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Comparative efficacy of topical tofacitinib versus topical tacrolimus in the treatment of localized vitiligo: a randomized investigator-blinded intraindividual trial

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Abstract

Background Topical ruxolitinib was recently approved by the US Food and Drug Administration for the treatment of vitiligo. Studies comparing other topical Janus kinase inhibitors with established topical therapies like tacrolimus are lacking.

Objectives To compare the efficacy and tolerability of topical tofacitinib and topical tacrolimus in patients with localized vitiligo using patient- and investigator-reported outcome measures.

Methods This was a prospective randomized investigator-blinded intraindividual single-centre comparative trial conducted over 16 weeks between January and December 2024. Thirty patients with 60 symmetrical vitiligo patches were enrolled. Eligible participants had slowly spreading, nonsegmental vitiligo affecting ≤5% of their body surface area. Patches were randomized to receive either topical tofacitinib 2% ointment or topical tacrolimus 0.1% ointment twice daily for 16 weeks. The primary outcome was percentage of patches achieving treatment success, defined as a Vitiligo Noticeability Scale (VNS) score of 4 ('a lot less noticeable') or 5 ('no longer noticeable'). Secondary outcomes included time to treatment success, trends of VNS among groups, extent of repigmentation and adverse effects. The study was registered with the Clinical Trial Registry of India (CTRI/2023/12/060431).

Results Of the patches treated with tofacitinib, 47% (n=14/30) achieved treatment success vs. 37% (n=11/30) of those treated with tacrolimus (P=0.60). The median time to treatment success was shorter for patches treated with tofacitinib [8 weeks; 95% confidence interval (CI) 4.333–11.667] than for those treated with tacrolimus [12 weeks; 95% CI 8.301–15.699 (P=0.18)]. Significant repigmentation was seen with both treatments, with 33% (n=10) of tofacitinib-treated patches and 20% (n=6) of those treated with tacrolimus achieving >80% repigmentation. There were fewer adverse events with tofacitinib (n=2) than with tacrolimus (n=7). Facial lesions responded better than acral or trunk lesions with both treatments.

Conclusions Topical tofacitinib demonstrated comparable efficacy to tacrolimus for localized vitiligo but showed trends toward earlier patient-reported response and a more favourable safety profile, a finding that could be validated in future studies with larger sample sizes.

An author video to accompany this article is available online.

Lay summary

Vitiligo is a persistent or chronic condition in which areas of skin lose their normal pigment (colour) and become very pale, white or light pink. Vitiligo is common, affecting about 1%, or 1 in 100 people, of the world's population. The condition can significantly affect a person's psychological well-being and quality of life. Although vitiligo cannot be cured, some treatments can stop it from spreading and help the skin regain its colour.

In this study, we compared two ointments. One is called 'tacrolimus' (which is commonly used) and the other is 'tofacitinib' (a newer option). We did this to see which worked better for treating small areas of vitiligo that were actively spreading. We focused on 30 people who had symmetrical patches of vitiligo and monitored them for 16 weeks. One side of their body was treated with tacrolimus, and the other with tofacitinib. We did this so that we could directly compare the two treatments. We looked at how visible the white patches were after treatment, how much colour came back and how well the new skin matched the surrounding area. We also recorded any side effects. We found that tofacitinib showed slightly better results in terms of how noticeable the patches were by the end of the study. Both ointments were well tolerated and safe.

Our findings suggest that tofacitinib ointment might be a useful new option for people with early or limited vitiligo. As tofacitinib works by targeting the immune system in the skin, it offers a different approach from traditional treatments. It could help more people with vitiligo get effective and safe relief from their symptoms.

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What is already known about this topic?

- Topical calcineurin inhibitors such as tacrolimus are an established treatment option for limited, active vitiligo, particularly in sensitive skin areas.
- Janus kinase inhibitors have emerged as a promising therapeutic approach for vitiligo based on their immunomodulatory role, but data on topical formulations remain limited.
- Previous studies on topical tofacitinib in vitiligo are largely open-label, uncontrolled or involve combination therapies, leaving uncertainty about its standalone efficacy.

What does this study add?

- This is the first randomized controlled trial to directly compare topical tofacitinib with topical tacrolimus in patients with active, limited vitiligo.
- Topical tofacitinib demonstrated comparable or superior efficacy in improving vitiligo noticeability and repigmentation in a head-to-head intraindividual comparison.
- The findings highlight distinct response patterns and colour match profiles between the two treatments, contributing to therapeutic decision-making in clinical practice.

