Effectiveness of Oral Tranexamic Acid in the Treatment of Melasma: A Comparative Randomized Controlled Study

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Abstract

Melasma is a chronic hyperpigmentation disorder influenced by multiple factors, including UV exposure, hormonal changes, and genetic predisposition. Oral tranexamic acid (TXA) has gained interest as a treatment potential option due to its ability to modulate melanogenesis and reduce pigmentation. However, evidence comparing its short-term efficacy to that of a placebo remains limited. This study evaluates the efficacy of a once-daily oral TXA pill in reducing melasma severity over a 4-week period compared to a placebo, providing insights into its early therapeutic effects. A randomized, placebo-controlled study was conducted with 40 participants diagnosed with melasma, divided into two groups (TXA group: n = 20, placebo group: n = 20). Participants received either oral TXA or a placebo for 4 weeks. Melasma severity was assessed using the modified Melasma Area and Severity Index (mMASI) at baseline and after 4 weeks. The TXA group demonstrated a significant reduction in the total mMASI score from baseline ($p < 0.001$), while the placebo group showed no significant change ($p = 0.859$). No severe adverse effects were reported, and only mild, self-limited gastrointestinal symptoms were noted in a few participants. These findings suggest that TXA 500 mg once daily may be an effective and well-tolerated short-term treatment for melasma.

Keywords: *melasma, oral tranexamic acid, placebo, mMASI, hyperpigmentation, randomized controlled trial*

1. Introduction

Melasma is a common acquired pigmentary disorder that primarily affects women of reproductive age, particularly those with Fitzpatrick skin types III to V (Handel et al., 2014). It manifests as irregular brown or grayish patches on sun-exposed areas, predominantly on the face. The pathogenesis of melasma is multifactorial, involving genetic predisposition, ultraviolet (UV) radiation exposure, hormonal influences such as pregnancy and oral contraceptive use, and inflammatory processes (Artzi et al., 2021).

Standard treatments such as hydroquinone, retinoids, and corticosteroids have variable efficacy and may cause side effects. Laser and chemical peel therapies are alternatives but remain limited by recurrence and inconsistent long-term results. Oral tranexamic acid (TXA), originally used for managing bleeding disorders, has emerged as a promising systemic treatment due to its effects on melanogenesis and angiogenesis pathways (Minni, & Poojary, 2020).

Previous studies have demonstrated the efficacy of oral TXA in reducing melasma severity, typically using divided-dose regimens (e.g., 250 mg taken twice or three times daily) over 8 to 12 weeks. For example, (Del Rosario et al., 2018) reported a 49% reduction in mMASI scores with 250 mg taken twice daily. A recent network meta-analysis by (Wang et al., 2023) indicated that 250 mg taken three times daily may be the most effective dose.

While earlier studies have demonstrated the effectiveness of oral TXA in divided doses (e.g., 250 mg taken twice or three times daily), the present study explores whether a simplified once-daily 500 mg regimen can offer comparable clinical efficacy while enhancing patient adherence and convenience. This study evaluates short-term outcomes such as mMASI score reduction, incidence of adverse effects, and early treatment responses over a 4-week period. If non-inferiority is demonstrated, this could support a more practical dosing approach and contribute to optimized melasma treatment strategies.

2. Objective

This study aims to evaluate the efficacy of a once-daily oral TXA pill in reducing melasma severity over a 4-week period, compared to a placebo, thereby providing insights into its early therapeutic effects.

3. Materials and Methods

This study was conducted from November 2024 to January 2025 at the Dermatology Outpatient Department (OPD) of Benchakitti Park Hospital. A total of 40 participants diagnosed with melasma were enrolled and randomly assigned to receive either oral tranexamic acid (TXA) (n=20) or a placebo (n=20) for a treatment duration of 4 weeks. This was an exploratory, randomized, double-blind, placebo-controlled trial.

