Survey Report

Perception Mapping of Indian Physician on Understanding the Place of Tofacitinib in Vitiligo

Version No.: 1.1

The study was conducted according to the approved protocol and in compliance with the protocol, Good Clinical Practice (GCP), and other applicable local regulatory requirements.

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1 INTRODUCTION

Vitiligo is a persistent autoimmune disorder characterized by the loss of melanocytes, leading to the development of hypopigmented white lesions on the skin [1]. The depigmentation, especially when it affects cosmetically sensitive areas such as the face, hands, and genital regions, can be psychologically distressing, particularly in individuals with darker skin tones. This condition is associated with significant emotional and psychosocial challenges for affected individuals [2,3].

Current treatments for vitiligo primarily involve topical steroids or topical calcineurin inhibitors, often combined with sun exposure or phototherapy, which produce the best outcomes on facial areas [4]. Although meta-analyses support the efficacy of these topical agents, the primary studies have generally included small sample sizes, and most treatments remain unapproved, resulting in off-label use [5].

Recent advancements in understanding vitiligo pathogenesis have highlighted the significant role of the interferon γ pathway in immune-mediated melanocyte destruction [6]. Targeting this pathway with Janus kinase (JAK) inhibitors presents a promising treatment option, with case reports and open-label studies indicating potential benefits of both topical and systemic JAK inhibitor applications for vitiligo [7,8].

Despite growing evidence supporting the use of tofacitinib in vitiligo management, real-world data regarding its implementation in clinical practice, particularly in the Indian context, remains limited. Understanding physician perspectives and prescribing patterns is crucial for establishing practical guidelines and optimizing treatment outcomes [9]. The varying approaches to patient selection, dosing regimens, and combination strategies among practitioners necessitate a comprehensive evaluation of current clinical practices.

This survey-based study aims to analyze the perception and clinical experience of Indian dermatologists regarding tofacitinib use in vitiligo management.

2 RATIONALE OF THE STUDY

Vitiligo, affecting approximately 4.25% of the Indian population, presented significant therapeutic challenges despite conventional treatment options. While traditional therapies, including topical corticosteroids, phototherapy, and systemic immunosuppressants, remained standard treatments, their efficacy was often limited, particularly in progressive or resistant cases. The emergence of tofacitinib, a JAK1/3 inhibitor, as a novel therapeutic option showed promising results in promoting repigmentation through targeted immunomodulation of the JAK-STAT pathway.

In the Indian context, where vitiligo carried a substantial psychosocial burden and demonstrated higher prevalence rates compared to global averages, understanding the real-world application of tofacitinib was crucial. However, there was currently limited data on how Indian physicians integrated this novel therapy into their clinical practice, particularly regarding patient selection criteria, dosing protocols, and monitoring strategies.

This survey-based study aimed to address this knowledge gap by mapping Indian physicians' perceptions and experiences with tofacitinib in vitiligo management. The findings provided valuable insights into prescribing patterns, observed efficacy, safety monitoring, and treatment optimization in the Indian healthcare setting. These insights were essential for developing standardized treatment protocols and ensuring optimal therapeutic outcomes in the Indian patient population.

3 OBJECTIVES

To assess the perception, practice patterns, and clinical experiences of Indian physicians regarding the use of tofacitinib in the treatment of vitiligo.

4 METHODS

The study employed a cross-sectional, questionnaire-based design to assess Indian physicians' perceptions and practices regarding tofacitinib use in vitiligo treatment. A structured 16-question survey was distributed electronically to 75 physicians, including dermatologists and general practitioners, who regularly treat vitiligo. The survey collected data on treatment protocols, physician experiences, and perceptions of tofacitinib's efficacy, safety, and tolerability. Responses were securely stored, and statistical analysis was conducted using descriptive statistics to summarize demographics and response frequencies. Inferential statistics, such as chi-square tests or logistic regression, were applied to examine associations between physician characteristics and their treatment practices. Ethical approval was obtained, and participants' confidentiality was maintained throughout the study. The findings were used to generate insights into current clinical practices and to inform future research or guidelines.

4 RESULTS

A total of 65 healthcare professionals (HCPs) participated in the survey. Below is the summary of the responses.

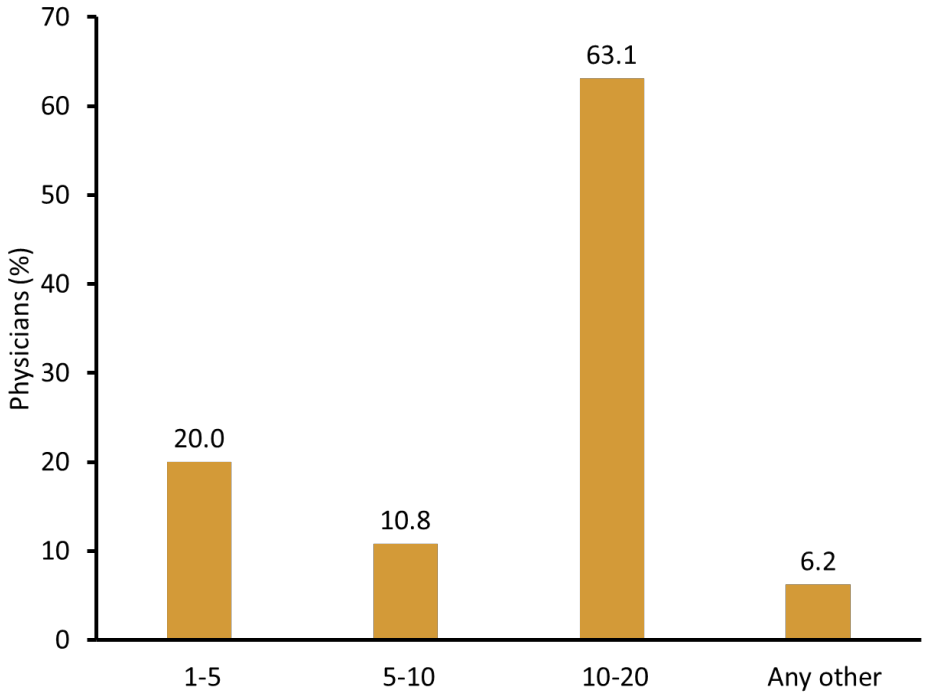
Question 1: In your routine practice, in a month, how many patients suffer from Vitiligo?

A. 1-5

B. 5-10

C. 10-20

D. Any other



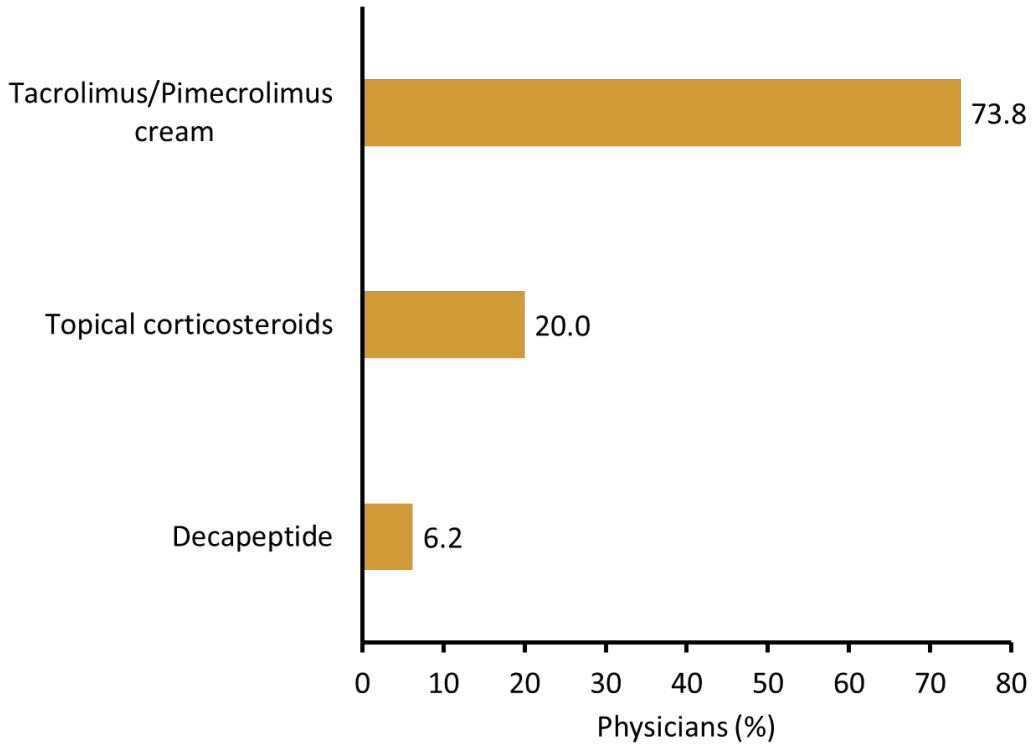
- Majority (63.1%) of physicians, reported seeing between 10 and 20 patients with Vitiligo in a month. This suggests that Vitiligo is a relatively common condition in their routine practice.
- Approximately 20% of physicians encountered 1 to 5 cases of Vitiligo each month, indicating a smaller proportion of cases for this group.
- Around 10.8% of physicians saw 5 to 10 patients with Vitiligo in a month, reflecting a moderate frequency of cases.
- Finally, about 6.2% of physicians reported seeing a number of cases outside these ranges, suggesting some variability in the occurrence of Vitiligo.

