RCT/Hydrocortisone/UC/ Induction

Treatment of ulcerative colitis with local hydrocortisone hemisuccinate sodium a report on a controlled therapeutic trial

Randomized-double blind controlled trial.
The study had 3 parts: 1) blind controlled trial of local treatment lasting one week; 2) open use of hydrocortisone and antibiotics for 2 weeks; 3) blind controlled trial of maintenance treatment using rectal drips twice a week for 6 months.
Patients with active ulcerative colitis (out-patients) were randomized to rectal 100 mg hydrocortisone hemisuccinate sodium vs placebo.
At the end of first week all patients were given hydrocortisone and antibiotics (penicillin 1 mega unit and streptomycin 1gr or neomicin 250mg) added to the hydrocortisone solution

Primary endpoints: Clinical remission at week 1.

Results: N=210
- Clinical remission at week 1: 55% hydrocortisone vs 5% placebo, p=0.01
- Endoscopic response at week 1: 60% hydrocortisone vs 10% placebo, p <0.01
- Maintenance therapy 2 doses of rectal hydrocortisone per week vs placebo did not differ in relapse rates.

Conclusion:
Rectal hydrocortisone hemisuccinate sodium induces rapid clinical remission in mild to moderate active ulcerative colitis but it is not effective for maintenance
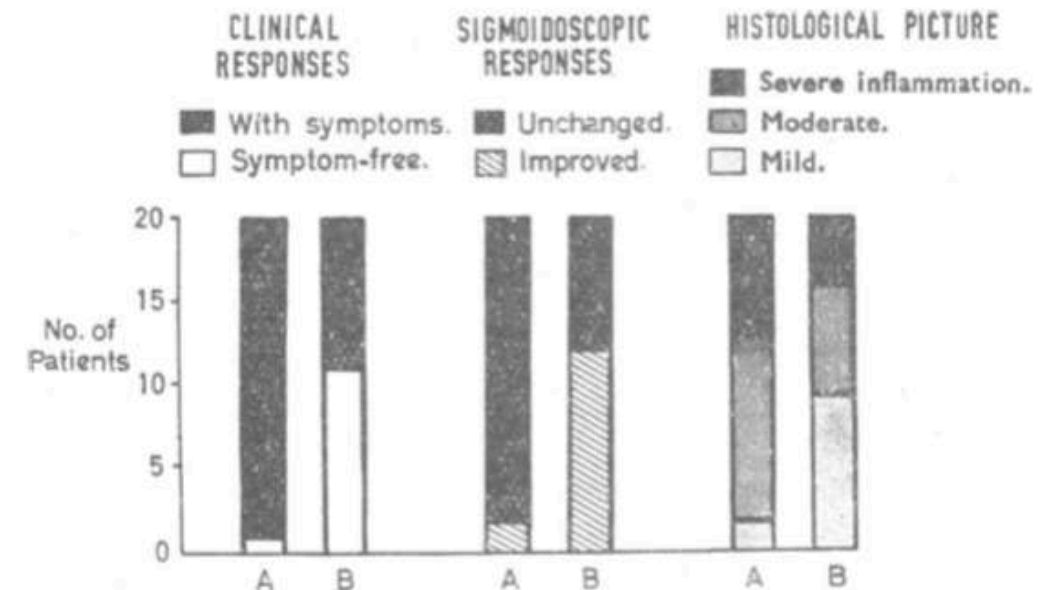

FIG. 1.—Position at end of Part I of trial, showing the differences in the clinical, sigmoidoscopic, and histological pictures after one week of topical treatment with either an inert preparation or real therapy. (A=Inert preparation. B=Hydrocortisone hemisuccinate sodium.)