RESEARCH PAPER

Comparative Evaluation of the Efficacy of Topical Tranexamic Acid (4%) Versus Hydroquinone (2%) in the Treatment of Melasma of the Adult Age Group (35-55 Yrs) in Tertiary Health Care Chennai

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ABSTRACT

Background: Topical hydroquinone (HQ) is the gold standard in melasma management; even when it causes many side effects. An antifibrinolytic tranexamic acid (TXA) emerged as an alternative in management of melasma, hence the current study was proposed to compare the effectiveness and safety of TXA over HQ.

Material and methods: Comparative study was done in patients with melasma attending dermatology department (sample size 100) after getting institute's ethical approval (IHEC-I/3987/25). Patients who met the inclusion criteria were grouped as Group A (50): Topical tranexamic acid was used, Group B: hydroquinone was used. Modified Melasma Area and Severity Index (MASI) scores at baseline, 4 week, 8 week, 12 weeks and patients satisfaction score at the end of study period were noted. Analysis done using SPSS version 22.

Results: Group A and B have statistically significant decrease in MASI scores by the end of study period. Paired analysis showed a significant within group effect in both the groups (group A = d/3.9, group B = d/3.69). Group A patients satisfaction score was significantly higher compared to group B (56% and 40% reported excellent improvement, P = 0.04).

Conclusion: Patients in both groups reported significant improvement in MASI scores, while group A (TXA) showed lower incidence of side effects and excellent patient satisfaction compared to group B.

Keywords: Comparative study, effectiveness, side effect profile, melasma, topical tranexamic acid (4%), hydroquinone (2%).

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Introduction

Melasma is a chronic skin condition which is characteristically relapsing with hyperpigmentation, seen as symmetrical, brown patches with macules, mainly on sun exposed areas in the face (1). The prevalence of this is more in reproductive age women, which was seen easily and having a psychological impact (2,3). Even when it is a benign condition, it has a significant psycho social burden, causing reduced self-esteem, and emotional stress (4). Topical hydroquinone (HQ) is the gold standard in melasma management since a long time; even when it causes many side effects, because of its tyrosinase inhibiting action that causes decreased melanin production (5). Its adverse effects profile includes, skin irritation, contact dermatitis due to allergic reaction skin irritation, exogenous ochronosis and

repigmentation upon discontinuing the treatment (6). These lead to the search for alternate treatment agents.

An antifibrinolytic tranexamic acid (TXA) emerged as an alternative in management of melasma was usually used to control bleeding. It works by suppressing plasminogen activation, reduced expression of vascular endothelial growth factor (VEGF) diminishing melanocyte tyrokinase functioning affecting melanogenesis and vascularity in the dermis (7,8). Topical TXA can be used locally and it has the advantage of less systemic exposure and less side effects as opined by previous clinical trials, which also mentioned that it works as good as HQ or even better than that, with a decreased repigmentation and better safety profile (9–10).

Despite encouraging results, existing studies on topical TXA are limited by small sample sizes, heterogeneous treatment regimens, and non-standardized outcome measures (11). Therefore, further well-designed, randomized controlled trials are warranted to establish its comparative efficacy, safety, and optimal use in melasma management. Also, clinical data comparing topical TXA and hydroquinone in a controlled, head-to-head fashion remain limited, especially in diverse skin types and longer treatment durations. So this study is being done to compare the efficacy and safety of topical TXA vs. HQ in a standardized and statistically robust manner by identifying a safer long-term treatment option for melasma, to improve patient outcomes and adherence by providing options with fewer side effects and better tolerability. This can further, contribute to dermatologic practice guidelines, especially in regions where hydroquinone use is limited or controversial.

Methodology

A comparative study was conducted at Chettinad Medical College from January 2025 to January 2026 in patients visiting the Dermatology OPD. The study protocol was reviewed and approved by the Institutional Ethics Committee (IHEC-I/3987/25) and adhered to the principles outlined in the Declaration of Helsinki. All participants provided written informed consent prior to enrollment.

