RCT/5ASA vs BDP enema/UC/Induction

Efficacy of mesalazine or beclomethasone dipropionate enema or their combination in patients with distal active ulcerative colitis

Single-centre randomized investigator blind trial.

Adult patients with clinical, endoscopic and histological active mild-moderate distal ulcerative colitis who were on oral 2.4gr/d were randomized during a flare-up to receive mesalazine enema 4g/60mL vs beclomethasone dipropionate (BDP) 3mg/60mL enema or both together 1.5g mesalazine+ BDP3mg/60mL per night for 8 weeks.

<u>Co-Primary endpoints</u>: Clinical remission, endoscopic (Mayo 0) and histologic remission at 8 weeks.

Results: N=120

- Complete remission at week 8 (clinical+endo+histo)was 52% 5ASA enema vs 47% BDP enema vs 67% both together, no statistical differences between groups

Conclusion:

All the three combinations achieved equivalent results in terms of symptoms in inducing symptoms relief and mucosa healing in distally active UC.

Complete remission week 8



