

Randomised, prospective, investigator-blind, parallel-group, controlled trial.

UC steroid dependent patients were randomized to AZA 2mg/kg/day or 5-ASA 3.2gr/day

Steroid dependence was defined as a requirement for steroid therapy ≥ 10 mg/day during the preceding six months.

Primary endpoints: Induction of clinical and endoscopic remission and steroid discontinuation at 6 months.

Results:

- Clinical and endoscopic remission at 6 months and steroid discontinuation: 5ASA 21% vs 53% AZA, $p=0.006$
- The Powell-Tuck index decreased from baseline to six months by 84% AZA vs 69% 5ASA, $p=0.009$; the Baron index 51% AZA and 18% 5ASA, $p=0.0001$; PGA 48% AZA and 19% 5ASA, $p=0.004$

Conclusion:

Azathioprine is significantly more effective than 5-aminosalicylic acid in inducing clinical and endoscopic remission and avoiding steroid requirement in the treatment of steroid dependent ulcerative colitis.

Table 3 Outcome of the study drugs

	AZA	5-ASA	Total	p Value*	OR* (95% CI)
Intent to treat					
Success	19 (53 %)	7 (19 %)	26	0.006	4.78 (1.57–14.5)
Failure	17 (47 %)	29 (81 %)	46		
Total	36	36	72		
Per protocol					
Success	19 (58 %)	7 (21 %)	26	0.003	5.26 (1.59–18.1)
Failure	14 (42 %)	27 (79 %)	41		
Total	33	34	67		

OR (95% CI), odds ratio (95% confidence interval).

AZA, azathioprine; 5-ASA, 5-aminosalicylic acid.

*From logistic regression models including terms for age and sex.

