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Switching from intravenous to subcutaneous infliximab is safe and feasible in patients with perianal Crohn's disease

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Abstract

Background and objectives: We assessed the evolution of perianal lesions after switching intravenous (IV) to subcutaneous (SC) infliximab in patients with Crohn's disease (CD).

Design: Subgroup analysis of REMSWITCH studies.

Methods: We described the clinical and MRI outcomes of patients with a prior or current CD perianal lesions after the switch.

Results: In REMSWITCH, 40 CD patients had a prior history of perianal lesions. No patient experienced a new perianal lesion (median follow-up = 18 months). Among the three patients (3/40, 7.5%) with clinically active perianal lesions at baseline, two patients had no more perianal lesions at month 18 while the last patient experienced lesions worsening. Another one with active perianal lesions on MRI but no symptom at baseline did not have any relapse within 18 months. Only one patient (1/40, 2.5%) had a perianal relapse (at month 25) with remission recapture after SC infliximab intensification.

Conclusion: Switching from IV to SC infliximab in CD with perianal lesions is safe and feasible.

Plain language summary

Reassuring data on switching from IV to SC infliximab therapy in patients with perianal Crohn's disease

In this sub-analysis of the REMSWITCH study, patients with prior history of Crohn's disease perianal lesions had reassuring evolution after switching from IV to SC infliximab. A prior history of perianal lesions should not prevent this switch in daily practice.

Keywords: Crohn's disease, infliximab, perianal lesions, subcutaneous, switch

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Introduction

The REMSWITCH study recently demonstrated that switching from intravenous (IV) to subcutaneous (SC) infliximab is feasible and well-accepted leading to a low risk of relapse in patients with inflammatory bowel diseases (IBD).[1,2] However, physicians could be reluctant to switch patients with past or current perianal Crohn's disease (CD)-related lesions as perianal relapse is felt as a complex situation by the physicians with detrimental impact on patient's quality of life, and reassuring data are still lacking in this situation. In this subgroup analysis of the REMSWITCH study, we assessed the evolution of perianal lesions after switching IV to SC infliximab (IFX) in patients with CD.

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Methods

During the multicenter REMSWITCH program[1,2] (study approved by local Ethics Committee IRB00013412, 'CHU de Clermont Ferrand IRB #1', IRB number 2022-CF001 and 2023-CF059, with compliance to the French policy of individual data protection), all IBD patients in clinical remission (Crohn's disease activity index, CDAI <150 or partial Mayo score ⩽2) were consecutively included in three IBD centres and were switched to SC infliximab 120 mg/2 weeks (regardless of IV dose) at the theoretical day of IV infusion (visit 0 = V0) with regular follow-up for at least 18 months. The study and the specific sub-study described here were conducted in three centres (University Hospitals of Clermont-Ferrand, Lille and Amiens, France).

In this sub-study, we included CD patients enrolled in the REMSWITCH study with past or current perianal lesions at the time of the switch. Perianal lesions had a specific evaluation at 6 and 18 months. A perianal lesion was defined as clinically active in case of discharge, abscess, anal pain or bleeding related to a primary (ulcers) and/or secondary (fistulizing) perianal lesion confirmed by proctological examination and/or pelvic MRI. On MRI (standardized protocol across the three centres), fistulizing perianal lesion was considered active in case of an abscess, or T2-weighted hyperintensity on the fistula tract. Fistulae were considered 'simple' if they were low (of superficial or low intersphincteric or low transsphincteric origin), had a single external opening and lacked evidence of abscesses, rectovaginal fistulas or anorectal strictures. 'Complex' fistulas were high (of high intersphincteric or high transsphincteric or extrasphincteric or suprasphincteric origin), may have multiple external openings and can be associated with the presence of abscesses, rectovaginal fistulae or anorectal strictures.[3,4]

Results

Among the 133 patients enrolled in the REMSWITCH programme, 40 patients with CD had a prior history of anoperineal lesions (Table 1) including anal fissure/ulceration in 13 patients (32.5%) or fistulizing lesions in 27 patients (67.5%). Fistulas were mainly complex (25/27, 92.6%) while the location was anoperineal in 92.6% of the patients (25/27) and rarely rectovaginal (2/27, 7.4%). The management of these perianal lesions encompassed drainage (26/27, 96.3%), one or more setons placements (21/27, 77.8%), transient stoma (3/27, 11.1%) and mesenchymal stem cell injections (1/27, 3.7%). No patient experienced the occurrence of a new perianal lesion within 18 months after the switch.