Question 2: Which topical therapy do you commonly use to treat vitiligo?

A. Topical corticosteroids

B. Tacrolimus/Pimecrolimus cream

C. Decapeptide



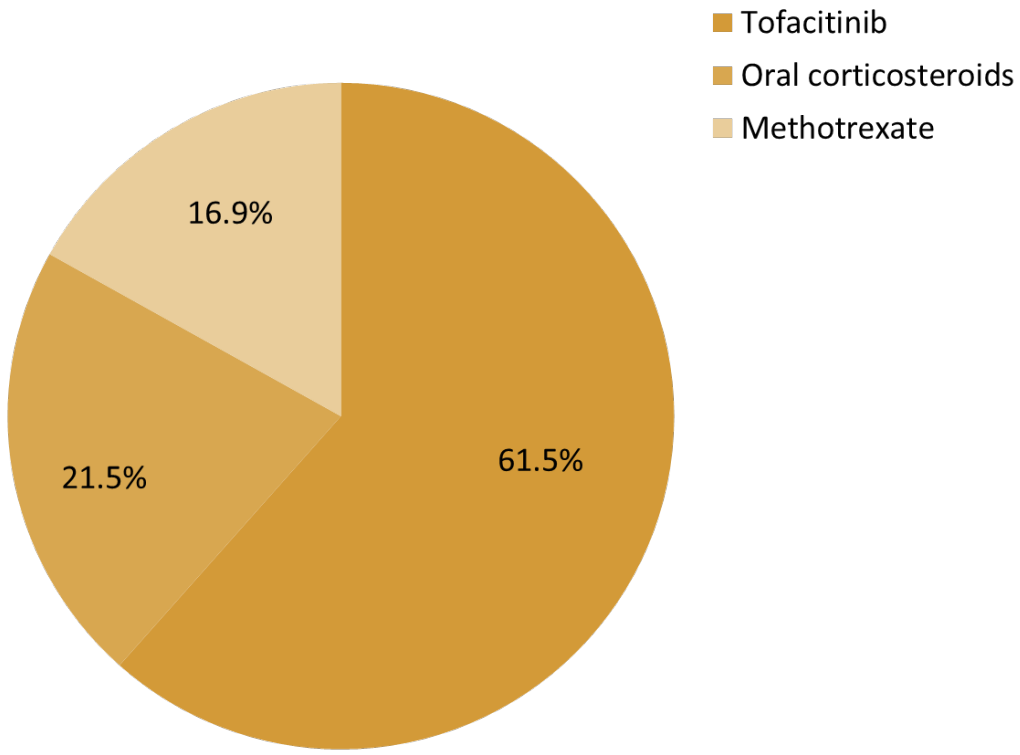
- The most commonly used topical therapy for treating Vitiligo is Tacrolimus/Pimecrolimus cream, with approximately 73.8% of physicians reporting its use.
- In comparison, 20% of physicians used topical corticosteroids as their preferred treatment, making it a less commonly used option compared to Tacrolimus/Pimecrolimus.
- About 6.2% of physicians used Decapeptide for Vitiligo treatment, suggesting that it is much less frequently prescribed and not as widely favored.
- Tacrolimus/Pimecrolimus cream is the most commonly used topical therapy for Vitiligo, followed by topical corticosteroids and a small proportion using Decapeptide.

Question 3: Which systemic therapy do you commonly use to treat vitiligo?

D. Methotrexate

E. Oral corticosteroids

F. Tofacitinib



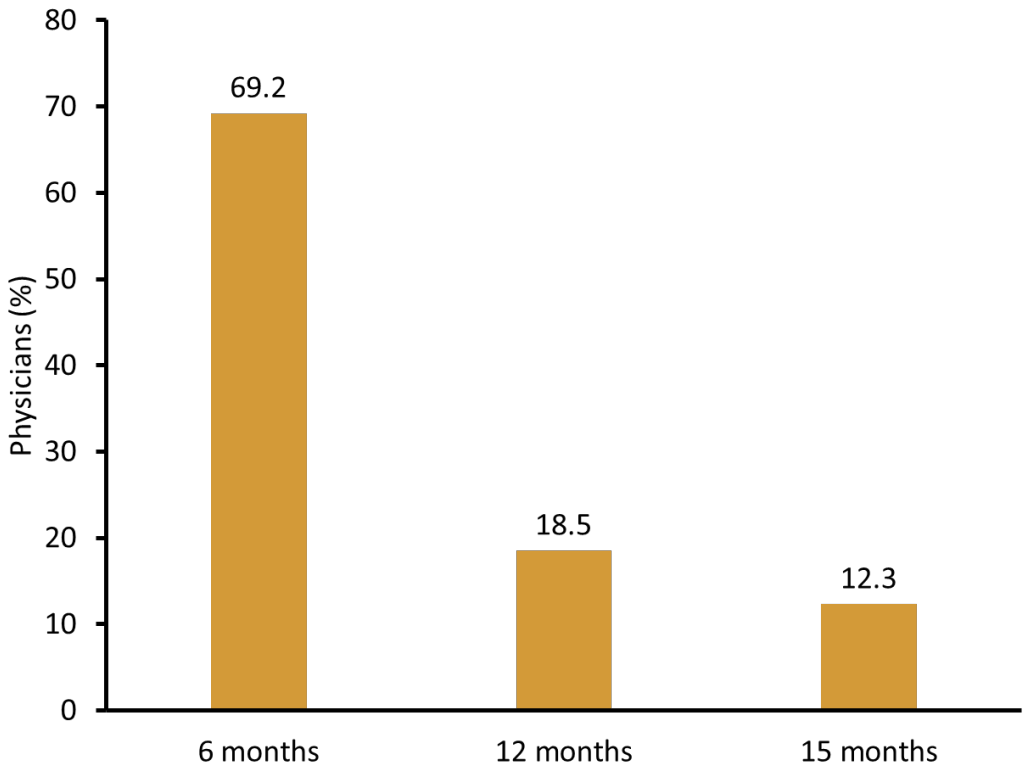
- The majority of physicians (61.5%), commonly used Tofacitinib as a systemic therapy to treat Vitiligo.
- This suggests that Tofacitinib was the most preferred and frequently prescribed option among physicians for managing this condition.
- Approximately 22% physicians used oral corticosteroids, indicating that while this therapy is still used, it is less common compared to Tofacitinib.
- Around 16.9% of physicians opted for methotrexate as a systemic treatment for Vitiligo, making it the least commonly used option among the three.

Question 4: What treatment duration do you advise for Oral Tofacitinib for vitiligo?