Vitiligo is the commonest depigmenting skin disorder, affecting approximately 1% of the global population and up to 3–4% of the Indian population.[1,2] Beyond its physical manifestations, vitiligo can have a significant psychological impact, severely affecting patients' quality of life and emphasizing the need for early and effective treatment.[3] Intrinsic melanocyte defects, like oxidative stress and metabolic abnormalities in genetically predisposed individuals, trigger the activation of innate and acquired immune responses.[4] Despite advances in understanding the disease, halting disease progression and achieving repigmentation remain challenging, especially for generalized disease. Localized vitiligo is more common, usually involving the face – a site that usually delivers optimal therapeutic response in the form of repigmentation. However, it is also a site that leads to maximum stigma.

Topical calcineurin inhibitors like tacrolimus (used in concentrations of 0.03% in children and 0.1% in adults) are widely used to treat localized vitiligo, particularly on the face and sensitive areas, due to their favourable safety profile and comparable efficacy relative to corticosteroids.[5,6] Recent research has positioned Janus kinase inhibitors (JAKi), both oral and topical, as promising therapeutic agents for the treatment of vitiligo.[7] However, many studies are uncontrolled or combine JAKi with other therapies, leaving a gap in understanding their comparative efficacy as standalone treatments. Additionally, studies comparing JAKi with conventional topical therapies are lacking.

This prospective randomized investigator-blinded study aimed to evaluate the efficacy and tolerability of topical tofacitinib ointment vs. topical tacrolimus ointment in patients with localized vitiligo and sought to address a critical gap in the literature, further informing future treatment strategies for vitiligo. The objective of this study was to compare the efficacy of topical tofacitinib 2% ointment vs. topical tacrolimus 0.1% ointment in the treatment of patients with localized vitiligo.

Materials and methods

Study design

This was a prospective randomized investigator-blinded intraindividual comparative trial carried out over 16 weeks. This study included 30 patients with localized vitiligo (60 symmetrical vitiligo patches) who attended the pigmentary clinic at the Department of Dermatology, Venereology and Leprology, Post Graduate Institute of Medical Education and Research, Chandigarh, India, between January and December 2024. The trial was registered with the Clinical Trials Registry of India (CTRI/2023/12/060431).

Study participants

Patients aged ≥ 5 years with a clinical diagnosis of nonsegmental vitiligo affecting ≤ 5% of their body surface area (BSA; localized disease) and having at least two symmetrical patches were recruited. Eligible participants were required to discontinue any active treatments for vitiligo at the time of randomization, be able to administer treatments at home as instructed and provide informed consent (or parental/guardian consent for paediatric patients).

Exclusion criteria included segmental, universal or generalized vitiligo (BSA > 5%); rapidly spreading disease (e.g. Koebner phenomenon, confetti-like or hypochromic lesions); the need for systemic treatment; a history of skin cancer, photosensitivity or radiotherapy; pregnancy or lactation; recent systemic immunosuppression or phototherapy (within 4 weeks); participation in other trials; or the inability to follow treatment instructions.

Patients were included regardless of sex, disease duration or previous treatment history. A 2-week washout period was implemented for patients who had received prior topical treatment for vitiligo.

Treatment regimen and randomization

After obtaining informed consent, each patient's two symmetrical target vitiliginous patches were randomized to receive either topical tofacitinib (2% ointment) or topical tacrolimus (0.1% ointment). A random sequence was generated using Microsoft Excel 2007, and allocation was performed at patch level, ensuring one patch per patient received each treatment. The sequence was prepared by an independent researcher, and allocation was concealed using opaque, sequentially numbered envelopes to maintain integrity. Treatment allocation, administration and outcome assessment were conducted by separate physicians to minimize bias.

As this was a nonfunded trial in which participants were responsible for procuring their own medications, patients were not blinded. However, the outcome assessors were blinded to treatment assignments, to ensure objective evaluation. The trial lasted for 16 weeks, with follow-up visits scheduled every 4 weeks.

To ensure the correct application of treatment, patients received verbal instructions detailing which ointment to apply to each designated lesion. These instructions were also clearly documented in their prescriptions (e.g. 'Apply tacrolimus to the left forearm patch, tofacitinib to the right forearm patch'), to reinforce compliance. Identification was based on the commercial packaging and labelling of the creams (i.e. by reading the medication name). At each study visit, adherence was verified by direct questioning and visual inspection of the ointment tubes, ensuring that the expected amount had been used and correctly applied.

