

Multicenter double-blind, double-dummy, randomised trial. CD patients with surgery in the preceding 6-24 months with subsequent clinical recurrence with CDAI<200 but endoscopic recurrence were randomised to:

Azathioprine 2-2.5mg/kg/d vs mesalazine 4gr/d

Primary endpoints: Therapeutic failure within 1 year defined as CDAI  $\geq$  200 and an increase of  $\geq$  60 points from baseline

Results:

- Treatment failure occurred in 22% (AZA) vs 10.8% (5ASA), p=0.19
- Clinical recurrence 0% AZA vs 10.8% 5ASA, p=0.031
- Patients with  $\geq$ 1 point reduction of Rutgeerts score at month 12 was 63.3% AZA vs 34.4% 5ASA, p=0.023

Conclusion:

In this population of patients with postoperative CD at high risk of clinical recurrence, superiority for azathioprine versus mesalazine could not be demonstrated for therapeutic failure.

**Table 2** Therapeutic failure during 1 year (primary end point) due to clinical recurrence (defined as Crohn's disease activity index score  $\geq$ 200 and an increase of  $\geq$ 60 points from baseline) or study discontinuation due to lack of efficacy or adverse drug reaction

	Azathioprine	Mesalazine	Difference in proportions* (95% CI)	p Value†
Intention-to-treat population	n=41	n=37		
Therapeutic failure	9 (22.0%)	4 (10.8%)	11.1% (-5.0% to 27.3%)	0.19
Clinical recurrence or discontinuation due to lack of efficacy	0	4 (10.8%)	-10.8% (-20.8% to -0.8%)	0.031
Discontinuation due to adverse drug reaction‡	9 (22.0%)	0	22.0% (9.3% to 34.6%)	0.002
Per-protocol population	n=33	n=31		
Therapeutic failure	9 (27.3%)	3 (9.7%)	17.6% (-0.8% to 36.0%)	0.072

\*Azathioprine-mesalazine.

†Two-sided  $\chi^2$  test.

‡Suspected relationship to study drug.