A. 6 months

B. 12 months

C. 15 months



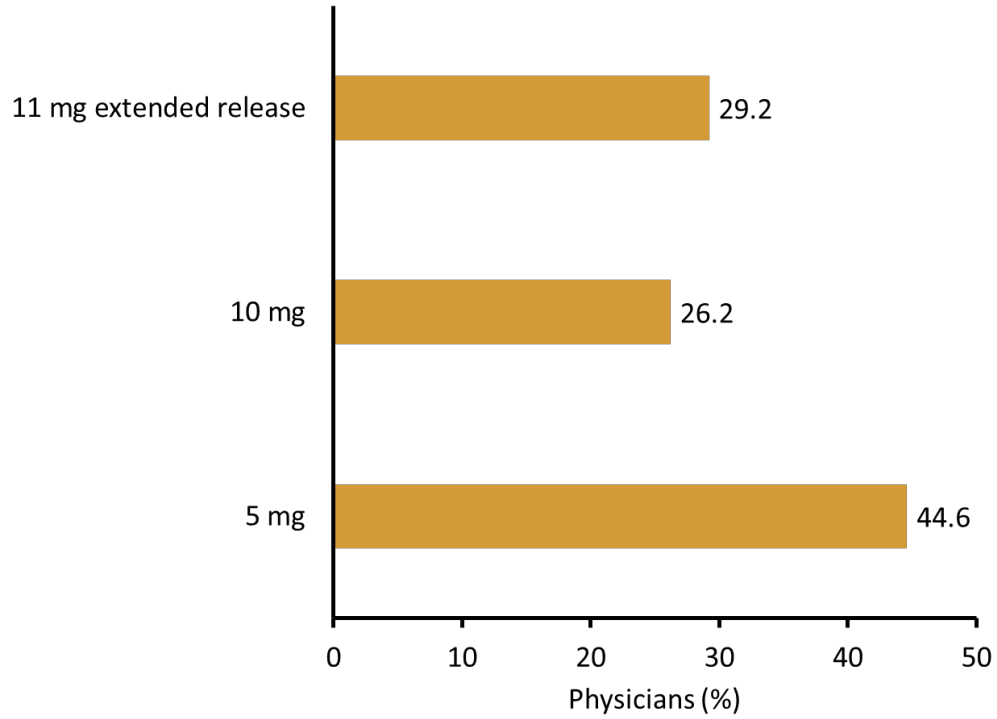
- Approximately 69.2% of physicians, advised a 6-month treatment duration for Oral Tofacitinib when treating Vitiligo.
- This suggests that most physicians typically recommended a shorter treatment course of about 6 months for this therapy.
- Around 18.5% of physicians, recommended a 12-month treatment duration, indicating that some physicians opted for a longer course depending on the patient's response.
- Approximately 12.3% of physicians advised a 15-month treatment duration, which is the least common recommendation.

Question 5: Which strength of Oral Tofacitinib do you advice for vitiligo?

A. 5 mg

B. 10 mg

C. 11 mg extended release



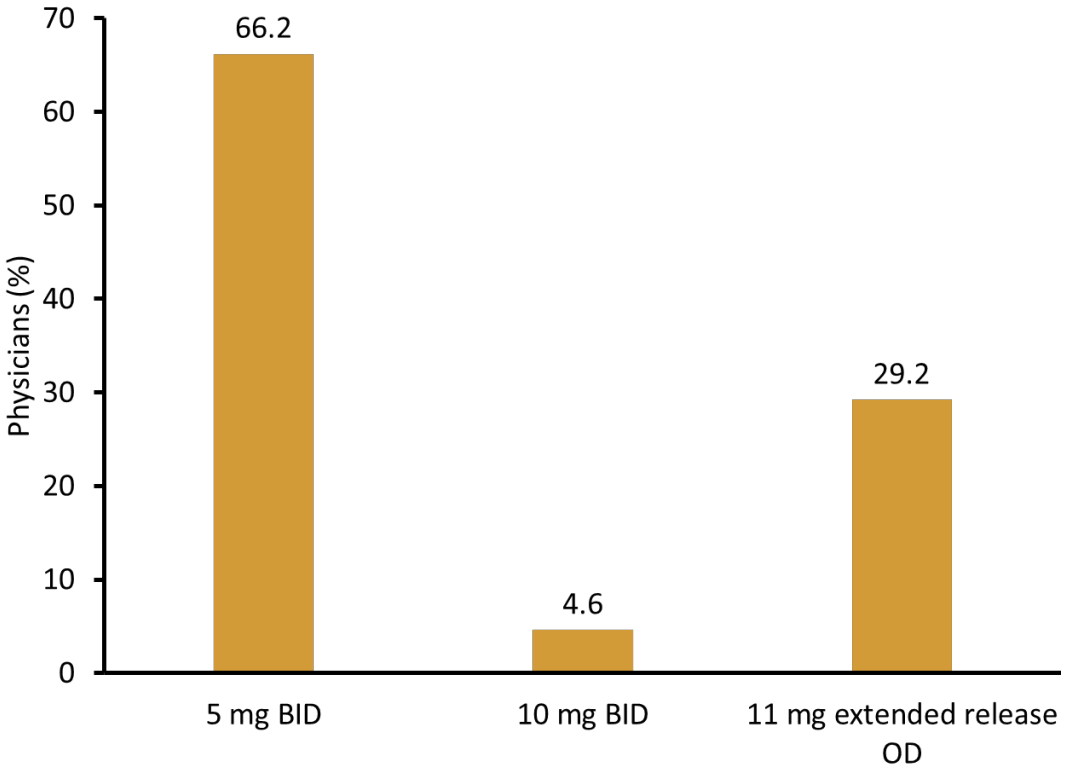
- The majority of physicians (44.6%), advised 5 mg as the preferred strength of Oral Tofacitinib for treating Vitiligo.
- This suggests that the 5 mg dose is the most commonly recommended option.
- Around 29.2% of physicians recommended the 11 mg extended release formulation, indicating a notable proportion of clinicians prefer this version, likely for its once-daily dosing convenience.
- Approximately 26.2% of physicians opted for 10 mg dose, making it the least commonly prescribed strength among the three options.
- 5 mg was the most commonly recommended strength for Oral Tofacitinib in Vitiligo treatment, followed by 11 mg extended release and 10 mg.

Question 6: What treatment regimen do you advise for Oral Tofacitinib for vitiligo?

A. 5 mg BID

B. 10 mg BID

C. 11 mg extended release OD



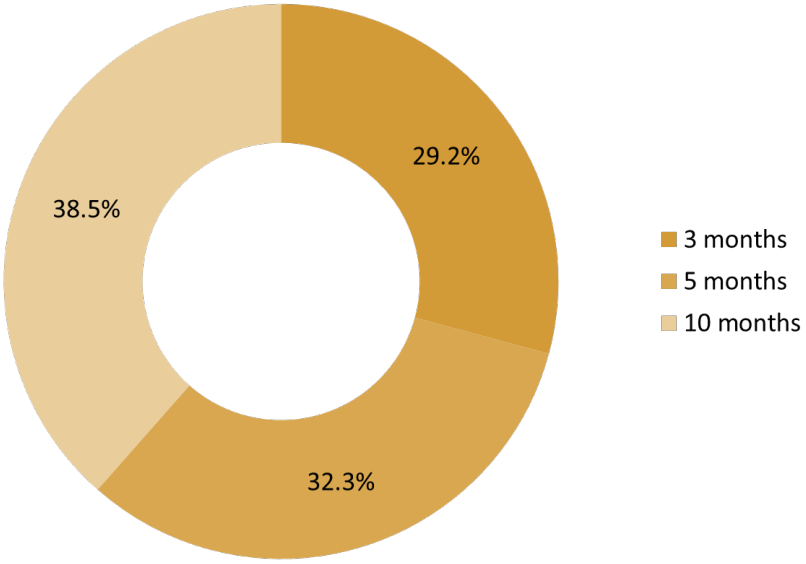
- The majority of physicians (66.2%) recommend a treatment regimen of 5 mg BID for Oral Tofacitinib in Vitiligo.
- The 5 mg BID regimen is clearly the most common choice, indicating that clinicians find it to be a well-tolerated and effective option for the majority of Vitiligo patients.
- A smaller proportion of physicians (29.2%) recommend the 11 mg extended-release OD regimen, indicating that some clinicians prefer the extended-release formulation, which may offer the convenience of once-daily dosing and potentially reduce side effects due to more gradual drug release.
- Only 4.6% of physicians advise the 10 mg BID regimen, making it the least commonly prescribed option.

Question 7: In how many months do you see complete repigmentation with Oral Tofacitinib in vitiligo?

