

Switching from intravenous to subcutaneous infliximab in Behçet's disease: feasibility, safety and early outcomes

E. Fiorin¹, L. Iorio¹, F. Davanzo¹, M. Codirenze¹, G. Iacomelli²,
E. Tombetti^{2,3}, J. Sota⁴, S. Gentileschi⁴, E. Chiara⁵, E. Biancalana⁶,
G. Emmi^{5,7}, A. Doria¹, R. Padoan¹

¹Rheumatology Unit, Department of Medicine DIMED, University of Padua, Italy;

²Unit of Medicine and Rheumatology, ASST Fatebenefratelli-Sacco, Milan, Italy;

³Department of Biomedical and Clinical Sciences, University of Milan, Italy;

⁴Rheumatology Unit, Department of Medical Sciences, Surgery and Neurosciences, University of Siena, Italy; ⁵Department of Medical, Surgery and Health Sciences, University of Trieste, and Clinical Medicine and Rheumatology Unit, Cattinara University Hospital, Trieste, Italy;

⁶Department of Experimental and Clinical Medicine, University of Florence, Italy;

⁷Centre for Inflammatory Diseases, Monash University Department of Medicine, Monash Medical Centre, Melbourne, Australia.

Abstract

Objective

To assess the feasibility on remission maintenance, safety and patient acceptance following switching from intravenous (IV) infliximab (IFX) to subcutaneous (SC) IFX in patients with Behçet's disease (BD) in sustained remission.

Methods

We conducted a multicentre, retrospective observational study across four Italian referral centres. Patients with BD in stable remission on IV-IFX were transitioned to SC-IFX (120 mg every two weeks). Inclusion criteria were age ≥ 18 years, fulfilment of the International Criteria for Behçet's Disease (ICBD), at least 12 months of prior IV-IFX therapy, and a minimum of six months of SC-IFX treatment. Clinical and laboratory variables, including C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), Behçet's Disease Current Activity Form 2006 (BDCAF 2006), prednisone use, and adverse events, were monitored longitudinally. Patient experience was assessed through the Self-Injection Assessment Questionnaire (SIAQ).

Results

Ten patients were included (median age 44 years; 60% male). Median IV-IFX duration before switch was 83.5 [IQR 24.7–145.3] months, median post-switch follow-up was 15.5 [IQR 7.50–19.00] months. Across follow-up, CRP, ESR, and BDCAF 2006 did not show major changes. Two relapses occurred, and both patients resumed IV therapy. Prednisone use decreased from 50% to 20%. Infections occurred in three patients. No significant systemic adverse events were reported. Patient feedback among respondents was generally positive, with high satisfaction scores regarding ease of use, self-confidence, and quality of life improvement associated with SC administration.

Conclusion

Switching stable BD patients from IV to SC-IFX was feasible and well-tolerated, with preliminary signals suggesting that disease control may be maintained in many patients.

Key words

Behçet's disease, infliximab, anti-rheumatic agents, systemic vasculitis, treatment outcome

Eleonora Fiorin, MD
 Luca Iorio, MD
 Federica Davanzo, MD
 Marta Codirenzi, MD
 Giacomo Iacomelli, MD
 Enrico Tombetti, MD
 Jurgen Sota, MD
 Stefano Gentileschi, MD
 Emanuele Chiara, MD
 Edoardo Biancalana, MD
 Giacomo Emmi, Prof, MD
 Andrea Doria, Prof, MD
 Roberto Padoan, MD

Please address correspondence to:
 Roberto Padoan
 Reumatologia,
 Dipartimento di Medicina (DIMED),
 Università di Padova,
 Via Giustiniani 2,
 35128 Padova, Italy.
 E-mail: roberto.padoan@unipd.it

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ORCID iD:

