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Original Research

Evaluation of therapeutic efficacy of oral tranexamic acid in Melasma

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ABSTRACT:

Background: Melasma, formerly known as chloasma, is an acquired pigmentary condition, occurring most commonly on the face. Tranexamic acid (TXA) (Trans-4-Aminomethylcyclohexane-carboxylic acid) is a synthetic derivative of the amino acid lysine. It binds reversibly to the lysine binding sites on plasminogen molecules and inhibits plasminogen activator (PA) and thus the conversion of plasminogen to plasmin. The present study was conducted for assessing the evaluating the therapeutic efficacy of oral tranexamic acid in Melasma. **Materials & methods:** 20 patients of facial Melasma were enrolled from outpatient. Diagnosis was based on history and clinical examination. They were randomly divided into 2 groups of 10 patients each. Group A received oral tablet tranexamic acid in a dose of 250 mg twice daily for 12 weeks. Group B patients were given tranexamic acid solution transepidermally into the melasma lesions using a dermaroller. Patients were evaluated using the Melasma Area and Severity Index (MASI) score for assessing the primary outcome measure. It was determined at the baseline and at the end of 4, 12, and 24 weeks. All the results were recorded and were analyzed using SPSS software. **Results:** Mean age of the patients of Group A and group B was 23.8 years and 24.8 years respectively. Among Group A, at baseline, mean MASI score at baseline, 4 weeks, 12 weeks and 24 weeks was 11.84, 9.13, 4.16 and 3.39 respectively. Among Group B, at baseline, mean MASI score at baseline, 4 weeks, 12 weeks and 24 weeks was 12.29, 9.95, 5.13 and 3.94 respectively. Significant improvement was seen among patients of group A and group B. However; doing intergroup comparison, non-significant results were obtained. While comparing the outcome, non-significant results were obtained. **Conclusion:** Oral and transepidermal TXA appear equally effective suggesting that the efficacy of TXA is perhaps independent of its route of administration.

Key words: Tranexamic acid, Melasma

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INTRODUCTION

Melasma, formerly known as chloasma, is an acquired pigmentary condition, occurring most commonly on the face. This disorder, which is more prevalent in females and darker skin types, is predominantly attributed to ultraviolet (UV) exposure and hormonal influences. Melasma is generally a clinical diagnosis consisting of symmetric reticulated hypermelanosis in three predominant facial patterns: 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 on the face, while mandibular melasma is present on the jawline and chin. The latter is thought to occur in older individuals and may be more related to severe photodamage.[1-3]

Tranexamic acid (TXA) (Trans-4-Aminomethylcyclohexane-carboxylic acid) is a synthetic derivative of the amino acid lysine. It binds reversibly to the lysine binding sites on plasminogen molecules and inhibits plasminogen activator (PA) and thus the conversion of plasminogen to plasmin. Plasminogen also exists in the basal epidermal cells and keratinocytes and induction of this keratinocyte-PA system by UV exposure results in melanogenesis through production of prostaglandins and leukotrienes. It is through prevention of binding of plasminogen to keratinocyte, TA inhibits UV-induced plasmin activity in keratinocytes, thereby decreasing melanogenesis through reduced production of PGs.[4-6] Hence; the present study was conducted for assessing the evaluating the therapeutic efficacy of oral tranexamic acid in Melasma.

MATERIALS & METHODS

The present study was conducted for assessing the evaluating the therapeutic efficacy of oral tranexamic acid in Melasma. 20 patients of facial Melasma were enrolled from outpatient. Diagnosis was based on history and clinical examination.They were randomly divided into 2 groups of 10 patients each. Group Areceived oral tablet tranexamic acid in a dose of 250 mg twice daily for 12 weeks. Group B patients were given tranexamic acid solution transepidermally into the melasma lesions using a dermaroller. Patients were evaluated using the Melasma Area and Severity Index (MASI) score for assessing the primary outcome measure. It was determined at the baseline and at the end of 4, 12, and 24 weeks. All the results were recorded and were analyzed using SPSS software.

