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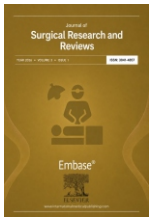

Research Article

Section: Dermatology

Comparative Evaluation of Liver Function Tests in Patients with Refractory Psoriasis Treated with Tofacitinib & Apremilast: A Retrospective Cohort Study

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HIGHLIGHTS

- Tofacitinib increased liver enzymes.
- Apremilast showed hepatic safety.
- ALT/AST elevations were higher.
- ALP/bilirubin remained stable.
- Regular monitoring remains essential.

Key Words:
Psoriasis; Tofacitinib
Apremilast
Liver function tests
Hepatotoxicity
Systemic therapy

ABSTRACT

Introduction: Psoriasis is a chronic inflammatory skin disorder often requiring long-term systemic therapy. Tofacitinib and apremilast are oral agents increasingly used in refractory cases; however, their impact on liver function remains a concern. **Aim & Objective:** To compare the hepatic safety of **tofacitinib and apremilast** in patients with refractory moderate-to-severe psoriasis over 12 months. **Materials & Methods:** A retrospective cohort study was conducted among 130 adult patients with refractory moderate to severe psoriasis receiving either tofacitinib (n=65) or apremilast (n=65) for 12 months. Liver function tests (ALT, AST, ALP, and bilirubin) were assessed at baseline, 3, 6, and 12 months. Changes in liver enzymes, incidence of elevations (>2× upper limit of normal), and treatment modifications were analyzed using appropriate statistical tests. **Results:** Baseline demographic and liver function parameters were comparable between the two groups ($p>0.05$). The tofacitinib group demonstrated a significant progressive increase in ALT and AST levels at all follow-up points compared to the apremilast group ($p<0.001$). Mean ALT increased from 26.3 ± 7.6 U/L to 42.1 ± 11.2 U/L, and AST from 22.9 ± 6.8 U/L to 35.5 ± 9.6 U/L. In contrast, apremilast showed minimal changes. The incidence of ALT and AST elevations (>2× ULN) was significantly higher with tofacitinib (24.6% and 20.0%) compared to apremilast (6.2% and 4.6%) ($p<0.01$). ALP and bilirubin remained stable in both groups. Two patients on tofacitinib required dose adjustment, while none in the apremilast group required modification. **Conclusions:** Tofacitinib is associated with significant liver enzyme elevations, whereas apremilast demonstrates a favorable hepatic safety profile. Regular monitoring is essential, and apremilast may be preferred in patients at risk of liver dysfunction.

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INTRODUCTION

Psoriasis is a chronic, immune-mediated inflammatory skin disorder characterized by erythematous, scaly plaques that commonly affect the scalp, elbows, knees, and lumbosacral region, with a global prevalence of approximately 2–3% [1,2]. Beyond cutaneous manifestations, psoriasis is increasingly recognized as a systemic disease associated with comorbidities such as psoriatic arthritis, metabolic syndrome, and cardiovascular disease, significantly impacting patients' quality of life and long-term health outcomes [3,4]. The pathogenesis of psoriasis involves a complex interplay between genetic predisposition, environmental triggers, and immune dysregulation, particularly involving T-helper 1 (Th1) and T-helper 17 (Th17) pathways, leading to excessive keratinocyte proliferation and chronic inflammation [5,6].

Management of moderate to severe psoriasis often necessitates systemic therapy. Conventional agents such as methotrexate, cyclosporine, and acitretin have been widely used; however, their long-term use is limited by potential adverse effects, including hepatotoxicity, nephrotoxicity, and immunosuppression [7,8]. In recent years, targeted therapies, including biologics and small-molecule inhibitors, have transformed the therapeutic landscape by offering improved efficacy and safety profiles. Nevertheless, biologics are often expensive and require parenteral administration, limiting their accessibility in many settings [9].

Oral small-molecule agents such as tofacitinib and apremilast have emerged as important alternatives in the management of refractory psoriasis. Tofacitinib, a Janus kinase (JAK) inhibitor, modulates the JAK-STAT signalling pathway, thereby reducing the activity of pro-inflammatory cytokines involved in psoriasis pathogenesis [10,11]. Clinical studies have demonstrated its efficacy in improving disease severity and patient-reported outcomes; however, concerns remain regarding its safety profile, particularly the risk of infections and hepatotoxicity [12,13]. On the other hand, apremilast, a phosphodiesterase-4 (PDE4) inhibitor, increases intracellular cyclic adenosine monophosphate (cAMP) levels, leading to downregulation of inflammatory mediators. It has shown favourable efficacy with a comparatively safer adverse effect profile, predominantly limited to gastrointestinal symptoms, and minimal hepatic involvement [14,15].