Randomization was performed using a computer-generated random number table with blocked randomization to ensure balanced allocation; the fixed block sizes were known only to the statistician. No stratification was applied. The sample size was determined based on feasibility and participant availability during the study period, as no formal sample size calculation was performed due to the exploratory nature of the study, which aimed to generate preliminary data for future larger-scale trials.

Eligible participants were males or females aged 18 years or older with a diagnosis of epidermal or mixed-type melasma. Each participant provided informed consent prior to enrollment. Exclusion criteria included the use of topical treatments such as hydroquinone, whitening agents (arbutin, kojic acid, vitamin C, retinoids, steroids) within 4 weeks before the study, recent chemical peels, or oral TXA intake within the past 3 months. Additional exclusions encompassed previous laser treatments, dermabrasion, or other skin-tightening procedures within 6 months prior to enrollment. Participants who had received botulinum toxin, , dermal fillers, collagen stimulators, or thread lifting within 12 months before the study were also excluded.

Other exclusion criteria included pregnancy, lactation, hormonal contraceptive use within 1 year, a history of thromboembolic disorders, recurrent miscarriages, impaired renal function, malignancy, smoking, severe cardiovascular conditions, and known allergies to TXA or melatonin. Patients diagnosed with Hori nevus were also deemed ineligible.

Participants were instructed to take one 500 mg tablet of TXA (Tranxamin™) or a placebo 1–2 hours before bedtime. Additionally, they were required to apply a broad-spectrum sunscreen with SPF 30 and PA+++ once in the morning and a moisturizing base cream at night for 4 weeks. To monitor compliance, participants were instructed to return the original packaging of both the sunscreen and oral medication at the end of the study. The sunscreen tube (50 g) was expected to last approximately 50 days with daily application of 1 g per day over the entire face. A reduction in tube weight was used as an indirect measure of adherence. Similarly, participants were required to return empty or unused blister packs of oral medication to verify dosage compliance

Melasma severity was assessed using the modified Melasma Area and Severity Index (mMASI) at baseline and at the end of the 4-week treatment period. Clinical outcomes will be analyzed to determine the efficacy of TXA compared to placebo.

The 4-week duration was chosen to evaluate the short-term efficacy and early therapeutic response of oral TXA. While previous studies typically assessed outcomes over 8 to 12 weeks, recent evidence suggests that clinical improvement can often be observed within the first month of treatment. This early time frame allows assessment of initial treatment effects and the onset of action, as well as the detection of early adverse effects factors that are important for evaluating tolerability and patient adherence. Additionally, the present study aims to evaluate the onset of action and potential for rapid pigment reduction, which are clinically relevant for determining patient adherence and motivation. The shorter duration was also selected in consideration of resource and time constraints during the study period.

4. Results and Discussion

4.1 Results

The study included 40 participants who were randomized into two groups: 20 in the TXA group (500 mg once daily) and 20 in the placebo group. Baseline characteristics, including age, gender, BMI, duration of melasma, Fitzpatrick skin phototype, and sunscreen use, are presented in Table 1.

