SWITCHING TO SUBCUTANEOUS INFLIXIMAB MAINTENANCE THERAPY IS EFFECTIVE IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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BACKGROUND AND AIMS

Stable disease activity and low relapse rates have been observed in relatively small real-world cohorts of inflammatory bowel disease (IBD) patients who switched from established intravenous (IV) maintenance infliximab (IFX) therapy to subcutaneous (SC) IFX therapy. Studies with larger patient populations are needed to confirm these results.

Aims of the study: to obtain real-world evidence after switching from IV IFX maintenance treatment to SC IFX in a comprehensive group of IBD patients

- Treatment persistence
- Clinical outcomes
- Drug concentrations
- Safety

PATIENTS AND METHODS

- **Study design**: Observational retrospective register-based study
- **Patients**: adult Crohn's disease (CD) and ulcerative colitis (UC) patients who switched from IV IFX maintenance therapy to SC IFX therapy in two tertiary centres from 1 January 2021 to 31 May 2023
- **Exclusion criteria**: a follow-up time of less than 6 months
- **Data collection and management**: data collected from the hospitals' IBD registers and electronic patient records, managed using REDCap electronic data capture tools, and combined by Finnish data permit authority Findata
- **Definitions of clinical remission**: Harvey Bradshaw Index (HBI) < 5 or Partial Mayo Score (PMS) < 2. In addition, faecal calprotectin (FC) < 100 was considered normal.
- **Data analysis**: SAS Studio, Version 3.81, Basic Edition

RESULTS

BASELINE INFORMATION

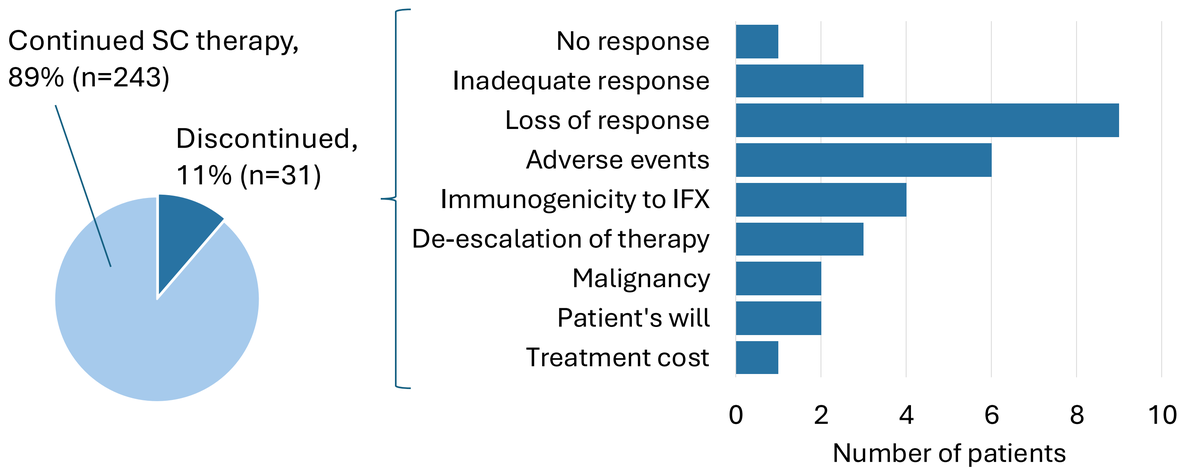
- A total of 274 patients (104 CD and 170 UC) were included
- Most CD patients had diagnosis at age 17-40 (64.4%), non-stricturing and non-penetrating disease behaviour (58.6%) and ileocolonic disease (41.8%), and most UC patients (65.3%) had extensive colitis
- **Clinical remission**: 94.2% of CD and 90.0% of UC patients
- **Influence of symptoms on daily life (IBD-VAS, 0-7):** median 1
- **Faecal calprotectin:** median 36 µg /g for CD and 34 µg /g for UC patients

BIOLOGICAL TREATMENT HISTORY AND CONCOMITANT MEDICATION

- **Adalimumab or ustekinumab**: 14.4% of CD and 2.4% of UC patients
- **Previous treatment course of IFX**: 10.6% of patients
- **IV IFX**: 19.3% had a shortened (less than 8 weeks) infusion interval and 7.3% had an escalated dose of 10 mg/kg
- **5-ASA**: 9.6% of CD and 38.2% of UC patients
- **Immunomodulator**: 67.2% of patients
- **Corticosteroid**: 2.2% of patients

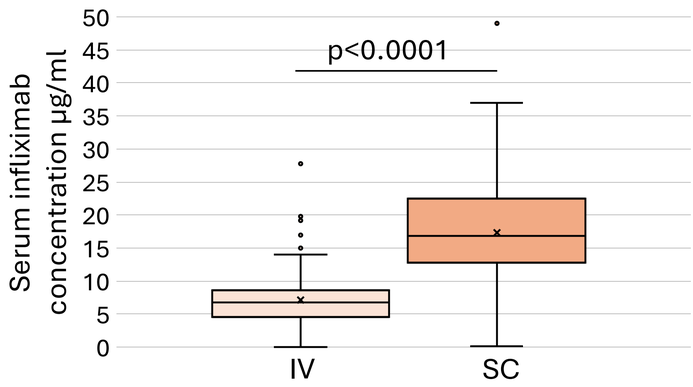
TREATMENT PERSISTENCE AND REASONS FOR DISCONTINUATION

After switching, treatment persistence at 12 months was 94.8% in CD patients and 88.8% in UC patients. During a median follow-up of 79 weeks, 11.3% of patients (n=9 CD, n=22 UC) discontinued the treatment. Adverse events leading to treatment discontinuation were rash (n=3), local reactions (n=1), general symptoms (a sense of balance difficulty and dizziness, n=1) and neutropenia (n=1).