Outcome measurements

Treatment success was defined as a participant's report that a vitiligo patch was either 'a lot less noticeable' or 'no longer noticeable'. This was measured using the validated Vitiligo Noticeability Scale (VNS), a patient-reported outcome measure consisting of a 5-point scale to quantify cosmetic improvement (1 = more noticeable, 2 = as noticeable, 3 = slightly less noticeable, 4 = a lot less noticeable, 5 = no longer noticeable).[8] The primary outcome was defined as the percentage/proportion of patches in a treatment group that achieved treatment success (VNS 4 or 5). Secondary outcomes included time to treatment success; intragroup and intergroup trends of VNS; correlation of site with treatment success; percentage of repigmentation (calculated as a percentage of baseline depigmented area using standardized photographic documentation); and the incidence of adverse effects (recorded via patient self-reports and investigator observations).

Statistical analysis

Sample size was calculated based on a paired intrapatient design, assuming a 20% effect size (60% vs. 40% success rates), moderate intrapatient correlation (0.5), a significance level of 0.05 and 80% power, resulting in 55 patches (28 per group). The final sample size was increased to 60 patches (30 patients) to account for potential dropouts.

Statistical analysis was conducted with SPSS Statistics 29.0 (IBM, Armonk, NY, USA), employing paired tests for the intrapatient design. The Wilcoxon matched-pair signed-rank test compared ordinal outcomes (e.g. VNS scores between groups), while changes in VNS scores within groups over time were analysed with the Friedman test. Binary outcomes, like treatment success, were analysed using the χ^2 test or Fisher's exact test. For time-to-event outcomes, such as onset of repigmentation and treatment success, a log-rank test was used to compare survival curves between the treatment groups, with censoring applied at last follow-up for patients reporting no events. Statistical significance was set at $P < 0.05$.

Results

A total of 108 patients were screened for eligibility, 78 of whom were excluded. Thirty patients were recruited; 25 completed the 16-week study (Figure 1).

Two patients were withdrawn due to the onset of rapidly progressive disease requiring systemic immunosuppressive therapy during the study (one each at weeks 4 and 8). Two others opted out at week 8 due to a lack of response to topical treatment, and one patient was lost to follow-up. All 30 patients were included in the final analysis according to the intention-to-treat principle. Missing data were handled using the last observation carried forward method.

Baseline clinical and demographic characteristics

The mean (SD) age of the participants was 19.5 (13.2) years (range 6–54). The study cohort included 12 male and 18 female patients. The mean (SD) duration of illness was 52 (48) months (range 3–180). Thirteen participants (43%) had received prior immunosuppressant therapy. In terms of site involvement, 10 participants (33%) had acral lesions, 13 (43%) had facial lesions and 7 (23%) had trunk lesions.

Primary outcome measure

Forty-four of 60 patches (73%) showed some degree of repigmentation. Twenty-three patches (77%) treated with tofacitinib and 21 (70%) treated with tacrolimus experienced some repigmentation. Of the patches treated with tofacitinib, 14 (47%) achieved treatment success (VNS 4 or 5) vs. 11 (37%) treated with tacrolimus ($\chi^2 = 0.617$, $P = 0.60$, Cramér's V = 0.101; Figures 2, 3).

Secondary outcome measures

Time to treatment success

The median time to onset of first patient-reported repigmentation was 8 weeks [95% confidence interval (CI) 6.166–9.834] for patches treated with tofacitinib and 8 weeks (95% CI 5.508–10.492) for those treated with tacrolimus. The log-rank test showed no significant difference in the time-to-onset distributions ($\chi^2 = 0.234$, $P = 0.63$). The median time to investigator-reported repigmentation was also 8 weeks (95% CI 5.936–10.064) for tofacitinib-treated patches and 8 weeks (95% CI 5.859–10.141) for those treated with tacrolimus. The log-rank test showed no significant difference in the time-to-onset distributions between the two treatments ($\chi^2 = 0.446$, $P = 0.50$). A Wilcoxon signed-rank test revealed a statistically significant difference between investigator- and patient-reported onset of repigmentation ($Z = -2.449$,