INCLUSION CRITERIA:

1. Adults aged 35-55 years
2. Clinical diagnosis of facial melasma
3. Fitzpatrick skin types Ill to V
4. Willingness to follow study protocol and provide informed consent

EXCLUSION CRITERIA:

1. Pregnant or lactating women
2. History of hypersensitivity to tranexamic acid or hydroquinone
3. Use of any topical or systemic depigmenting treatment in the past 2 months
4. Active skin infections or inflammatory dermatoses
5. Known coagulation disorders or systemic illness

SAMPLE SIZE:

Based on the study by Janney MS et al on "A Randomized Controlled Study comparing the efficacy of Topical 5% Tranexamic Acid solution versus 3% Hydroquinone Cream in Melasma" revealed that highest prevalence of mixed melasma is 63% (12).

$n = 4pq / d^2$

$p = 63$

$q = 100-p = 37$

$d = 10$

95% Confidence interval

$= 4 \times 63 \times 37/100 = 93.2$

Hence the minimum required sample size is **94** participants which was rounded up to 100.

Sampling method used was purposive sampling method

Informed Consent Process:

Informed consent was obtained from all participants before participation. The process involved a detailed verbal and written explanation of the study's objectives, methodology, potential benefits, and possible risks. Consent forms were provided in each participant's regional language to facilitate comprehension.

Study grouping:

Patients who met the inclusion criteria were included in the study and were grouped as follows.

- Group A (50 patients): Topical TXA (4%) was prescribed to apply twice in a day on affected areas.
- Group B (50 patients): Topical HQ (2%) was prescribed to apply at night on affected areas.

Clinical History and Data Collection:

A detailed history was taken using a semi structured questionnaire, which included patients' demographic details, personal history, family history on melasma, patients' past medical and surgical history.

Physical Examination:

A complete general physical examination was performed for all patients. Dermatological evaluation was carried out by a single board-certified dermatologist to minimize inter-observer variability. The dermatologist classified the clinical form of melasma and assessed disease extent using the Modified Melasma Area and Severity Index (MASI).

Modified Melasma Area and Severity Index (MASI) Assessment:

The MASI divides the face into four regions:

- Forehead (F): 30% of total face area
- Right malar (RM): 30%
- Left malar (LM): 30%
- Chin (C): 10%

For each region, three parameters were scored:

- **Area of involvement (A):** 0 = absent, 1 = <10%, 2 = 10–29%, 3 = 30–49%, 4 = 50–69%, 5 = 70–89%, 6 = 90–100%.
- **Darkness (D):** 0 = absent, 1 = slight, 2 = mild, 3 = marked, 4 = severe.
- **Homogeneity (H):** 0 = minimal, 1 = slight, 2 = mild, 3 = marked, 4 = severe.

The MASI score was calculated using the following formula:

MASI=0.3(DF+HF)AF+0.3(DRM+HRM)ARM+0.3(DLM+HLM)ALM+0.1(DC+HC)AC

where subscripts F, RM, LM, and C denote forehead, right malar, left malar, and chin, respectively. The total MASI score ranges from 0 to 48, with higher scores indicating more severe pigmentation. In this study, the MASI was calculated exclusively for the malar areas.

Patient Satisfaction Assessment:

At study completion, participants self-assessed the improvement in their melasma using a four-point scale:

1 = Excellent (>75% lightening),
2 = Good (51–75% lightening),
3 = Fair (26–50% lightening),
4 = Poor (0–25% lightening).

Area (A): 0. absent ,1. <10% ,2. 10%-29% ,3.30%-49% ,4. 50%-69% ,5. 70%-89% ,6. 90%-100%

Darkness (D) and Homogenesity of pigmentation(H): 0 . absent , 1. slight ,2. mild ,3. marked ,4. Severe

Follow up evaluation was done at 4, 8 and 12 weeks post treatment, to compare MASI scores, patient satisfaction score and side effects.

This patient-reported measure supplemented the objective MASI scoring to provide a comprehensive evaluation of treatment outcomes.

