2004. 6MP/5ASA postop

RCT/6MP-5ASA/CD/Postop

Postoperative maintenance of Crohn's disease remission with 6-mercaptopurine, mesalamine, or placebo: a 2-year trial

Randomized, multicenter placebo-controlled trial.
Patients with CD who underwent ileocolonic resection with primary anastomosis were randomized to mercaptopurine (6MP) 50mg/day, mesalazine 3gr/day or placebo.

Primary endpoints: percentage of patients with a clinical, radiographic, endoscopic recurrence (Rutgeerts>1) at 24 months.

Results: N=131

- Clinical recurrence at 24 months, 50%6MP, 58% 5ASA, and 77% placebo, 6MP vs placebo, p=0.045, no differences with 5ASA
- Fistulising disease was a predictor of clinical recurrence irrespectively od the treatment received, HR 2, p=0.04
- Endoscopic recurrence at 24 months 43% 6MP, 63% 5ASA and 64% placebo, 6MP vs pbo, p=0.03
- Radiographic recurrence, 33% 6MP vs 46% 5ASA vs 49%pbo, p=0.19

Conclusion:
6-MP, 50 mg daily, was more effective than placebo at preventing postoperative recurrence of Crohn's disease and should be considered as a maintenance therapy after ileocolic resection.

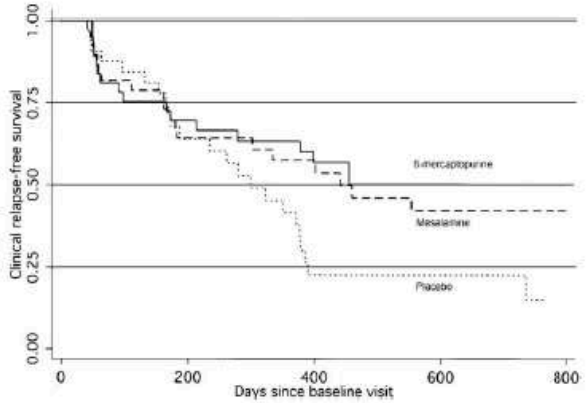

Figure 1. Clinical relapse–free survival. Likelihood of avoiding clinical relapse following ileocolic resection with primary anastomosis ("baseline") in patients with Crohn's disease randomized to treatment with 6-MP, mesalamine, or placebo. 6-MP vs. placebo: HR, 0.52; P = 0.045. Mesalamine vs. placebo: HR, 0.62; P = 0.123.

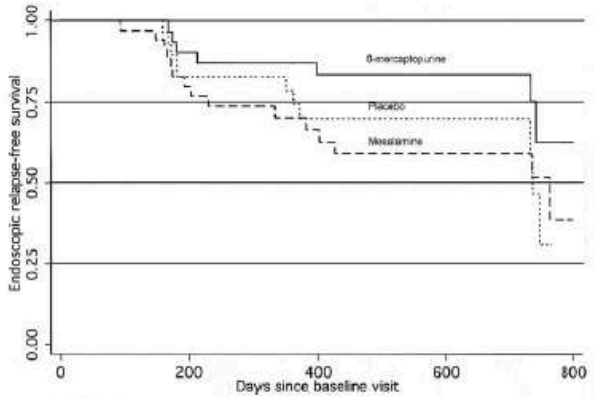

Figure 3. Endoscopic relapse–free survival. Likelihood of avoiding moderately severe endoscopic relapse (Rutgeerts' endoscopic score >2) following ileocolic resection with primary anastomosis ("baseline") in patients with Crohn's disease randomized to 6-MP, mesalamine, or placebo. 6-MP vs. placebo: HR, 0.48; P = 0.13. Mesalamine vs. placebo: HR, 1.10; P = 0.82.

Hanauer SB et al. Gastroenterology 2004;127:723–729.