

Acute severe UC patients were randomized to IV ciclosporin (2 mg/kg per day for 1 week, followed by oral drug until day 98) or infliximab (5 mg/kg on days 0, 14, and 42).

Both groups, azathioprine was started at day 7 in patients with a clinical response.

Primary efficacy outcome: treatment failure defined by absence of a clinical response at day 7, a relapse between day 7 & day 98, absence of steroid-free remission at day 98, a severe adverse event leading to treatment interruption, colectomy, or death.

ITT analysis.

Results:

- Clinical response day 7, 86% ciclosporin vs 84% IFX, $p=ns$.
- Treatment failure day 98, 60% ciclosporin vs 54% infliximab, $p=0.52$
- Adverse event, 16% ciclosporin vs 25% infliximab

Conclusions:

Ciclosporin was not more effective than infliximab in patients with acute severe ulcerative colitis refractory to intravenous steroids. In clinical practice, treatment choice should be guided by physician and centre experience.

Ciclosporin versus infliximab in patients with severe UC refractory to IV steroids: a parallel, open-label randomised controlled trial

	Ciclosporin (n=58)	Infliximab (n=57)	p
Absence of clinical response at day 7	8	9	0.80
Withdrawal	0	1	1.00
Surgery	2	3	1.00
Relapse	6	5	1.00
Failure after day 7 and before day 98*	13	11	0.82
Withdrawal	2	1	1.00
Severe adverse event	0	1	1.00
Surgery	1	1	0.81
Relapse	10	8	0.81
Failure at day 98†	14	11	0.62
Relapse	3	4	1.00
Lack of remission	10	7	0.68
Steroids not withdrawn	1	0	1.00
Total treatment failure	35	31	

*n=50 for ciclosporin and 48 for infliximab. †n=37 for both ciclosporin and infliximab.

Table 2: Suboutcomes of treatment failure for ciclosporin and infliximab

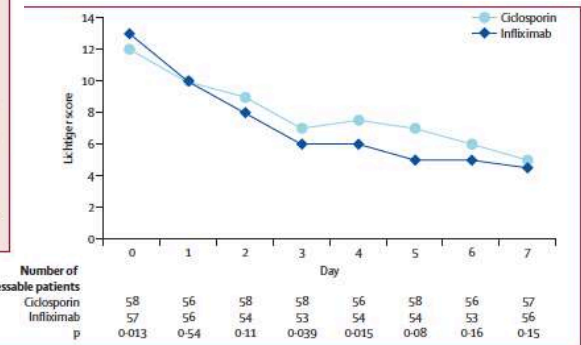


Figure 2: Lichtiger scores from day 0 to day 7, by treatment

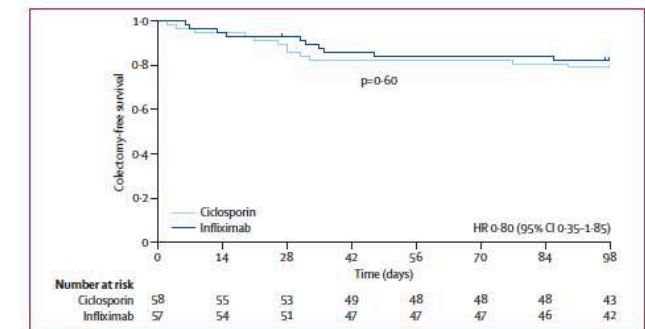


Figure 3: Kaplan-Meier curves for colectomy-free survival