Statistical Analysis:

Data were entered into a secured database and analyzed using **IBM SPSS Statistics for Windows, Version 22 (IBM Corp., Armonk, NY, USA)**. Continuous variables were expressed as mean ± standard deviation (SD). Categorical variables were presented as frequencies and percentages. The **Shapiro–Wilk test** was used to assess normality of continuous data. Comparisons between pre- and post-treatment MASI scores were performed using the **paired t-test** for normally distributed variables. Repeated measures analysis was used to compare MASI scores at different time points. Categorical variables, including patient satisfaction scores, were compared using the **Chi-square test** or **Fisher's exact test** as appropriate. A *p*-value of <0.05 was considered statistically significant. All analyses were two-tailed.

Results

A total of 100 patients (mean age = 44.12 ± 5.77 years) were enrolled, with 50 participants assigned to each group. The mean age in the Tranexamic Acid group was 44.36 years (SD = 5.68) and in the Hydroquinone group was 43.88 years (SD = 5.91). An independent samples *t*-test indicated no significant difference in age between the groups, $t(98) = 0.39$, $p = .698$, $d = 0.08$ (95% CI [−1.79, 2.75]). Study population have 84 females and 16 males, thus showing more prevalence in females. There is no significant difference in both the groups with respect to gender (p=0.58) (Table 1).

Table 1: ***Age and sex distribution of study participants by group***

Measure	**Tranexamic Acid (n=50) Mean ± SD / n (%)**	**Hydroquinone (n=50) Mean ± SD / n (%)**	**Test Statistic**	***p* value**
Age	44.36±**5.68**	**43.88±5.91**	*t*(98)= 0.39	0.698
Gender				
Female (84)	43 (86%)	41 (82%)	χ^2 = 0.298	0.58
Male (16)	7 (14%)	9 (18%)		

MASI Score Changes Over Time

Both groups demonstrated statistically significant reductions in MASI scores from baseline to week 12. Repeated measures analysis indicated a large within-group effect size for both Tranexamic Acid ($d = 3.90$) and Hydroquinone ($d = 3.69$). Between-group

differences favored Tranexamic Acid at week 8 (p = .087) and week 12 (p = .072), although these did not reach statistical significance at the p < .05 level (Table 2, 3 & Figure 1).

Table 2: Comparison of MASI scores over time between groups

Time point	Group A: Mean ± SD	Group B: Mean ± SD	Mean difference (A–B)	*t*(98)	*p*	Cohen's *d*	95% CI for difference
Baseline	14.52 ± 2.10	14.48 ± 2.05	0.04	0.09	.929	0.02	[−0.87, 0.95]
4 weeks	11.76 ± 1.95	12.10 ± 1.92	−0.34	−0.85	.397	0.17	[−1.14, 0.46]
8 weeks	9.62 ± 1.85	10.28 ± 1.88	−0.66	−1.73	.087	0.35	[−1.42, 0.10]
12 weeks	7.94 ± 1.72	8.48 ± 1.78	−0.54	−1.82	.072	0.37	[−1.13, 0.05]

Table 3: Within-group changes in MASI score from baseline (Paired t-test)

Group	Comparison	Mean difference ± SD	*t*	*p*	Cohen's *d*	95% CI for difference
A: Tranexamic Acid	Baseline → 4 weeks	2.76 ± 0.95	20.53	<.001	2.90	[2.47, 3.05]
	Baseline → 8 weeks	4.90 ± 1.12	30.97	<.001	4.38	[4.44, 5.36]
	Baseline → 12 weeks	6.58 ± 1.30	37.54	<.001	5.31	[6.17, 6.99]
B: Hydroquinone	Baseline → 4 weeks	2.38 ± 0.91	18.57	<.001	2.63	[2.16, 2.60]
	Baseline → 8 weeks	4.20 ± 1.08	27.56	<.001	3.90	[3.72, 4.67]
	Baseline → 12 weeks	6.00 ± 1.25	34.42	<.001	4.87	[5.21, 6.39]

