The Feasibility and Consistency of Frontal Fibrosing Alopecia Scores for Evaluating the Efficacy of Oral Tofacitinib in Patients with Recalcitrant Frontal Fibrosing Alopecia: A Pilot Study

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Abstract

Frontal fibrosing alopecia (FFA) poses a challenge for middle-aged women due to its hairline recession, scaling, and redness, with treatment options lacking definitive guidelines. Currently, no standardized evaluation score is in place for assessing patients with frontal fibrosing alopecia. Finding a standard scoring system to assess frontal fibrosing alopecia would simplify the evaluation process and improve the patient by providing a standardized assessment method. This preliminary investigation seeks to evaluate the practicality and correlation of three frontal fibrosing alopecia scoring systems - the Frontal Fibrosing Alopecia Severity Index (FFASI), Frontal Fibrosing Alopecia Severity Score (FFASS), and Lichen Planopilaris Activity Index (LPPAI) - in assessing the effectiveness of oral Tofacitinib therapy among Thai patients with recalcitrant FFA. This study comprised a pilot single-arm clinical trial with 11 eligible participants. Data gathering encompassed demographic information, medical history, and initial lab assessments. Participants underwent a 12-week regimen of oral tofacitinib 5 mg twice daily for the treatment of FFA. Evaluation entailed FFASI, FFASS, LPPAI, and photographic/dermoscopic assessments. Data analysis employed descriptive statistics and statistical tests, utilizing the Wilcoxon rank test to measure changes from baseline to 12 weeks (delta) and Spearman correlation to assess score correlations. The study involved eleven participants. After 12 weeks of Tofacitinib treatment, LPPAI scores significantly decreased compared to baseline (0.5 vs. 1.83) with a Wilcoxon Test (W) value of 0, p = .005. Conversely, FFASI scores saw a significant decrease (47.42 vs. 47.57) with W = 1.5, p = .012. However, no significant change was observed in FFASS scores (16.0 vs. 16.1) with W = 12, p = .062. Spearman correlation analysis indicated no significant correlation between LPPAI and FFASI (r = 0.28, p = .403), LPPAI and FFASS (r = 0.24, p = 0.487), delta LPPAI and delta FFASI (r= 0.46, p = 0.157), delta LPPAI and delta FFASS (r = 0.32, p = 0.34). *In conclusion, LPPAI* and FFASI exhibited the capability to detect clinical changes after 12 weeks of tofacitinib therapy, unlike FFASS. Remarkably, no significant correlation was found between LPPAI and either FFASI or FFASS. These findings suggest the potential feasibility of using LPPAI and FFASI scores for measurement. However, the consistency among LPPAI, FFASI, and FFASS needs more repeated studies.

***Keywords**: Frontal Fibrosing Alopecia, Oral Tofacitinib Therapy, Correlation*

1. Introduction

Frontal fibrosing alopecia (FFA) was first described in 1994 by Kossard (1994a). FFA is most common in 50-60-year-old females. This condition can be found in up to 13 percent of women of reproductive age and 4 percent in men of color. When comparing the incidence of FFA among women of reproductive age, the number was higher in the black ethnic than in white women (Kerkemeyer, Eisman, S., Bhoyrul, Pinczewski, & Sinclair, 2021). Patients with FFA usually present with symmetrical bandlike hairline recession

in the frontotemporal region with scaling and redness in the perifollicular region of the lesion (Kossard, 1994b). FFA has three patterns: linear, diffuse, and pseudo "fringe signs". The progression of hairline recession can spread to the posterior ear hairline and occipital area. It could be noticed that the skin in the hairline recession area was lighter and glossier after prolonged exposure to the sun when compared to the normal skin area. The "lonely hairs sign" is a clinical clue to the diagnosis. Terminal scalp hairs in the original 3-7 cm hairline were found in more than 50% of FFA patients (Kerkemeyer et al., 2021). Currently, there is no standard guideline for treating FFA (To, & Beecker, 2018). The FFA treatments include 5-alpha reductase inhibitors, topical and oral corticosteroids, hydroxychloroquine, isotretinoin, mycophenolate mofetil and pioglitazone (Autrup, Thurlow, & Warwick, 1975; Rakowska, Gradzińska, Olszewska, & Rudnicka, 2017; Tan, & Messenger, 2009). Those treatments showed different outcomes and no definitive information regarding the efficacy of individual drugs. Systemic therapies may only slow down the progression of the disease(Autrup et al., 1975; Tan, & Messenger, 2009).

