1962.

Sulphasalazine

RCT/Sulphasalazine/UC/ Induction

Randomized double-blind placebo-controlled trial. Patients with mildly active ulcerative colitis were randomized to: Sulphasalazine 4gr/day (1st week) then 2 gr/day (for 2 weeks) vs salicylazosulphadimidine* 4gr/day (1st week) then 2 gr/day (for 2 weeks) vs placebo.

*From the clinical results of the first 30 patients it was noted that salicylazosulphadimidine was not better than placebo and it was stopped.

<u>Primary endpoints:</u> Clinical and endoscopic improvement at week 3

Results: N=50

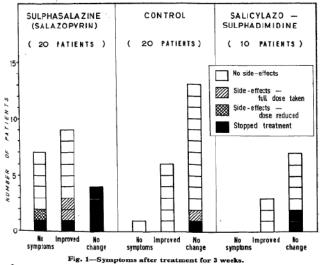
- Clinical remission at week 3: 35% sulphasalazine vs 5% placebo vs 0% salicylazosulphadimidine, p<0.02
- Clinical response week 3: 80% sulphasalazine vs 35% placebo vs 30% salicylazosulphadimidine
- Endoscopic remission week 3: 45% sulphasalazine vs 5% placebo vs 1% salicylazosulphadimidine

Conclusion:

Sulphasalazine, but not salicylazosulphadimidine, was significantly better than placebo. The optimum dose and duration of treatment have yet to be established.

Sulphasalazine leads to upper GI symptoms. It was postulated that side effects were due to the sulphapyridine, therefore substituting sulphadimidine for sulphapyridine mayimprove

Sulphasalazine And Salicylazosulphadimidine In Ulcerative Colitis



Improvement occurred significantly more often in the sulphasalazine-treated than in the control group $(\chi_c^*=6.5, n=1, 0.01 < P < 0.02)$.

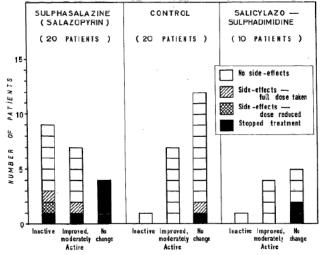


Fig. 2—Sigmoidoscopic appearances after treatment for 3 weeks. Improvement occurred significantly more often in the sulphasalazine-treated than the control group ($\chi_c^1 = 5$ -1, n = 1, 0.02 < P < 0.05).