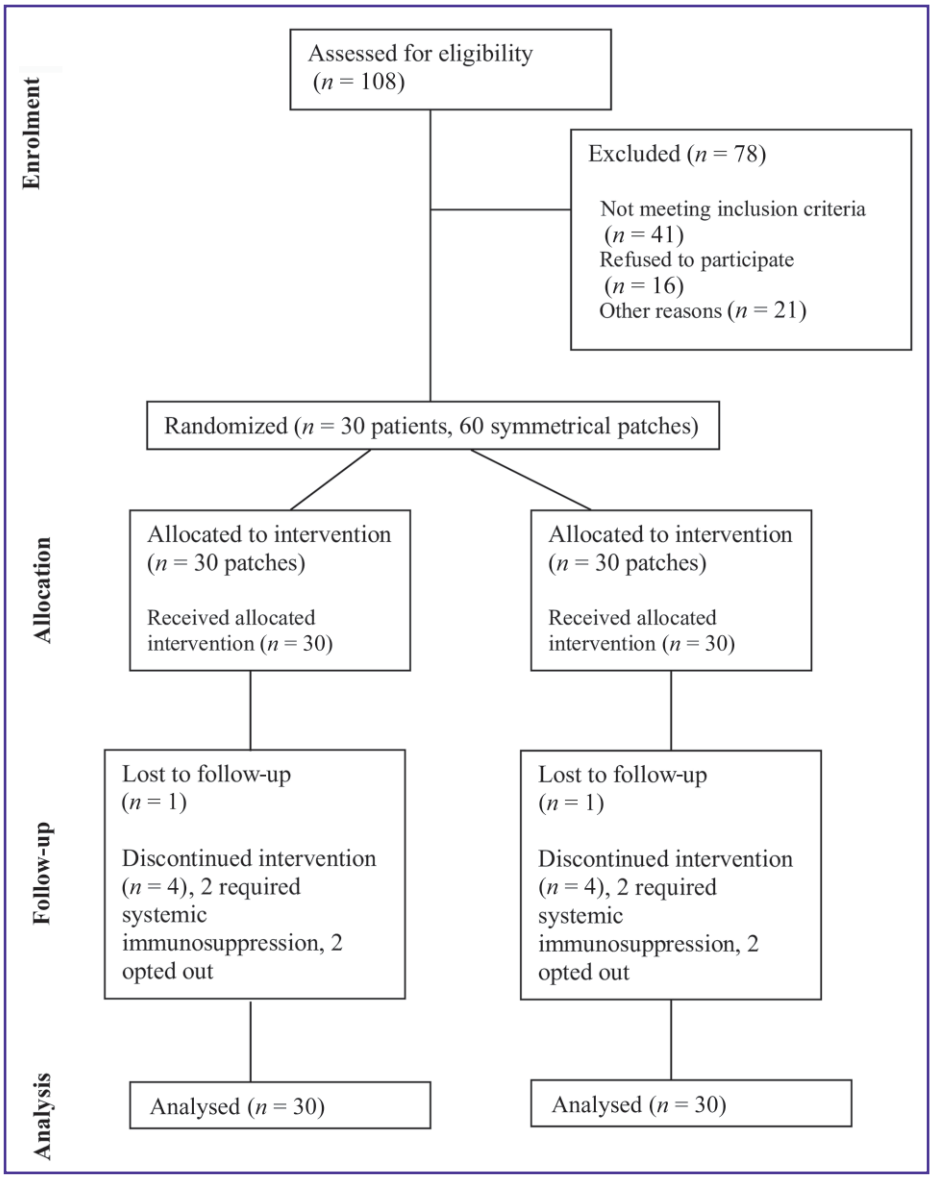


Figure 1 Flow of patients through the study.

$P=0.01$). Investigators identified repigmentation earlier in six patches, while no cases showed patient-reported onset occurring earlier than investigator-reported onset.

The median time to treatment success was 8 weeks (95% CI 4.333–11.667) for tofacitinib and 12 weeks (95% CI 8.301–15.699) for tacrolimus. The log-rank test showed no statistically significant difference between the two groups [$\chi^2=1.834$, $P=0.18$; Figure S1 (see Supporting Information)]. However, treatment success was seen as early as 4 weeks in three patches treated with tofacitinib, whereas none of the patches treated with tacrolimus achieved success at this timepoint.

Intra- and intergroup trends for Vitiligo Noticeability Scale scores

Intragroup comparison. Intragroup pairwise comparisons of VNS scores for patches treated with topical tofacitinib (analysed with the Friedman test followed by post hoc pairwise Wilcoxon signed-rank tests with Bonferroni correction; Figure 4) showed significant improvements from week 4 to week 8 ($P=0.02$), from week 4 to week 12 ($P=0.02$) and from week 4 to week 16 ($P<0.001$), with no significant differences observed between other timepoints ($P>0.05$). In contrast, pairwise comparisons of VNS scores for tacrolimus showed no significant improvement from week 4 to week 8 ($P=0.48$), with significant changes only seen later, from week 4 to week 12 ($P=0.02$) and from week 4 to week 16 ($P<0.001$).