Tofacitinib, categorized as an immunomodulator within the Janus kinase inhibitor family, functions by inhibiting the tyrosine kinases associated with the Janus kinase family (Shreberk-Hassidim et al., 2017). This medication was approved to treat rheumatoid arthritis (RA) and ulcerative colitis (UC); however, many research studies found its potential benefits in various inflammatory dermatoses (Samadi, Ahmad Nasrollahi, Hashemi, Nassiri Kashani, & Firooz, 2017). Oral tofacitinib, administered at doses of 5 or 10 mg twice daily, has demonstrated a significant reduction in IL-17 levels, leading to favorable clinical outcomes (Welsch, Holstein, Laurence, & Ghoreschi, 2017). The emerging evidence advocates for the efficacy of oral tofacitinib in frontal fibrosing alopecia (FFA) treatment.

Currently, no standardized scoring system is available for evaluating frontal fibrosing alopecia. Various scoring systems have been employed for assessing patients, with one instance being the adoption of LPPAI as a standard measure for evaluation. In 2016, the British Hair and Nails Society (BHNS) introduced the Frontal Fibrosing Alopecia Index (FFASI) as a method to clinically evaluate patients with FFA. FFASI was divided into four sections. Alopecia severity is categorized on a scale of 1 to 5, determined by the extent of hairline recession, in a manner akin to the criteria suggested by Vano Galvan for the evaluation of frontal fibrosing alopecia (Vañó-Galván et al., 2014). Non-scalp hair loss (eyebrow, eyelash, limb and flexural) and related features(facial papules, cutaneous, nail and oral and genital mucosal lichen planus; and generalized scalp lichen planopilaris) are also considered for scoring, despite their uncertain implications(Holmes et al., 2016). In 2018, the Frontal Fibrosing Alopecia Severity Score (FFASS) was developed as an additional tool for evaluating the severity of frontal fibrosing alopecia. The score was published by the Journal of the American Academy of Dermatology after using evaluate FFA patients. The scoring system ranges from 0 to 25 and is divided into two components: clinical signs, encompassing hairline recession, loss of eyebrows, and perifollicular inflammation, and associated symptoms, which include the severity and frequency of pain and pruritus (Saceda-Corralo et al., 2018). Understanding the feasibility and reliability of frontal fibrosing alopecia (FFA) scoring systems such as the Frontal Fibrosing Alopecia Severity Index (FFASI), Frontal Fibrosing Alopecia Severity Score (FFASS), and Lichen Planopilaris Activity Index (LPPAI) is crucial to monitor disease progression and severity.

In advancing clinical research on Tofacitinib's effectiveness in treating FFA, it is imperative to employ standardized and dependable scoring systems. These systems are vital for ensuring consistent outcome

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assessments across diverse studies. Understanding their feasibility and reliability guarantees the credibility of research outcomes and streamlines inter-study comparisons. These scoring tools play a crucial role in evaluating FFA severity and activity, as well as treatment response. Their reliability and feasibility are instrumental in ensuring precise assessments of treatment effectiveness, empowering clinicians to make well-informed decisions regarding patient care.

2. Objectives

The objective is to assess the feasibility and reliability of three scoring systems for FFA - FFASI, FFASS, and LPPAI - in gauging the efficacy of oral Tofacitinib treatment among Thai individuals with recalcitrant FFA. The study seeks to ascertain whether these measures can accurately reflect clinical enhancements post-tofacitinib therapy and explore any correlations between them.

