

2001. CICLO VS STEROID

RCT/ Ciclosporine vs IV steroids/ ASUC

RCT double blind controlled trial, patients admitted with acute severe UC were randomized to:

IV cyclosporine, 4 mg/kg/d or methylprednisolone 40 mg/d.

After 8 days, if response received the same medication orally in combination with azathioprine for 3-4 months and then AZA alone

Primary endpoint: Clinical improvement, endoscopy improvement and remission up to 12 months after IV therapy.

Results: N=30

- Response day 8: 64% on ciclosporine vs 53% on steroids, $p=0.4$
- 40% of non responders, responded after combination of both drugs.
- Remission at 12 months, 78% ciclosporine vs 37% of steroids. But in steroids group only 3/7 took AZA.
- Colectomy rate at 1 year, 36% for ciclosporine vs 40% steroids

Conclusions:

Ciclosporine monotherapy is an effective and safe alternative to glucocorticosteroids in patients with ASUC

Intravenous Cyclosporine Versus Intravenous Corticosteroids as Single Therapy for Severe Attacks of Ulcerative Colitis

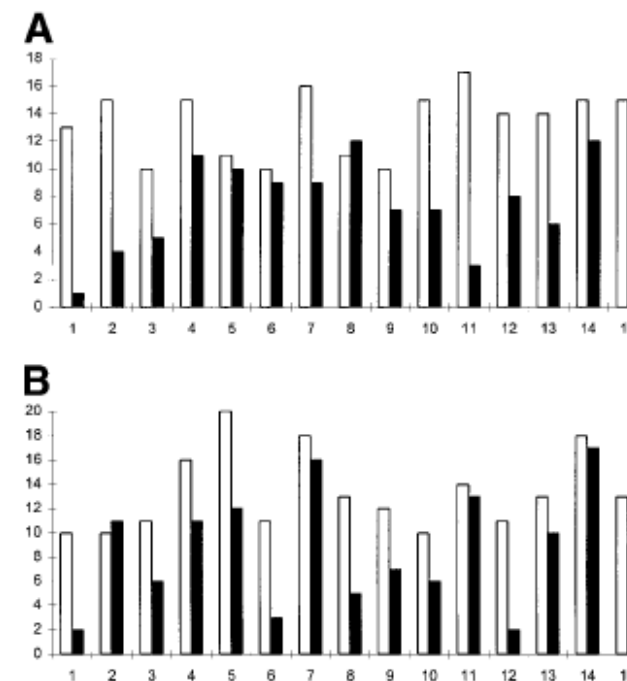


Figure 1. Response to (A) cyclosporine and (B) methylprednisolone treatments in all patients. Scores (Lichtiger score, modified Truelove and Witts) represent those before the start of therapy (day 0, □) and on day 8 (■).

Table 3. Changes in Endoscopic and Histologic Disease Parameters (\pm SEM) During Therapy With Cyclosporine or Methylprednisolone Before Treatment and After 1 and 4 Weeks of Treatment

	Start	1 week	4 weeks
Endoscopy score			
Cyclosporine	2.3 \pm 0.2	1.8 \pm 0.2 ($P = 0.06$)	0.6 \pm 0.1 ($P < 0.001$)
Methylprednisolone	2.5 \pm 0.2	2.0 \pm 0.9 ($P = 0.07$)	0.6 \pm 0.2 ($P < 0.001$)
Histology score			
Cyclosporine	10.7 \pm 0.6	9.7 \pm 0.7 ($P = 0.3$)	7.0 \pm 1.4 ($P = 0.03$)
Methylprednisolone	10.8 \pm 1.2	9.3 \pm 1.0 ($P = 0.3$)	5.0 \pm 0.9 ($P = 0.002$)

NOTE. P values represent differences between day 8 and month 1 and the initial day 0 (start) score.

