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Original Research Article

Efficacy of Tofacitinib in Recalcitrant Prurigo Nodularis: An Observational Study

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Abstract

Background: Prurigo nodularis (PN) is a chronic, intensely pruritic skin disorder characterized by hyperkeratotic nodules, significantly impacting the quality of life. The disease is often recalcitrant to conventional treatments such as topical corticosteroids, antihistamines, and immunosuppressants. Emerging evidence suggests that the Janus kinase (JAK)-STAT pathway plays a crucial role in the pathophysiology of PN, making JAK inhibitors such as tofacitinib a promising therapeutic option.

Objective: This study aims to evaluate the efficacy and safety of oral tofacitinib in patients with recalcitrant PN who have failed conventional treatments.

Methods: A prospective observational study was conducted on 50 patients with histopathologically confirmed recalcitrant PN. Patients received oral tofacitinib (5 mg twice daily) for 12 weeks. The primary outcome was assessed using the Investigator Global Assessment (IGA) scale and the Numeric Rating Scale (NRS) for pruritus. Secondary outcomes included Dermatology Life Quality Index (DLQI) scores, the percentage of patients achieving 50% improvement in pruritus, and safety assessments.

Results: At the end of 12 weeks, 80% (40/50) of patients showed significant improvement in IGA scores ($p < 0.001$), while NRS scores decreased from 8.2 ± 1.4 to 2.3 ± 1.1 ($p < 0.001$). DLQI scores improved significantly, reflecting a better quality of life ($p < 0.01$). Mild adverse effects such as headaches and gastrointestinal discomfort were reported in 10% of patients, but no serious adverse events occurred.

Conclusion: Tofacitinib demonstrates significant efficacy in reducing pruritus and improving quality of life in patients with recalcitrant PN. It may serve as an effective alternative for patients unresponsive to conventional treatments, with a favorable safety profile.

Keywords: Recalcitrant Prurigo Nodularis, Tofacitinib, Prurigo Nodularis.

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Introduction

Prurigo nodularis is a chronic dermatological disorder characterized by persistent pruritus and multiple hyperkeratotic nodules. The disease is often associated with repeated scratching, secondary excoriations, lichenification, sleep disturbance and considerable psychosocial burden. In many patients, symptoms persist for several years and significantly impair daily activities and quality of life. Recalcitrant prurigo nodularis remains a therapeutic challenge because conventional treatment modalities, including topical corticosteroids, antihistamines and phototherapy, may provide only partial or temporary relief [1].

The pathogenesis of prurigo nodularis is complex and involves immune dysregulation, neural sensitization and chronic inflammation. Increasing evidence suggests that cytokine-mediated signalling pathways play an important role in the maintenance of inflammation and pruritus. The Janus kinase–signal transducer and activator of transcription pathway is involved in several inflammatory and pruritogenic mechanisms, making it a potential therapeutic target in chronic pruritic dermatoses [2].

Tofacitinib is an oral Janus kinase inhibitor that has shown benefit in several inflammatory skin conditions. Its ability to modulate cytokine signalling provides a scientific basis for its use in patients with recalcitrant prurigo nodularis3. However, clinical data regarding its efficacy and safety in this condition remain limited. Therefore, the present study was undertaken to assess the clinical response, quality of life improvement and adverse event profile of oral tofacitinib in patients

with moderate-to-severe recalcitrant prurigo nodularis.

Materials and Methods

This prospective observational study was conducted at a tertiary care centre over a period of 12 months. A total of 50 adult patients diagnosed with recalcitrant prurigo nodularis were enrolled after obtaining written informed consent. Patients aged 18 years and above with clinically and/or histopathologically confirmed prurigo nodularis were considered eligible for inclusion. Only patients with moderate-to-severe disease, defined by an Investigator's Global Assessment score of 3 or more and a Numerical Rating Scale score for pruritus of 7 or more, were included. All included patients had failed to respond adequately to conventional treatment modalities such as topical corticosteroids, antihistamines or phototherapy.