Intergroup comparison. To evaluate between-group differences while accounting for the paired design, we conducted Wilcoxon signed-rank tests comparing paired differences in VNS scores between tofacitinib- and tacrolimus-treated patches at each timepoint. A statistically significant difference favouring tofacitinib was seen at week 12 ($Z=-2.530$, $P=0.01$); differences at weeks 4, 8 and 16 were not statistically significant ($P=0.10$, $P=0.06$ and $P=0.29$, respectively).

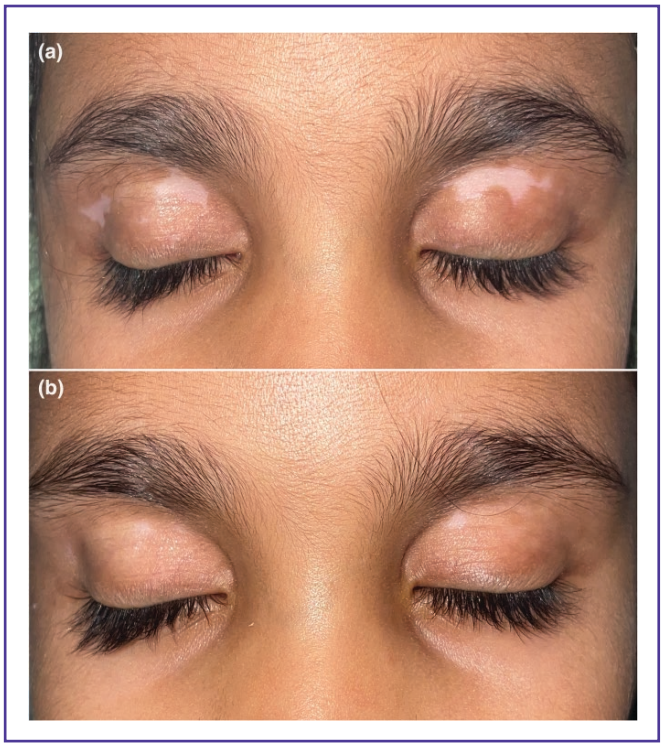


Figure 2 (a) Vitiligo lesions on the eyelids at baseline. (b) By week 16, both sides achieved a Vitiligo Noticeability Scale score of 4 ('a lot less noticeable').

Correlation of site with treatment success. The site of target patches was significantly associated with treatment success to either therapy ($P=0.01$, Fisher's exact test), with a large effect size (Cramér's V = 0.393). Facial patches had higher success rate ($n=15/24$; 63%) than acral ($n=4/22$; 18%) and trunk patches ($n=6/14$, 43%). No significant associations were found for age, duration of illness or prior immunosuppressant use.

Percentage of repigmentation

Of the patches treated with tofacitinib ($n=30$), 10 (33%) achieved > 80% repigmentation, 7 (23%) showed 51–79% repigmentation, 1 (3%) had 26–50% repigmentation and 12 (40%) showed 0–25% repigmentation at week 16. Of the patches treated with tacrolimus ($n=30$), 6 (20%) achieved > 80% repigmentation, 8 (27%) showed 51–79% repigmentation, 4 (13%) had 26–50% repigmentation and 12 (40%) showed 0–25% repigmentation at week 16. Wilcoxon signed-rank test revealed no statistically significant difference in repigmentation between the two groups ($Z=-1.485$, $P=0.19$).

At week 16, significant associations were observed between VNS scores and investigator-reported percentage repigmentation in both treatment groups. For tofacitinib-treated patches, 71% achieving a VNS of 4 or 5 corresponded to > 80% repigmentation ($\chi^2=29.778$, $P=0.003$, Cramér's V = 0.575). A similar correlation was seen in tacrolimus-treated patches ($\chi^2=31.448$, $P=0.002$, Cramér's V = 0.591), linking higher repigmentation with patient-perceived treatment success (Table S1; see Supporting Information).

Adverse effects

Two adverse events (AEs) were reported with tofacitinib: one case of pain and one of pruritus at application site. Seven AEs were reported with tacrolimus use, including five cases of a burning sensation at the application site, and one case each of transient erythema and pruritus. No serious AEs occurred, and no treatment discontinuations were attributed to AEs. The overall incidence of AEs showed borderline significance between the two treatments ($P=0.07$).

