ORIGINAL RESEARCH

Comparison of oral versus intralesional tranexamic acid in melasma

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ABSTRACT

Background: A chronic acquired hypermelanosis of the skin, melasma is characterized by uniformly distributed muddy brown macules on sun-exposed areas of the body, particularly the face. The edges of the lesions are serrated, and they are frequently limited to the face, including the cheeks. The present study was conducted to assess the oral versus intradermal Tranexamic acid infusion for the treatment of melasma.

Materials & Methods:78 patients of melasma of both genderswere divided into 2 groups of 39 each. Patients in group I were given tablet tranexamic acid (250 mg) twice daily for 3 months. In group II, patients were administered intradermal injections of tranexamic acid.

Results: Depth was dermal in 8 and 7, and epidermal in 11 and 13 patients and mixed in 20 and 19 patients in group I and II respectively. Fitzpatrick type II was seen in 5 and 7, III in 23 and 22, and IV in 11 and 10 patients in group I and II respectively. Pattern was Centrofacial in 24 and 20, mandibular in 17and 18 and dermal in 10 and 12 patients in group I and II respectively. The difference was non- significant ($P > 0.05$). In group I and group II, the mean MASI score at 1st sitting was 4.78 and 4.64, at 2nd sitting was 3.02 and 3.74, at 3rd sitting was 2.12 and 2.36, at 4th sitting was 2.14 and 2.75, at 5th sitting was 1.84 and 1.34 and at 6th sitting was 2.03 and 2.52 respectively. The difference was significant ($P < 0.05$).

Conclusion: For the treatment of melasma, tranexamic acid is a medication that is both safe and well tolerated. Melasma can be effectively administered orally or intradermally. The mean MASI scores for both Group 1 and Group 2 significantly decreased from the first to the fifth sitting, indicating that the severity of their melasma improved over time. However, because the MASI scores for each group was consistent, there were no appreciable variations in the magnitude of this improvement between the two groups.

Keywords: tranexamic acid, MASI, melasma

Introduction

A chronic acquired hypermelanosis of the skin, melasma is characterized by uniformly distributed muddy brown macules on sun-exposed areas of the body, particularly the face. The edges of the lesions are serrated, and they are frequently limited to the face, including the cheeks.[1] They also extend to the dorsum of the nose, the temple (especially the area above the eyebrows), and the upper lip, excluding the area beneath the nose. Between 50% and 70% of pregnant women have it. Melasma affects between 20.55% and 25.83% of Indian men. In the great majority of nations, the precise prevalence of melasma is unknown. The illness affects people of all races and ethnicities.[3]

Few men can be impacted, although the majority of cases occur in females. Centro-facial, malar, and mandibular are common clinical patterns found. The types of melasma reported are mixed, ambiguous, dermal, and epidermal, according to Wood's lamp examination.

The initiation of hyperpigmentation has been linked to several routes. A genetic predisposition, exposure to UV light, and hormonal impacts are examples of etiologic causes.[3] Although the precise pathophysiology is still unknown, melanin pigment alterations are implicated. Melasma develops as a result of increased melanogenesis, alterations in the extracellular matrix, inflammation, and angiogenesis. Its multifactorial nature makes it prone to recurrence. Hydroquinone, retinoic acid, kojic acid, azelaic acid, rucinol, chemical strips, laser treatment, dermabrasion, L-ascorbic acid, zinc, and other therapeutic methods have all been tried to cure melasma, but the results are inconsistent and the recurrence rate is significant.[4] Although tranexamic

acid was recently licensed for the treatment of melasma, consistent outcomes have been inconsistent. By disrupting the structure of the plasminogen molecules, tranexamic acid, a lysine analogue, stops plasminogen from attaching to the lysine-binding site.[5]

The present study was conducted to assess the oral versus intradermal Tranexamic acid infusion for the treatment of melasma.

Materials & Methods

The present study was conducted on 78 patients of melasma of both genders. All were informed regarding the study and their written consent was obtained.