Liver function monitoring is a critical component in patients receiving systemic therapies for psoriasis. Liver function tests (LFTs), including alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and bilirubin, serve as important biomarkers for detecting hepatocellular injury and cholestatic dysfunction [16]. Drug-induced liver injury remains a significant concern, especially with long-term therapy, necessitating regular monitoring and timely intervention [17]. Previous studies have reported variable effects of systemic agents on hepatic parameters, highlighting the need for comparative evaluation of newer oral therapies [18]. **Figure 1:** Comparative mechanisms of action, hepatic metabolism, and 12-month liver function test trends of tofacitinib and apremilast in refractory psoriasis.

Given the increasing use of tofacitinib and apremilast in refractory psoriasis, it is essential to understand their relative impact on liver function. However, limited real-world data exist comparing their hepatic safety profiles over time. Therefore, this study aims to evaluate and compare the changes in liver function tests in patients with refractory psoriasis treated with tofacitinib and apremilast over a 12-month period, and to assess the incidence of clinically significant liver enzyme elevations associated with these therapies.

MATERIALS & METHODS

This retrospective cohort study included adult patients (≥18 years) with refractory moderate to severe plaque psoriasis who were treated with systemic therapy for a minimum duration of 12 months. A total of 130 patients were enrolled and divided into two groups based on the treatment received: tofacitinib (5 mg twice

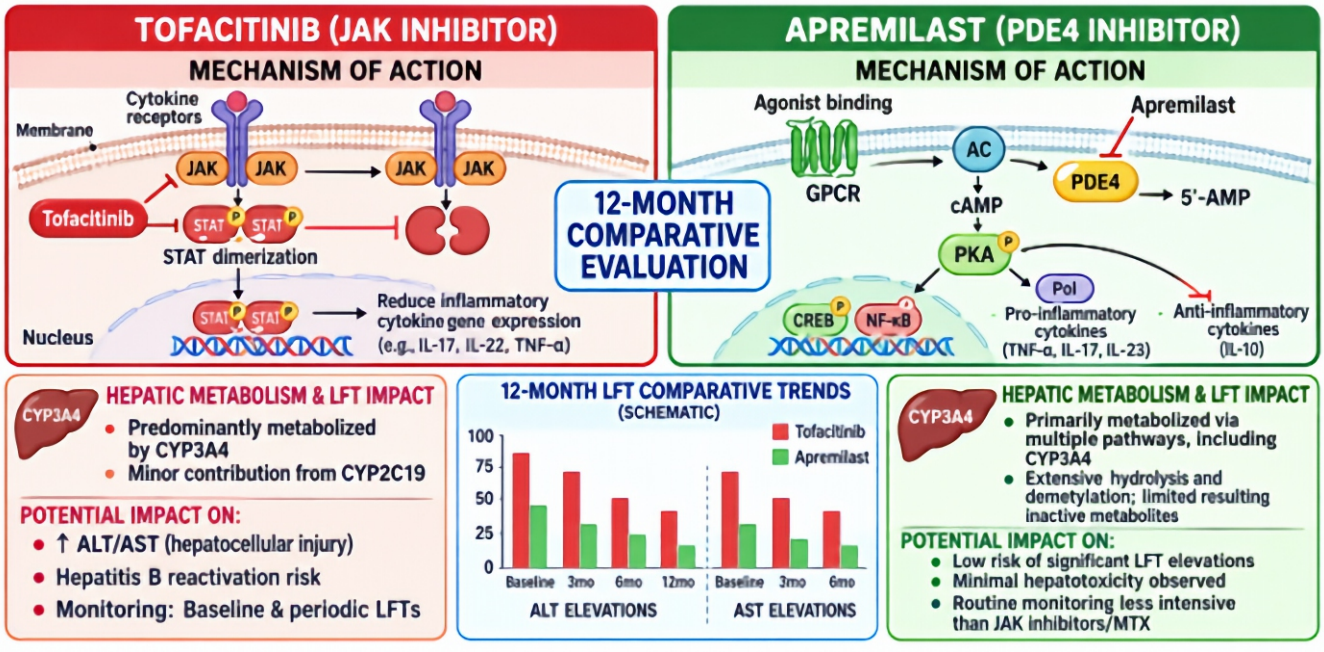

Figure 1: Comparative hepatic effects of tofacitinib and apremilast in psoriasis.

daily) and apremilast (30 mg twice daily), with 65 patients in each group. Patients with a history of liver disease, significant alcohol consumption, use of concomitant hepatotoxic medications, pregnancy, or incomplete medical records were excluded from the study.

