2000. MCP-MTX-5ASA

RCT/MCP or MTX/ IBD/Induction

6-Mercaptopurine or methotrexate added to prednisone induces And mantains remission in steroid-dependent inflammatory Bowel disease

Randomized controlled, single-centre clinical trial.
Steroid dependent patients with IBD were randomised to: Group A 1.5mg/kg/d 6-MP, Group B 15mg MTX/week or 3g/d 5ASA.
Study divided in 2 parts: first 30 weeks for those achieving remission then entering maintenance for 76 weeks.

Primary endpoints: Remission at week 30 and remission at end of follow-up.

Results:
- W30 for UC remission, 6MP 78.6% vs 25% 5ASA (p<0.05) vs 58.3% MTX (p=0ns)
- W30 for CD remission, 6MP 93.7% vs 80% MTX vs 14% 5ASA, comparisons against 5ASA p<0.001 and 0.01
- Maintenance in UC, 6MP 50% vs 8% MTX vs 0% in 5ASA (p<0.0015 and p<0.001)
- Maintenance for CD, MCP 50% vs MTX 53% vs 0% in 5ASA both p<0.001 compared to 5ASA

Conclusion:
These results suggest that 6-MP or MTX added to prednisone could be effective in steroid sparing, as well as in achieving and maintaining remission in steroid-dependent IBD patients. MTX was less effective in maintaining remission in UC patients.

Table 2 Proportion of patients in remission at 30 weeks of treatment

	UC patients			CD patients		
	Group A	Group B	Group C	Group A	Group B	Group C
No. of patients	14	12	8	16	15	7
Completed 30 weeks of study and obtained remission	11	7	2	15	12	1
Drop-outs due to treatment failure	0	3	6	0	1	6
Withdrawal due to side effects	3	2	0	1	2	0
Remission rates	11/14 (78.6%)	7/12 (58.3%)	2/8 (25%)	15/16 (93.7%)	12/15 (80%)	1/7 (14%)

Group A, prednisone plus 6-MP
Group B, prednisone plus MTX
Group C, prednisone plus 5-ASA

UC patients
Group A vs group C, $P < 0.05$
Group B vs group C, NS

CD patients
Group A vs group C, $P < 0.001$
Group B vs group C, $P < 0.01$

Table 4 Proportion of patients who achieved and maintained remission on completing the 106 week study

UC patients			CD patients		
Group A	Group B	Group C	Group A	Group B	Group C
14	12	8	16	15	7
7	1	0	8	8	0
50%	8%	–	50%	53%	–

Treatment groups as in Table 2
Group A vs group C, $P < 0.01$
Group A vs group B, NS
Group B vs group C, $P < 0.01$

Maté-Jiménez J et al. Eur J Gastroenterol Hepatol. 2000; 12:1227-1233