Randomized double-blind controlled trial. Patients with active mild-moderate ulcerative colitis (up to splenic) were randomized to receive 5ASA enemas 4gr/day vs topical hydrocortisone hemisuccinate sodium 100mg/day for 15 days. Oral sulphasalazine was permited and patients were balanced according to it.

Primary endpoints: Clinical remission at week 4

Results: N=86

- Clinical remission at day 15: 93% 5ASA vs 57% hydrocortisone, p<0.0005.</li>
- Endoscopic remission at day 15: 93% 5ASA vs 54% hydrocortisone, p<0.005
- Histological improvement day 15: 77% 5ASA vs 33% hydrocortisone, p<0.005

Conclusion:

Topical treatment with 5-ASA, 4 g daily, is superior to topical treatment with hydrocortisone 100 mg daily.

## TABLE III-CLINICAL, SIGMOIDOSCOPIC, AND HISTOLOGICAL RESULTS

Trial enemas	No. of patients	No. in clinical remission	No. in sigmoidoscopic remission	No. with pronounced histological improvement
No additional treatment				
5-ASA Hydro-	10	10	10	9
cortisone 2 g sulpha- salazine daily	11	8	7	5
5-ASA Hydro-	34	31	31	25
cortisone	31	16	16	10
Overall results 5-ASA	44	41 (93%)*	41 (93%)*	34 (77%)*
Hydro- cortisone	42	24 (57%)	23 (54%)	15 (33%)

\*Superior to hydrocortisone. χ<sup>2</sup>: p<0.0005.

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