

Randomized double-blind placebo-controlled trial. Patients with mild-moderate active proctitis were randomized to: Prednisolone-21-phosphate 5 mgx2 nightly suppositories for 3 weeks vs placebo. If a patient did not respond within 3 weeks it was given the alternative suppository for 3 more weeks.

Primary endpoints: Clinical and endoscopic improvement at week 3

#### Results: N=46

- Clinical remission at week 3: 56.3% pred-sup vs 8.7% placebo,  $p < 0.01$
- Endoscopic remission week 3: 46.7% pred-sup vs 21.7% placebo,  $p < 0.05$

#### Conclusion:

Prednisolone-21 phosphate suppositories improve the symptoms and endoscopic appearance of active proctitis and are superior to placebo.

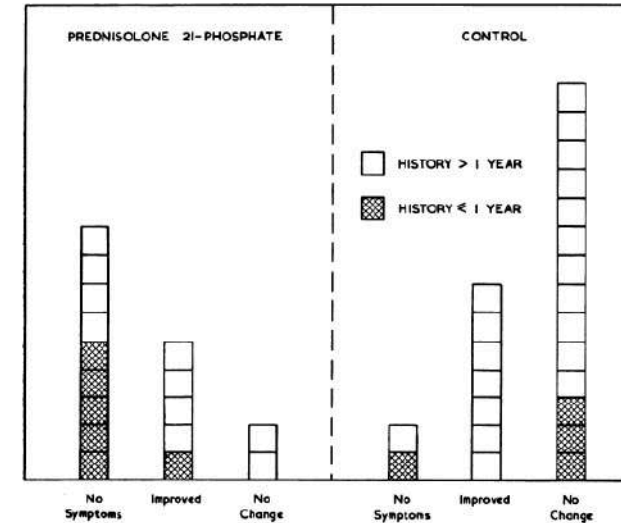


FIG. 1. Symptoms after treatment for three weeks. Improvement occurred significantly more often in the prednisolone-treated group than in the control group ( $\chi^2 = 7.23$ ,  $n = 1$ ,  $0.001 < P < 0.01$ ).

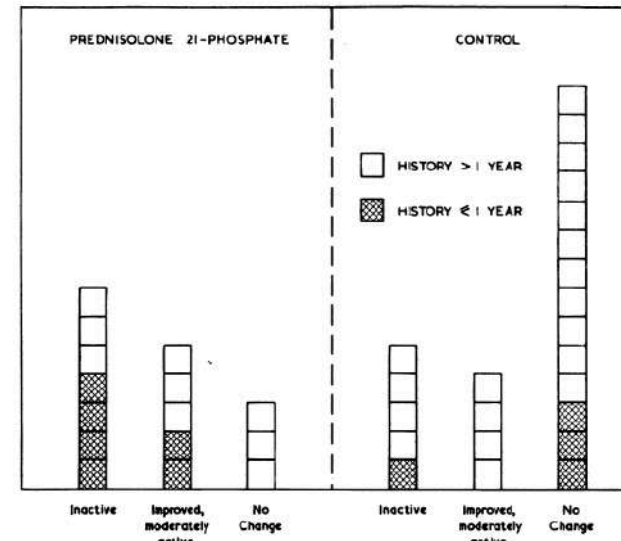


FIG. 2. Sigmoidoscopic appearances after treatment for three weeks. Improvement occurred significantly more often in the prednisolone-treated group than in the control group ( $\chi^2 = 4.59$ ,  $n = 1$ ,  $0.02 < P < 0.05$ ).

