1993. AZA+ST CD

RCT/AZA +/- steroid/ CD/Induction

Single centre, placebo controlled trial Adult patients with active CD (CDAI>150) were randomized into two groups. Both groups receiving prednisolone 60mg in a tapering regime to a maintenance dose of 10mg and then receiving 2.5mg/kg/d azathioprine or placebo for 4 months. (Prednisolone dose could be increased twice if patient not in remission)

<u>Primary endpoint</u>: Clinical remission

Results: N=42

- Clinical remission at 4 months, 76% pred+AZA vs 38% pred+placebo, p=0.03
- Differences in activity indices between groups became significantly different after 8w

Conclusion:

The combination of prednisolone and AZA was superior to the treatment with prednisolone alone in active CD. Patients receiving AZA showed remission more frequently, more quickly, and with lower doses of prednisolone.

Azathioprine Combined With Prednisolone or Monotherapy Prednisolone in Active Crohn's Disease

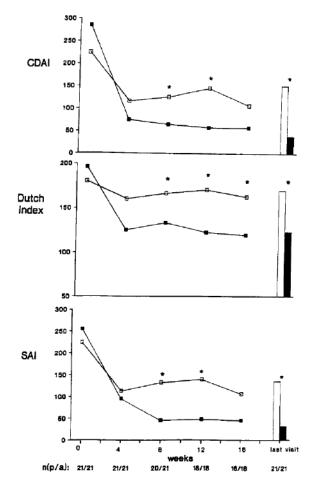


Figure 2. Median of activity indices month by month in the AZA- (a, and placebo-treated (p, \Box) groups. n, no. of patients. Last visit, median of activity indices (regular term or insufficient treatment) for CDAI,¹³ Dutch index,¹⁴ and SAI.¹⁵ *P < 0.05.