

**Comparative Study of Oral Tranexamic Acid and Topical Tranexamic Acid in Patients with Melasma**Lokesh Chawala<sup>1</sup>, Shailesh Kumar<sup>2</sup><sup>1</sup>Department of Dermatology, JLN Medical College and Associated Groups of Hospitals, Ajmer, Rajasthan, India<sup>2</sup>Department of Dermatology, JLN Medical College and Associated Groups of Hospitals, Ajmer, Rajasthan, India

Received: 20-05-2023 / Revised: 21-06-2023 / Accepted: 25-07-2023

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Conflict of interest: Nil

**Abstract:****Background:** Melasma is one of the most common causes of hyperpigmentation and is a prevalent cosmetic concern for patients.**Aim:** To evaluate and compare the therapeutic effectiveness of topical and oral tranexamic acid for the treatment of melasma.**Materials and Methods:** A total of 50 patients who presented to dermatology OPD with melasma were divided into two groups, namely A and B. Group A patients were treated with oral tranexamic acid 250 mg twice daily, and patients in Group B were treated with topical 5% tranexamic acid with follow-up every 4 weeks until 3 months.**Results:** Among the oral treatment and topical patient groups, a statistically significant difference in the mean percentage of reduction in MASI score from baseline was observed at 12 weeks.**Conclusion:** Oral tranexamic acid gave a more promising result when compared to topical tranexamic acid.**Keywords:** Melasma, Oral Tranexamic Acid, Topical Tranexamic Acid, Tranexamic Acid.

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**Introduction**

Melasma is an acquired pigmentary condition, characterised by irregular brown macules and patches, primarily affecting women.[1] Three facial patterns have been described: centrofacial, malar, and mandibular. The major clinical pattern in 50–80% of cases is the centrofacial pattern, which affects the forehead, nose, and upper lip, excluding the philtrum, cheeks, and chin. The malar pattern is restricted to the malar cheeks, while mandibular melasma is present on the jawline and chin. Extra-facial melasma can occur on non-facial body parts, including the neck, sternum, forearms, and upper extremities. Melasma can be divided on the basis of morphology – epidermal, dermal, and mixed.[2] Commonly implicated etiological factors are genetic susceptibility, ultraviolet light exposure, pregnancy, sex hormones, contraceptive pills, thyroid disease, cosmetics and phototoxic drugs.[3] Various treatment modalities are used for melasma. These include the use of sunscreens, hypopigmenting agents, superficial peeling agents such as glycolic and lactic acid and laser therapy.[4] Tranexamic acid is a fibrinolytic agent, it has a role in the inhibition of paracrine melanogenic factors that normally stimulate

melanogenesis.[5] Therefore, it has been evaluated for the treatment of melasma in topical and oral formulations with varying efficacy and safety, which requires further large-scale randomised controlled trials.[6]

**Material and Methods**

50 Patients with melasma were selected for the study. Patients were randomly categorised into two groups, namely A and B. Group A patients were administered oral tranexamic acid 250 mg twice daily, and patients in group B applied topical 5% tranexamic acid to designated sites on their faces twice daily, along with sunscreen three times daily in both groups. Clinical evaluation with MASI score of melasma was performed at baseline at 4 weeks and 12 weeks.

**Melasma severity is assessed by three variables:**

1. A-percentage of total area involved on a scale of 0 (no involvement) to 6 (90–100% involvement).
2. D-darkness on a scale of 0 (absent) to 4 (maximum)

3. H-homogeneity hyperpigmentation on a scale of 0 (minimal) to 4 (maximum) now.
4. MASI is then calculated by the equation:  $(DF+HF) AF + 0.3 (DMR+HMR) AMR + 0.1 (DC+HC) AC$ .