Data such as name, age, gender etc. was recorded. All patients were divided into 2 groups of 39 each. Patients in group I were given tablet tranexamic acid (250 mg) twice daily for 3 months. In group II, patients were administered intradermal injections of tranexamic acid. To obtain a concentration of roughly 2.5 mg/unit (5 mg/ml) of tranexamic acid, 2 U of the drug was drawn in a 40 U/ml 30-gauge insulin syringe and diluted with regular saline up to 1 ml (the remaining 38 U out of 40 U). Following topical anesthetic treatment, intradermal injections were administered at the melasma site at a distance of approximately 1 cm from one another, with a maximum of 8 mg administered in a single session. Three similar sessions were conducted at one-month intervals. For the following six months, a number of stringent photoprotection measures were recommended. The patient was clinically assessed using the modified MASI score. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

Results

Table: I Assessment of parameters

Parameters	Variables	Group I (39)	Group II (39)	P value
Depth	Dermal	8	7	0.87
	Epidermal	11	13	
	Mixed	20	19	
Fitzpatrick skin type	II	5	7	0.94
	III	23	22	
	IV	11	10	
Pattern	Centrofacial	24	20	0.75
	Mandibular	17	18	
	Dermal	10	12	

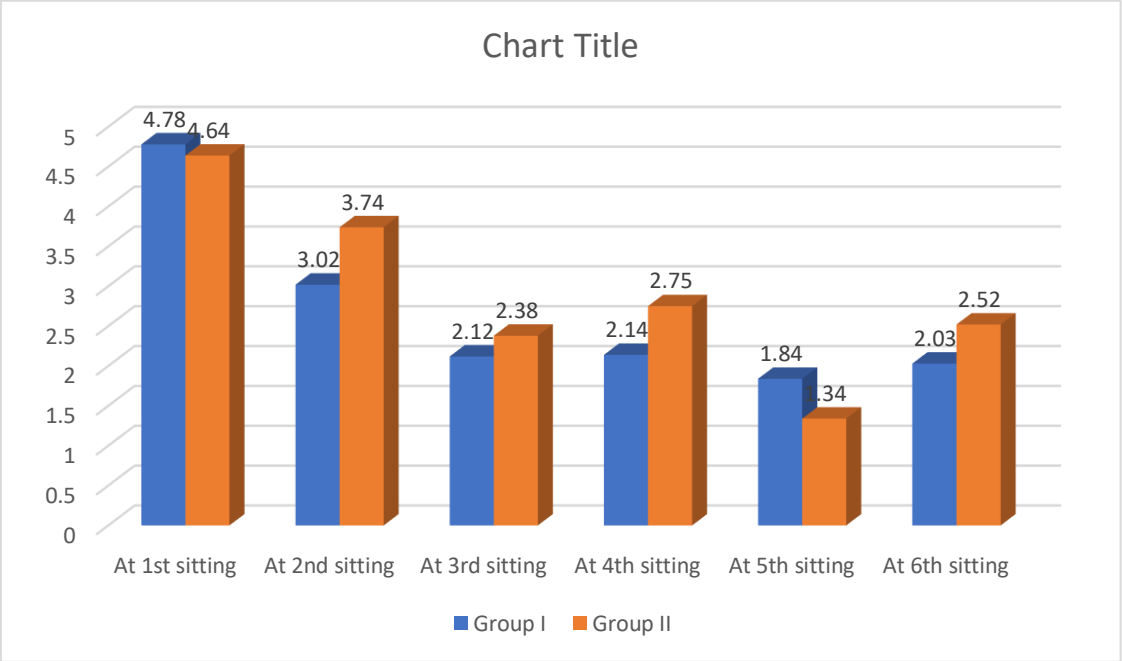
Table I shows that depth was dermal in 8 and 7, and epidermal in 11 and 13 patients and mixed in 20 and 19patientsin group I and II respectively. Fitzpatrick type II was seen in 5 and 7, III in 23 and 22, and IV in 11 and 10 patients in group I and II respectively. Pattern was Centrofacial in 24 and 20, mandibular in 17 and 18 and dermal in 10 and 12 patients in group I and II respectively. The difference was non- significant (P> 0.05).

Table: II Severity Index (MASI) score

Duration	Group I	Group II	P value
At 1st sitting	4.78	4.64	0.05
At 2nd sitting	3.02	3.74	
At 3rd sitting	2.12	2.38	
At 4th sitting	2.14	2.75	
At 5th sitting	1.84	1.34	
At 6th sitting	2.03	2.52	

Table II, graph I shows that in group I and group II, the mean MASI score at 1st sitting was 4.78 and 4.64, at 2nd sitting was 3.02 and 3.74, at 3rd sitting was 2.12 and 2.36, at 4th sitting was 2.14 and 2.75, at 5th sitting was 1.84 and 1.34 and at 6th sitting was 2.03and 2.52 respectively. The difference was significant (P< 0.05).

