Determining the Success of the Treatment of Inflammatory Bowel Disease with Ustekinumab as a First-Line Advanced Therapy

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Background

In recent years, there have been several new treatment options for inflammatory bowel disease (IBD). Tumour necrosis factor α (TNF-α) inhibitors have been joined by novel advanced therapies, including ustekinumab (UST). These drugs are mostly used as second-line treatment after TNF-α inhibitors, with subsequent lower efficacy. There are few data available on the efficacy of treatment with UST in biologically naïve patients. We aimed to assess the efficacy of UST in biologically naïve patients in a retrospective cross-sectional study at a tertiary referral IBD centre (University Medical Centre Ljubljana, Slovenia).

Methods

- Retrospective cross-sectional study
- 71 biologically naïve patients who started first-line treatment with UST were included (60 patients with Crohn's disease (CD), 11 patients with ulcerative colitis (UC))
- Determining treatment persistence
- Determining treatment efficacy based on clinical, biochemical and endoscopic parameters (three timelines)
- Determining the correlation between serum concentration of UST and remission

Results

- One-year treatment persistence: 88% (92% for CD, 82% for UC)
- Two-year treatment persistence: 72% (74% for CD, 68.5% for UC)

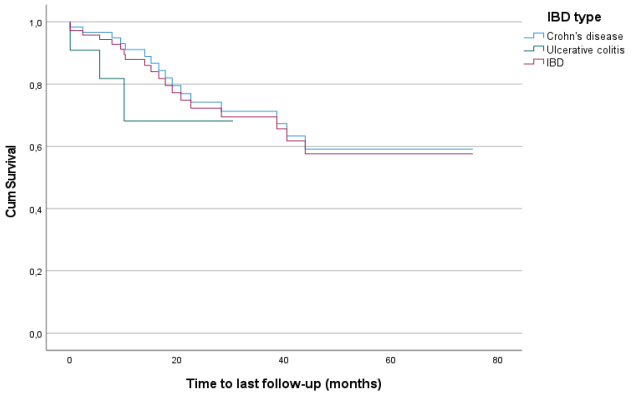

Figure 1. Kaplan-Meier curve of UST treatment persistence.

Table 1. Percentage of patients who achieved remission. All data refer to the last follow-up. IBD – inflammatory bowel disease, CD – Crohn's disease, UC – ulcerative colitis, CRP – C-reactive protein, FC – faecal calprotectin.
Clinical remission for CD: absence of abdominal pain and liquid stools
Clinical remission for UC: pMayo score ≤1
Biochemical remission: CRP ≤5 mg/l or FC <100 mg/kg
Endoscopic remission for CD: absence of ulcers at endoscopy
Endoscopic remission for UC: Mayo score ≤1

Type of remission	IBD (%)	CD (%)	UC (%)
Clinical	44.3	41.2	90.9
Biochemical (CRP)	77.6	75.4	90.0
Biochemical (FC)	71.1	71.4	70.0
Endoscopic	58.3	58.1	60.0

- No significant difference between the median serum concentrations of UST in the group of patients who achieved remission and who did not achieve remission

Table 2. Comparison of median UST serum concentration in the group of patients who achieved remission and who did not achieve remission. Me – median, UST – ustekinumab, CRP – C-reactive protein, FC – faecal calprotectin.

Type of remission	Me UST serum concentration in group of patients who achieved remission (μg/ml)	Me UST serum concentration in group of patients who did not achieve remission (μg/ml)	p-value
Clinical	5.86	5.31	0.689
Biochemical (CRP)	5.93	3.25	0.476
Biochemical (FC)	5.63	4.47	0.412
Endoscopic	7.14	4.64	0.439

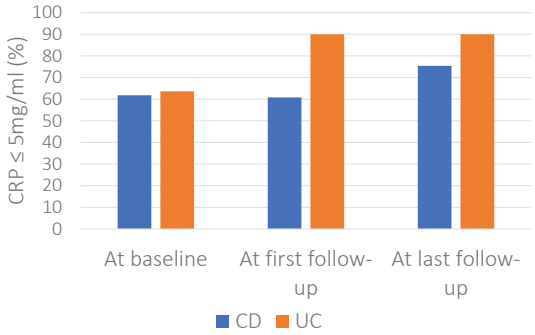

Figure 2. Percentage of patients who achieved biochemical remission according to C-reactive protein (CRP) levels at baseline, at first and last follow-up. CD – Crohn's disease, UC – ulcerative colitis.
First follow-up: median 3.7 months (IQR 3.5–3.9 months).
Last follow-up: median 16.8 months (IQR 7.8–38.0 months).

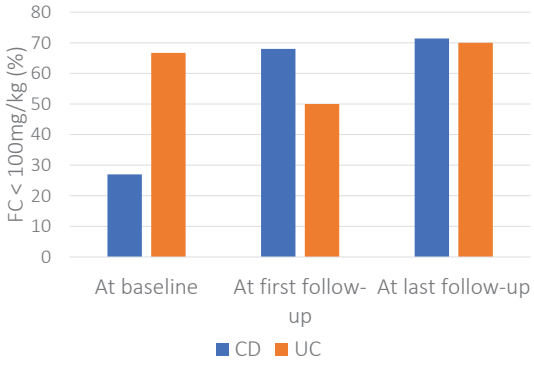

Figure 3. Percentage of patients who achieved biochemical remission according to faecal calprotectin (FC) levels at baseline, at first and last follow-up. CD – Crohn's disease, UC – ulcerative colitis.
First follow-up: median 3.7 months (IQR 3.7–3.8 months).
Last follow-up: median 17.0 months (IQR 6.2–29.6 months).

Conclusions

- The persistence of UST treatment in biologically naïve patients is high. Compared to the data in literature, it's higher than the persistence in second- or third-line treatment.
- With the use of UST as the first-line treatment, high rates of clinical, biochemical and endoscopic remission are achieved.

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