A. 3 months

B. 5 months

C. 10 months

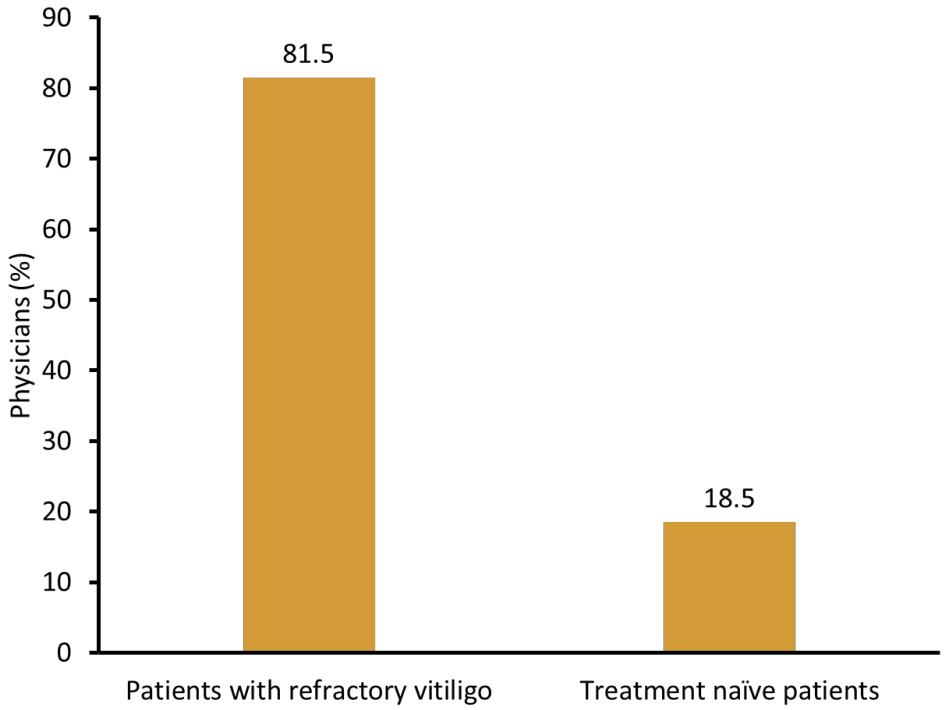


- Approximately 38.5% of physicians, reported seeing complete repigmentation with Oral Tofacitinib in 10 months.
- This suggests that, for most of the physicians, it typically takes around 10 months for patients to experience full repigmentation with this treatment.
- Around 32.3% of physicians saw complete repigmentation in 5 months, indicating a somewhat shorter time frame for some patients.
- Approximately 29.2% of physicians observed complete repigmentation in 3 months, representing the smallest group with a quicker response to treatment.
- 10 months is the most common time frame for complete repigmentation with Oral Tofacitinib in Vitiligo, with some patients responding in 5 months or 3 months depending on individual factors.

Question 8: In which cases of vitiligo do you advice oral tofacitinib?

A. Patients with refractory vitiligo

B. Treatment Naïve patients



- Majority (81.5%) of physicians advised Oral Tofacitinib for patients with refractory Vitiligo those who have not responded to other treatments.
- This suggests that Tofacitinib is commonly recommended for more difficult cases where other therapies have failed to produce satisfactory results.
- In contrast, 18.5% of physicians recommended Oral Tofacitinib for treatment-naïve patients those who have not previously received treatment for Vitiligo.
- This smaller proportion of clinicians indicates that Tofacitinib is less frequently considered as a first-line option.
- Treatment-naïve patients are generally treated with topical therapies or phototherapy first, as these are less aggressive and have fewer potential side effects.

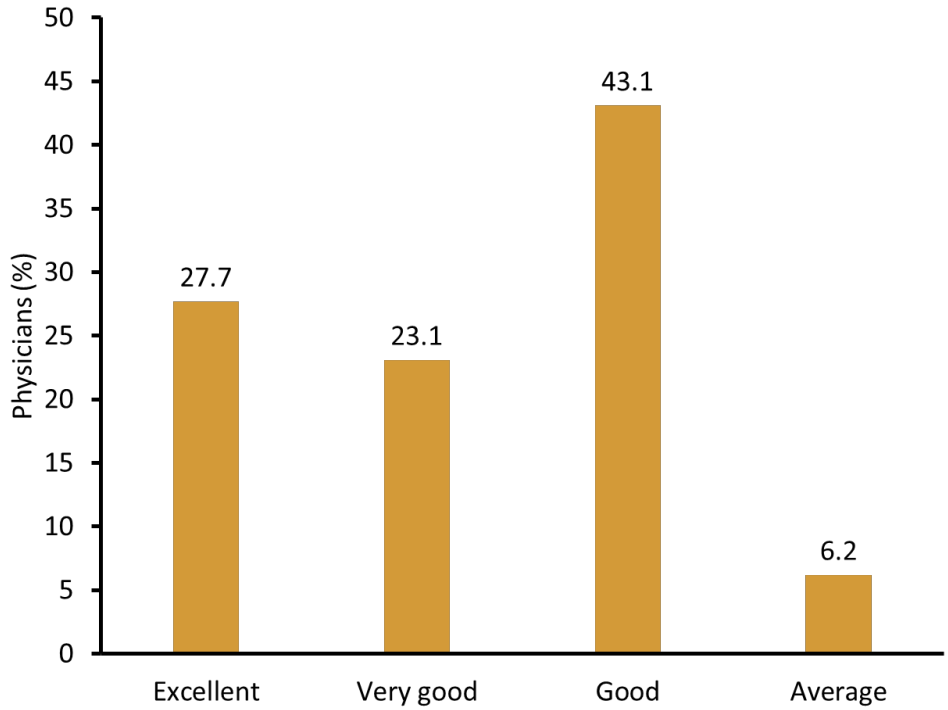
Question 9: Please rate the efficacy of Oral Tofacitinib in Vitiligo?

A. Excellent

B. Very good

C. Good

D. Average



- The majority of physicians, approximately 43.1%, rated the efficacy of Oral Tofacitinib in treating Vitiligo as good.
- This suggests that most healthcare providers find it to be an effective treatment, though not necessarily outstanding.
- Around 27.7% of physicians rated its efficacy as excellent, indicating that a significant portion of practitioners are highly satisfied with the results of Tofacitinib in treating Vitiligo.
- Approximately 23.1% rated its efficacy as very good, suggesting that a smaller group considers it a strong treatment option, though not as exceptional as "excellent."
- Only 6.2% of physicians rated its efficacy as average, indicating that a small proportion of practitioners feel the results are only moderately effective.

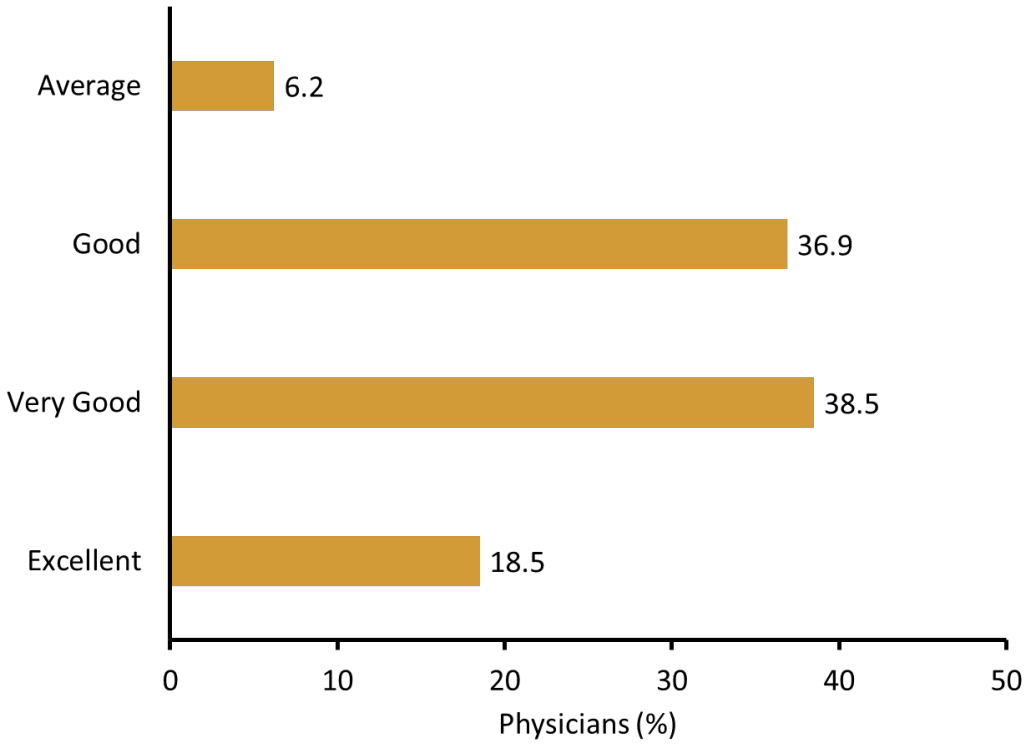
Question 10: Please rate the tolerability of Oral Tofacitinib in Vitiligo?