Table 1 Baseline characteristics of participants

Characteristics	Tranexamic acid (n = 20)	Placebo (n = 20)	p-value	
Gender				
Female	18 (90.0)	19 (95.0)	1.000	d
Male	2 (10.0)	1 (5.0)		
Age (years)	48.85 ± 6.68	45.30 ± 6.67	0.101	a
Body mass index (kg/m²)	27.23 ± 3.99	26.07 ± 6.10	0.479	a
Duration of melasma (years)	5 (2.5 - 10)	4 (3 - 5)	0.427	b
Family history of melasma				
Yes	13 (65.0)	15 (75.0)	0.853	d
No	6 (30.0)	4 (20.0)		
Unknown	1 (5.0)	1 (5.0)		
Occupation				
Housekeeper	4 (20.0)	3 (15.0)	0.057	d
Nurse	2 (10.0)	2 (10.0)		
Freelance	2 (10.0)	0 (0.0)		
Government/State enterprise employee	0 (0.0)	6 (30.0)		
Private sector employee	4 (20.0)	5 (25.0)		
Entrepreneur	1 (5.0)	2 (10.0)		
Others	7 (35.0)	2 (10.0)		
Outdoor activities or work (per day)				
0-4 hours	16 (80.0)	17 (85.0)	1.000	d
4-8 hours	4 (20.0)	3 (15.0)		
Sunscreen (per week)				
Every day	13 (65.0)	13 (65.0)	0.906	d
5-6 days	1 (5.0)	3 (15.0)		
3-4 days	2 (10.0)	1 (5.0)		
1-2 days	2 (10.0)	1 (5.0)		
Never used	2 (10.0)	2 (10.0)		
Fitzpatrick Skin Phototype				
III	12 (60.0)	16 (80.0)	0.301	d
IV	8 (40.0)	4 (20.0)		
Types of melasma				
Epidermal	8 (40.0)	2 (10.0)	0.065	d
Mixed	12 (60.0)	18 (90.0)		

Data are presented as numbers (%), means ± standard deviation or medians (interquartile range).
P-value corresponds to [a]Independent samples t-test, [b]Mann-Whitney U test, [c]Chi-square test or [d]Fisher's exact test.

Baseline characteristics, including gender, age, BMI, and Fitzpatrick skin type, did not differ significantly between the TXA and placebo groups ($p > 0.05$), ensuring a balanced comparison. The majority of participants were female (TXA: 90%, Placebo: 95%), with a mean age of 48.85 ± 6.68 years in the TXA group and 45.30 ± 6.67 years in the placebo group.

The most common melasma type was mixed (TXA: 60%, Placebo: 90%). Sunscreen usage was consistent across all groups, with 65% of participants applying it daily.

Comparison of mMASI Scores Between the TXA vs Placebo Groups at the Point of Time (Between groups)

The study compared the modified Melasma Area and Severity Index (mMASI) scores between the experimental group receiving oral tranexamic acid and the control group at two time points: before treatment and after four weeks of treatment.

Results indicated no significant difference in the mean Area (AREA) score for melasma on the right cheek between the experimental and control groups, both before treatment (4.20 ± 1.28 vs. 4.10 ± 1.52) and after four weeks (4.05 ± 1.28 vs. 4.05 ± 1.50). Similarly, the mean Darkness score for melasma on the right cheek was 2.60 ± 0.60 in the experimental group and 2.25 ± 0.64 in the control group before treatment, decreasing to 2.25 ± 0.55 and 2.25 ± 0.64 after four weeks, with no significant difference observed between the groups. The mean mMASI score for the right cheek was 3.35 ± 1.48 in the experimental group and 2.99 ± 1.60 in the control group before treatment, decreasing to 2.82 ± 1.34 and 2.97 ± 1.64 after four weeks, respectively, without significant differences.

For the left cheek, the mean AREA score was 4.15 ± 1.18 in the experimental group and 3.55 ± 1.23 in the control group before treatment, changing to 3.85 ± 1.18 and 3.65 ± 1.18 after four weeks, respectively, with no significant difference observed. The mean Darkness score for the left cheek was 2.55 ± 0.76 in the experimental group and 2.10 ± 0.79 in the control group before treatment, decreasing to 2.20 ± 0.52 and 2.10 ± 0.72 after four weeks, again showing no significant difference. Similarly, the mean mMASI score for the left cheek was 3.30 ± 1.50 in the experimental group and 2.46 ± 1.46 in the control group before treatment, changing to 2.61 ± 1.14 and 2.45 ± 1.36 after four weeks, with no statistically significant differences noted.

When considering the overall mMASI score for both cheeks, there was no significant difference was observed at baseline. The mean score before treatment was 6.65 ± 2.82 in the experimental group and 5.45 ± 3.00 in the control group. After four weeks, the scores changed to 5.43 ± 2.29 and 5.42 ± 2.88, respectively, with no statistically significant difference between the groups (Table 2).