3. Materials and Methods

3.1 Population of study

Patients diagnosed with recalcitrant frontal fibrosing alopecia, who were treated as out-patients at The Hair and Nails Center, Institute of Dermatology, between November 2023 and February 2023, and met the inclusion criteria. Due to the absence of prior studies in Thailand, a pilot study was conducted to assess the efficacy and safety of the treatment. Eleven volunteers were recruited for this study from the department's records of worldwide research case series and case reports.

Inclusion criteria encompassed Thai individuals aged 18 or older diagnosed with frontal fibrosing alopecia (FFA), meeting specified diagnostic criteria, having failed treatment with at least one drug for more than three months, maintaining medication adherence, possessing relevant medical records, and not requiring washout from current medication. Exclusion criteria included diagnoses of conditions affecting hair growth within six months, pregnancy, contraindications to oral tofacitinib, recent taking solid or moderate to strong CYP3A4 medications, and positive Hepatitis B and C (HBsAg and/or HCV) status.

3.*2 Research procedure*

This pilot single-arm before-and-after clinical trial was conducted at the Institute of Dermatology, Bangkok, Thailand. The study protocol was approved by the Institutional Review Board of the Institute of Dermatology and the Department of Medical Services, Ministry of Public Health, Thailand.

1. A total of 11 patients with recalcitrant FFA were eligible for the study if they were 18 or older, met the diagnosis criteria of FFA, and had been on systemic medication for at least six months. Patients were excluded if they had any other hair loss that could interfere with treatment outcomes.
2. Patient demographic data were collected, including disease duration, medical and medication history, symptoms, diagnoses, FFA type, comorbidities, and family history, as well as baseline laboratory testing including Complete Blood Count (CBC), liver function tests, lipid profile, fasting blood sugar, renal function tests, hepatitis B and C screening, chest X-ray, and urine pregnancy test for reproductive-age women. Photography and dermoscopy were performed for evaluation purposes.
3. Patients with recalcitrant FFA received oral tofacitinib 5 mg, twice daily, for 12 weeks, with scheduled follow-up visits every four weeks during the treatment period and for an additional four

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weeks post-medication cessation, culminating in a total research duration of 16 weeks, during the follow-up period the effectiveness are evaluated through assessments using FFASI, FFASS, and LPPAI, as well as photographic and dermoscopic evaluations, culminating in data collection and statistical analysis.

3.3 Data analysis

In this research investigation, data collection involves discrete entries in a specific format, ensuring restricted access to safeguard the anonymity and confidentiality of participants. Utilizing a case record form, patient-specific information is deliberately omitted and limited to authorized personnel only. After publication, all data will be securely deleted to uphold participant privacy.

Data analysis included demographic information analysis, utilizing descriptive statistics for qualitative data and the median with interquartile range for quantitative data. The comparison of FFASI, FFASS, and LPPAI before and after oral tofacitinib administration was conducted using statistical tests, with significance determined by a p-value ≤ 0.05.

3.4 Research instruments

The Frontal Fibrosing Alopecia Severity Index (FFASI) is a scoring system employed to evaluate the severity of FFA. It assigns most of its points (80 out of 100) to assess the recession of the frontal and temporal hairlines. Subsequently, it takes into account factors such as inflammation, eyebrow loss, the presence of facial papules, cutaneous lichen planus (LP), oral or genital LP lesions, and nail involvement, which significantly contribute to the overall score (Saceda-Corralo et al., 2018).

The Frontal Fibrosing Alopecia Severity Score (FFASS) involves assessing its criterion validity through the Investigator's Global Assessment and evaluating construct validity by examining the convergence with other severity measures such as the Patient's Global Assessment, clinical features, the Lichen Planopilaris Activity Index, and quality of life assessments like the Dermatology Life Quality Index and Hospital Anxiety Depression Scale. Additionally, intra-observer and interobserver reliability were assessed (Saceda-Corralo et al., 2018).

