

Placebo-controlled double-blind randomized trial.
Patients with CD recently diagnosed <8 weeks were randomized to Azathioprine 2.5mg/kg/d or placebo.

Primary endpoint: Steroid free remission at week 74

Results: N=50

- At 76 w, 44.1% AZA vs 36.5% placebo were in steroid free remission, p=0.48
- Rates of relapse (CDAI >175) and need of steroid were similar between groups.
- A post hoc analysis of relapse, defined as CDAI >220 showed lower relapse rates in AZA 11.8% vs 30.2% placebo, p=0.01
- Adverse events AZA 20.6% vs 6.4% placebo, p=0.02

Conclusion:

In a study of adults with Crohn's disease, early azathioprine therapy was no more effective than placebo to achieve sustained corticosteroid free remission but was more effective in preventing moderate to severe relapse in a post hoc analysis.

Early Azathioprine Therapy Is No More Effective Than Placebo for Newly Diagnosed Crohn's Disease

Table 2. Efficacy of Azathioprine Compared With Placebo in Adults With Newly Diagnosed CD: Primary and Secondary End Points

Characteristics	Placebo (n = 63)	Azathioprine (n = 68)	P value
Sustained corticosteroid-free clinical remission ^a			
Week 28	34 (53.97)	35 (51.47)	.86
Week 50	27 (42.86)	30 (44.12)	.99
Week 76 (primary end point)	23 (36.51)	30 (44.12)	.47
Requirements of corticosteroids			
Patients needing corticosteroids	40 (63.50)	34 (50.00)	.15
Mean dose of corticosteroids per patient (mg) (SD)	2200 (2199)	1669 (2878)	.24
Mean days on corticosteroid therapy (SD)	64.25 (57.80)	47.35 (74.17)	.15
Development of fistula	5 (7.94)	6 (8.82)	.99
Internal penetrating disease	3 (4.76)	4 (5.88)	.99
Perianal fistulizing disease	2 (3.17)	2 (2.94)	.99
Patients hospitalized	5 (7.94)	11 (16.18)	.18
CD-related surgery	1 (1.59)	1 (1.47)	1

NOTE. All values are expressed as n (%) unless otherwise noted.

^aRemission defined as CDAI score ≤ 150 and no corticosteroid use.

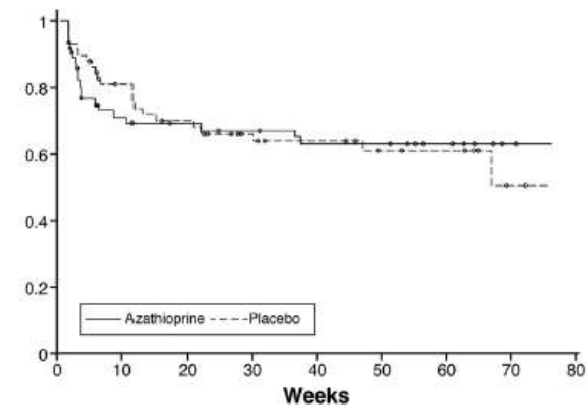


Figure 1. Actuarial probability of survival free of relapse defined as a CDAI score >175 in patients treated with azathioprine and placebo.