Comparison of Changes in mMASI Scores at Baseline vs at Week 4 in TXA and Placebo Groups (Within Group)

The study compared the modified Melasma Area and Severity Index (mMASI) scores before and after four weeks of treatment in the experimental group.

Results showed no significant change in the mean Area (AREA) score for melasma on the right cheek, which was 4.20 ± 1.28 before treatment and 4.05 ± 1.28 after four weeks. However, the mean Darkness score on the right cheek significantly decreased from 2.60 ± 0.60 to 2.25 ± 0.55, with a mean reduction of 0.35 points (95% CI: -0.58 to -0.12; $p = 0.005$). Similarly, the mean mMASI score for the right cheek significantly declined from 3.35 ± 1.48 to 2.82 ± 1.34, with a reduction of 0.53 points (95% CI: -0.82 to -0.23; $p = 0.002$).

On the left cheek, the mean AREA score significantly decreased from 4.15 ± 1.18 before treatment to 3.85 ± 1.18 after four weeks, with a mean reduction of 0.30 points (95% CI: -0.57 to -0.03; $p = 0.030$). The mean Darkness score also significantly decreased from 2.55 ± 0.76 to 2.20 ± 0.52, with a reduction of 0.35 points (95% CI: -0.63 to -0.08; $p = 0.015$). Additionally, the mean mMASI score for the left cheek decreased from 3.30 ± 1.50 to 2.61 ± 1.14, with a significant reduction of 0.69 points (95% CI: -1.06 to -0.32; $p = 0.001$).

When considering the overall mMASI score for both cheeks, the mean score significantly decreased from 6.65 ± 2.82 before treatment to 5.43 ± 2.29 after four weeks. This represents a mean reduction of 1.22 points (95% CI: -1.77 to -0.66; $p < 0.001$), indicating a statistically significant improvement in melasma severity following oral tranexamic acid treatment (Table 2).

Table 2 Comparison of the modified Melasma Area and Severity Index between groups and within group

mMASI	Tranexamic acid (n = 20)	Placebo (n = 20)	Mean difference (95%CI)	p-value†
	Mean ± SD	Mean ± SD		
Right side of the melasma				
AREA (0-6)				
Baseline	4.20 ± 1.28	4.10 ± 1.52	0.10 (-0.80, 1.00)	0.823
4 weeks	4.05 ± 1.28	4.05 ± 1.50	0.00 (-0.89, 0.89)	1.000
Mean difference (95%CI)	-0.15 (-0.32, 0.02)	-0.05 (-0.16, 0.06)		
p-value[α]	0.083	0.330		
Darkness (0-4)				
Baseline	2.60 ± 0.60	2.25 ± 0.64	0.35 (-0.05, 0.75)	0.082
4 weeks	2.25 ± 0.55	2.25 ± 0.64	0.00 (-0.38, 0.38)	1.000
Mean difference (95%CI)	-0.35 (-0.58, -0.12)	0.00 (-0.15, 0.15)		
p-value[α]	0.005*	1.000		
mMASI (Each area)				
Baseline	3.35 ± 1.48	2.99 ± 1.60	0.36 (-0.63, 1.35)	0.465
4 weeks	2.82 ± 1.34	2.97 ± 1.64	-0.15 (-1.11, 0.81)	0.753
Mean difference (95%CI)	-0.53 (-0.82, -0.23)	-0.02 (-0.23, 0.20)		
p-value[α]	0.002*	0.886		
Left side of the melasma				
AREA (0-6)				
Baseline	4.15 ± 1.18	3.55 ± 1.23	0.60 (-0.17, 1.37)	0.125
4 weeks	3.85 ± 1.18	3.65 ± 1.18	0.20 (-0.56, 0.96)	0.596
Mean difference (95%CI)	-0.30 (-0.57, -0.03)	0.10 (-0.16, 0.36)		
p-value[α]	0.030*	0.428		
Darkness (0-4)				
Baseline	2.55 ± 0.76	2.10 ± 0.79	0.45 (-0.05, 0.95)	0.074
4 weeks	2.20 ± 0.52	2.10 ± 0.72	0.10 (-0.30, 0.50)	0.618
Mean difference (95%CI)	-0.35 (-0.63, -0.08)	0.00 (-0.22, 0.22)		
p-value[α]	0.015*	1.000		
mMASI (Each area)				
Baseline	3.30 ± 1.50	2.46 ± 1.46	0.84 (-0.11, 1.79)	0.080
4 weeks	2.61 ± 1.14	2.45 ± 1.36	0.17 (-0.64, 0.97)	0.680
Mean difference (95%CI)	-0.69 (-1.06, -0.32)	-0.02 (-0.27, 0.24)		
p-value[α]	0.001*	0.904		
Total mMASI				
Baseline	6.65 ± 2.82	5.45 ± 3.00	1.20 (-0.67, 3.07)	0.201
4 weeks	5.43 ± 2.29	5.42 ± 2.88	0.02 (-1.65, 1.68)	0.986
Mean difference (95%CI)	-1.22 (-1.77, -0.66)	-0.03 (-0.38, 0.32)		
p-value[α]	<0.001*	0.859		