The Lichen Planopilaris Activity Index (LPPAI) is a numerical scoring system designed to quantify the signs and symptoms of LPP and frontal fibrosing alopecia (FFA) for statistical comparison. This scoring system was widely used among hair experts to assess LPP and FFA before FFASI and FFASS were introduced. It encompasses symptoms such as pruritus, pain, and burning, along with signs like erythema, perifollicular erythema, and scale, and includes measures of disease activity such as the anagen pull test and extension of the disease. The equation for calculating the LPPAI (ranging from 0 to 10) involves assigning weights to these subjective and objective measures. Symptoms and signs are assessed on a 4-point scale ranging from absent to severe. The anagen pull test, indicative of local disease activity, involves grasping hair shafts and pulling firmly to evaluate the presence of anagen hairs, recorded both as a binary value and as the ratio of anagen hairs to total hairs pulled (Rácz, Gho, Moorman, Noordhoek Hegt, & Neumann, 2013).

4. Results and Discussion

4.1 Demographic data

All 11 volunteers were women, with an average age of 56 years, an average BMI of 24.58, an average waist circumference of 78 cm, an average age at onset of 44.9 years, and an average age of diagnosis of 50 years. These details are shown in Table 1.

Table 1 Baseline characteristic of the eleven volunteers

Baseline Characteristic	Total	
	n	%
Gender		
Male	0	0%
Female	11	100%
Age		
≥ 60	4	36.33%
< 60	7	63.66%
Mean±SD.	56.09 ± 9.63	
Median	55 (42 - 71)	
Body weight (kg)		
Mean±SD.	58.86 ± 9.92	
Median	58 (46 – 75)	
Height (cm)		
Mean±SD.	155 ± 0.05	
Median	155 (146 – 162)	
BMI		
Mean±SD.	24.58 ± 3.7	
Median	24.22 (19.4 - 30.59)	
Waist circumference (cm)		
Mean±SD.	78 ± 10.15	
Median	75 (62.5 – 95)	
Age at the onset (years old)		
Mean±SD.	44.91 ± 9.35	
Median	46 (29 – 63)	
Age at the diagnosis (years old)		
Mean±SD.	50 ± 6.83	
Median	49 (40 – 61)	
The delay from onset to diagnosis (years)		
Mean±SD.	5.09 ± 6.92	
Median	2 (2-20)	

4.2 The efficacy of Tofacitinib

4.2.1 Comparing baseline and after 12 weeks of LPPAI

Table 2 The change of The LPPAI between baseline (L0) and at week 12 (L12)

	Mean	Median	Standard deviation
LPPAI at the baseline (week 0)	1.87	1.83	1.01

	Mean	Median	Standard deviation
LPPAI after follow-up (week 12)	0.6	0.5	0.48
	z	**p**	**r**
Change in week 12 from baseline	-2.8	.005	0.85

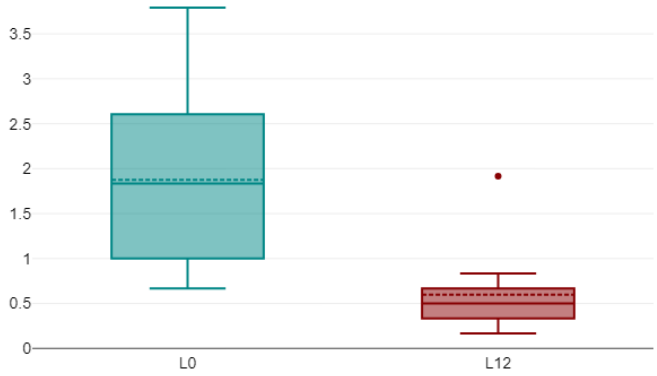

Figure 1 Box plot shows the change of The LPPAI between baseline (L0) and at week 12 (L12)

The baseline LPPAI median of 1.83 significantly exceeded the week 12 median of 0.5, according to a Wilcoxon Test ($W = 0$, $p = .005$), surpassing the significance level of 0.05. This suggests rejection of the null hypothesis, implying likely distinct populations. The effect size ($r = 0.85$) indicates a large effect.

