

Open label, prospective, randomized trial.  
Patients with Crohn's disease after surgery for stricturing CD were randomised to: azathioprine 2mg/Kg/day or mesalazine 3gr/day for 24 months started within 2 weeks from surgery.  
On study entry all patients CDAI ≤150

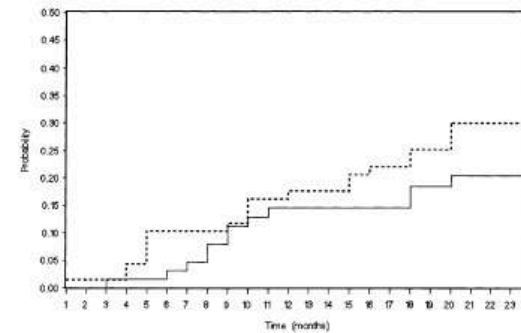
Primary endpoints: Clinical relapse as per CDAI score >200 and surgical relapse (symptoms refractory to medical treatment or complications requiring surgery).

Results:

- At 24 months, clinical relapse comparable between AZA and 5ASA, (OR 2.04, 95%CI, 0.89-4.67)
- No differences in surgical recurrence
- In a subgroup analysis AZA was more effective than 5ASA in patients with previous intestinal surgery (OR4.83, 1.47-15.8)
- More patients withdrew AZA due to adverse events 22% vs 8% 5ASA, p=0.04

Conclusion:

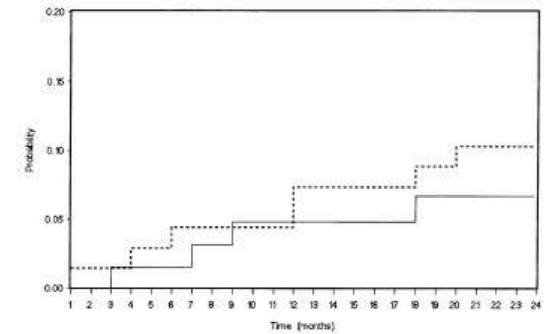
While no difference was observed in the efficacy of azathioprine and mesalamine in preventing clinical and surgical relapses after conservative surgery, azathioprine is more effective in those patients who have undergone previous intestinal resection.



Cumulative clinical relapse rate (%)

Month	AZA	5-ASA
6	4	11
12	15	16
18	18	25
24	20	30

Figure 2. Cumulative clinical relapse rates according to treatment at 24 months. Log-rank test:  $\chi^2$  (1 df), 1.34;  $P = 0.2$ .



Cumulative surgical relapse rate (%)

Month	AZA	5-ASA
6	2	5
12	5	5
18	7	8
24	7	10

Figure 3. Cumulative surgical relapse rates according to treatment at 24 months. Log-rank test:  $\chi^2$  (1 df), 0.51;  $P = 0.5$ .