A. Excellent

B. Very Good

C. Good

D. Average

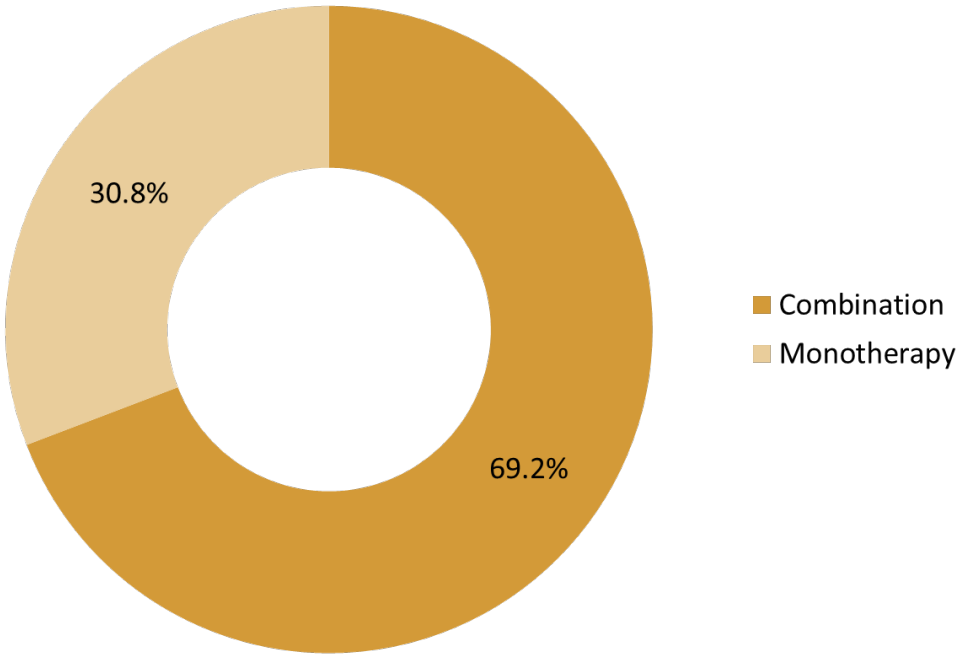


- Approximately 38.5% of physicians rated its tolerability as very good, suggesting that most healthcare providers find that patients tolerate the treatment well with only mild or manageable side effects.
- About 36.9% of physicians rated it as good, indicating that a significant portion of practitioners consider it generally well-tolerated, though some patients might experience minor side effects.
- Around 19% of physicians rated it as excellent, suggesting that a smaller group of practitioners find it exceptionally well-tolerated, with minimal to no issues.
- Only 6.2% of physicians rated its tolerability as average, reflecting a small number of practitioners who may see more frequent or moderate side effects in some patients.

Question 11: In your routine clinical practice do you use oral Tofacitinib as a monotherapy or in combination in vitiligo?

A. Monotherapy

B. Combination



- The majority of physicians (69.2%), used Oral Tofacitinib in combination with other treatments for Vitiligo.
- This indicates a strong preference for a combined treatment approach among healthcare providers.
- This suggests that many physicians preferred a combined approach, possibly to enhance efficacy or target multiple pathways involved in Vitiligo.
- In contrast, 30.8% of physicians used Oral Tofacitinib as a monotherapy, indicating that a smaller proportion of clinicians opted for Tofacitinib alone as the primary treatment for Vitiligo.

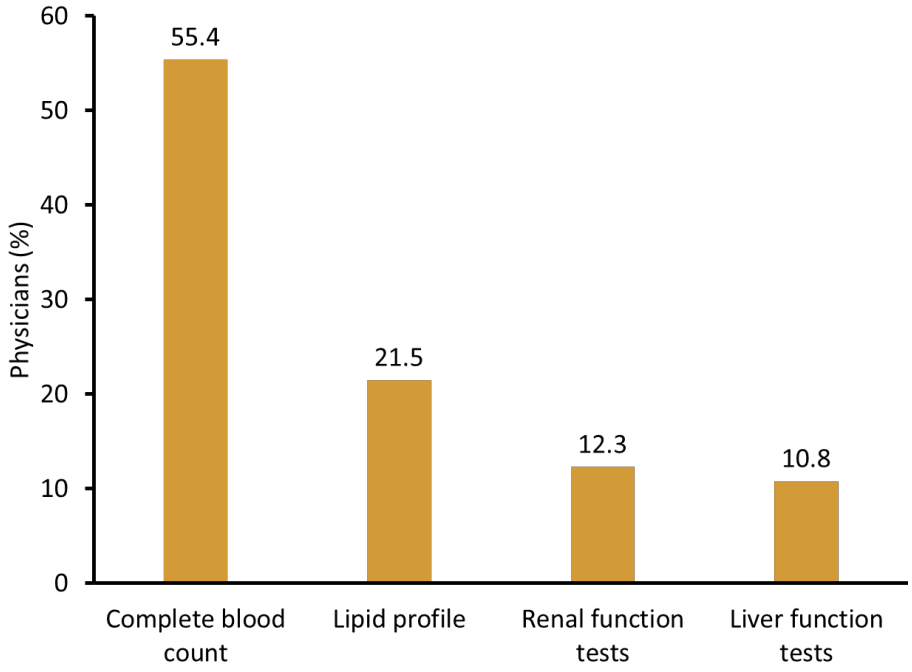
Question 12: Which baseline investigations do you advice before putting the patients on Tofacitinib?

A. Complete Blood count (CBC)

B. Renal function tests

C. Liver function tests

D. Lipid profile



- The most commonly advised baseline investigation before starting Tofacitinib for Vitiligo was a CBC, with 55.4% of physicians recommending it.
- Lipid profile was the second most commonly recommended baseline investigation, with 21.5% of physicians advising it.
- Renal function tests were recommended by 12.3% of physicians, reflecting a smaller proportion who considered it important to assess kidney function prior to treatment.
- Liver function tests were advised by 10.8% of physicians, making it the least commonly performed baseline investigation in this group, although still relevant for ensuring liver safety.

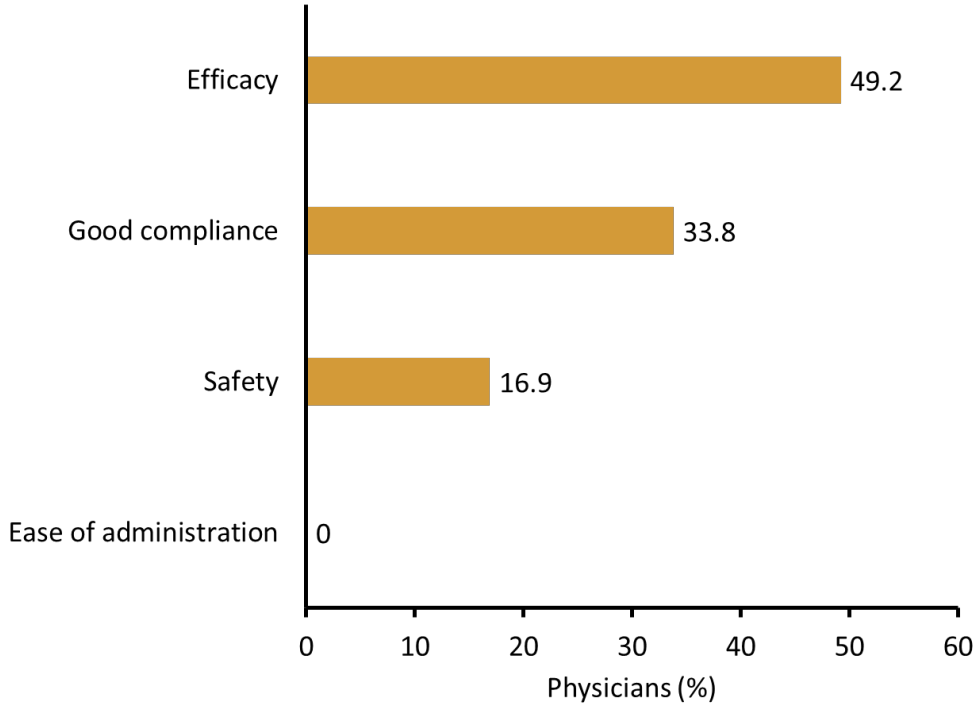
Question 13: Which is the most important factor in choosing a systemic treatment for vitiligo?