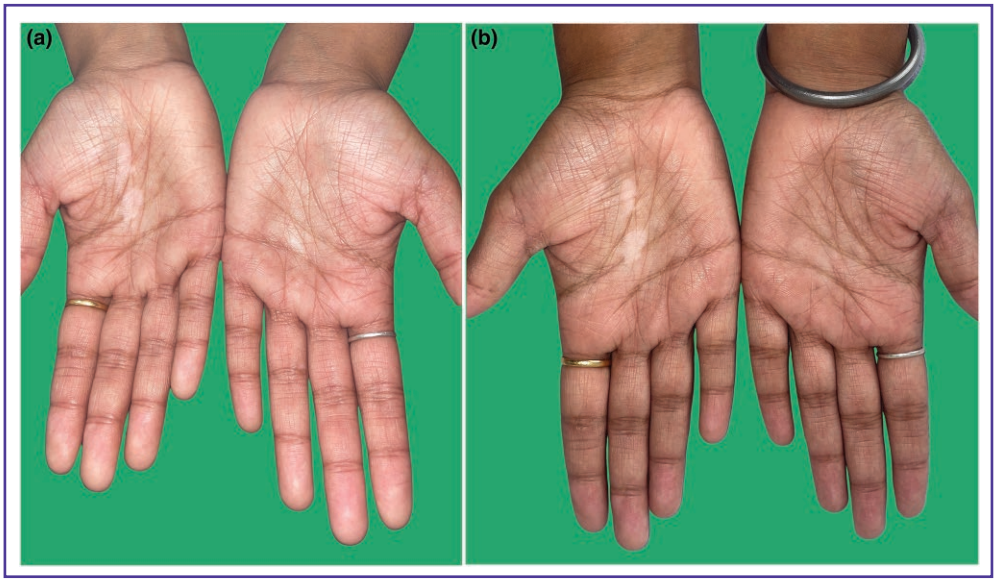
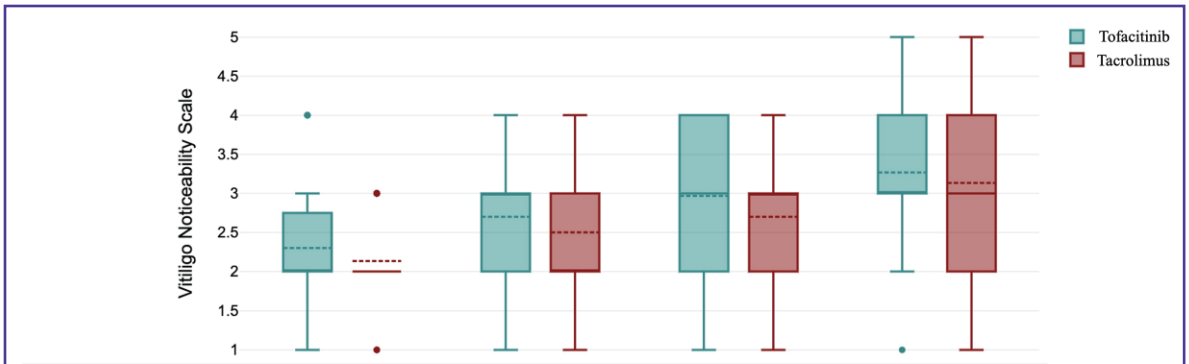


Figure 3 (a) Baseline presentation of acral vitiligo. (b) Comparison of treatment response at week 16. The left hand, treated with topical tofacitinib, achieved a Vitiligo Noticeability Scale (VNS) score of 4 ('a lot less noticeable'), while the right hand, treated with topical tacrolimus, remained at a VNS score of 2 ('as noticeable').



Time point	4 weeks	8 weeks	12 weeks	16 weeks
Topical Tofacitinib, Median VNS (IQR)	2.0 (2.0–3.0)	3.0 (2.0–3.25)	3.0 (2.0–4.0)	3.0 (2.75–4.0)
Topical Tacrolimus, Median VNS (IQR)	2.0 (2.0–2.0)	2.0 (2.0–3.0)	3.0 (2.0–3.0)	3.0 (2.0–4.0)

VNS: Vitiligo Noticeability Scale

Figure 4 Vitiligo Noticeability Scale (VNS) scores over 16 weeks for patches treated with topical tofacitinib and tacrolimus. The boxes represent the interquartile range (IQR), with the solid horizontal line indicating the median. The dashed horizontal line represents the mean VNS score at each timepoint. Whiskers extend to the minimum and maximum values within 1.5 times the IQR, while datapoints beyond this range are plotted as individual outliers (circles). Median VNS scores (with IQR) at each time point are shown in the table below the boxplot.