#### Inclusion Criteria

Patients willing to give written informed consent and Patients willing for follow up

#### Exclusion Criteria

1. Pregnant females.
2. Women taking contraceptive pills during studies.
3. Patients taking drugs like tetracycline, non-steroidal anti-inflammatory drugs, phenytoin, and spironolactone.
4. Patients on anticoagulants or having any bleeding disorders.
5. Patients have impaired renal function test.

#### Results

**Table 1: Age distribution**

Age (years)	Group-A (oral TXA)	Group-B (Topical TXA)
≤ 30	7	4
31-40	12	10
41-50	5	8
> 50	1	3

**Table 2: Sex distribution**

Gender	Group-A (oral TXA)	Group-B (Topical TXA)
Female	21 (84%)	23 (92%)
Male	4 (16%)	2 (8%)

**Table 3: Pattern of melasma**

Pattern	Group-A (oral TXA)	Group-B (Topical TXA)
Centrofacial (I)	17	19
Malar (II)	8	5
Mandibular (III)	0	1

**Table 4: The mean MASI score of the baseline and all reassessment visits after treatment with oral TXA VS Topical TXA**

	Group-A (oral TXA)	Group-B (Topical TXA)
Pre MASI score	21.50	19.45
MASI at 4 Weeks	12.55	15.83
MASI at 12 Weeks	7.19	11.30
P value	0.000	0.000

**Table 5: The amount of changes in the mean MASI score of each group**

GROUP	Baseline- 4 weeks	Baseline- 12 weeks
Group-A (oral TXA)	8.95	14.31
Group-B (Topical TXA)	3.62	8.14

We included 50 patients in our study, of which 44 were females and 6 were males. 11 patients were younger than or equal to 30, 22 patients were in the age group of 31-40 and 17 patients were more than 41. The patients were categorised into two groups. Group A – oral tranexamic acid 250 mg twice daily, whereas Group B – topical 5% tranexamic acids for 12 weeks. The mean MASI score at baseline with oral TXA and topical TXA was 21.50 and 19.45, respectively, which by the end of the 12th week

reached 7.19 and 11.30 (table-4). The changes in the MASI scores of both groups were statistically significant during the study period. But the fall in mean MASI score was more in patient taking oral TXA than those who applied topical TXA. Systemic side effects, gastritis seen in 2 patients and oligomenorrhea reported by 1 patient. Erythema and skin irritation reported by 2 patients after topical application. No change in coagulation parameter was seen.



**Figure 1: Patient treated with oral tranexamic acid – before and after treatment**



**Figure 2: Patient treated with topical tranexamic acid – before and after treatment**

## Discussion

Tranexamic acid (trans 4 aminomethylcyclohexanecarboxylic acid) is a plasmin inhibitor used to prevent abnormal fibrinolysis to reduce blood loss.[7] It has been hypothesised that TXA can inhibit the release of paracrine melanogenic factors that normally stimulate melanocytes. The usual effective dose for melasma is 250–500 mg 2–3 times daily, which is much lower than the dose to reduce bleeding. In study by Vinod K. Khurana et al, the mean MASI score at the 12th week with oral tranexamic acid was  $3.18 \pm 1.93$ , and the p value was highly significant.[8] In the study by Bahareh Ebrahimi et al mean MASI score at the 12th week in patients receiving topical TXA is  $10.76 \pm 9.43$  which means that with the use of topical TXA, a reduction in MASI score was observed.[9] In our study of 50 patients, the mean MASI score at 12 weeks after starting treatment in patients who received oral tranexamic acid was 7.19 and in patients receiving topical tranexamic acid was 11.30. Both groups had a reduction in MASI score, and the p value in both groups is 0.000, which is highly significant. Few

Side effects were noted in both the groups but the usually subside after cessation of therapy.

## Conclusion

The melasma area and severity index scores showed a significant decrease in baseline to the end of 12th week in both the arms. But a comparative analysis suggested that results were better with oral tranexamic acid than topical tranexamic acid. Patient compliance was higher with oral tranexamic acid.

## Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms

**Financial support and sponsorship:** Nil.

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