Patients below 18 years of age, those with other dermatological conditions mimicking prurigo nodularis such as atopic dermatitis or psoriasis, and those who had received Janus kinase inhibitors within the previous three months were excluded. Patients with active infections such as tuberculosis, hepatitis B, hepatitis C or HIV, severe immunosuppression, uncontrolled hepatic or renal disease, and history of malignancy within the previous five years, pregnancy, lactation or poor compliance with follow-up were also excluded from the study.

All patients received oral tofacitinib at a dose of 5 mg twice daily for 12 weeks. Clinical assessments were carried out at baseline, 4 weeks, 8 weeks and 12 weeks. The primary outcome measures were improvement in Investigator's Global Assessment score and reduction in pruritus severity as assessed by the Numerical Rating Scale. Secondary outcome measures included improvement in Dermatology Life Quality Index score and occurrence of adverse events during treatment. Safety monitoring was performed throughout the study period, and all reported adverse events were documented.

Results

A total of 50 patients with recalcitrant prurigo nodularis were included in the study. The mean age of the study population was 42.3 ± 9.5 years. There were 28 males and 22 females, accounting for 56% and 44% of the study population, respectively. The mean duration of prurigo nodularis was 5.7 ± 3.2 years (Table 1). The extremities were the most commonly affected sites, observed in 82% of patients, followed by the trunk in 14% and scalp in 4%.

Clinical improvement was observed progressively during the 12-week treatment period. The mean Investigator's Global Assessment score decreased from 3.8 ± 0.6 at baseline to 2.7 ± 0.8 at 4 weeks, 1.9 ± 0.5 at 8 weeks and 1.2 ± 0.3 at 12 weeks. Similarly, the mean Numerical Rating Scale score for pruritus showed a steady reduction from 8.2 ± 1.4 at baseline to 5.4 ± 1.2 at 4 weeks, 3.1 ± 1.0 at 8 weeks and 2.3 ± 1.1 at 12 weeks. At the end of treatment, 80% of patients had improved from severe disease to mild or almost clear disease status. The reduction in pruritus score from baseline to 12 weeks was statistically significant (Chart 1). Representative clinical photographs showing reduction in nodular lesions and excoriations before and after 12 weeks of tofacitinib therapy are shown in Figure 1A and Figure 1B.

Quality of life also improved substantially following treatment. The mean Dermatology Life Quality Index score at baseline was 18.3 ± 4.2, indicating severe impairment in quality of life.

At 12 weeks, the mean score decreased to 5.7 ± 2.9, reflecting marked improvement in daily functioning and overall well-being. This improvement was statistically significant. (Chart 2)

Tofacitinib was generally well tolerated. Mild adverse events were reported in 5 patients, representing 10% of the study population. Headache was reported in 3 patients, mild gastrointestinal discomfort in 2 patients and transient elevation of liver enzymes in 1 patient. No serious infections, thromboembolic events or major adverse cardiovascular events were observed during the study period (Chart 3).

Table 1: Baseline Characteristics of the Study Population

Characteristic	Value
Age, mean ± SD	42.3 ± 9.5 years
Male	28 (56%)
Female	22 (44%)
Duration of disease, mean ± SD	5.7 ± 3.2 years

