2016. PREVENT

RCT/IFX/ CD/ Postop recurrence

Infliximab Reduces Endoscopic, but Not Clinical, Recurrence of Crohn's Disease After Ileocolonic Resection

Phase 3, multicenter, randomized, double-blind, placebo-controlled trial comparing IFX standard dose 5 mg/kg q8w vs placebo in the prevention of recurrence in CD post surgery.
Adult patients undergoing ileocolonic resection with ileocolonic anastomosis. An end or loop ileostomy within 1 year was permited if stoma closure and ileocolonic anastomosis occurred within 45.
No evidence of macroscopic CD and no active CD elsewhere.
Patients receiving AZA, MCO or MTX pre-surgery could continue treatment with maintenance of stable doses after resection.

<u>Primary endpoints:</u> Clinical recurrence before or at week 76.
Defined as ≥ 70 points increase of CDAI or CDAI ≥ 200.
Secondary endpoint: endoscopic recurrence by Rutgeert score.

<u>Results:</u>
- W76 clinical recurrence, IFX 12.9% vs 20% placebo, p=ns
- W76 endoscopic recurrence: IFX 22.4% vs 51.3% pbo, p<0.001
- Predictors of clinical recurrence: patients with more than one resection and patients previously exposed to antiTNF prior surgery

<u>Conclusion:</u>
IFX is not superior to placebo in preventing clinical recurrence after CD-related resection. However, infliximab does reduce endoscopic recurrence

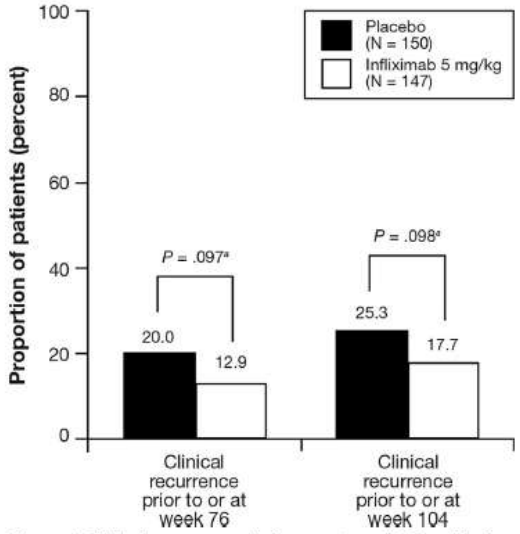

Figure 1. Clinical recurrence before or at week 76 and before or at week 104. *P* values based on the Cochran-Mantel-Haenszel χ^2 test stratified by the number of risk factors for recurrence of active Crohn's disease (1 or >1) and baseline use (yes/no) of an immunosuppressives (ie, azathioprine, 6-mercaptopurine, or methotrexate). [a]Nominal *P* value.

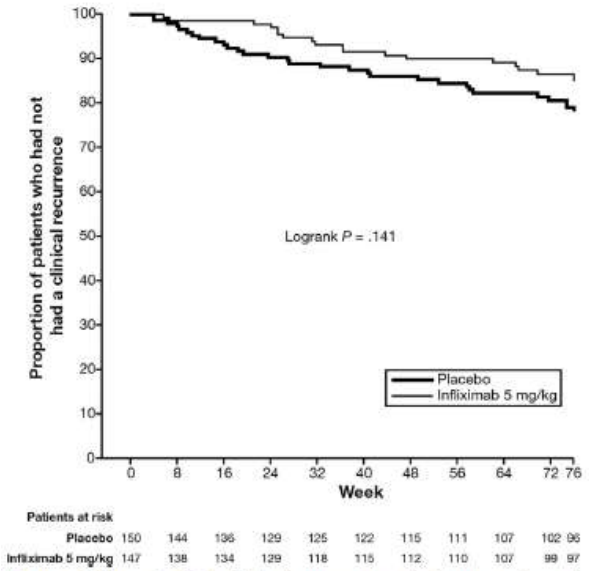

Figure 2. Time to first clinical recurrence before or at week 76; all randomized patients.

Regueiro M et al. Gastroenterology. 2016; 150: 1568-1578