Baseline demographic characteristics, duration of disease, previous systemic treatments, and presence of comorbid conditions were recorded. Liver function tests (LFTs), including alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP), and total bilirubin, were assessed at baseline and at 3, 6, and 12 months following initiation of therapy. The primary outcome was the change in liver enzyme levels over time, while secondary outcomes included the incidence of liver enzyme elevations (defined as >2× upper limit of normal) and any treatment modifications due to liver-related adverse events.

Statistical analysis was performed using SPSS software. Continuous variables were expressed as mean ± standard deviation and compared using independent t-test and paired t-test, while categorical variables were analyzed using chi-square test. A p-value <0.05 was considered statistically significant. Ethical approval was obtained, and confidentiality of patient data was maintained.

RESULTS

Demographic characteristics

The baseline demographic and clinical characteristics of the study population **(Table 1)** demonstrated that the two groups were well comparable, with no statistically significant differences observed across all variables (p>0.05). The mean age was similar between the tofacitinib and apremilast groups (46.1 ± 12.4 vs 44.8 ± 11.7 years; p=0.541), indicating comparable age distribution. The proportion of male participants was also nearly equal (55.4% vs 52.3%; p=0.724), suggesting balanced gender representation. Mean BMI values were closely matched (27.9 ± 4.2 vs 27.4 ± 3.8 kg/m²; p=0.477), reflecting similar baseline nutritional and metabolic status. The duration of psoriasis was comparable between the groups (12.4 ± 5.7 vs 11.8 ± 6.1 years; p=0.563), indicating a similar chronicity of disease. Furthermore, both groups had received a comparable number of previous systemic treatments (3.2 ± 1.1 vs 3.1 ± 1.0; p=0.589), suggesting similar prior therapeutic exposure. The prevalence of comorbid conditions was also nearly equivalent (38.5% vs 36.9%; p=0.853). Overall, the absence of statistically significant differences across these key baseline variables confirms that the two groups were well matched, thereby minimizing selection bias and confounding, and ensuring that any observed differences in outcomes can be more reliably attributed to the effects of the respective treatments rather than underlying baseline disparities.

Baseline liver function tests

The baseline liver function test parameters **(Table 2)** were comparable between the tofacitinib and apremilast groups, with no statistically significant differences observed for any variable (p>0.05). The mean ALT levels were similar in both groups (26.3 ± 7.6 U/L vs 25.6 ± 7.2 U/L; p=0.591), as were AST levels (22.9 ± 6.8 U/L vs 22.3 ± 6.5 U/L; p=0.608).

Alkaline phosphatase (ALP) values were also closely matched (80.3 ± 20.1 U/L vs 78.6 ± 19.7 U/L; p=0.628), and total bilirubin levels were identical in both groups (0.7 ± 0.2 mg/dL; p=0.812). These findings indicate that hepatic function was similar at baseline in both treatment groups, ensuring that any subsequent changes in liver enzyme levels can be more reliably attributed to the effects of the respective therapies rather than pre-existing differences in liver function.

Changes in liver function tests over time

The changes in liver function tests over time **(Table 3; Figures 2 and 3)** demonstrated a clear divergence between the two treatment groups. In the tofacitinib group, there was a progressive and statistically significant increase in both ALT and AST levels at 3, 6, and 12 months compared to the apremilast group (p<0.001 at all follow-up points).

Mean ALT increased markedly from **26.3 ± 7.6 U/L at baseline to 42.1 ± 11.2 U/L at 12 months**, while AST rose from **22.9 ± 6.8 U/L to 35.5 ± 9.6 U/L**, indicating a sustained upward trend suggestive of hepatocellular stress. In contrast, the apremilast group showed only minimal increases in ALT (**25.6 ± 7.2 to 28.8 ± 7.6 U/L**) and AST (**22.3 ± 6.5 to 24.3 ± 6.9 U/L**) over the same period. These trends are clearly illustrated in **Figures 1 and 2**, where the slope of increase is notably steeper for the tofacitinib group.