At the time of the switch, only three patients (3/40, 7.5%, including two receiving 5 mg/kg/8 weeks and one treated with 10 mg/kg/4 weeks) had clinically active perianal lesions with complex perianal fistula and four patients (4/40, 10.0%) had active perianal lesions on MRI (three symptomatic patients and one asymptomatic patient with abnormal MRI).

Among the three patients with clinically active perianal lesions at baseline, one was considered in remission at 6 months, another one as partial improvement and the last one as stable (physicians' judgement). At 18 months, two out of these three patients (one had to be optimized to 120 mg/week) had no more perianal lesions (remission) while the last patient experienced a worsening of these lesions. The asymptomatic patient with active perianal lesions on MRI did not have any relapse after 18 months of follow-up but still has stable active lesions on MRI.

During the follow-up (median follow-up = 18 (15–20) months), only one patient (1/40, 2.5%) treated with infliximab 10 mg/kg/6 weeks before the switch, presented with perianal relapse occurring as complex perianal fistula after 25 months of follow-up leading to drainage with intensification of SC infliximab. The rate of patients with perianal lesions considered in clinical remission at 18 months was 95.0% (38/40) compared to 92.5% (37/40) before the switch (Figure 1).

Discussion

As perianal involvement is one of the most debilitating conditions in patients with CD, some physicians could be reluctant to therapeutic modification, especially for patients with a previous history of complex perianal disease. In this line, among the 249 eligible patients screened for entering the REMSWITCH study,[1] 22 were excluded by the physicians owing to active perianal lesions. While accumulating data confirmed that the switch from IV to SC infliximab is safe and feasible leading to a low risk of relapse in

Table 1. Baseline characteristics of the 40 patients with a prior history of perianal lesions in the REMSWITCH-LAP sub-study.

Characteristics	*N* = 40 patients
Age at the time of inclusion (mean ± SD)	39.7 ± 15.7 years
Female gender (*n*, %)	22 (55.0%)
Disease duration at baseline (mean ± SD)	13.8 ± 9.6 years
Montreal classification	
CD location	
L1 (*n*, %)	5 (12.5%)
L2 (*n*, %)	11 (27.5%)
L3 (*n*, %)	24 (60.0%)
CD behaviour	
B1 (*n*, %)	18 (45.0%)
B2 (*n*, %)	9 (22.5%)
B3 (*n*, %)	13 (32.5%)
Symptomatic perianal lesions at baseline (*n*, %)	3/40 (7.5%)
Active perianal lesions on MRI at baseline (*n*, %)	4/40 (10.0%)
Disease activity at baseline	
Harvey–Bradshaw index, median (IQR)	0 (0–1)
C-reactive protein level, mg/L, median (IQR)	3.0 (1.0–4.0)
Faecal calprotectin level, median (IQR)	34 (21–81)
Infliximab trough level at baseline, µg/mL median (IQR)	6.2 (4.4–9.9)
Detectable anti-infliximab antibodies (*n*, %)	0 (0.0%)
Concomitant immunosuppressive therapy (*n*, %)	13 (32.5%)

IQR, interquartile range; *n*, number; SD, standard deviation.

patients with IBD, whether the switch is suitable in the specific situation of CD patients with past or current perianal lesions remains to be addressed. A recent meta-analysis of individual data found only four studies (including two posters not published so far) reporting the outcomes after switching patients with perianal CD.[5] Among 25 patients with perianal CD from the UK, only two patients (8%) had worsening of perianal CD and required dedicated therapeutic intervention.[6] Another group did not report any relapse among nine patients with perianal disease.[7] These findings are in line with our results showing a very low risk of relapse in CD patients with a history of perianal lesions. However, the small number of patients performing the switch with active perianal disease should prevent drawing any firm conclusion on active perianal lesions. The meaning of our results has to take into account the fact that the original REMSWITCH