A. Efficacy

B. Safety

C. Ease of administration

D. Good compliance



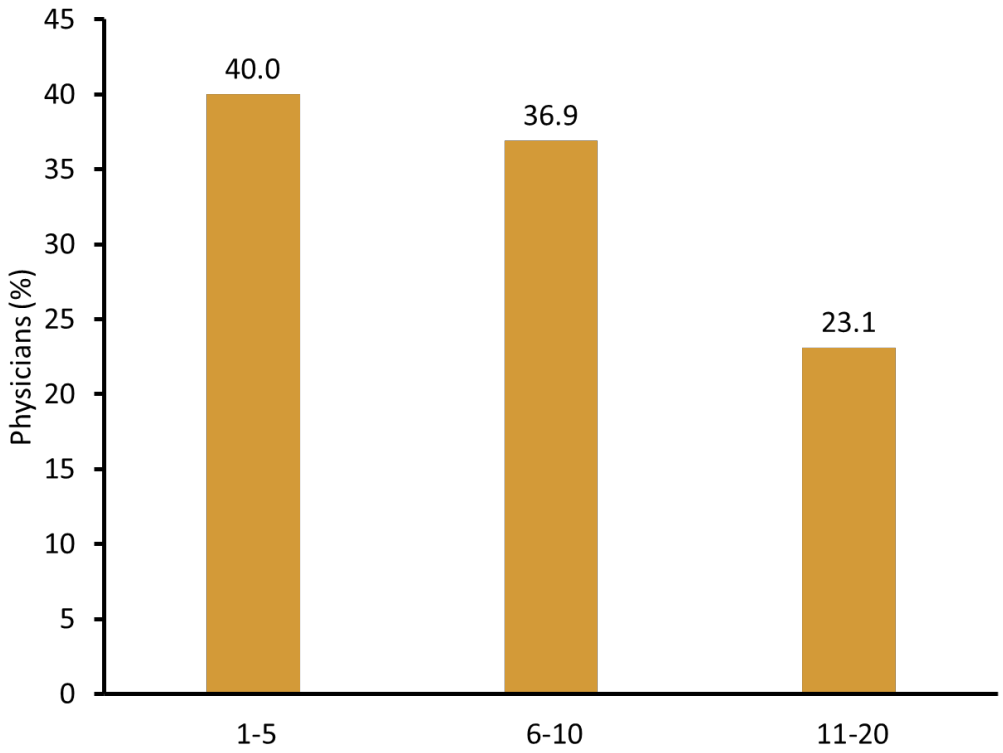
- The most important factor in choosing a systemic treatment for Vitiligo was efficacy, with 49.2% of physicians prioritizing it.
- This suggested that the effectiveness of the treatment in achieving repigmentation was the primary consideration for most healthcare providers when selecting a systemic therapy.
- Around 33.8% of physicians prioritized good compliance, indicating that ease of adherence to the treatment regimen was a significant factor for a substantial portion of clinicians.
- Safety was considered the most important factor by 16.9% of physicians, highlighting that while safety was important, it was not as highly prioritized as efficacy or patient compliance.

Question 14: In your routine clinical practice how many patients do you prescribe Oral Tofacitinib every month for vitiligo?

A. 1-5

B. 6-10

C. 11-20



- The majority of physicians (40%), prescribed Oral Tofacitinib for 1-5 patients with Vitiligo each month.
- It suggests that Oral Tofacitinib is being used in clinical practice for a modest number of patients, which could be reflective of the therapy's more targeted use, perhaps in patients with refractory or difficult-to-treat cases of Vitiligo.
- This indicated that most physicians treated a relatively small number of patients with this therapy.
- Around 36.9% of physicians prescribed it for 6-10 patients monthly, suggesting that a moderate number of cases were managed with this treatment.
- Approximately 23.1% of physicians prescribed Oral Tofacitinib for 11-20 patients each month, reflecting a smaller but still notable group of clinicians who treated a higher volume of Vitiligo patients with this systemic therapy.

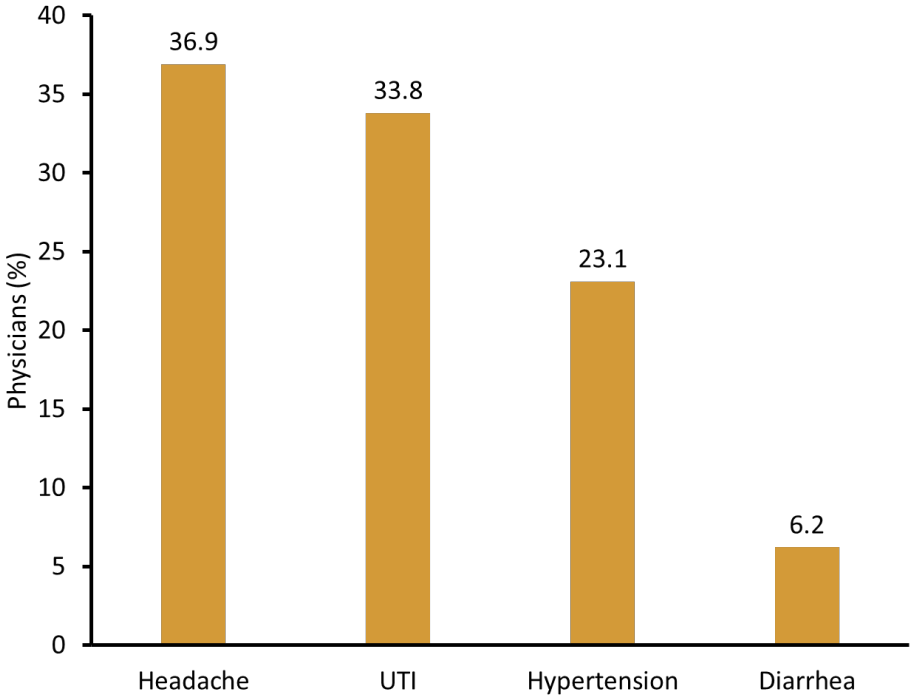
Question 15: Which common adverse effect do you observe with Oral Tofacitinib in vitiligo in your routine clinical practice?

A. Upper respiratory tract infections

B. Diarrhea

C. Headache

D. Hypertension



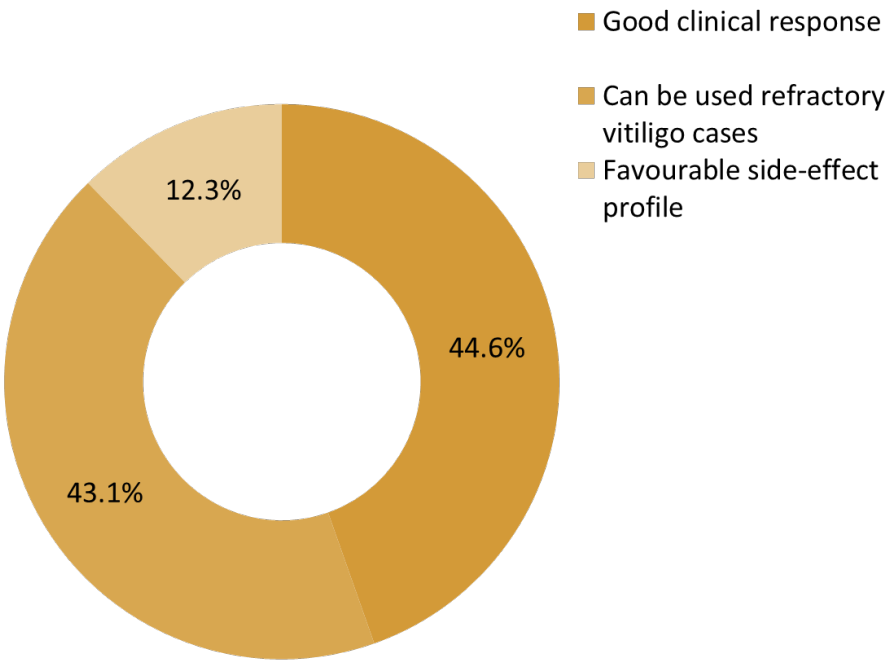
- The most commonly observed adverse effect of Oral Tofacitinib in Vitiligo treatment was headache, reported by approximately 36.9% of physicians.
- This suggested that headaches were a relatively frequent side effect among patients on this therapy.
- The second most commonly observed adverse effect was UTIs, reported by 33.8% of physicians, indicating that UTIs were also a notable concern.
- Hypertension was observed by 23.1% of physicians, making it a less common but still significant side effect in patients using Tofacitinib.
- Diarrhea was the least commonly reported adverse effect, observed by only 6.2% of physicians.