E. Fiorin: 0009-0007-6262-9532
 L. Iorio: 0009-0000-2388-7001
 F. Davanzo: 0009-0004-9429-419X
 G. Iacomelli: 0009-0001-5775-7691
 E. Tombetti: 0000-0002-7122-9713
 J. Sota: 0000-0002-7549-2922
 S. Gentileschi: 0000-0001-6658-1037
 E. Chiara: 0000-0002-1380-6180
 E. Biancalana: 0000-0002-1410-4375
 G. Emmi: 0000-0001-9575-8321
 A. Doria: 0000-0003-0548-4983
 R. Padoan: 0000-0002-2356-375X

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Introduction

Behçet's disease (BD) is a rare chronic, relapsing, multisystem inflammatory vasculitis affecting blood vessels of all sizes (1), characterised by recurrent oral and genital aphthosis, skin lesions, non-granulomatous uveitis and other variable manifestations (2).

Disease flares can lead to irreversible organ damage, with significant implications for patients' quality of life (2), making sustained control a key therapeutic goal (3). Tumour necrosis factor-alpha inhibitors (TNF-i) are widely used for refractory or severe BD (3,4), and intravenous (IV) infliximab (IFX) has long been part of real-world management across multiple organ manifestations (4).

Subcutaneous (SC) formulation of IFX [CT-P13] has recently received regulatory approval, offering practical advantages over IV administration, including improved pharmacokinetics (5). Across several immune-mediated diseases, including rheumatoid arthritis, spondylarthritis, psoriatic arthritis, Crohn's disease, ulcerative colitis, and psoriasis, SC administration yielded steadier exposure and reduced immunogenicity (6, 7) effectively maintaining remission in many settings (5, 8). While switching from IV to SC-IFX has been implemented in other indications, evidence specific to BD remains to be explored. Understanding the feasibility and early outcomes of switching is clinically relevant for BD, where long-term maintenance strategies are often individualised and constrained by access, capacity, and patient preferences.

The aim of our study was to evaluate the feasibility of switching from IV-IFX to SC-IFX in patients with BD in sustained remission and to generate preliminary evidence regarding remission maintenance, safety, and patient acceptability in a real-world setting. Our primary objective was to describe feasibility and remission maintenance after switching, while the secondary objectives included treatment persistence, relapses, longitudinal trends in clinical indices and inflammatory markers, adverse events and patient-reported acceptability.

Methods

Patients, inclusion and exclusion criteria

We conducted a multicentre observational retrospective cohort study across four referral centres in Italy from January 2022 to July 2025. We included consecutive adults with Behçet's disease in sustained clinical remission on IV infliximab (administered every four or eight weeks at doses ranging from 3 mg/kg to 5 mg/kg) who underwent a routine-care switch to subcutaneous infliximab at a dosage of 120 mg every two weeks, per product labelling (6, 9). This design intentionally selected patients at lower short-term relapse risk, reflecting real-world switching practice in a maintenance context. Patients with active major-organ involvement (e.g. ocular, vascular, neurological) at the time of switch, or those initiating infliximab, were not included. The study was approved by the Ethics Committee of Padova University Hospital (EC CET-ACEV protocol n. 6329/EST/25). All the patients provided informed consent for participation and the use of their data retrospectively.

Inclusion criteria: Eligible patients were ≥18 years old, fulfilled the International Criteria for Behçet's Disease (ICBD), and were in clinically stable remission on maintenance IV-IFX for ≥12 months before switching to SC-IFX. We required at least 6 months of follow-up after the switch.

Exclusion criteria: We excluded patients switched during active major organ flares or with incomplete data or without written informed consent.