4.2.2. Comparing baseline and after 12 weeks of FFASI

Table 3 The change of The FFASI between baseline (L0) and at week 12 (L12)

	Mean	Median	Standard deviation
FFASI at the baseline (week 0)	52.14	47.5	13.25
FFASI after follow-up (week 12)	48.59	47.5	13.8
	z	**p**	**r**
Change in week 12 from baseline	-2.5	.012	0.75

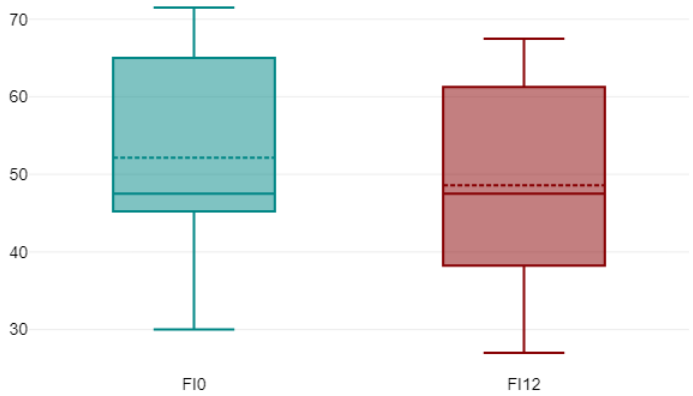

Figure 2 Box plot shows the change of The FFASI between baseline (FI0) and at week 12 (FI12)

The baseline with median FFASI = 47.5 showed significantly higher values than after 12 weeks follow up = 47.5, per a Wilcoxon Test (W = 1.5, p = .012), falling below the 0.05 significance level. This signifies the rejection of the null hypothesis, suggesting distinct populations. The effect size (r = 0.75) indicates a large effect.

4.2.3. Comparing baseline and after 12 weeks of FFASS

Table 3 The change of The FFASS between baseline (L0) and at week 12 (L12)

	Mean	**Median**	**Standard deviation**
FFASS at the baseline (week 0)	17.12	16.3	4.07
FFASS after follow-up (week 12)	15.73	16	4.8
	z	**p**	**r**
Change in week 12 from baseline	-2.04	.041	0.52

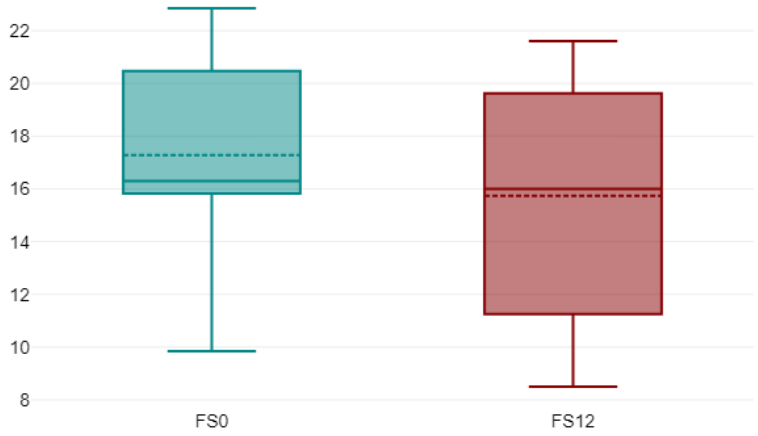

Figure 3 Box plot shows the change of The FFASS between baseline (FS0) and at week 12 (FS12)

The baseline with median FFASS = 16.3 showed no statistically significant change after 12 weeks follow-up = 16.0, per a Wilcoxon Test (W = -2.04, p = .041), falling below the 0.05 significance level. This signifies the rejection of the null hypothesis, suggesting distinct populations.

4.3 Correlation between the change (delta) of score at week 12 and baseline

A Spearman correlation revealed **a low positive correlation** (r=0.46) between the difference in LPPAI from baseline to Week 12 (DL012) and the difference in FFASI from baseline to Week 12 (dFI012). However, this correlation was not statistically significant (p = .157), suggesting **no significant relationship** between DL012 and dFI012 in this sample, as shown in **Figure 4**.

