse events.

Conclusion:

The results demonstrate that mesalamine suppositories are efficacious, well tolerated, and safe for the long-term maintenance of remission of ulcerative proctitis.

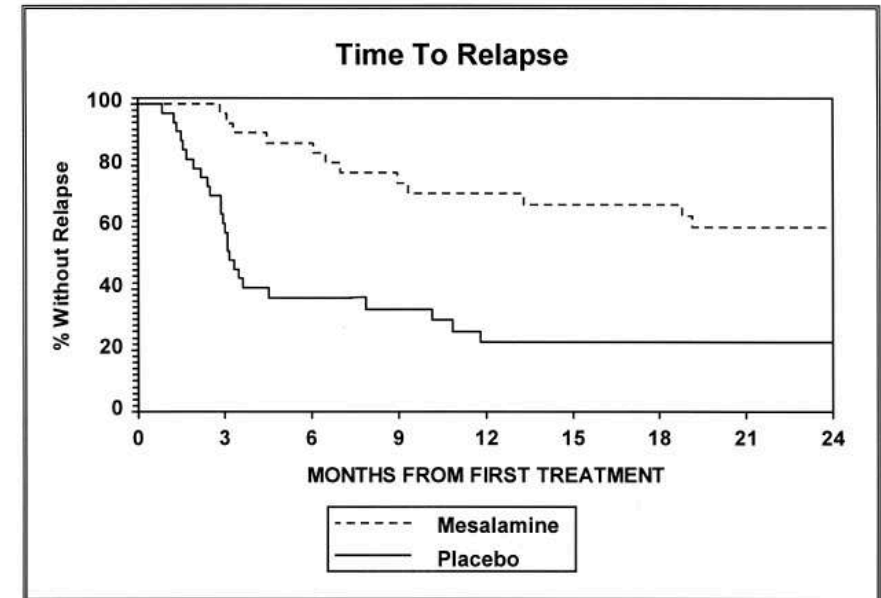


Figure 1. Kaplan-Meier survival curve. Relapse rates for each treatment group were estimated using Kaplan-Meier survival analysis (29).