Assessment of clinical and laboratory features

We collected baseline clinical features, previous therapies and history of relapses. Baseline levels of C-reactive Protein (CRP) and erythrocyte sedimentation rate (ESR) were also recorded. Clinical assessments and laboratory tests were collected during follow up, as well as concomitant therapies (glucocorticoids, csDMARDs/biologics) and any modifications. Disease activity was evaluated according to Behçet's

Disease Current Activity Form 2006 (BDCAF 2006) (10) and clinical judgment. The BDCAF 2006 integrates patient and clinician assessments, specifically inquiring about disease-related symptoms occurring within the past four weeks, with emphasis on ocular, neurological, and major vascular involvement (10). Patients were considered in stable remission when they met all of the following criteria: a BDCAF 2006 total score ≤ 3 with no new or worsening major-organ activity (ocular posterior uveitis/retinal vasculitis, large-vessel vascular involvement, parenchymal CNS disease or dural sinus thrombosis, gastrointestinal ulceration with bleeding or perforation, or life-threatening cardiac involvement); a Physician Global Assessment (PGA) ≤ 3 on a 0–10 scale; glucocorticoids ≤ 5 mg/day prednisone-equivalent, stable for at least 8 weeks (no increase ≥ 5 mg/day within the prior 8 weeks); no treatment intensification within the prior 8 weeks (no new csDMARD or biologic and no dose escalation of existing csDMARD/biologic); and no new organ involvement since the previous visit. The CRP and ESR levels were not part of the formal definition but are reported descriptively.

Relapse during follow-up was defined by any of the following. First, a major-organ relapse, *i.e.* new or worsening major-organ manifestations that prompted treatment intensification. Second, a clinically significant systemic relapse, defined by BDCAF ≥ 3 or an increase of ≥ 2 points from the prior visit together with PGA $\geq 3/10$ and treatment intensification. Third, a therapy-driven relapse, defined as a return to IV-infliximab judged by the treating physician to address BD activity, provided the decision was due to BD rather than logistical reasons. Increases in BDCAF of ≤ 2 points without major-organ involvement and without treatment intensification were classified as minor flares and were not counted as relapses.

Safety assessments included monitoring liver enzyme levels, specifically Alanine Aminotransferase (ALT) and Aspartate Aminotransferase (AST), to detect potential liver toxicity, and a complete blood count. Adverse events

and side effects were carefully recorded. At the conclusion of follow-up, patients completed the Self-Injection Assessment Questionnaire (SIAQ), adapted from Keininger and Coteur (11, 12), to evaluate different quality-of-life domains.

Domains assessed on a 10-point scale (0 worst; 10 best) included patient feelings regarding self-injection, self-confidence, self-image, satisfaction with self-injection, injection-related pain and skin reactions and ease of using the self-injection device (11).

Data were collected systematically from electronic medical records using a standardised data collection form shared across participating centres.

Therapeutic drug monitoring was not performed as part of routine care during the study period; trough infliximab concentrations and anti-drug antibodies were therefore unavailable. Treatment adherence could not be objectively quantified, while it was assessed indirectly through routine clinical documentation, including patient reports at visits or contacts and confirmation of ongoing prescriptions.

Data analysis

Categorical variables are summarised as percentages and frequencies, while continuous variables as median and interquartile ranges (IQRs). Analyses were restricted to patients with data available at each specific time point. The normality of data distribution was assessed using the Shapiro-Wilk test.

Given the small, feasibility-oriented design in a maintenance-switch setting, we focused inference on effect sizes with 95% confidence intervals (CI) rather than hypothesis testing. For paired longitudinal outcomes (BDCAF 2006, PGA, CRP, ESR, and daily glucocorticoid dose) we calculated the Hodges-Lehmann (HL) estimator of the median within-patient change between baseline and each follow-up timepoint (3, 6, 12 months, and last observation), with bootstrap 95% CIs. As a complementary, direction-of-change metric, we calculated Cliff's delta for the paired differences with bootstrap 95% CIs. For small-sample proportions (*e.g.*, relapse, return to IV-IFX), we provided exact (Clopper-Pearson) 95% CIs. Time-to-

event outcomes (time to relapse; time to return to IV-IFX) were summarised using Kaplan-Meier curves.