Discussion

Vitiligo, even when localized, can significantly affect patients' quality of life.[3,9] Recently, JAKi have shown promise by targeting key cytokines involved in melanocyte destruction.[10] However, head-to-head comparisons with established therapies like tacrolimus are lacking. This study aimed to address this gap by comparing the efficacy of topical tofacitinib and tacrolimus in localized, slowly spreading vitiligo, using the VNS.

Outcome measures used in the present study align with recommendations from the International Initiative for Outcomes for Vitiligo, which emphasizes the importance of patient-reported outcomes alongside traditional efficacy measures like repigmentation.[11] A strong correlation was found between VNS scores and percentage repigmentation (see Table S1), with nearly 60% of treatment successes occurring in patients who achieved > 80% repigmentation based on investigator-reported outcomes. The consistent median time of 8 weeks for treatment success and the onset of repigmentation in patches treated with tofacitinib probably also reflects the overlapping nature of these outcomes, as patient-reported improvements in vitiligo visibility often coincide with visible repigmentation.

Our findings align with and expand on previous case series that evaluated the efficacy of topical JAKi for vitiligo treatment. Mobasher *et al.* highlighted robust responses on facial lesions, reporting that they improved significantly compared with nonfacial lesions ($P = 0.02$), with some patients achieving > 90% repigmentation.[12] This aligns with our observation of high success rates for facial patches (63%). McKesey and Pandya reported a 70% improvement in Vitiligo Area Scoring Index with tofacitinib 2% cream over 8–16 weeks when combined with narrowband ultraviolet B phototherapy,[13] while Berbert Ferreira *et al.* observed significant facial repigmentation with the same combination over 36 weeks.[14] In contrast, our study focused exclusively on topical monotherapy and demonstrated comparable outcomes, with 33% of patches achieving > 80% repigmentation.

Reported outcomes with topical tacrolimus in vitiligo vary widely across studies, with success rates ranging from 29% for monotherapy in mixed lesions to 65% for facial vitiligo.[15,16] Radakovic *et al.* reported that only 13% of patches achieved > 75% repigmentation with twice-daily application of tacrolimus over a 6-month period.[17] Our findings that 37% of patients attained treatment success and that 20% of patches achieved > 80% repigmentation over 16 weeks are generally consistent with prior studies, reflecting the influence of lesion location and treatment duration on outcomes. Similarly, Stinco *et al.* and Ho *et al.* found that facial lesions respond better than nonfacial lesions, a trend mirrored in our results.[18,19] The improved response over facial lesions may, in part, reflect incidental sun exposure, as these areas are typically uncovered. However, the intraindividual design and symmetrical site selection aimed to mitigate this effect when comparing treatments.

Our study directly compared tacrolimus with tofacitinib, highlighting comparable efficacy. However, there was a notable trend toward an earlier response with tofacitinib, as shown by shorter median times to treatment success and earlier onset of repigmentation in some patients. This suggests that topical tofacitinib may be a viable alternative to corticosteroids, which are traditionally favoured for their rapid action but often limited by adverse effects.[20,21] Future trials directly comparing topical tofacitinib with corticosteroids could further clarify its potential as a first-line treatment option for localized vitiligo.

Topical tacrolimus and tofacitinib both demonstrated a favourable safety profile in our study, with no serious AEs reported. While tacrolimus 0.1% is only approved for the treatment of people aged > 15 years, it is frequently used off-label to treat younger children with atopic dermatitis.[22] Similarly, case series in alopecia areata have documented the safe use of topical tofacitinib in paediatric patients.[23] Our findings further support the tolerability of both agents in children with localized vitiligo. Topical tofacitinib demonstrated a more favourable safety profile than tacrolimus,

with fewer local application site reactions, such as burning or erythema, which are commonly reported challenges with tacrolimus.[24,25] This advantage may improve patient adherence and tolerability, further supporting its use in long-term vitiligo management. Unlike systemic JAKi, topical tofacitinib offers the advantage of ease of application without the need for extensive blood monitoring, making it a more convenient and accessible option for patients with localized vitiligo.

Although ruxolitinib has been approved by the US Food and Drug Administration for the treatment of vitiligo, the findings of this study reinforce the value of incorporating other topical JAKi into treatment algorithms, particularly in settings where ruxolitinib is not available or in patients who are unresponsive to or unable to tolerate calcineurin inhibitors or corticosteroids.