Meanwhile, ALP and bilirubin levels remained relatively stable in both groups throughout the study period, with no statistically significant differences at any time point (p>0.05). Overall, these findings indicate that tofacitinib is associated with significant elevations in liver enzymes over time, whereas apremilast demonstrates a more stable hepatic profile, suggesting a comparatively safer liver function profile.

The within-group change analysis **(Table 4)** demonstrated that patients treated with tofacitinib experienced statistically significant increases in key liver enzymes over the 12-month period. In the tofacitinib group, mean ALT levels increased significantly from baseline to 12 months (**+15.8 U/L; p<0.001**), and AST levels also showed a significant rise (**+12.6 U/L; p<0.001**), indicating a notable impact on hepatocellular function. In contrast, the apremilast group exhibited only a modest but statistically significant increase in ALT (**+3.2 U/L; p=0.041**), while the change in AST was minimal and not statistically significant (**+2.0 U/L; p=0.062**).

Changes in ALP and bilirubin levels were small and not statistically significant in either group (p>0.05), suggesting no meaningful effect on cholestatic parameters or bilirubin metabolism. Overall, these findings indicate that tofacitinib is associated with significant within-group elevations in liver enzymes over time, whereas apremilast demonstrates minimal and largely non-significant changes, reinforcing its comparatively favourable hepatic safety profile.

Incidence of liver enzyme elevations

The incidence of liver enzyme elevations **(Table 5; Figure 3)** was significantly higher in the tofacitinib group compared to the apremilast group. Elevated ALT levels (>2× ULN) were observed in **24.6%** of patients receiving tofacitinib compared to **6.2%** in the apremilast group (p=0.003).

Similarly, AST elevations were noted in **20.0%** of the tofacitinib group versus **4.6%** in the apremilast group (p=0.007). These differences were statistically significant, indicating a markedly higher risk of hepatocellular enzyme elevation with tofacitinib therapy.

The comparative distribution is clearly illustrated in **Figure 4 & Table 5**, where the proportion of affected patients is substantially greater in the tofacitinib group for both ALT and AST parameters. Overall, these findings reinforce that tofacitinib is associated with a higher incidence of clinically significant liver enzyme elevations, whereas apremilast demonstrates a comparatively safer hepatic profile.

Treatment modifications

In the tofacitinib group, **two patients** required dose adjustment due to elevated liver enzymes. These abnormalities were managed successfully after dose modification, and no patient required permanent discontinuation of therapy. In the apremilast group, no patient required dose adjustment or discontinuation due to liver-related adverse events.

Summary of findings

Overall, patients treated with tofacitinib showed a greater increase in ALT and AST levels over 12 months compared with those treated with apremilast. ALP and bilirubin levels remained relatively stable in both groups. These findings suggest that tofacitinib is associated with a higher risk of liver enzyme elevation, while apremilast demonstrates a comparatively favourable hepatic safety profile.

Table 1. Baseline characteristics of the study population

Characteristics	Tofacitinib group (n=65)	Apremilast group (n=65)	p-value
Age (years)	46.1 ± 12.4	44.8 ± 11.7	0.541
Gender, male	36 (55.4%)	34 (52.3%)	0.724
BMI (kg/m²)	27.9 ± 4.2	27.4 ± 3.8	0.477
Duration of psoriasis (years)	12.4 ± 5.7	11.8 ± 6.1	0.563
Previous systemic treatments	3.2 ± 1.1	3.1 ± 1.0	0.589
Comorbid conditions	25 (38.5%)	24 (36.9%)	0.853

Table 2. Baseline liver function tests

Parameter	Tofacitinib group	Apremilast group	p-value
ALT (U/L)	26.3 ± 7.6	25.6 ± 7.2	0.591
AST (U/L)	22.9 ± 6.8	22.3 ± 6.5	0.608
ALP (U/L)	80.3 ± 20.1	78.6 ± 19.7	0.628
Bilirubin (mg/dL)	0.7 ± 0.2	0.7 ± 0.2	0.812