Where appropriate, we also present paired non-parametric tests using the Friedman test with *post-hoc* Wilcoxon signed-rank tests as exploratory analyses. Multiplicity was controlled using the Holm-Bonferroni method. Adverse-event rates were expressed per 100 patient-years with exact Poisson 95% CIs. Categorical variables were analysed using the χ^2 test or Fisher's exact test, as appropriate, with *p*-values ≤ 0.006 considered statistically significant based on the Bonferroni correction for multiple comparisons.

Results

A total of thirteen patients with BD were initially screened for inclusion; three were excluded (two for active disease at switch, and one for incomplete six-month follow-up). Consequently, 10 patients were finally included in the study. Details of the cohort at diagnosis and at switch are summarised in Table I and Table II. Median age at switch was 44 [IQR 34.0–52.3] years and 6 (60%) patients were male.

Prior to IFX conversion, all patients had received prednisone; cyclosporine was used in 6 patients (60%), colchicine, azathioprine, methotrexate and adalimumab in 4 patients (40%) each, and tocilizumab in 1 patient (10%). Most (9, 90%) patients had failed at least one cDMARD, 7 (70%) had failed at least two cDMARDs, and 5 (50%) had also failed a biologic drug (anti TNF-alpha or anti-interleukin-6-receptor). Infliximab was originally prescribed for BD with severe or refractory clinical manifestations, most frequently major-organ involvement and, less commonly, persistent mucocutaneous-articular disease despite prior conventional immunosuppression. For the two patients with predominant joint involvement, the indication for IV-IFX was refractory inflammatory arthritis and/or sacroiliitis. One patient developed gastrointestinal lesions and venous thrombosis while receiving adalimumab. A second patient had mucocutaneous, articular, and ocular disease with intolerance to colchicine and cyclosporine, and a third

Table I. Patient demographic and clinical characteristics at disease diagnosis and initiation of subcutaneous infliximab treatment.

Behçet's disease patients (n=10)		
Demographics	Male, n (%)	6 (60%)
	Age at diagnosis, years	33 [26.3-39.7]
	Age at switching, years	44 [34.0-52.3]
	Disease duration at switching, years	7.5 [3.3-14.0]
Genetic profile	Positive HLA-B51, n (%)	4 (40 %)
Clinical manifestations at diagnosis, n (%)	Oral ulcers	10 (100%)
	Genital ulcers	6 (60%)
	Ocular involvement	6 (60%)
	Arthritis	6 (60%)
	Skin lesions	4 (40%)
	Gastrointestinal symptoms	3 (30%)
	Central nervous system involvement	3 (30%)
	Vascular involvement	2 (20%)
Previous therapies, n (%)	Epididymitis	0 (0%)
	Prednisone	10 (100%)
	Colchicine	4 (40%)
	Apremilast	0 (0%)
	Azathioprine	4 (40%)
	Cyclosporine A	6 (60%)
	Methotrexate	4 (40%)
	Cyclophosphamide	0 (0%)
Disease activity and laboratory data at switching	Adalimumab	4 (40%)
	Tocilizumab	1 (10%)
	Number of previous relapses	1 (0-1)
	0 relapses, n (%)	3 (30%)
	1 relapse, n (%)	6 (60%)
	2 relapses, n (%)	1 (10%)
	Intravenous infliximab therapy duration, months	83.5 [24.7-145.3]
	CRP at switching, mg/L	0.77 [0.20-0.90]
	ESR at switching, mm/h	10 [5.8-17.5]
	BDCAF 2006	0 [0-2]
	PGA	1.5 [1.0-3.0]

Continuous variables are expressed by median and interquartile range, whereas categorical variables are expressed by percentage.

