

Randomized double-blind controlled trial.

Patients with a severe flare of UC were started on corticosteroids (prednisolone 40mg/day) and were randomized to start at the same time 2.5mg/kg of azathioprine or placebo.

Patients were subdivided according to the length of history into three categories: first attack; short history (less than five years); and long history (more than five years).

Primary endpoints: Remission after a month and at 1 year.

Results: N=80

- Remission within a month: 77.5% AZA+steroid vs 67.5% steroid, p=ns
- No statistical differences in endoscopic appearance after a month.
- No differences in histological findings after a month.
- Differences at 1 year were observed in those on AZA in the group of patients who had relapse rather than first UC attack.

Conclusion:

In the treatment of an actual attack of ulcerative colitis the addition of azathioprine showed no benefit to a standard course of corticosteroid therapy.

Azathioprine in Ulcerative Colitis: Final Report on Controlled Therapeutic Trial

TABLE I—Clinical Severity of Attacks on Entry to Trial and at End of One Month in Two Treatment Groups

Severity of Attack	On Entry to Trial		After One Month	
	Azathioprine Group	Control Group	Azathioprine Group	Control Group
Remission ..			31	27
Mild ..	16	17	4	6
Moderate ..	21	19	2	3
Severe ..	3	4	1	2
Failed ..			2	2
Total ..	40	40	40	40

TABLE II—Sigmoidoscopic Grades on Entry to Trial and at End of One Month in Two Treatment Groups

Sigmoidoscopic Grade	On Entry to Trial		After One Month	
	Azathioprine Group	Control Group	Azathioprine Group	Control Group
0			15	9
1	7	15	20	18
2	29	21	3	9
3	4	4		2
Failed			2	2
Total	40	40	40	40

TABLE III—Histological Grades of Rectal Biopsy Specimens on Entry to Trial and at End of One Month in Two Treatment Groups

Histological Grade	On Entry to Trial		After One Month	
	Azathioprine Group	Control Group	Azathioprine Group	Control Group
1	1	1	24	15
2	20	21	7	9
3	19	18	7	14
Failed			2	2
Total	40	40	40	40