Question 16: As per your opinion which is/are the benefit(s) associated with usage of oral tofacitinib in vitiligo?

A. Good clinical response

B. Favourable side-effect profile

C. Can be used refractory vitiligo cases



- The majority of physicians (44.6%), reported observing a good clinical response with Oral Tofacitinib in Vitiligo, suggesting that most healthcare providers see positive outcomes in terms of repigmentation and disease control when using this treatment.
- Approximately 43.1% of physicians highlighted the ability to treat refractory Vitiligo cases as a key benefit of Tofacitinib.
- This indicates that a significant proportion of physicians used it for patients who have not responded to other therapies, offering a promising option for difficult-to-treat cases.
- Around 12.3% of physicians mentioned a favorable side-effect profile as an advantage, suggesting that some healthcare providers consider Tofacitinib to have relatively mild or manageable side effects compared to other systemic treatments.

5 SUMMARY

This survey-based study aimed to assess the clinical practices and perceptions of Indian physicians regarding the use of oral tofacitinib in the treatment of vitiligo. A total of 65 healthcare professionals participated, revealing key insights into the use of this therapy. The majority of physicians (81.5%) recommended tofacitinib for refractory cases of vitiligo, with a preference for a 6-month treatment duration (69.2%) and a 5 mg BID regimen (66.2%). Most clinicians (69.2%) combined it with other treatments, and a substantial proportion (44.6%) reported seeing good clinical responses. Adverse effects like headaches and upper respiratory tract infections were commonly noted, with a favorable side-effect profile being a benefit for some.

The study highlighted the growing role of tofacitinib in managing difficult cases of vitiligo, particularly where other therapies have failed, while also emphasizing its more targeted use in clinical practice.

6 DISCUSSION

The results of this survey-based study provide valuable insights into the clinical practices and perceptions of Indian physicians regarding the use of oral tofacitinib in the treatment of vitiligo. The findings suggest that vitiligo is a relatively common condition in routine dermatological practice in India, with the majority of physicians reporting seeing 10-20 cases per month. This aligns with the high prevalence of vitiligo in India, where the condition affects approximately 4.25% of the population, often leading to significant psychological distress, particularly in individuals with darker skin tones.

The study highlights that topical therapies, particularly Tacrolimus/Pimecrolimus, are the most commonly used treatments for vitiligo, with 73.8% of physicians indicating they prescribe these agents regularly. This is consistent with current guidelines that advocate for the use of topical calcineurin inhibitors in sensitive areas, as they are well-tolerated and have a lower risk of skin atrophy compared to corticosteroids. However, the survey also reflects a notable shift towards systemic treatments, particularly oral tofacitinib, which was used by 61.5% of physicians as a first-line or adjunctive therapy for vitiligo. This is significant given that tofacitinib, a Janus kinase

(JAK) inhibitor, represents a relatively new class of systemic therapies for vitiligo and has shown promise in both clinical trials and real-world studies.

The majority of physicians in the survey favored a shorter treatment duration of six months for oral tofacitinib, with 69.2% recommending this timeframe. This aligns with the findings of clinical studies that suggest rapid onset of action and improvement in repigmentation, often within 3-6 months of starting treatment. The recommended dosing regimen varied, with most physicians (66.2%) opting for 5 mg twice daily, which is consistent with the dosage commonly prescribed for other indications of tofacitinib. Interestingly, 29.2% of physicians preferred the 11 mg extended-release formulation, which might be favored for its once-daily dosing schedule, potentially improving patient compliance and minimizing side effects.

In terms of efficacy, the majority of respondents rated tofacitinib's clinical response as "good" (43.1%), while 27.7% considered it "excellent," indicating that while many physicians are satisfied with the treatment's outcomes, it may not always lead to complete or rapid repigmentation in all patients. The survey also found that most physicians saw complete repigmentation within 10 months, but a significant proportion reported repigmentation occurring earlier (5 or 3 months). This variability in response underscores the individualized nature of vitiligo treatment, where factors such as disease duration, severity, and the area affected can influence the response to treatment.

Regarding the choice of patients for oral tofacitinib, it is noteworthy that 81.5% of physicians indicated they reserved the medication for refractory cases, those who had not responded to conventional treatments. This is in line with the general approach to systemic therapies, which are typically considered after first-line treatments, such as topical steroids and phototherapy, have failed. Only a smaller proportion (18.5%) of physicians used tofacitinib as a first-line treatment, which suggests a cautious approach to its use in treatment-naïve patients, likely due to concerns about its safety profile and the availability of less aggressive alternatives.

Safety and tolerability were major considerations in the treatment process. While a significant proportion of physicians (38.5%) rated the tolerability of tofacitinib as "very good," side effects such as headaches, upper respiratory tract infections, and hypertension were commonly reported, with headaches being the most frequently observed (36.9%). These side effects are consistent with the known adverse effects of

JAK inhibitors, which include infections and gastrointestinal symptoms, as well as cardiovascular concerns. The relatively mild and manageable nature of these side effects likely contributes to the overall positive perception of tofacitinib among physicians.

Another important finding was the preference for using tofacitinib in combination with other therapies, as 69.2% of physicians reported combining oral tofacitinib with topical therapies or phototherapy. This reflects the growing trend of multimodal treatment strategies for vitiligo, as combination therapies may enhance efficacy and help address multiple pathogenic mechanisms simultaneously. The use of oral tofacitinib in combination may be particularly beneficial in patients with extensive or progressive disease, where monotherapy may not suffice.

Finally, baseline investigations before initiating treatment with tofacitinib primarily focused on monitoring blood counts (CBC), with 55.4% of physicians recommending this test. Lipid profiles were also commonly checked (21.5%), and renal and liver function tests were advised by a smaller proportion of physicians (12.3% and 10.8%, respectively). These findings are consistent with the general guidelines for monitoring patients on JAK inhibitors, where regular assessments of blood counts, lipid levels, and organ function are essential to ensure patient safety and detect any potential adverse effects early.

7 CLINICAL RECOMMENDATIONS

Based on the survey findings, oral tofacitinib has emerged as a widely utilized and well-established systemic treatment for vitiligo, particularly for patients with refractory forms of the disease. It has become a preferred option for many dermatologists in India, with the majority recommending its use primarily for patients who have not responded adequately to conventional therapies, such as topical corticosteroids, phototherapy, or other systemic immunosuppressants. This highlights the increasing recognition of tofacitinib's role in managing more challenging or advanced cases of vitiligo that are resistant to standard treatments.

The most commonly recommended dosing regimen for oral tofacitinib is 5 mg twice daily (BID), with a notable proportion of physicians also opting for the 11 mg extended-release formulation, administered once daily (OD), likely due to the convenience and

potentially improved patient adherence associated with a once-daily regimen. This flexibility in dosing is an advantage for clinicians, allowing them to tailor the treatment plan to individual patient needs and preferences. The treatment duration typically spans 6 months, which aligns with the general consensus among practitioners who reported observing complete repigmentation in the range of 5 to 10 months, depending on individual patient factors such as disease severity, response to treatment, and overall health.

In terms of efficacy, the survey reveals that most physicians rate tofacitinib's effectiveness in treating vitiligo as "good", with a substantial proportion finding it to be "excellent" or "very good". The medication appears to provide satisfactory results for a large number of patients, though it may not always lead to dramatic repigmentation in every case. Nevertheless, the consistency of positive clinical responses in difficult-to-treat cases underscores its potential as a key therapeutic tool in the management of vitiligo. This is particularly important in the context of vitiligo's psychological and social impact, where any visible repigmentation can significantly improve a patient's quality of life and self-esteem.

From a tolerability standpoint, oral tofacitinib is generally well-tolerated by most patients, with the most common side effects being headaches and upper respiratory tract infections. These mild side effects are reported by a significant number of physicians but tend to be manageable, suggesting that tofacitinib is a safer alternative compared to other systemic treatments like methotrexate or oral corticosteroids, which may have more serious adverse effects. Notably, gastrointestinal issues, such as diarrhea, were less frequently reported, indicating that tofacitinib may have a relatively favorable side-effect profile compared to some other immunosuppressive agents.