BDCAF: Behçet's Disease Current Activity Form; CNS: central nervous system; CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; PGA: physician global assessment.

experienced an ischaemic stroke during cyclosporine therapy. Two patients started IV-IFX at diagnosis because of severe multisystem disease with uveitis and central nervous system involvement. Another patient received IV-IFX for severe cutaneous and ocular manifestations. In the remaining cases, IV-IFX was initiated for mucocutaneous disease associated with sacroiliitis or refractory arthritis, including one patient who discontinued methotrexate for pregnancy planning and adalimumab because of a generalised rash, and two who switched from adalimumab following epileptic seizures or ocular relapse. A patient-level summary of the indication for infliximab initiation and clinical phenotype is provided in Table II. The median duration of IV-IFX therapy before switch was 83.5 [IQR 24.7–

145.3] months. The median disease duration at switch was 7.5 [IQR 3.3–14.0] years. Seven patients (70%) had ≥ 1 prior disease relapse.

Median follow-up after switching was 15.5 [IQR 7.50–19.0] months; 8/10 patients completed 12 months, and 2/10 reached 24 months.

Disease activity and inflammatory markers did not demonstrate a consistent rise at the cohort level following the switch. Using the Hodges-Lehmann estimator, the median change from baseline to 3, 6, and 12 months, and to the last observation, was close to zero for BDCAF 2006, PGA, CRP, and ESR, with bootstrap 95% confidence intervals spanning zero at all time-points. These complete-case estimates, together with minimal directional bias by Cliff's delta, do not indicate a sig-

nificant worsening of disease activity or inflammation following transition to SC-IFX.

Longitudinal changes in inflammatory markers, disease activity, prednisone use, and safety outcomes during SC-IFX treatment are listed in Table III. Across the follow-up, CRP and ESR remained stable ($p=0.799$ and $p=0.150$, respectively). Median CRP was 0.77 [IQR 0.20–0.90] mg/L at baseline and 0.50 [IQR 0.30–0.80] mg/L at last follow-up, while median ESR was 10 [IQR 5.8–17.5] mm/h and 9 [IQR 5–11] mm/h, respectively. Physician Global Assessment (PGA) showed a numerical improvement over time, although not significant ($p=0.590$). BDCAF 2006 remained consistently low throughout the study period ($p=0.710$), with median values of 0 [0–2] at base-

Table II. Detailed clinical and therapeutic characteristics of patients undergoing subcutaneous infliximab switching. Continuous variables are expressed by median and interquartile range, whereas categorical variables are expressed by percentage.

Patient	Patient history from IV-IFX start to switching					Patient characteristics at SC-IFX switching				
	Clinical manifestations at IFX start	IV IFX therapy duration, m	IV IFX maintenance regimen	n. of relapses	Type of relapse	Disease duration, y	CRP, mg/L / ESR, mm/h	Concomitant therapy	BDCAF 2006	PGA
1	Intestinal tract lesions, arterial and venous involvement	228	5mg/kg/5w	1	CNS	35	0.9/29	-	0	1
2	Oral ulcers, ocular (chorioretinitis, retinal vasculitis) involvement, arthritis	120	3 mg/kg/8w	1	Ocular, Skin	11	0.4/2	-	3	4
3	Ischemic stroke	146	5 mg/kg/4w	1	Venous	21	2/8	PDN (3.75 mg/day), MTX	0	3
4	Oral and genital ulcers, skin lesions (erythema nodosum), CNS, intestinal tract lesions, PNS	143	5 mg/kg/5w	2	CNS, Mucocutaneous	14	0.75/5	PDN (5 mg/day)	2	3
5	Oral ulcers, CNS and ocular (uveitis) involvement	47	3 mg/kg/4w	1	Mucocutaneous	4	2.1/8	-	2	4
6	Oral and genital ulcers, ocular involvement	149	4 mg/kg/8w	0	-	14	0.12/3	-	0	0
7	Oral and genital ulcers, arthritis (sacroiliitis)	15	5 mg/kg/4w	0	-	1	0.8/18	-	0	0
8	Oral ulcers, skin lesions, arthritis, sacroiliitis	21	5mg/kg/5w	0	-	3	0.9/16	PDN (5 mg/day), Clc	0	1
9	CNS (sterile brain abscess, epileptic crisis) involvement	36	5 mg/kg/4w	1	Ocular	4	0.1/12	PDN (6.75 mg/day), MMF	0	0
10	Ocular (uveitis, retinal vasculitis) involvement	11	5 mg/kg/4w	1	Mucocutaneous	2	0.13/18	PDN (5 mg/day), Clc, MTX	1	2