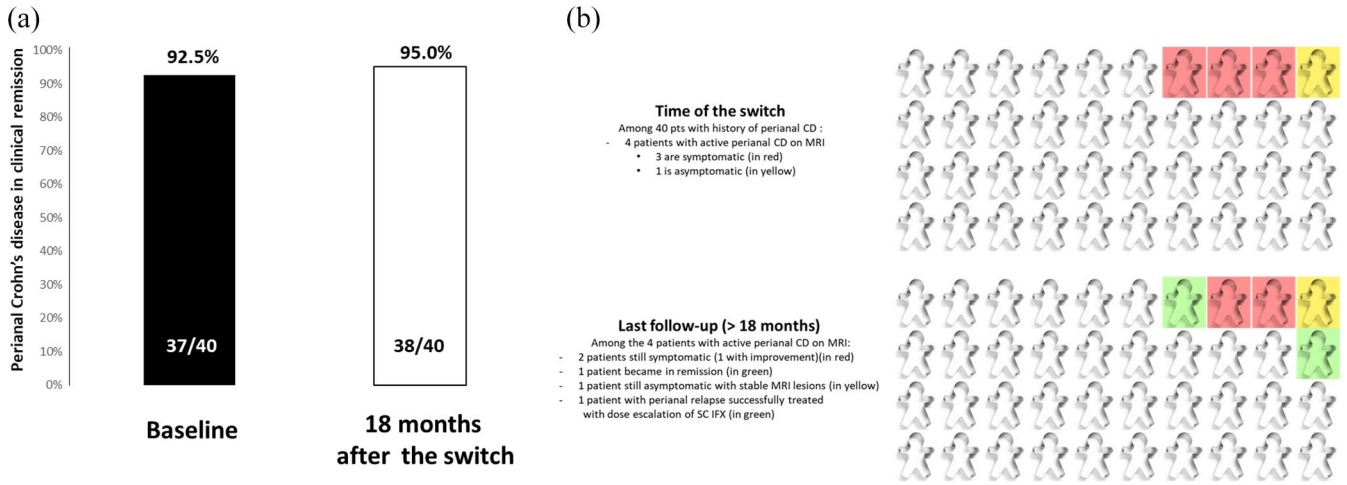

Figure 1. Rate of patients in perianal clinical remission (a) and evolution of perianal Crohn's disease (b) after switching from IV to SC infliximab.
IV, intravenous; SC, subcutaneous.

study included only patients who agreed to switch (acceptance rate = 72.3%) and that among the 249 eligible patients, 22 were not included by the physicians owing to complex perianal lesions. Recently, data from the GETAID group were presented at a DDW meeting and reported that the effectiveness of SC formulation seemed to be close to the efficacy of IV infliximab reported in the literature in patients with perianal disease.[8] They concluded that SC formulation appeared to be effective and safe for active perianal lesions as well as for maintaining remission in inactive perianal CD. The main limitations of this sub-study are the small sample size and the lack of systematic MRI evaluations.

In this specific analysis of the REMSWITCH study, the subgroup of CD patients with a prior history of perianal lesions had a reassuring evolution after switching from IV to SC infliximab. A prior history of perianal lesions should not prevent such a switch in daily practice.

Declarations

Ethics approval and consent to participate

This study was performed in accordance with the Declaration of Helsinki, Good Clinical Practice, and applicable regulatory requirements. The study was approved by the local ethics committee (IRB00013412, "CHU de Clermont Ferrand IRB #1," number 2022-CF001 and 2023-CF059) with compliance with the French policy of individual data protection.

Consent for publication

Not applicable.

Author contributions

Pauline Wils: Data curation; Formal analysis; Writing – original draft.

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Maria Nachury: Conceptualization; Formal analysis; Investigation; Writing – review & editing.

Clara Yzet: Data curation; Formal analysis; Investigation; Writing – review & editing.

Dilek Coban: Data curation; Investigation; Project administration; Supervision; Writing – review & editing.

Anthony Buisson: Conceptualization; Data curation; Formal analysis; Supervision; Writing – original draft.

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Competing interests

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Availability of data and materials

Data are available from the authors upon reasonable request.

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