In clinical practice, combination therapy is favored by the majority of physicians, with oral tofacitinib often being used alongside other treatment modalities, such as topical therapies (e.g., tacrolimus) or phototherapy. This combined approach aims to enhance efficacy and improve the chances of repigmentation, particularly in patients with widespread or difficult-to-treat lesions. Physicians also highlight the importance of baseline investigations before starting treatment, with complete blood count (CBC) being the most commonly recommended test. This is essential for monitoring potential hematologic side effects, which could arise with the use of JAK inhibitors like tofacitinib. Other tests, such as lipid profiles, renal function tests, and liver function

tests, are also considered by some physicians, although they are less universally recommended.

Regarding the selection of patients for oral tofacitinib, it is predominantly prescribed for those with refractory vitiligo, where previous treatments have failed to produce satisfactory results. A smaller proportion of clinicians have started prescribing tofacitinib for treatment-naïve patients, particularly in cases where conventional therapies have not been effective or have not been well-tolerated. However, treatment-naïve patients are more commonly managed with topical therapies or phototherapy before escalating to systemic treatments.

In terms of treatment selection, physicians place the highest priority on efficacy when choosing a systemic treatment for vitiligo, followed by patient compliance and ease of administration. This is consistent with the broader goals of vitiligo treatment, which aim to achieve effective repigmentation while minimizing treatment burden and ensuring that patients adhere to their therapy. Safety is also a key consideration, although it ranks lower than efficacy and compliance, which may reflect the growing confidence in the safety profile of tofacitinib based on clinical experience and existing research.

8 CONSULTING OPINION

Based on the survey findings, oral tofacitinib has emerged as a highly favored systemic treatment for vitiligo, especially in cases that are refractory to conventional therapies. It is predominantly prescribed for patients who have not responded to topical treatments or phototherapy, highlighting its role as an option for difficult-to-treat cases of the disease. The most common dosing regimen is 5 mg twice daily (BID), with a significant proportion of physicians also opting for the 11 mg extended-release formulation for its once-daily dosing convenience. Physicians reported that tofacitinib demonstrated good to excellent efficacy, with many observing complete repigmentation within 5 to 10 months of treatment initiation. This makes it an attractive option for patients seeking substantial cosmetic improvement, particularly in cosmetically sensitive areas.

The treatment is generally well-tolerated, with mild side effects such as headaches, upper respiratory infections, and gastrointestinal disturbances being the most commonly reported. These side effects are usually manageable and do not significantly impact the overall patient experience. Physicians in the survey also noted

that combination therapy is frequently used in practice, combining tofacitinib with other treatments to enhance efficacy or target multiple pathways involved in vitiligo's pathogenesis. This reflects a growing trend toward a more integrated approach to treatment, which may optimize outcomes for patients.

Before initiating therapy, most physicians routinely recommend baseline investigations such as complete blood count (CBC) to ensure patient safety, and some also consider liver and kidney function tests. This helps monitor potential adverse effects and manage treatment risks effectively.

Although tofacitinib is becoming an increasingly common choice in clinical practice, it is still primarily used in refractory cases of vitiligo, rather than as a first-line therapy for newly diagnosed or milder forms of the condition. Its growing use in these more challenging cases underscores its valuable role in the vitiligo treatment armamentarium. Overall, tofacitinib is seen as a promising and effective therapeutic option for vitiligo, particularly for patients with severe or treatment-resistant forms of the disease, offering a new avenue for hope where traditional treatments may have failed.

9 MARKET OPPORTUNITIES

The survey findings reveal multiple market opportunities for oral tofacitinib in the management of vitiligo, especially within the Indian healthcare setting. Oral tofacitinib has gained significant traction among physicians, particularly for treating refractory vitiligo, a group of patients who do not respond to traditional therapies. This creates a clear market opportunity to position tofacitinib as a go-to solution for difficult-to-treat cases, which make up a substantial portion of vitiligo cases. With a strong preference for the 5 mg BID dosing regimen (66.2%) and the 11 mg extended-release formulation (29.2%), there is potential for further market penetration through tailored dosing options that accommodate clinical preferences, enhancing convenience for both physicians and patients.

Another key opportunity lies in expanding the use of tofacitinib beyond refractory cases to treatment-naïve patients. Although the majority of physicians currently prescribe it for resistant cases, a smaller but significant proportion (18.5%) are already using it for patients with early-stage vitiligo. This presents a growing market for

tofacitinib as a first-line treatment, particularly in patients with more aggressive or psychosocially burdensome disease. Clinical studies supporting its efficacy in early-stage vitiligo and targeted educational campaigns for healthcare professionals could help further establish its role in this broader patient population.

Moreover, the growing trend of combination therapies (69.2% of physicians) indicates a significant opportunity to position tofacitinib in conjunction with other topical treatments, phototherapy, or immunosuppressants. Pharmaceutical companies could explore collaborations with other treatment providers to develop integrated regimens that offer enhanced efficacy, thereby increasing tofacitinib's appeal as part of a multi-modality approach.

Patient adherence and safety are critical factors influencing treatment choices. The relatively mild side-effect profile of tofacitinib, alongside its convenience, especially with the once-daily extended-release formulation, makes it an attractive option for both patients and physicians. Highlighting these advantages in marketing campaigns, along with patient education and support tools to improve compliance, could further increase uptake. Digital platforms designed to educate physicians about optimal usage, dosing flexibility, and safety monitoring could play a crucial role in fostering a more robust clinical adoption of tofacitinib.

Finally, the high prevalence of vitiligo in India (affecting approximately 4.25% of the population) presents a significant market opportunity. By focusing on localized marketing strategies and offering tools for early diagnosis, patient monitoring, and side-effect management, pharmaceutical companies can strengthen their position in this burgeoning market. Expanding these efforts to other regions with similarly high vitiligo prevalence, such as Southeast Asia and the Middle East, could further amplify tofacitinib’s market potential. Overall, these opportunities point to a growing and dynamic market for oral tofacitinib, especially in markets with high unmet need, like India, where its introduction could significantly improve patient outcomes and treatment accessibility.

10 MARKET POSITIONING

The market positioning of oral tofacitinib for vitiligo treatment in India is strongly influenced by its established efficacy and increasing recognition for managing refractory and difficult-to-treat cases. As the preferred systemic therapy for patients who have not responded to conventional treatments such as topical steroids or phototherapy, tofacitinib is becoming an essential part of the treatment armamentarium for vitiligo in India. Approximately 81.5% of surveyed physicians indicate that they recommend tofacitinib primarily for refractory cases, solidifying its role as a go-to treatment for patients with persistent or progressive vitiligo. This positions oral tofacitinib as a critical option in a market where there is a substantial unmet need for effective therapies, particularly in cases that have been resistant to traditional treatments.

Tofacitinib's favorable safety profile and efficacy are key elements of its market appeal. The drug is reported to have good tolerability, with most physicians rating its side-effect profile as "very good" or "good," which enhances its attractiveness for long-term use in patients who require chronic management. The flexibility of dosing regimens, including the 5 mg twice-daily (BID) and the 11 mg extended-release once-daily (OD) formulations, provides additional advantages in terms of patient convenience and adherence, further supporting its broad use. The once-daily extended-release option is particularly favored for its convenience, which can improve patient compliance and ease of management.

Furthermore, there is an increasing trend toward combining tofacitinib with other therapies, a practice endorsed by 69.2% of physicians in the survey. This indicates that tofacitinib is not only viewed as an effective monotherapy but also as a valuable component of combination treatment regimens. This opens up additional market opportunities for partnerships with other pharmaceutical companies, as combination therapies could enhance therapeutic outcomes and allow tofacitinib to target multiple pathways involved in vitiligo pathogenesis.

The drug’s high efficacy in promoting repigmentation—most physicians report significant results within 5 to 10 months—also positions it as a promising treatment for improving clinical outcomes and enhancing the quality of life for patients. In a country like India, where vitiligo has a higher-than-average prevalence, these results are

particularly impactful, offering a new hope for millions of people affected by this challenging and often stigmatized condition. With the number of patients seeking treatment for vitiligo rising and increasing awareness about new treatment options, oral tofacitinib is well-positioned for broader adoption in the Indian market, especially as more physicians and patients experience its benefits firsthand.

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