Table 3. Changes in liver function tests from baseline to 12 months

Parameter	Time point	Tofacitinib group	Apremilast group	p-value
ALT (U/L)	Baseline	26.3 ± 7.6	25.6 ± 7.2	0.591
	3 months	34.4 ± 9.7	27.2 ± 7.4	<0.001
	6 months	37.5 ± 10.2	27.9 ± 7.5	<0.001
	12 months	42.1 ± 11.2	28.8 ± 7.6	<0.001
AST (U/L)	Baseline	22.9 ± 6.8	22.3 ± 6.5	0.608
	3 months	29.2 ± 8.3	23.1 ± 6.6	<0.001
	6 months	31.6 ± 8.8	23.6 ± 6.7	<0.001
	12 months	35.5 ± 9.6	24.3 ± 6.9	<0.001
ALP (U/L)	Baseline	80.3 ± 20.1	78.6 ± 19.7	0.628
	3 months	82.6 ± 20.9	79.4 ± 20.1	0.376
	6 months	83.8 ± 21.3	80.1 ± 20.2	0.309
	12 months	85.2 ± 21.9	81.1 ± 20.3	0.271
Bilirubin (mg/dL)	Baseline	0.7 ± 0.2	0.7 ± 0.2	0.812
	3 months	0.8 ± 0.2	0.7 ± 0.2	0.155
	6 months	0.8 ± 0.2	0.7 ± 0.2	0.121
	12 months	0.8 ± 0.2	0.7 ± 0.2	0.108

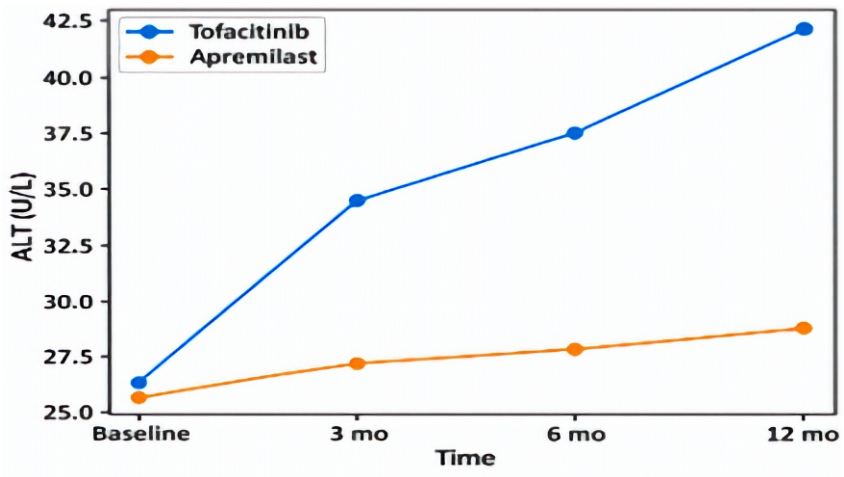

Figure 2. Temporal trend of alanine aminotransferase (ALT) levels in patients treated with tofacitinib and apremilast over 12 months, demonstrating a progressive increase in the tofacitinib group.

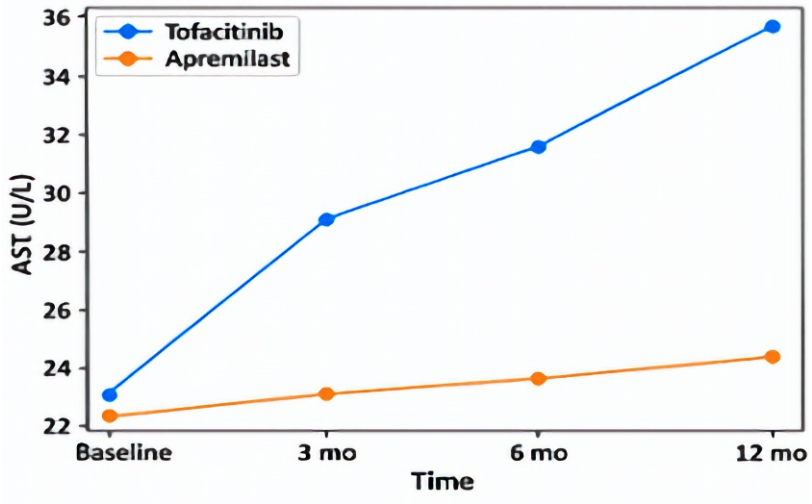

Figure 3. Changes in aspartate aminotransferase (AST) levels over time, showing significantly higher elevations in the tofacitinib group compared to apremilast.