RESULTS

Mean age of the patients of Group A and group B was 23.8 years and 24.8 years respectively. Among Group A, at baseline, mean MASI score at baseline, 4 weeks, 12 weeks and 24 weeks was 11.84, 9.13, 4.16 and 3.39 respectively. Among Group B, at baseline, mean MASI score at baseline, 4 weeks, 12 weeks and 24 weeks was 12.29, 9.95, 5.13 and 3.94 respectively. Significant improvement was seen among patients of group A and group B. However; doing intergroup comparison, non-significant results were obtained. While comparing the outcome, non-significant results were obtained.

Table 1: Comparison of MASI score

Time intervals	Group A	Group B	p-value
Baseline	11.84	12.29	0.12
4 weeks	9.13	9.95	0.28
12 weeks	4.16	5.13	0.22
24 weeks	3.39	3.94	0.95
p-value	0.001*	0.000*	-

Table 2: Comparison of percentage improvement

Percentage improvement	Group A		Group B	
	Number	Percentage	Number	Percentage
Mild	1	10	1	10
Moderate	1	10	1	10
Good	2	20	3	30
Very good	6	60	5	50
Total	10	100	10	100
p-value	0.122			

DISCUSSION

Melasma is a common acquired pigmentary skin disorder characterized by a symmetrical macular pigmentation of sun-exposed areas like the face. The three major patterns of pigmentation in melasma are centrofacial (cheeks, forehead, upper lip, and nose), malar (cheeks and nose), and mandibular (mandibular area of cheeks). Melasma affects females much more commonly than males and majority of patients are in the third and fourth decades of their life. Several factors such as genetics, sunlight, cosmetics, pregnancy, hormonal treatments, thyroid dysfunction, and drugs have been implicated in the pathogenesis of melasma.The treatment of melasma includes various topical and/or systemic agents.[7- 9]Tranexamic acid, a synthetic version of lysine and a hemostatic agent, has been increasingly used in the topical, oral, and injectable forms to treat melasma. Studies have demonstrated occasional negative findings when used as a monotherapy, but increased efficacy when used in combination with other pigmentation-based therapies. The topical formulation of tranexamic acid, however, has had limited success and less efficacy than when used in oral form. Topical flutamide, an antiandrogenic agent, has also been studied in comparison to HQ 4%, and was found to have statistically significant MASI scores and patient satisfaction; however, no difference in the mexameter melanin assay was observed between the two groups.[10- 12]Hence; the present study was conducted for assessing the evaluating the therapeutic efficacy of oral tranexamic acid in Melasma.

Mean age of the patients of Group A and group B was 23.8 years and 24.8 years respectively. Among Group A, at baseline, mean MASI score at baseline, 4 weeks, 12 weeks and 24 weeks was 11.84, 9.13, 4.16 and 3.39 respectively. Among Group B, at baseline, mean MASI score at baseline, 4 weeks, 12 weeks and 24 weeks was 12.29, 9.95, 5.13 and 3.94 respectively. Significant improvement was seen among patients of group A and group B. However; doing intergroup comparison, non-significant results were obtained. While comparing the outcome, non-significant results were obtained.TXA is available as 5 mL ampoule containing 500 mg of the drug. In a study conducted by Budamakuntla et al in Bangalore, 60 patients were enrolled; 30 in each treatment arm. Thirty patients were administered with localised microinjections of TA in one arm, and other 30 with TA with microneedling. The procedure was done at monthly intervals (0, 4 and 8 weeks) and followed up for three consecutive months. In the microinjection group,

there was 35.72% improvement in the MASI score compared to 44.41% in the microneedling group, at the end of third follow-up visit. Six patients (26.09%) in the microinjections group, as compared to 12 patients (41.38%) in the microneedling group, showed more than 50% improvement. However, there were no major adverse events observed in both the treatment groups.[13] A study conducted by Lee et al enrolled 10 patients in a prospective split face trial lasting 12 weeks. One side of the face received tranexamic acid 4 mg/ml while the other side received placebo(normal saline solution). Patients were given weekly treatment with a dermaroller. The MASI score showed a decreasing trend as the treatment continued.[14]In another study conducted in Korea on melasma patients, TXA was directly administered intradermally (4 mg/mL) weekly for a period of 12 weeks. More than 75% patients experienced a statistically significant improvement.[15]

CONCLUSION

Oral and transepidermal TXA appear equally effective suggesting that the efficacy of TXA is perhaps independent of its route of administration.

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