Relapse rates after stopping anti-TNF therapy in patients with IBD - the STATIC-study

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Conclusion

- A substantial proportion of IBD-patients who discontinue anti-TNF treatment when in stable remission remain in remission
- The risk of having a relapse is significantly lower in patients treated with an immunomodulator
- Analyses of baseline tissue samples are underway, aiming at identifying predictive biomarkers for relapse
  Such biomarkers may support clinical decision making

Background

The possibilities for withdrawal of anti-TNF therapy in patients with Crohn's disease (CD) or ulcerative colitis (UC) in remission are debated, more specifically concerning timing and patient selection.

The STATIC study addresses this issue. The study is ongoing, and this is a report of preliminary data.

Aims

- To investigate relapse rates during 2 years after anti-TNF discontinuation in patients with CD or UC.
- To identify predictive biomarkers for relapse after anti-TNF discontinuation.

Results

- 118 patients were enrolled in the study
- 95 patients (UC n = 53, CD n = 42) have completed the 2-year follow-up or have had a relapse
- 49 patients (52%) were treated with an immunomodulator at inclusion and during follow-up
- The total relapse rate in the patient cohort was 57% (Figure 1)
- The relapse rate among patients treated with an immunomodulator was 47%, compared with 67% in those without immunomodulator, p = 0.016 (Figure 2)
- The faecal calprotectin concentration at baseline was 29 (12 – 81) mg/kg in the relapse group, and 13 mg/kg (7 – 44) in those with persistent remission, p = 0.16

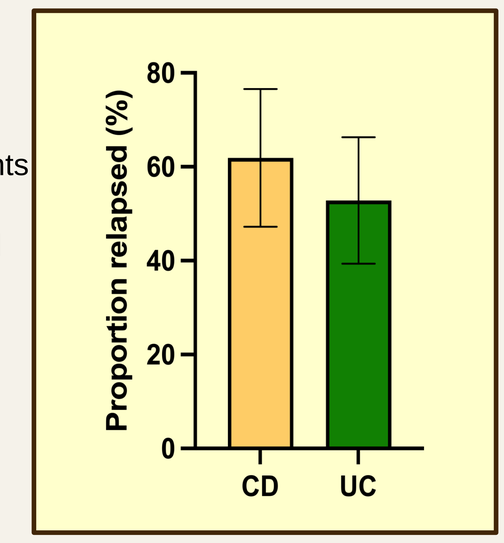

Figure 1. Proportion of patients stratified according to diagnosis, that have relapsed during the 2-year follow-up period after anti-TNF withdrawal. Errorbars show 95% confidence intervals

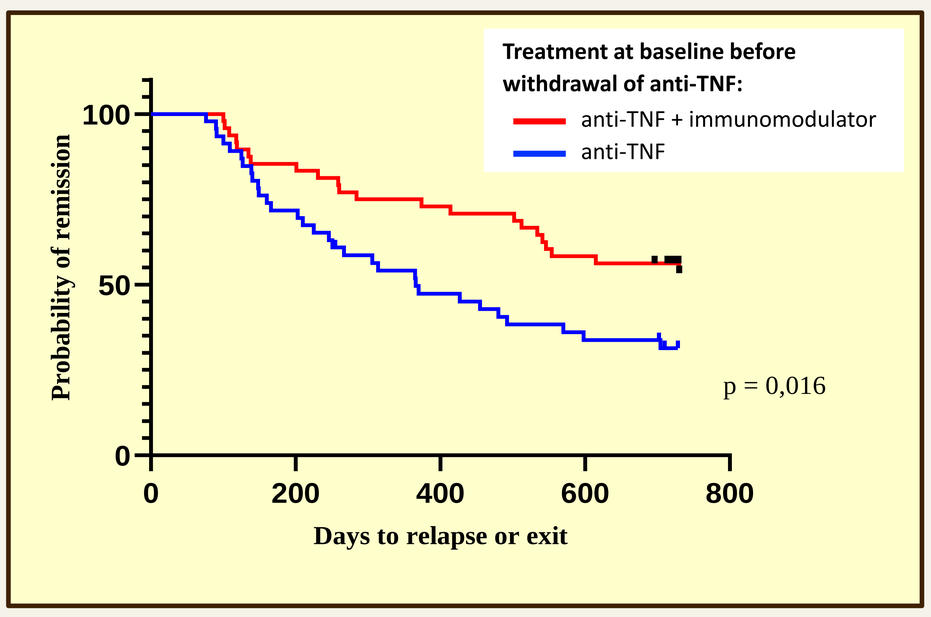

Figure 2. Days to relapse after anti-TNF withdrawal. Patients are stratified according to immunomodulatory treatment or not

Table 1. Baseline characteristics of the patients who have completed the 2-year follow-up or relapsed. IQR; interquartile range

	IBD, n = 95 (100%)	CD, n = 42 (44%)	UC, n = 53 (56%)
Male gender, n (%)	63 (66)	24 (57)	39 (74)
Female gender, n (%)	32 (34)	18 (43)	14 (26)
Active smoker, n (%)	2 (2)	1 (2)	1 (2)
Previous smoker, n (%)	48 (51)	13 (31)	35 (66)
Never smoker, n (%)	45 (47)	28 (67)	17 (32)
Disease duration, years (IQR)	10.0 (7.0 - 15.0)	10.2 (7.0 - 15.1)	9.9 (6.9 - 15.1)
Age at inclusion, years (IQR)	33.0 (28.0 - 43.3)	31 (27.5 - 39.5)	36 (28.0 - 46.0)
Age (Montreal)			
A1b (10-16)	12 (13)	5 (12)	7 (13)
A2a (17-26 years)	45 (47)	23 (55)	22 (42)
A2b (26-40 years)	25 (26)	9 (21)	16 (30)
A3 (>40 years)	13 (14)	5 (12)	8 (15)
Disease location CD (Montreal)			
L1, ileal		13 (25)	
L2, colonic		17 (32)	
L3, ileocolonic		14 (26)	
L4, proximal disease		1 (2)	
Disease extension UC (Montreal)			
E1, proctitis			2 (4)
E2, left sided			12 (23)
E3, extensive			39 (73)
Concomitant treatment at inclusion			
5-aminosalicylate, n (%)	41 (43)	5 (5)	36 (38)
Immunomodulator, n (%)	49 (51.6)	19 (45.2)	30 (56.6)
Anti-TNF treatment			
Adalimumab, n (%)	25	17 (40)	8 (15)
Infliximab, n (%)	70	25 (60)	45 (85)
Anti-TNF treatment, years (IQR)	5.7 (3.7 - 7.5)	6.2 (4.0 - 7.6)	5.7 (3.2 - 7.5)
Faecal calprotectin, mg/kg (IQR)	25.3 (8.1 - 58.0)	28.5 (11.3 - 45.8)	22.7 (5.8 - 83.7)

Methods

- Prospective cohort study of patients with CD or UC
- Patients were included who had been treated with infliximab or adalimumab for a minimum of one year, and were in clinical and endoscopic remission at inclusion
- Patients have been followed for 2 years or until relapse with regular monitoring and sampling
- Clinical symptom scores and faecal calprotectin were recorded at predefined timepoints during follow-up
- Relapse was defined endoscopically
- Blood, faeces and mucosal samples have been collected at inclusion and during follow-up for biomarker studies

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