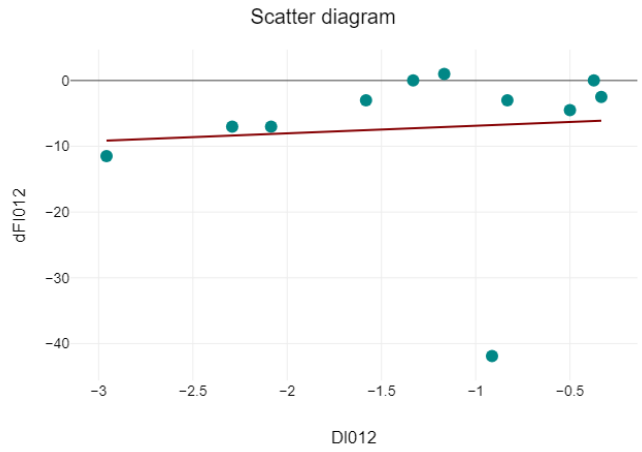

Figure 4 The scatter plot correlation of LPPAI difference between baseline and 12 weeks 12 (DL012) and FFASI differences between baseline and Week 12 (dFI012)

A Spearman correlation revealed **a low positive correlation** (r=0.32) between the difference in LPPAI from baseline to Week 12 (DL012) and the differences in FFASS from baseline to Week 12 (dFS012). However,

this correlation was not statistically significant (p = .36), suggesting **no significant relationship** between DL012 and dFS012 in this sample, as shown in **Figure 5**.

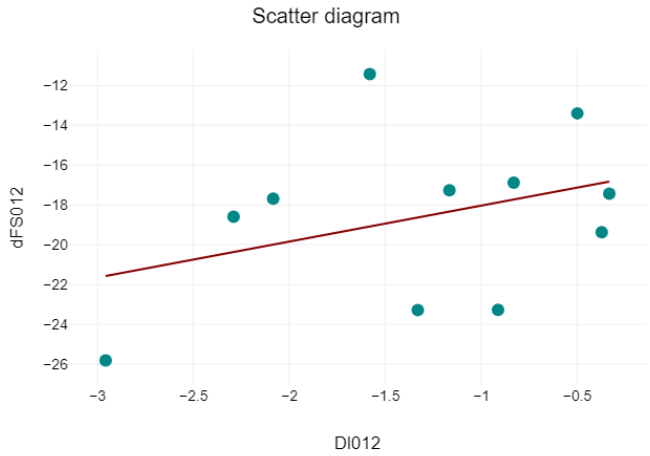

Figure 5 shows the scatter plot correlation of LPPAI difference between baseline and 12 week 12 (DL012) and FFASS differences between baseline and Week 12 (dFS012)

The additional analysis for the analysis revealed notable enhancements in LPPAI, FFASI, and FFASS from baseline to Week 12, which were depicted in the supplementary part.

Discussion

The results of this pilot study offer valuable insights into the efficacy of oral tofacitinib in treating certain dermatological conditions, particularly LPP and FFA. Throughout the 12-week treatment period, significant improvements were noted in key metrics such as the Lichen Planopilaris Activity Index (LPPAI), Frontal Fibrosing Alopecia Severity Index (FFASI), and Frontal Fibrosing Alopecia Symptom Score (FFASS).

Firstly, the analysis revealed notable enhancements in LPPAI, FFASI, and FFASS from baseline to Week 12. The Wilcoxon tests conducted indicated statistically significant differences in both LPPAI and FFASI between baseline and Week 12. This suggests substantive changes in the activity and severity of LPP and FFA throughout treatment with oral tofacitinib. These findings underscore the potential effectiveness of the medication in FFA. Additionally, the absence of a significant correlation between LPPAI and FFASI or FFASS suggests that these scores can be evaluated as distinct parameters in assessing the response to treatment. This lack of correlation implies that changes in LPP activity may not necessarily correspond directly to alterations in FFA severity. Therefore, clinicians must assess each aspect separately when monitoring patients' progress undergoing treatment for these conditions.