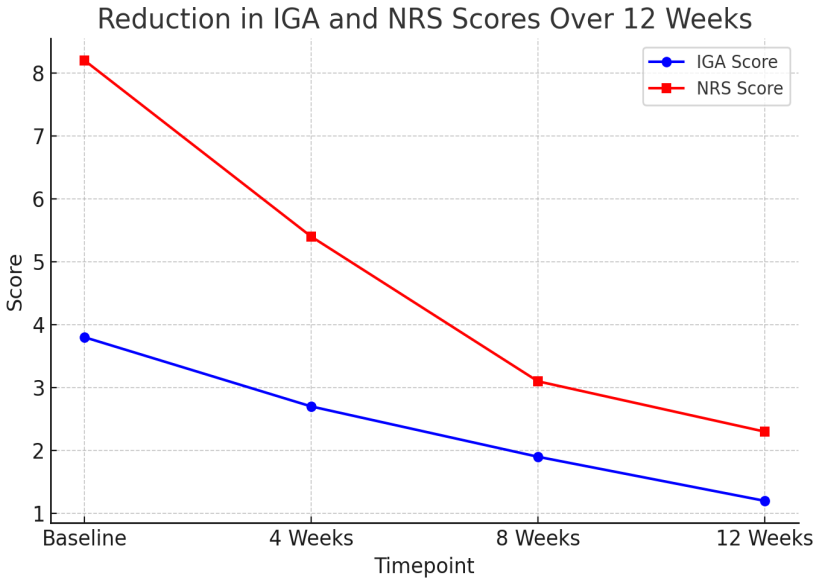

Chart 1: IGA and NRS Score Reduction

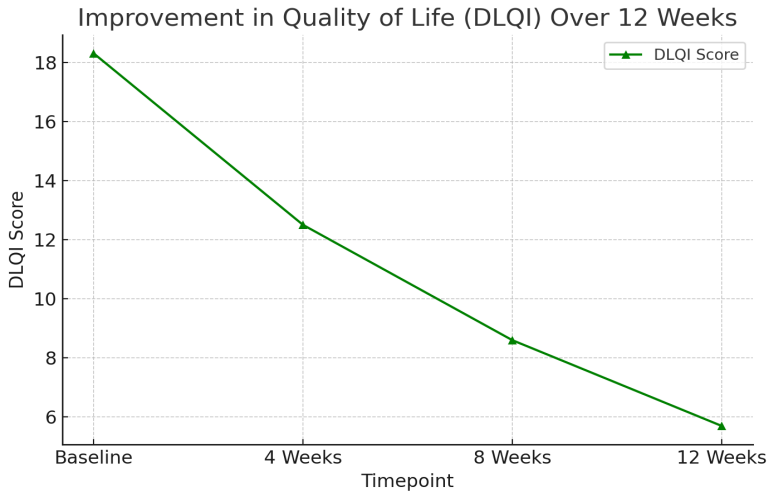

Chart 2: Change in Dermatology Life Quality Index Score

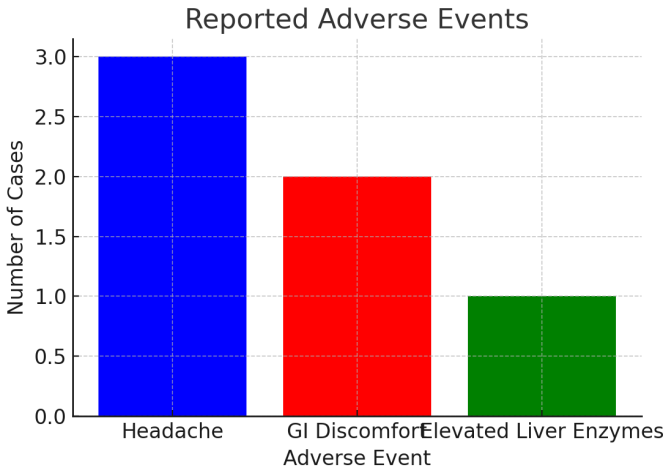

Chart 3: Adverse Events Observed During Treatment

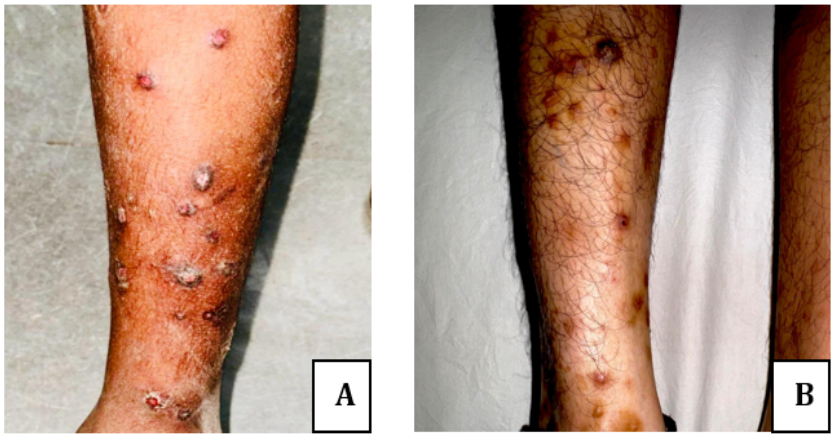

Figure 1A & 1B: Clinical appearance of prurigo nodularis lesions before and after treatment with tofacitinib.

Discussion

Prurigo nodularis is a chronic, intensely pruritic inflammatory dermatosis in which persistent itching, repeated scratching and neuroimmune dysregulation contribute to disease chronicity and poor quality of life. The present study evaluated oral tofacitinib in 50 patients with recalcitrant prurigo nodularis and demonstrated progressive improvement in clinical severity, pruritus and quality of life over 12 weeks.

In this study, the mean pruritus Numerical Rating Scale score decreased significantly from 8.2 ± 1.4 at baseline to 2.3 ± 1.1 at 12 weeks. Since pruritus is the most disabling symptom of prurigo nodularis, this reduction represents a clinically meaningful response. The antipruritic effect of tofacitinib may be related to inhibition of JAK-STAT mediated inflammatory and itch-related cytokine signaling, which has been implicated in prurigo nodularis pathogenesis. [3,4]

Objective improvement was also observed, with the mean Investigator's Global Assessment score decreasing from 3.8 ± 0.6 at baseline to 1.2 ± 0.3 at 12 weeks. At the end of treatment, 80% of patients improved from severe disease to mild or almost clear disease. Similar improvement with tofacitinib has been reported in recalcitrant cases, supporting the possible therapeutic role of JAK inhibition in prurigo nodularis. [5]