Table 4: Within-Group Change Analysis (Baseline vs 12 Months)

Parameter	Group	Baseline	12 Months	Mean Change	p-value (paired t -test)
ALT (U/L)	Tofacitinib	26.3 ± 7.6	42.1 ± 11.2	+15.8	<0.001*
	Apremilast	25.6 ± 7.2	28.8 ± 7.6	+3.2	0.041*
AST (U/L)	Tofacitinib	22.9 ± 6.8	35.5 ± 9.6	+12.6	<0.001*
	Apremilast	22.3 ± 6.5	24.3 ± 6.9	+2.0	0.062
ALP (U/L)	Tofacitinib	80.3 ± 20.1	85.2 ± 21.9	+4.9	0.089
	Apremilast	78.6 ± 19.7	81.1 ± 20.3	+2.5	0.112
Bilirubin (mg/dL)	Tofacitinib	0.7 ± 0.2	0.8 ± 0.2	+0.1	0.131
	Apremilast	0.7 ± 0.2	0.7 ± 0.2	0.0	0.210

Table 5. Incidence of liver enzyme elevations

Parameter	Tofacitinib group (n=65)	Apremilast group (n=65)	p-value
ALT >2× ULN	16 (24.6%)	4 (6.2%)	0.003
AST >2× ULN	13 (20.0%)	3 (4.6%)	0.007

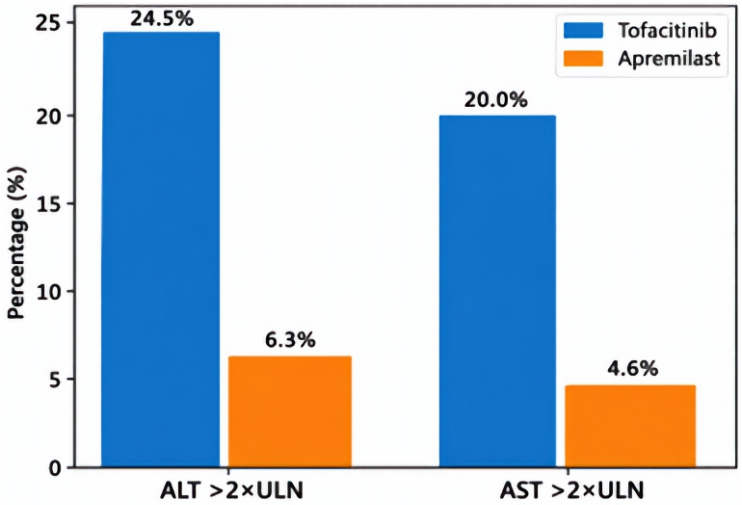

Figure 4. Comparison of incidence of significant liver enzyme elevations (ALT and AST >2× ULN) between treatment groups, highlighting higher hepatotoxicity in the tofacitinib group.

DISCUSSION

The present study evaluated and compared the impact of tofacitinib and apremilast on liver function parameters in patients with refractory psoriasis over a 12-month period. The findings demonstrated that patients receiving tofacitinib experienced significant elevations in serum transaminases (ALT and AST) over time, whereas those treated with apremilast showed minimal and largely non-significant changes. These results highlight important differences in the hepatic safety profiles of these commonly used oral systemic agents.

The progressive increase in ALT and AST observed in the tofacitinib group is consistent with the known pharmacological effects of Janus kinase (JAK) inhibition. Tofacitinib modulates cytokine signaling through the JAK-STAT pathway, which, while effective in controlling inflammation, may also contribute to hepatocellular stress [10,11]. Similar findings have been reported by Álvaro-Gracia et al [12], who described elevations in liver enzymes associated with tofacitinib use in clinical and real-world settings. Furthermore, Sandborn et al [13] also reported increased transaminase levels in patients receiving tofacitinib for ulcerative colitis, reinforcing the association between JAK inhibition and hepatotoxicity.

In contrast, apremilast demonstrated a relatively stable hepatic profile, with only mild increases in ALT and AST that were not clinically significant. This aligns with the mechanism of action of apremilast as a phosphodiesterase-4 (PDE4) inhibitor, which primarily modulates intracellular cyclic AMP levels without directly affecting hepatocellular metabolism [14]. Crowley et al [15], in a pooled analysis of long-term clinical trials, similarly reported no significant hepatotoxic effects with apremilast, supporting its favorable safety profile.