BDCAF: Behçet's Disease Current Activity Form; Clc: colchicine; MMF: mycophenolate mofetil; MTX: methotrexate; PDN: prednisone; CNS: central nervous system; CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; IFX: infliximab; PGA: physician global assessment; PNS: peripheral nervous system; SC: subcutaneous.

line and 0 [0–1] at the last follow-up. Only 2 (20.0%, exact Clopper-Pearson 95% CIs 2.5–55.6%) patients experienced a relapse during follow-up. One patient (patient no. 4) (Table II) developed active arthritis after 12 months of treatment. Despite the addition of azathioprine and the shortening of SC-IFX interval from 14 to 7 days, symptoms persisted, prompting a return to IV-IFX with partial response. The second patient (patient no. 10) (Table II) relapsed at 3 months with mucocutaneous and articular manifestations and resumed IV-IFX, with clear benefit. Among the

two patients who discontinued, the median time to discontinuation was 7.5 months (IQR 5.3–9.8).

Treatment persistence on subcutaneous infliximab was high. The Kaplan-Meier estimate of persistence was 0.90 (95% CI 0.47–0.99) at 6 months and 0.77 (95% CI 0.35–0.94) at 12 and 24 months (2/10 discontinuations at 3 and 12 months), and the median time to discontinuation in the overall cohort was not reached (Fig. 1).

Prednisone use numerically decreased from 50% at baseline to 20% at last follow-up ($p=0.423$). The median daily

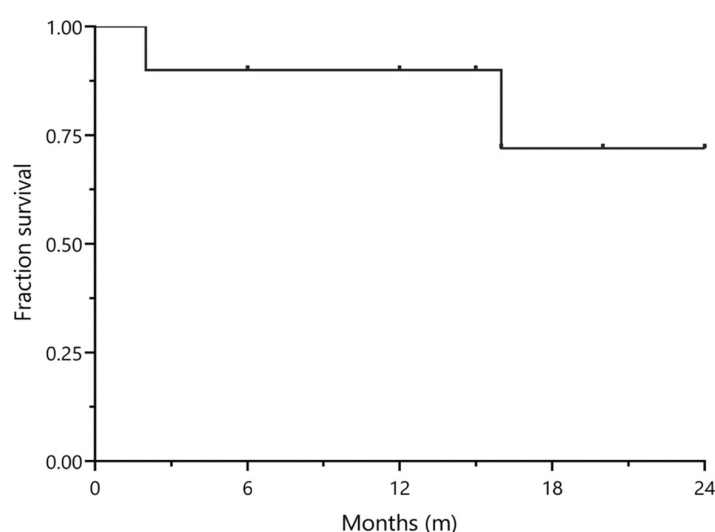
prednisone dose fell from 3.75 [IQR 0–5.0] mg/day to 0 [IQR 0–2.5] mg/day at last follow-up. Three patients were also receiving concomitant cDMARD therapy, with one discontinuing it after 6 months.

Adverse events were infrequent, with isolated occurrences at 6 months (14.3%) and at the last follow-up (10%), consisting of mild local injection-site reactions. Infections occurred in three patients, yielding an incidence of 25.90 per 100 patient-years (95% CI 5.34–75.69). Two patients had multiple upper-airway infections (at 6 and

Table III. Longitudinal changes in acute phase reactants, disease activity, prednisone use and safety outcomes over the follow-up.