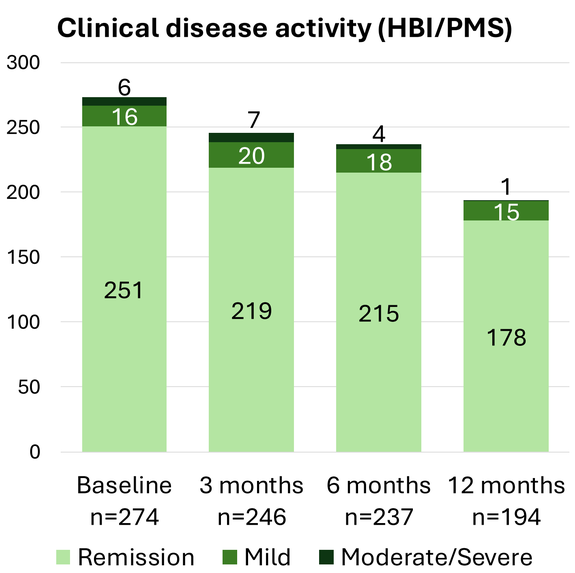
SC IFX TREATMENT AND DRUG CONCENTRATIONS

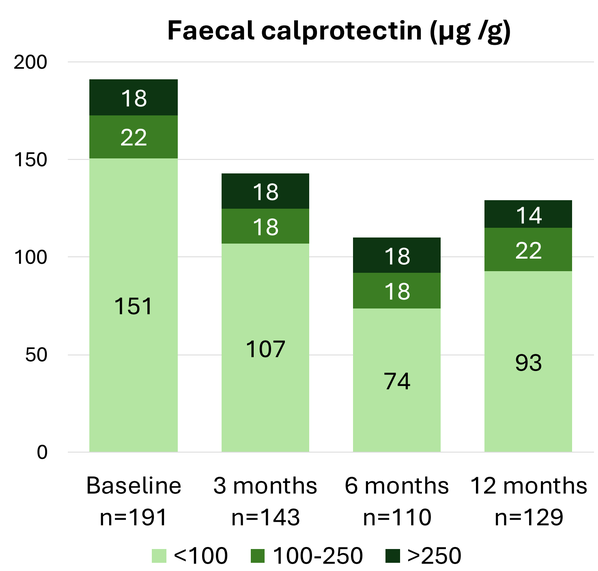
Most patients (96.7%) started SC treatment with 120mg dose every other week; the rest of the patients with a shortened interval. IFX concentrations were significantly higher during SC treatment (median 16.75 µg/m) compared to IV trough levels before switching (6.71 µg/m). Antibodies to IFX were detected in six patients after switching. During follow-up, 10.2% of patients needed shortening of SC administration interval.



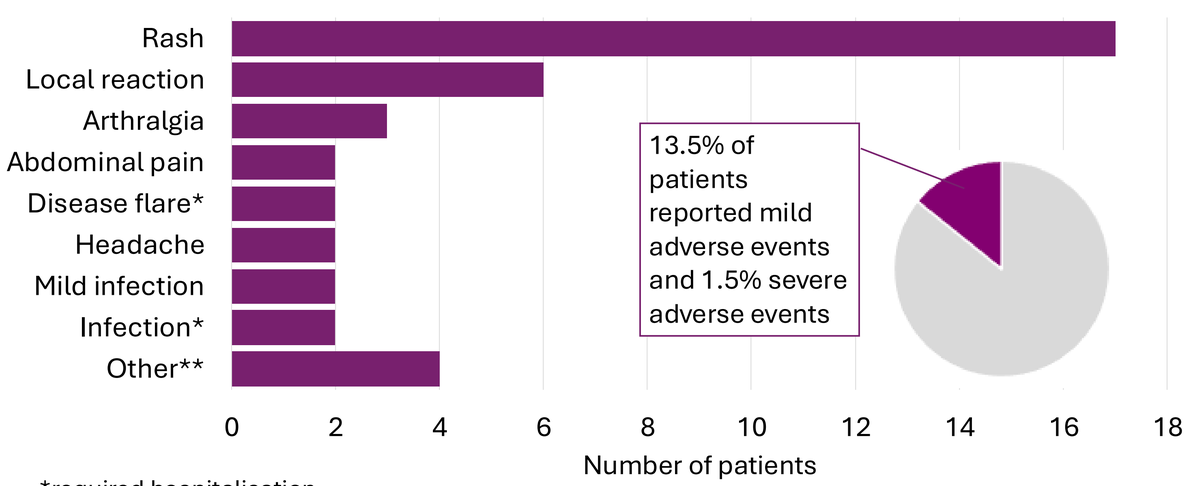
CLINICAL OUTCOMES

Compared to baseline, no statistically significant change occurred in disease activity at timepoints 3, 6 and 12 months based on HBI or PMS or FC (p=0.792, p=0.426, and p=0.20). In addition, the impact of IBD on everyday life measured with IBD-VAS score remained low (at 1 out of 7) after the switch and during follow-up.





ADVERSE EVENTS



*required hospitalisation
**1 self-reported memory-loss, 1 neutropenia, 1 self-reported faintness, and 1 self-reported feeling of balance difficulties and dizziness

CONCLUSION

Switching to SC IFX maintenance treatment was associated with high treatment persistence, stable disease course, increased IFX concentrations and acceptable safety profile.