2003. CYCLO 2/4

RCT/cyclosporin/UC/Induction

Randomized, double-blind comparison of 4 mg/kg versus 2 mg/kg intravenous cyclosporine in severe ulcerative colitis.

Single center, randomized, double-blind, controlled trial.
Patients with acute severe UC randomised to:
-Cyclosporin IV 4 mg/kg vs 2mg/kg.

Primary endpoint: clinical response day 8

Results:

- Clinical response day-8. cyclo4 84.2% vs ciclo2 85.7%.
- Short-term ccolectomy rates, 13.1% Cyclo4 vs 8.6% cyclo2

Conclusions:
High-dose IV cyclosporine has no additional clinical benefit over low dose in the treatment of severe UC. Although we did not observe differences in adverse effects on the short term, the use of 2 mg/kg IV cyclosporine should provide an improved toxicity profile for medical treatment of severe UC.

Table 2. Efficacy End Points of the Study

	Group	
	4 mg/kg	2 mg/kg
Response rate	84.2% (32/38)	85.7% (30/35)
Median time to response	4 (1–7) days	4 (1–8) days
Colectomy rate (within 14 days)	13.1% (5/38)	8.6% (3/35)
Median drop CAI (day 8 vs. day 0)	−7 (+1 to −12)	−6 (0 to 11)
Mean drop in CRP (day 8) (*mg/mL*)	−41.5 ± 56.9	−41.2 ± 54.9
Median endoscopy score		
D0	2 (1–3)	2 (1–3)
D8	2 (1–3)	2 (1–3)

NOTE. All values were not significantly different between treatment groups.

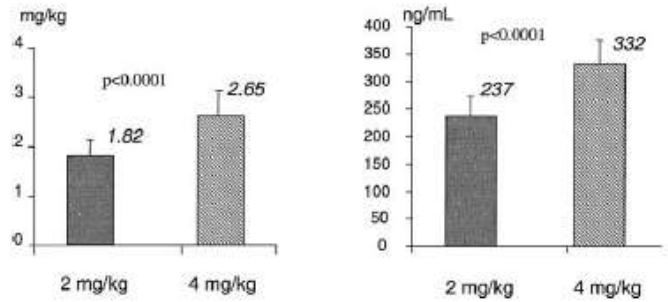

Figure 2. Difference in mean cyclosporine doses and blood concentrations between the 2 treatment groups. Data are expressed as means ± SD. Blood levels were strictly controlled to vary between 150 and 250 ng/mL for the 2-mg/kg group and 250 and 350 for the 4-mg/kg group.

Van Assche G et al. Gastroenterology 2003;125:1025–31