	Baseline (n=10)	3 months (n=8)	p-value	6 months (n=7)	p-value	12 months (n=8)	p-value	Last follow-up (n=10)	p-value
CRP, mg/L	0.77 [0.20-0.90]	0.9 [0.45-2.37]	0.195	0.65 [0.37-1.25]	0.833	1.20 [0.60-4.58]	0.375	0.50 [0.30-0.80]	0.799
ESR, mm/h	10 [5.8-17.5]	10 [5-14]	0.554	7 [5-13]	0.293	10 [5-15]	0.855	9 [5-11]	0.150
PGA	1.5 [1.0-3.0]	2.0 [1.0-2.5]	0.850	1.5 [1.0-3.0]	0.590	1.0 [0.8-1.5]	1.000	1.0 [1.0-3.0]	0.590
BDCAF 2006	0 [0-2]	0.5 [0-1.0]	1.000	0 [0-0]	0.181	0 [0-0.5]	0.586	0 [0-1]	0.710
Patients on PDN	5 (50.0)	5 (62.5)	0.596	3 (42.9)	0.771	3 (37.5)	0.596	2 (20)	0.160
PDN, mg/day	3.75 [0-5.0]	4.4 [0-5.0]	1.000	0 [0-3]	1.000	0 [0-5]	1.000	0 [0-2.5]	0.423
Adverse events	0 (0)	0 (0)	1.000	1 (14.3)	0.218	0 (0)	1.000	1 (10)	0.305
Infections	0 (0)	0 (0)	1.000	2 (28.6)	0.072	1 (12.5)	0.250	2 (20)	0.136

Data are expressed as absolute number (%) and median (IQR). Each follow-up timepoint is compared with the baseline. Categorical variables were compared using the χ^2 test with Bonferroni correction for multiple comparisons (p -values ≤ 0.006 considered statistically significant); continuous variables were analysed using the Friedman test, followed by post hoc analysis with Wilcoxon signed-rank tests with a Bonferroni correction applied for multiple testing. BDCAF: Behçet's Disease Current Activity Form; CRP: C-reactive protein; ESR: erythrocyte sedimentation rate; PDN: prednisone; PGA: physician global assessment.

**Fig. 1.** Kaplan-Meier curve for treatment persistence on subcutaneous infliximab.

Event was drug discontinuation due to relapse; patients without an event were censored at last follow-up. Two discontinuations occurred (at 3 and 12 months). Greenwood 95% CIs are reported in the text; the median time to discontinuation was not reached.

12 months), and one developed herpes zoster followed by SARS-CoV-2 infection (the latter in the patient who relapsed at one year). No severe adverse events were recorded, and liver enzymes remained within normal limits throughout follow-up.

Five patients accepted to complete the SIAQ at the end of follow up. The mean scores were as follows: overall negative feelings about self-injection 2.73, self-confidence 10, injection site reactions 2.25, ease of use 9.52, and overall satisfaction 8.66.

Discussion

In this multicentre, retrospective cohort of adults with BD in stable remission on long-term IV-IFX, switching to SC-IFX was feasible and generally well

tolerated over a median 15.5-month follow-up, with no consistent signal of loss of disease control at the group level. Given the small sample size and absence of a comparator, these observations are preliminary and hypothesis-generating, and do not establish equivalence of efficacy or safety relative to continued IV-IFX. Across follow-up, disease-activity scores and inflammatory markers remained generally stable. Two relapses occurred (both necessitating a return to IV-IFX), and no serious adverse events were observed. Although the small sample size, the safety profile of SC-IFX was consistent with the EU product information (9).

Our observations align with experience from other immune-mediated diseases in which SC-IFX switching has been

adopted for reasons of convenience, potential pharmacokinetic steadiness, and health-system efficiency. In rheumatoid arthritis, SC-IFX has been associated with improvements in disease activity scores, higher clinical response rates, increased achievement of low disease activity, and improved functional outcomes compared to both IV biosimilar IFX and reference IV IFX (8, 13). For patients with durable control on IV-IFX, the central concern is whether switch could precipitate relapse. In our cohort, only two patients relapsed. These cases highlight the importance of close monitoring in the first months after conversion and a low threshold to revert to IV dosing if domain-specific activity emerges.

