

Open label, parallel-group, multi-center, randomized clinical trial. Ulcerative colitis patients in remission were randomized to plantago ovata seeds (10gr BD), mesalazine 500mg (TID) and plantago ovata + mesalazine at same doses.

Primary endpoints: Maintenance of remission at 12 months.

Results:

- Treatment failure at 12 months: plantago ovata 40%; mesalazine 35% and combination 30%, probability of continued remission similar $p=0.67$
- Significant increase in fecal butyrate levels was observed after plantago ovata admisnitration $p=0.018$

Conclusion:

Plantago ovata seeds (dietary fiber) might be as effective as mesalamine to maintain remission in ulcerative colitis.

Randomized Clinical Trial of Plantago ovata Seeds (Dietary Fiber) as Compared With Mesalamine in Maintaining Remission in Ulcerative Colitis

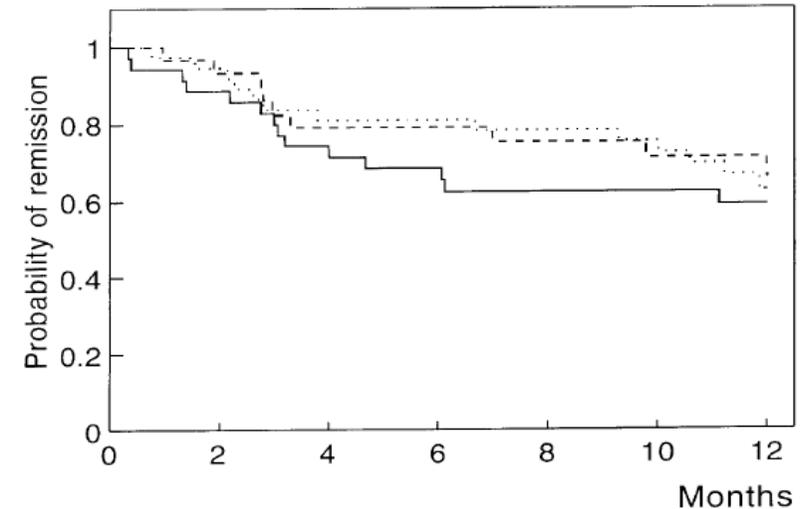


FIG. 2. Remission curves by the intention-to-treat rule for the three groups (solid line: *Plantago ovata* seed group; dotted line: Mesalamine group; dashed line: *Plantago ovata* seed plus mesalamine group). There were no differences in the 12-month probability of remission (Mantel-Cox test, $p = 0.67$; Breslow test, $p = 0.56$).

