1999. IFX

RCT/IFX/CD/ Induction

Efficacy and Safety of Retreatment With Anti–Tumor Necrosis Factor Antibody (Infliximab) to Maintain Remission in Crohn's Disease

Randomized double-blind, placebo-controlled parallel group trial. Patients with moderate-severe active Crohn's disease resistant to conventional therapy who had clinical response to a single IFX or placebo infusion (CDAI decrease of ≥70*) at week 8 were randomized to receive four IV infusion of IFX 10mg/kg or placebo every 8 weeks starting at week 12.

Primary endpoints: Clinical response evaluated every 4 weeks up to week 44

Results: N=73

- Discontinuation occured in 33.3% placebo vs 10.8% IFX due to worsening disease.
- Clinical response at week 44: 62% IFX vs 37% placebo, p=0.16
- Clinical remission week 44: 52.9% IFX vs 20% placebo, p=0.013
- Clinical response at week 36: 72% IFX vs 44% placebo,p=0.018

Conclusion:
Long-term treatment with IFX is better than placebo maintaining remission in Crohn's disease.

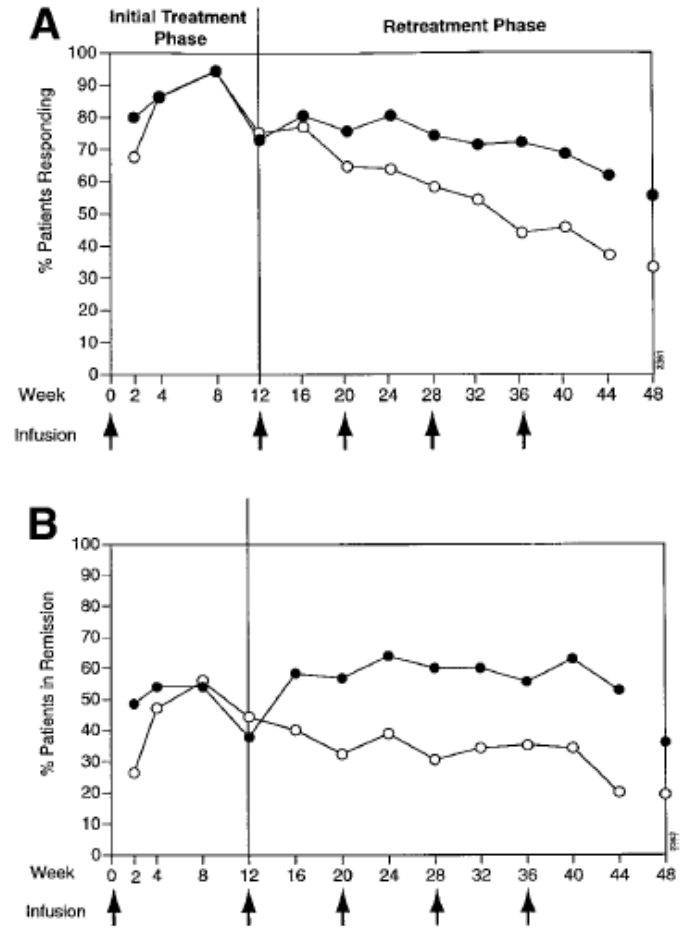

Figure 2. Percentage of patients achieving clinical (*A*) response or (*B*) remission in patients undergoing retreatment with placebo (○) or infliximab (●) after an initial treatment with infliximab.

* These patients come from the trial published in 1997

Rutgeerts P et al. Gastroenterology. 1999; 117:761-769