## An Assessment Of Prednisone, Salazopyrin, And Topical Hydrocortisone Hemisuccinate Used As-out-patient Treatment For Ulcerative Colitis

Two consecutive randomized controlled trial not blinded. Patients with mildly active ulcerative colitis distal to splenic flexure treated as out-patients

- 1st trial: <u>prednisone (</u>40 to 60 mg/day first week then tappering) <u>vs calcium lactate (inert substance)</u>
- 2nd trial: <a href="mailto:prednisone">prednisone</a> (60mg/day 1st week and 45mg 2nd week, 30mg 3rd week) vs salazopyrin e (4gr/day) vs rectal drip <a href="hydrocortisone">hydrocortisone</a> (100mg/day)

Primary endpoints: Clinical remission at week 3

## Results: N=37 & 60

- 1st trial: clinical remission was achived 68.4% prednisone vs 16.7% calcium, p<0.01.
- 2<sup>nd</sup> trial: clinical remission at week 3 was achieved 40% salazopyrin vs 55% prednisone vs 15% topical hydrocortisone, p<0.02 for the difference between prednisone and topical.
- Side effects occurred in 33.3% prednisone, 60% salazopyrine.

## **Conclusion:**

In the 1<sup>st</sup> trial oral prednisone gave significantly better results than placebo. In the 2<sup>nd</sup> trial salazopyrin gave final results approaching those of prednisone, although over a longer time and with a higher incidence of unpleasant side-effects, but topical hydrocortisone gave disappointing results, probably because the technique of administration was not suitable for ordinary out-patient use.

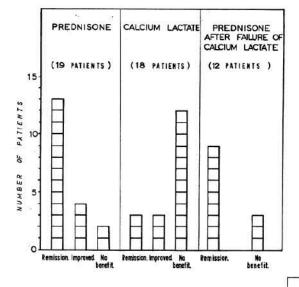


FIG. 1.—The results of treatment with prednisone and calcium lactate. The number of patients in whom remission of the disease occurred was significantly greater during initial treatment with prednisone than during treatment with calcium lactate  $((\chi^2_{T_c} = 10^{-1},$  $n = 1, P = <00^{-1})$ .

