2014. ADAFI

RCT/ADA+/-CIPRO/perianal CD

ADA combined with ciprofloxacin is superior to ADA monotherapy in perianal fistula closure in CD: a randomised, double-blind, Placebo controlled trial (ADAFI)

Randomised, double-blind placebo controlled trial.
Patients with perianal CD received an induction regimen ADA.
At week 4, patients received 40 mg ADA q2w until 24w.
Patients were randomly assigned to ciprofloxacin 500 mg or placebo twice daily from day 0 on for 12 weeks.

Primary outcome: at least 50% reduction of the number of draining fistulas from baseline to w12.
Secondary outcome: The proportion of patients with closure of all draining fistulas from baseline, defined as remission, at w12 and w24.

Results:
- Clinical response was observed in 71% of ADA-CIPRO vs 47% ADA-PBO (p=0.047).
- Remission rate at w12 was higher (p=0.009)in ADA-CIPRO (65%) vs ADA-PBO(33%).
- ADA-CIPRO higher mean CDAI change and mean IBDQ change at week 12 (p=0.005 and p=0.009, respectively).
- At w24, no difference in clinical response between the two treatment groups was observed (p=0.22).

Conclusions:
Combination therapy of ADA and ciprofloxacin is more effective than ADA monotherapy to achieve fistula closure in CD. However, after discontinuation of antibiotic therapy, the beneficial effect of initial coadministration is not maintained.

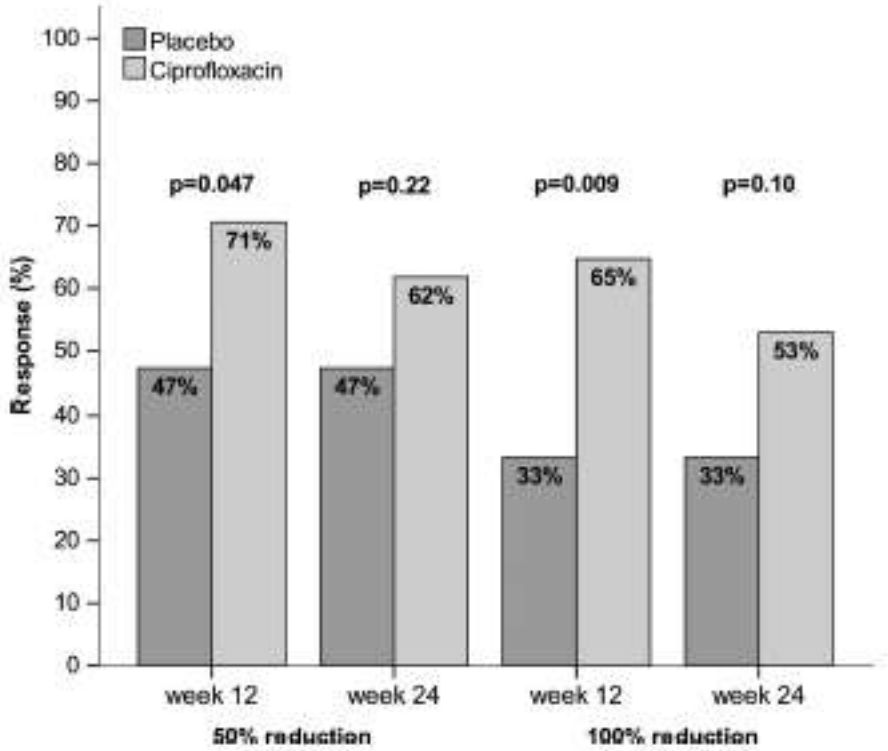

Figure 2 Percentage of patients with response (≥50% closure of draining fistulas from baseline) and remission (100% closure of draining fistulas) at week 12 (primary endpoint) and at week 24 in the two treatment arms.

Dewint P, et al. Gut 2014;63:292–299.