The incidence of clinically significant liver enzyme elevations (>2× ULN) was markedly higher in the tofacitinib group compared to the apremilast group, further emphasizing the differential safety profiles. This observation is clinically relevant, as drug-induced liver injury remains a major concern in long-term systemic therapy [16,17]. The findings of the present study are in agreement with existing literature, which suggests that while tofacitinib is effective, it requires careful monitoring due to potential hepatic adverse effects [12,13].

Importantly, despite the observed elevations in liver enzymes, only a small proportion of patients in the tofacitinib group required dose modification, and no patients required treatment discontinuation. This suggests that while hepatotoxicity is more frequent with tofacitinib, it is generally manageable with appropriate monitoring and timely intervention. In contrast, the absence of treatment modifications in the apremilast group further reinforces its safety in clinical practice.

The strengths of this study include its comparative design, longitudinal follow-up, and evaluation of both biochemical changes and clinically significant outcomes. However, certain limitations must be acknowledged. The retrospective design may introduce selection bias, and the absence of long-term follow-up beyond 12 months limits assessment of chronic hepatic effects. Additionally, other confounding factors such as diet, concomitant medications, and subclinical liver disease could not be fully controlled.

Overall, the findings of this study suggest that while both tofacitinib and apremilast are effective treatment options for refractory psoriasis, apremilast demonstrates a more favorable hepatic safety profile. These results underscore the importance of regular liver function monitoring in patients receiving tofacitinib and support the consideration of apremilast as a safer alternative, particularly in patients at higher risk of liver dysfunction.

CONCLUSION

This study demonstrates that tofacitinib is associated with significant elevations in liver enzymes, particularly ALT and AST, over a 12-month treatment period, along with a higher incidence of clinically significant hepatocellular injury compared to apremilast. In contrast, apremilast exhibited minimal changes in liver function parameters and a favorable hepatic safety profile. Although liver enzyme elevations with tofacitinib were generally manageable and did not necessitate treatment discontinuation, they highlight the need for regular and careful monitoring. These findings suggest that while both agents are effective in the management of refractory psoriasis, apremilast may be a safer option in patients at risk of

liver dysfunction. Clinicians should consider individual patient risk factors when selecting therapy and ensure appropriate monitoring to optimize treatment outcomes.

LIMITATIONS & FUTURE PERSPECTIVES

The study's limitations include a single-centre setting, a relatively small sample size, and a short study duration, which may limit the broader applicability of the results. Future studies should incorporate multi-centre designs with larger populations to enhance validity, assess long-term outcomes, and investigate advanced diagnostic & management approaches. Such efforts will improve overall patient care & help minimize complications.

CLINICAL SIGNIFICANCE

The clinical significance of this study lies in its potential to bridge the gap between research findings and practical healthcare, diagnosis, and treatment outcomes. By highlighting real-care applications. It emphasizes the importance of translating scientific observations into meaningful improvements in patient world relevance, the study contributes to evidence based medical practice and supports informed clinical decision making. Ultimately, the findings aim to enhance patient quality of life, optimize therapeutic strategies, and promote better disease management in clinical settings.

ABBREVIATIONS

ALT: Alanine Aminotransferase
AST: Aspartate Aminotransferase
ALP: Alkaline Phosphatase
ULN: Upper Limit of Normal
LFT: Liver Function Test

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AUTHOR CONTRIBUTIONS

All authors significantly contributed to the study conception and design, data acquisition, or data analysis and interpretation. They participated in drafting the manuscript or critically revising it for important intellectual content, consented to its submission to the current journal, provided final approval for the version to be published, and accepted responsibility for all aspects of the work. Additionally, all authors meet the authorship criteria outlined by the International Committee of Medical Journal Editors (ICMJE) guidelines.

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CONFLICT OF INTEREST

Authors declared that there is no conflict of interest.

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ETHICAL APPROVAL & CONSENT TO PARTICIPATE

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CONSENT FOR PUBLICATION

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DATA AVAILABILITY

All data generated and analyzed are included within this research article. The datasets utilized and/or analyzed in this study can be obtained from the corresponding author upon a reasonable request.

USE OF ARTIFICIAL INTELLIGENCE (AI) & LARGE LANGUAGE MODEL (LLM)

The authors confirm that no AI & LLM tools were used in the writing or editing of the manuscript, and no images were altered or manipulated using AI & LLM.

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This article serves as an important educational tool for the scientific community, offering insights that may inspire future research diretions. However, they should not be relied upon independently when making treatment decisions or developing public health policies.

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