This study had several strengths. The use of the VNS as a primary outcome aligns with recommendations for patient-centred research, while combining patient- and investigator-reported measures ensures a balanced assessment. However, the small sample size and 16-week duration limit its generalizability and the evaluation of long-term outcomes. Additionally, the study's unblinded design for patients may have introduced bias. Although the intraindividual design should have reduced interpatient variability, it relied on patients correctly applying the designated ointment to the assigned lesion throughout the study. This introduces the possibility of treatment misapplication due to confusion, preference or cost bias. The findings of the current study do not apply to generalized or segmental vitiligo.

This study highlights the promise of topical tofacitinib as a viable alternative to topical tacrolimus for localized vitiligo, with trends suggesting earlier patient-reported response and a favourable safety profile. Long-term studies with larger sample sizes assessing the durability of repigmentation and safety outcomes with head-to-head comparisons between tofacitinib and other widely used monotherapies, such as corticosteroids, would help refine treatment algorithms and validate our findings.

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This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Conflicts of interest

The authors declare no conflicts of interest.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

Ethics statement

The study was approved by our Institute Ethics Committee (IEC-INT/2022/Study-825).

Patient consent

Written patient consent for publication was obtained.

Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's website.

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Bimzelx®▼ (bimekizumab) offers the opportunity for complete, fast, and lasting skin clearance and proven PsA efficacy [1–7]

68.2% (n=238/349)

of patients with PsO achieved **PASI 100 at Week 16**

(vs 1.2% placebo [n=1/86], p<0.0001)*** [2]

75.9% (n=265/349)

of patients with PsO achieved **PASI 75 at Week 4**

(vs 1.2% placebo [n=1/86], p<0.0001)*** [2]

76.9% (N=52)†

of patients with PsO achieved **PASI 100 at 5 years**[3]

51.5% (n=222/431) and **50.6%** (n=135/267)

of biologic-naïve and TNFi-IR PsA patients achieved **ACR 50 at Week 104/100,** respectively‡ [1,4–6]

BIMZELX was well tolerated, the most frequently reported adverse reactions were: upper respiratory tract infections and oral candidiasis. Other common reported adverse reactions include tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis, headache, rash, dermatitis, eczema, acne, injection site reactions, fatigue, and vulvovaginal mycotic infection (including vulvovaginal candidiasis).[4]

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BIMZELX is indicated for the treatment of: moderate to severe plaque PsO in adults who are candidates for systemic therapy; active PsA, alone or in combination with methotrexate, in adults who have had an inadequate response, or who have been intolerant, to one or more DMARDs; active nr-axSpA with objective signs of inflammation as indicated by elevated CRP and/or MRI, in adults who have responded inadequately, or are intolerant, to NSAIDs; active AS in adults who have responded inadequately or are intolerant to conventional therapy; and active moderate to severe HS (acne inversa) in adults with an inadequate response to conventional systemic HS therapy.[4]

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▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.mhra.gov.uk for the UK. Adverse events should also be reported to UCB Pharma Ltd at UCBCares.UK@UCB.com or 0800 2793177 for UK.

These data are from different clinical trials and cannot be directly compared.

Co-primary endpoints PASI 90 and IGA 0/1 at Week 16 were met.**Secondary endpoints. †N= mNRI, missing data were imputed with mNRI (patients with missing data following treatment discontinuation due to lack of efficacy or a TRAE were counted as non-responders; multiple imputation methodology was used for other missing data). ‡43.9% (n=189/431), and 43.4% (n=116/267) of biologic-naïve and TNFi-IR PsA patients achieved the primary endpoint of ACR 50 at Week 16 in BE OPTIMAL and BE COMPLETE, respectively (vs 10.0% [n=28/281] and 6.8% [n=9/133] placebo, p<0.0001); 54.5% (n=235/431) and 51.7% (n=138/267) maintained it at Week 52 (NRI).[4–6]

ACR 50, ≥50% response in the American College of Rheumatology criteria; **AS**, ankylosing spondylitis; **CRP**, C-reactive protein; **DMARD**, disease-modifying antirheumatic drug; **HS**, hidradenitis suppurativa; **IGA**, Investigator's Global Assessment; **(m)NRI**, (modified) non-responder imputation; **MRI**, magnetic resonance imaging; **nr-axSpA**, non-radiographic axial spondyloarthritis; **NSAID**, non-steroidal anti-inflammatory drug; **PASI 75/90/100**, ≥75/90/100% improvement from baseline in Psoriasis Area and Severity Index; **PsA**, psoriatic arthritis; **PsD**, psoriatic disease; **PsO**, psoriasis; **TNFi-IR**, tumour necrosis factor-α inhibitor – inadequate responder; **TRAE**, treatment-related adverse event.

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