The improvement in Dermatology Life Quality Index score from 18.3 ± 4.2 to 5.7 ± 2.9 further indicates that reduction in itching and lesion severity translated into meaningful improvement in daily activities, sleep, social functioning and psychological well-being. Recent targeted therapies for prurigo nodularis have also emphasized pruritus reduction, lesion clearance and quality-of-life improvement as important treatment outcomes. [6,7]

Tofacitinib was generally well tolerated in the present study. Mild adverse events were observed in 10% of patients, including headache, gastrointestinal discomfort and transient elevation of liver enzymes. No serious infections, thromboembolic events or major adverse cardiovascular events were noted during the study period. However, because tofacitinib is an immunomodulatory drug, baseline screening and periodic monitoring remain important, especially during prolonged use.

The limitations of the study include its observational design, small sample size, absence of a control group and short follow-up period. Long-term efficacy, relapse after discontinuation and delayed adverse effects could not be assessed. Nevertheless, the findings suggest that oral tofacitinib may be an effective and well-tolerated treatment option for selected patients with recalcitrant prurigo nodularis. Larger randomized controlled studies with longer follow-up are required to confirm its sustained efficacy and safety.

Conclusion

Oral tofacitinib showed significant efficacy in the treatment of recalcitrant prurigo nodularis. It produced marked reduction in pruritus, improvement in lesion severity and substantial enhancement of quality of life over 12 weeks. The treatment was generally well tolerated, with only mild adverse events reported.

Tofacitinib may be considered a promising therapeutic option for selected patients with moderate-to-severe recalcitrant prurigo nodularis who fail to respond to conventional therapies.

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