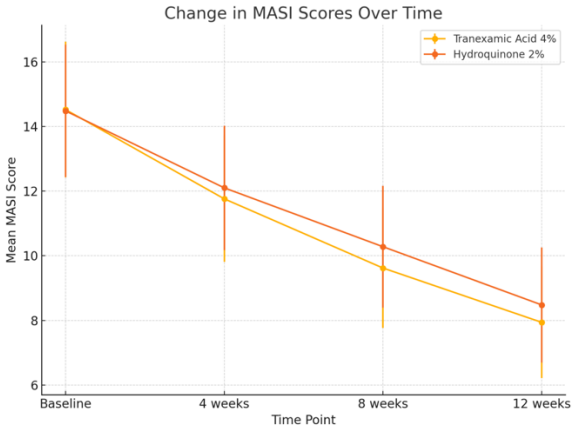

Figure 1: Changes in MASI scores over time

Patient satisfaction assessment

At study completion, a significantly higher proportion of participants in the **Tranexamic Acid** group rated their improvement as *Excellent* compared with the **Hydroquinone** group (56% vs. 40%; χ^2 = 4.05, p = .044). Mean area (A), darkness (D), and homogeneity (H) scores at 12 weeks were all significantly lower in the Tranexamic Acid group, indicating greater reduction in pigmentation severity (A: $t(98) = –2.73$, p = .008; D: $t(98) = –3.00$, p = .003; H: $t(98) = –3.37$, p = .001). (Table 4, Figure 2)

Table 4: Patient satisfaction scores and pigment severity components at study completion

Measure	Tranexamic Acid (n=50) Mean ± SD / n (%)	Hydroquinone (n=50) Mean ± SD / n (%)	Test Statistic	*p* value
Self-assessed improvement				
Excellent (>75%)	28 (56%)	20 (40%)	χ^2 = 4.05	0.044*
Good	15 (30%)	17 (34%)		

(51–75%)				
Fair (26–50%)	5 (10%)	9 (18%)		
Poor (0–25%)	2 (4%)	4 (8%)		
Area score (A) (12 weeks)	2.1 ± 0.8	2.6 ± 0.9	*t*(98) = –2.73	0.008*
Darkness score (D) (12 weeks)	1.4 ± 0.6	1.8 ± 0.7	*t*(98) = –3.00	0.003*
Homogeneity score (H) (12 weeks)	1.5 ± 0.5	1.9 ± 0.6	*t*(98) = –3.37	0.001*

A = area involved; D = darkness; H = homogeneity of pigmentation. Lower scores indicate greater improvement.

Figure 2: Patient satisfaction at study completion

Side Effect Profile

The incidence of any side effect was 18% in the Tranexamic Acid group and 34% in the Hydroquinone group. A chi-square test indicated this difference was statistically significant, $\chi^2(1, N = 100) = 4.50$, $p = .034$, $\varphi = 0.21$, indicating a small-to-moderate association between treatment type and side effect occurrence (Table 5, Figure 3).

Table 5: Side effect profile by group

Side effect	**Group A (n = 50)**	**Group B (n = 50)**	**χ^2**	***p***	**φ**
Erythema	6 (12%)	3 (6%)	4.50	.034	0.21
Burning sensation	2 (4%)	5 (10%)			
Irritation	1 (2%)	7 (14%)			
Hypopigmentation	0 (0%)	2 (4%)			
Any side effect	**9 (18%)**	**17 (34%)**			

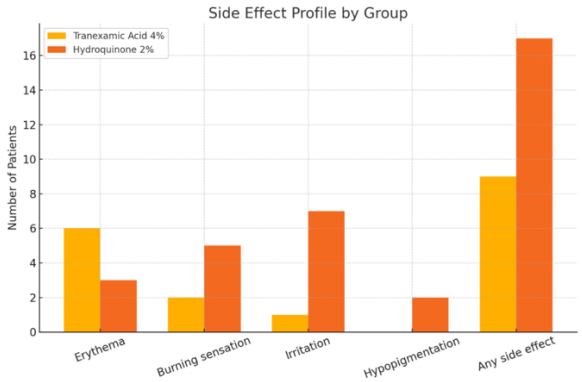

Figure 3: Side effect profile by group

Discussion:

In this randomized comparative study, both topical tranexamic acid (4%) and hydroquinone (2%) treatments produced clear and clinically meaningful reductions in MASI, but the tranexamic acid (TA) arm showed a trend toward greater numeric improvement at intermediate (8 weeks) and final (12 weeks) time points and achieved significantly better scores on area (A), darkness (D), and homogeneity (H) at 12 weeks. These findings concur with several randomized and split-face trials showing that topical TA (typically 3–5% or liposomal formulations) yields MASI reductions comparable to hydroquinone, with some studies reporting transient or modest advantages for TA at interim assessments or when TA is delivered in enhanced vehicles. For example, Janney et al found similar percentage MASI reductions for topical 5% TA versus 3% HQ at 12 weeks (≈27% vs ≈26.7%), with no statistically significant between-group difference but large within-group effect sizes for both agents; the time course of reduction in that study mirrors our pattern of early and steady improvement in both arms.(12) Banihashemi et al. (2015) — a split-face study of 5% liposomal TA versus 4% HQ — likewise reported significant MASI decreases on both sides and a numerically greater decline with liposomal TA that did not reach statistical significance.(13)

In study by El-Husseiny, R., findings matched our study where a significant reduction in area % of melanin was recorded with TA 5% than HQ 4% creams (P = .000). TA appears to be a promising therapeutic option in treating melasma with fewer adverse effects. Also study by Zohreh Tehranchina done in 55 melasma patients had similar findings where the mean of MASI score in week 16 decreased in both groups significantly ($p < 0.01$). The therapeutic outcomes were significantly better in TA+HQ group than HQ group (p=0.001). Patients satisfaction with treatment was significantly higher in the TA + HQ group.(14,15)

Mechanistically, the similarity in MASI improvement is plausible: hydroquinone acts by inhibiting tyrosinase and melanogenesis directly, while tranexamic acid reduces plasmin activity in keratinocytes, down-regulating melanocyte-stimulating mediators. Differences in magnitude/timing across studies are therefore likely influenced by vehicle (liposomal vs simple solution), concentration, mode of application, baseline lesion depth (epidermal vs dermal), and adherence — all factors that have varied across the TA literature.(16,17)

Regarding the side-effect profile, our cohort experienced significantly fewer and milder adverse events with topical TA (18% any side effect) than with HQ (34%), and the difference was statistically significant. This pattern is well supported by the literature: multiple trials and systematic reviews report that topical TA is generally well tolerated, with mostly transient, mild cutaneous complaints (erythema, dryness, transient irritation), whereas hydroquinone more frequently causes irritant reactions and—with prolonged use—rare complications such as exogenous ochronosis reported in case series and safety reviews.(12,13,18) The better tolerability of TA has been consistently noted as a practical advantage in trials comparing formulations or routes of administration.(13,19)

Patient-reported outcomes in our study favored TA: a significantly greater proportion of participants rated their improvement as Excellent (>75% lightening) in the TA arm (56% vs 40%; $\chi^2 = 4.05$, $p = .044$). This aligns with Janney et al., who also found higher patient satisfaction with topical TA in part because of fewer adverse events, despite similar objective MASI reductions between arms.(12) The concordance between objective (A, D, H, MASI) and subjective (patient satisfaction) measures in our TA group suggests that tolerability (fewer irritant side effects) contributes importantly to perceived benefit — an effect underscored in prior randomized and split-face studies.(13,10)

Where our findings extend the literature is in offering granular severity-component data (A, D, H) and explicit patient satisfaction distribution at study end. Not all prior trials reported these components in detail; studies that did (including split-face trials and formulation comparisons) often observed that improved delivery systems (liposomal vehicles, microneedling-assisted delivery) can produce modestly larger reductions in area and darkness components of pigmentation, consistent with our observation that liposomal TA yielded better A, D, and H scores at 12 weeks.(13,20)

Conclusion:

Both topical liposomal tranexamic acid (4%) and hydroquinone (2%) produced significant improvement in melasma as measured by MASI scores over 12 weeks. While the overall MASI reduction was comparable, liposomal tranexamic acid achieved greater improvement in area, darkness, and homogeneity scores at study completion, with a significantly lower incidence of adverse effects and higher patient satisfaction. These findings suggest that liposomal tranexamic acid is an effective and better-tolerated alternative to hydroquinone for short-term melasma management, particularly in patients prone to irritation or seeking high cosmetic acceptability.

Limitations

Long term follow up was not done; hence relapse cannot be ascertained.

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