1995. MTX

RCT/MTX/CD/ Induction

Methotrexate for the treatment of Crohn's disease

Phase 3, randomised, double-blind, placebo-controlled trial.
Patients with chronically active CD in spite of 3 months of prednisone therapy of at least 12.5mg were randomly assigned to intramuscular methotrexate 25 mg/week or placebo for 16 weeks.
Patients also received 20 mg prednisone, which was tapered over a period of 10 weeks.
No other drugs were permitted.

Primary endpoint: Clinical remission at week 16 (defined by discontinuation of prednisone and CDAI ≤150)

Results: N=141

- Clinical remission at week 14: 39.4% MTX vs 19.1% placebo, p=0.025. RR 1.95; 95%CI 1.09-3.48
- Patients on MTX received less prednisone overall than those in placebo arm, p=0.026
- There were more side effects on MTX than placebo, specially nausea

Conclusion:
In patients with chronically active CD, MTX was better than placebo improving symptoms and reducing the need of prednisone.

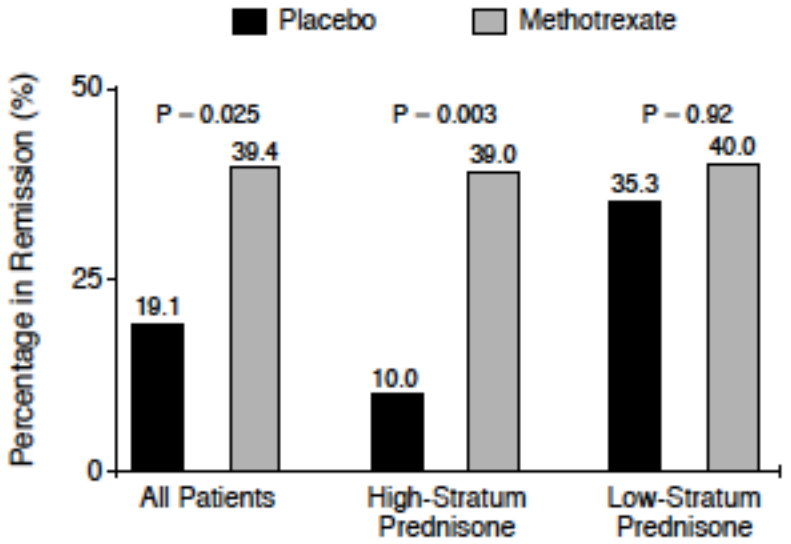

Figure 1. Percentages of Patients in Remission at Week 16, According to Study Group and Stratum of Daily Prednisone Dose before Entry into the Study.

The high-prednisone stratum was receiving a daily dose of more than 20 mg of prednisone, and the low-prednisone stratum a daily dose of 20 mg or less, more than two weeks before randomization. The actual percentages are shown above the bars. P values were derived by the Mantel–Haenszel chi-square test, with adjustment for study center. For the definition of remission, see the Methods section under "Outcome Measures."

Feagan B et al. N Engl J Med. 1995; 332 (5): 292-297