[α]Paired samples t-test

†Independent samples t-test

* Significant at p-value < 0.05

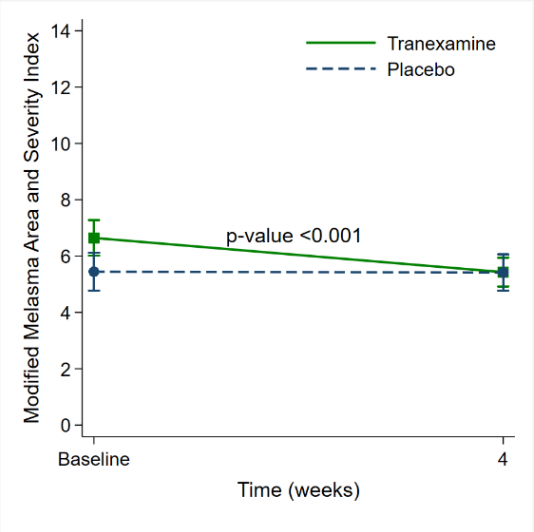

Figure 1 Comparison of modified Melasma Area and Severity Index (mMASI) scores over time between the tranexamic acid and placebo groups

Figure 1 compares the modified Melasma Area and Severity Index (mMASI) scores over time between participants receiving tranexamic acid and those in the placebo group. The x-axis represents time in weeks, while the y-axis displays mMASI scores, which indicate the severity of melasma.

At the beginning of the study, both groups have similar baseline mMASI scores. Over a 4-week period of study, the graph demonstrates a significant reduction in mMASI scores in the tranexamic acid group ($p < 0.001$) compared to the placebo group, suggesting a treatment effect. The difference between the groups becomes more apparent as the study progresses, indicating that tranexamic acid may be effective in improving melasma severity.

4.2 Discussion

The comparison between the TXA and placebo groups highlights the efficacy of oral TXA 500 mg administered once daily in reducing melasma severity. The TXA group exhibited statistically significant improvements in total mMASI scores, darkness scores, and mMASI per area, while the placebo group showed no meaningful changes. These findings suggest that TXA effectively diminisheshyperpigmentation and melasma severity over a short treatment period.

Although the TXA group showed significant intra-group improvements in mMASI scores, the inter-group comparisons between the TXA and placebo groups did not reach statistical significance for many parameters. This discrepancy may be attributed to several factors. First, the relatively small sample size may have limited the statistical power to detect differences between the groups. Second, the placebo group also demonstrated a mild decrease in mMASI scores, suggesting a possible placebo effect or natural fluctuations in melasma severity over time. Third, while the effect size within the TXA group was clinically meaningful, the variability in baseline characteristics and individual responses may have diluted the between-group effect. These factors should be considered when interpreting the results and underscore the need for larger trials to validate the observed trends.

