

Randomized, prospective, three-armed, unblinded (not triple dummy) controlled trial with parallel group design.

Patients with CD within 4 weeks after surgery were randomized to: ADA 40mg q2w, AZA 2mg/kg every day or mesalazine 3gr /day.
*Ileocolonic anastomosis, side to side and stapled.

Primary endpoints: Endoscopic and clinical recurrence at 2 years from surgert.

Results:

- Endoscopic recurrence: ADA 6.3% vs AZA 64.7% vs 83.3% mesalazine, $p < 0.05$ for all comparisons.
- Clinical recurrence: ADA 12.5%, AZA 64.7% and mesalazine 50%, $p < 0.05$ for all comparisons
- Quality of life was higher in ADA than AZA or mesalazine groups.

Conclusion:

The administration of ADA after intestinal resective surgery was greatly effective in preventing endoscopic and clinical recurrence of CD.

Adalimumab Is More Effective Than Azathioprine and Mesalazine at Preventing Postoperative Recurrence of Crohn's Disease: A Randomized Controlled Trial

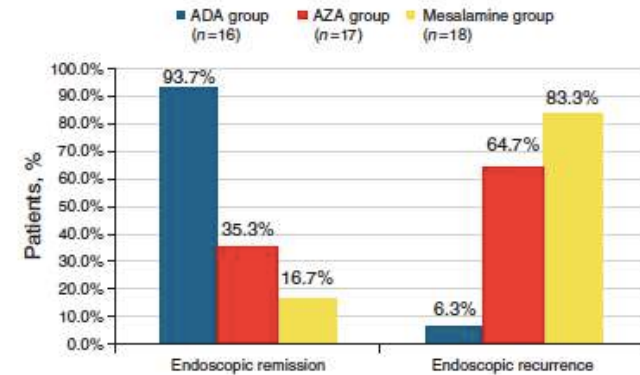


Figure 2. Percentage of patients in remission (endoscopic grade score of i0 or i1) and with recurrence (endoscopic grade score of i2, i3, or i4) of Crohn's disease at the 2-year endoscopic evaluation by random assignment to adalimumab (ADA) or azathioprine (AZA) or mesalazine.

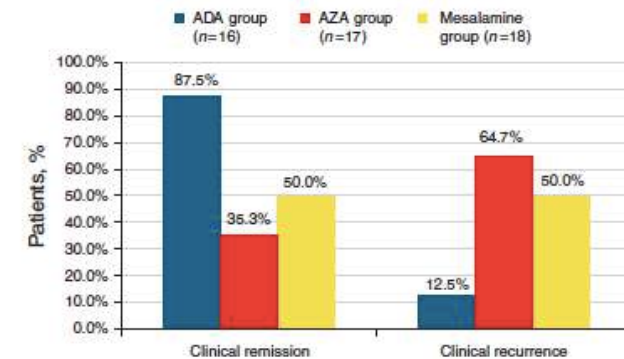


Figure 4. Clinical grade and percentage of patients with endoscopic recurrence of Crohn's disease at 2-year follow-up evaluation by random assignment to adalimumab (ADA) or azathioprine (AZA) or mesalazine.