In the context of modern healthcare, the use of SC biologics offers an important strategy for reducing overall costs. SC administration can streamline resources by minimising the organisational burden associated with IV infusions (14). Moreover, self-administered biologics align with the growing trend toward telemedicine and remote patient management, which accelerated following the COVID-19 pandemic (5).

Successful switching depends on adherence, injection technique, and realistic expectation-setting. A study on 180 BD patients found that one-third admitted to skipping doses or adjusting their therapy without consulting a physician (15). Non-adherence was associated with younger age, longer disease duration, and greater psychological disease impact (15). Similarly, Cinar *et al.* reported intermediate levels of adherence

in a cohort of 125 BD patients using the Compliance Questionnaire on Rheumatology (CQR), with higher adherence observed in patients diagnosed at older ages (16). These findings underscore the importance of reinforcing adherence in patients using home-administered biologics and tailoring switching strategies to individual patient profiles. Although SIAQ results suggested low anxiety about self-injection and high acceptability, only half of the cohort completed the instrument; selection toward more motivated patients is possible. Our practice delivers the first SC dose in hospital with structured training, likely supporting higher ease-of-use and self-confidence scores. Patients were generally satisfied with the switch, citing home administration, minimal disruption to daily life, and time savings from fewer/shorter hospital visits compared with IV infusions. Only one patient initially expressed concerns about reduced physician contact. Strengths include the multicentre setting, long prior exposure to IV-IFX before conversion reducing the likelihood of misclassifying naturally fluctuating disease as a switch effect, and repeated, routine-care assessments of activity and inflammation. However, the sample is small, follow-up is variable, and there is no parallel control group remaining on IV-IFX. Patients had heterogeneous baseline IV-IFX dosing regimens and concomitant immunosuppressive therapies during follow-up. All patients received SC-IFX every two weeks; we did not explore de-escalation strategies to extend dosing intervals after achieving remission. Furthermore, in contrast to IV-IFX, whose dosage can be increased up to 10 mg/kg, there is a paucity of knowledge regarding the potential for up-titration of the SC formulation. In one patient of our cohort, an attempt was made to shorten the SC-IFX dosing interval from 14 to 7 days, but no clinical benefit was observed. We must finally acknowledge the lack of therapeutic drug monitoring and anti-drug antibody data as limitation that prevents mechanistic attribution of relapses or returns to IV-IFX and underscores the need for prospective studies with standardised anti-drug antibody

measurements and exposure-response analyses. A further limitation is the lack of objective adherence measures after switching to self-administered SC therapy, unlike infusion-based treatment where administration is directly observed. Objective metrics (*e.g.* electronic injection tracking, pharmacy refill data, or drug-level monitoring) and therapeutic drug monitoring with serum infliximab trough levels and anti-drug antibodies were not systematically available in this multicentre real-world setting. Adherence could only be inferred from routine-care documentation and ongoing prescription records. This limitation should be considered when interpreting persistence outcomes.

Conclusion

This multicentre real-world study suggests that, in carefully selected BD patients in sustained remission on IV-IFX, switching to SC-IFX is feasible and generally well tolerated. Given the preliminary nature of these findings, we aim to provide pragmatic, hypothesis-generating evidence to guide clinicians considering this switch in routine care. Any therapeutic switch should be preceded by a comprehensive and personalised risk-benefit analysis. Careful patient selection and close monitoring are in fact essential to minimise the risk of relapse. In parallel, integrating adherence support tools, such as remote monitoring tools and adherence support programs, could further enhance the effectiveness of home-administered therapies and ensure sustained disease control.

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