Additionally, the study's short duration prevents assessment of long-term outcomes and recurrence rates. The limited sample size also restricts subgroup analyses and may have contributed to the lack of statistically significant inter-group differences. Self-reported adherence measures, such as sunscreen tube return and medication pack checks, may also be subject to reporting or recall bias. These limitations highlight the need for longer, larger studies using objective adherence measures and provide extended follow-up.

Several potential biases must be considered in interpreting the study findings. The short duration of the study limits the ability to assess long-term treatment effects and recurrence. Additionally, the study did not include biomarker confirmation or histopathological evaluation of the melasma subtype, which may have influenced response variability. Although sunscreen use was recommended for all participants, differences in compliance or prior sun exposure may have introduced confounding effects.

While previous studies have used TXA 250 mg twice or three times daily (Calacattawi et al., 2024), this study suggests that 500 mg once daily provides comparable benefits. This dosing regimen may enhance patient adherence due to its simplicity while maintaining therapeutic effectiveness. Oral TXA is believed to inhibit plasminogen activation, thereby reducing melanocyte activation and limiting UV-induced melanogenesis, contributing to its effectiveness in melasma treatment (Del Rosario et al., 2018).

To the best of our knowledge, this is the first study to evaluate the efficacy of oral TXA 500 mg once daily for melasma treatment. Previous research has assessed divided-dose regimens (250 mg taken twice or three times daily), but no prior studies have examined whether a single higher dose can yield similar clinical benefits. The positive outcomes observed in this study suggest that a once-daily TXA regimen may be a viable alternative, offering greater convenience while maintaining efficacy. This finding is particularly relevant for improving patient adherence and minimizing potential dosing errors (Wang et al., 2023).

Despite the promising results, some limitations exist. The short study duration (4 weeks) prevents conclusions about long-term recurrence rates. Previous research with extended follow-ups has noted melasma recurrence after TXA discontinuation, suggesting the need for maintenance therapy (Arellano et al., 2012). Future studies should investigate long-term outcomes, optimal treatment duration, and combination therapies with topical agents or laser treatments to maximize efficacy.

While this study demonstrated short-term efficacy, longer-term research is necessary to determine the durability of treatment effects, assess recurrence rates, and evaluate the necessity for maintenance therapy. The potential role of combination therapies-such as TXA with topical depigmenting agents, chemical peels, or laser therapy-should also be explored. Additionally, future studies should aim to identify biomarkers or predictors of treatment response to personalize TXA therapy for individual patients.

Importantly, this is the first study to examine the effectiveness of a once-daily 500 mg TXA regimen in melasma treatment, offering a potential new standard for oral TXA administration. Future research should confirm these findings across diverse populations, longer treatment durations, and different skin types to establish comprehensive treatment guidelines. Despite its limitations, this study provides a strong foundation for further research and may contribute to a shift in clinical practice by offering a convenient, effective, and well-tolerated treatment option for melasma.

These findings offer valuable insights into melasma treatment strategies, supporting the potential of once-daily TXA as a practical and effective intervention.

5. Conclusion

While the TXA group demonstrated significant intra-group improvements, many inter-group comparisons did not reach statistical significance. This limitation should be considered when interpreting the overall effectiveness of the treatment. The findings of this study underscore the significant efficacy of oral TXA 500 mg taken once daily in reducing melasma severity compared to placebo over a short treatment period. This study contributes to the growing body of evidence supporting TXA as an effective therapeutic option for melasma, particularly for patients who prefer a simplified once-daily regimen to enhance adherence. The observed improvements in total mMASI scores and darkness reduction suggest that this dosing strategy provides clinical benefits comparable to previously studied divided-dose regimens.

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