Understanding the nuances of how these variables evolve independently can provide clinicians with a more comprehensive understanding of the treatment's efficacy and its impact on different aspects of the diseases being treated. Moreover, these findings highlight the importance of regular monitoring and evaluation throughout the treatment process. Clinicians can monitor changes in disease activity, severity, and symptoms by assessing multiple parameters such as LPPAI, FFASI, and FFASS separately, facilitating more informed treatment decisions and adjustments as necessary.

Our study findings align with previous research indicating the potential efficacy of oral tofacitinib in treating frontal fibrosing alopecia (FFA). Tofacitinib, a Janus kinase (JAK) inhibitor, operates by targeting

the inflammatory pathways implicated in FFA pathogenesis. Numerous case reports and small-scale studies have documented encouraging outcomes with tofacitinib therapy in FFA patients, resulting in notable improvements in hair regrowth and disease stabilization. For instance, a case series involving six FFA patients treated with tofacitinib demonstrated significant hair regrowth and symptom reduction after six months of treatment. Similarly, another case report highlighted a patient who achieved complete hair regrowth following six months of tofacitinib therapy (Yang, Khanna, Sallee, Christiano, & Bordone, 2018). These individual reports underscore the potential therapeutic benefit of tofacitinib in managing FFA. Moreover, a larger study conducted by Vano-Galvan et al. assessed the efficacy and safety of tofacitinib in 28 FFA patients over a 12-month period. The results revealed that 75% of patients experienced stabilization or improvement in their condition, further supporting the potential of oral tofacitinib as a treatment option for FFA (Vañó-Galván et al., 2014). However, despite these promising findings, larger controlled trials are necessary to establish the effectiveness and safety profile of tofacitinib in treating FFA comprehensively. It is imperative for patients undergoing tofacitinib therapy to receive close monitoring from their healthcare providers, as with any medication. Regular monitoring allows for the timely detection of any adverse effects and ensures optimal management of the condition.

Our study possesses notable strengths as the first of its kind in Thailand, employing a prospective design that enables data collection over a defined period. This approach enhances result quality and minimizes recall bias. By focusing on clinically relevant outcomes like the LPPAI, FFASI, and FFASS, the improvement in treatment outcome was verified by objective measurements. However, several limitations warrant consideration. The study's small sample size may hinder generalizability and limit statistical power to detect smaller effects or associations. Additionally, the 12-week study duration might not fully capture the long-term effects or durability of oral tofacitinib treatment for FFA. Longer follow-up periods would provide a more comprehensive understanding of treatment outcomes and disease progression over time. Furthermore, the study's single-centre setting may restrict the diversity of the patient population and limit the generalizability of findings to other settings or populations with differing demographics or disease characteristics. Considering these limitations is crucial for interpreting and applying the study findings effectively.

5. Conclusion

The study examined the effectiveness of LPPAI, FFASI, and FFASS in detecting changes following 12 weeks of Tofacitinib therapy. Notably, LPPAI and FFASI showed sensitivity in identifying clinical alterations, unlike FFASS. Surprisingly, no significant correlation was observed between LPPAI and either FFASI or FFASS. These results imply the potential utility of LPPAI and FFASI scores for clinical assessment. However, further repeated studies are warranted to confirm the consistency among LPPAI, FFASI, and FFASS in measuring treatment outcomes accurately. Nonetheless, this study has never been conducted using oral Tofacitib in recalcitrant FFA in Thailand, and the high cost of the medicine. Moreover, only many case series and case reports have been identified in the department in worldwide research; researchers intend to conduct a pilot study to determine the score of frontal fibrosing alopecia; there were a total of eleven volunteers. So, the sample sizes may be too small to see the statistical correlation between the three scoring systems.

6. Acknowledgements

The authors wish to thank the College of Medicine ,Rangsit University, Institute of Dermatology and the Dermatological Society of Thailand for helping fund the work done. Moreover, we wish to thank the Hair and Nail Clinic, institute of Dermatology, Bangkok, for helping to collect complete data.

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