Graph: I Severity Index (MASI) score



Discussion

A symmetric hyperpigmentation condition that develops gradually is melasma. Amorphous brown spots known as melasma lesions mostly impact the mandibular, malar, and centrofacial facial patterns. According to several studies, the general population's overall melasma prevalence was estimated to be between 1 and 50%.[6,7] UV radiation exposure and female hormone activity are the two primary risk factors for melasma development. A positive family history has also been identified as a risk factor in 55–64 percent of cases. Melasma can be treated in a number of ways, including topical treatments, oral drugs, laser ablation, mesotherapy, microinjections, and combination therapies.[8] Topical hydroquinone (HQ) is the gold standard for treating melasma lesions that have a high recurrence rate.However, tranexamic acid (TA), a recently approved new therapy for melasma, is the only drug that can prevent melanocytes from being activated by hormones and sunlight. TA is commonly used at different concentrations in oral, topical, and intradermal administration solutions.[9]The present study was conducted to assess the oral versus intradermal Tranexamic acid infusion for the treatment of melasma.

We found that depth was dermal in 8 and 7, and epidermal in 11 and 13 patients and mixed in 20 and 19patients in group I and II respectively. Fitzpatrick type II was seen in 5 and 7, III in 23 and 22, and IV in 11 and 10 patients in group I and II respectively. Pattern was Centrofacial in 24 and 20, mandibular in 17and 18 and dermal in 10 and 12 patients in group I and II respectively. Ayuthaya et al[10] assessed the efficacy and safety of topical tranexamic acid (TA) for the treatment of melasma is limited. Twenty-three women with bilateral epidermal melasma enrolled in a split-face trial lasting 12 weeks. Patients blindly applied topical 5% tranexamic acid and its vehicle, to the designated sides of the face twice daily in addition to the assigned sunscreen each morning. Pigmentation and erythema were measured objectively using a mexameter and Melasma Area and Severity Index (MASI), in addition to physician and patient global assessments.Twenty-one patients completed the study. Eighteen out of twenty-three patients (78.2%) showed decrease in the melanin index on either or both sides of the face by the end of 12 weeks compared to baseline. The MASI scores were also significantly reduced on both tested sides. However, lightening of pigmentation induced by TA gel was neither superior nor different ($p > 0.05$) compared to its vehicle although erythema was significant on the TA-applied site ($p < 0.05$).Although lightening of pigmentation was obtained, the results were not significant between the two regimens. However, topical TA produced erythema.

We found thatin group I and group II, the mean MASI score at 1st sitting was 4.78 and 4.64, at 2nd sitting was 3.02 and 3.74, at 3rd sitting was 2.12 and 2.36, at 4th sitting was 2.14 and 2.75, at 5th sitting was 1.84 and 1.34 and at 6th sitting was 2.03and 2.52 respectively. Lee et al[11]evaluated the efficacy and side effects of this potentially new method for the treatment of melasma. A total of 100 women with melasma, after written consent, were enrolled for a prospective open pilot study of 12 weeks. After applying topical anesthesia, 0.05 mL TA (4 mg/mL) was injected intradermally into the melasma lesion at 1 cm intervals by using a 0.5 mL insulin syringe with a 30-gauge needle. This was repeated weekly for 12 weeks. A clinical investigator evaluated the results by using the Melasma Area and Severity Index (MASI) at baseline and at 4, 8, and 12 weeks. The patient

satisfaction questionnaire was documented at 12 weeks. Safety evaluations were performed at each follow-up visit.Eighty-five patients completed the trial. A significant decrease in the MASI from baseline to 8 and 12 weeks was observed (13.22+/-3.02 vs 9.02+/-2.62 at week 8 and vs. 7.57+/-2.54 at week 12; p<.05 for both). The patients' self-assessment of melasma improvement was as follows: 8 of 85 patients (9.4%) rated as good (51-75% lightening), 65 patients (76.5%) as fair (26-50% lightening), and 12 patients (14.1%) as poor (0-25% lightening). Side effects were minimal and all the patients tolerated the treatment well.
The shortcoming of the study is small sample size.

Conclusion

For the treatment of melasma, tranexamic acid is a medication that is both safe and well tolerated. Melasma can be effectively administered orally or intradermally. The mean MASI scores for both Group 1 and Group 2 significantly decreased from the first to the fifth sitting, indicating that the severity of their melasma improved over time. However, because the MASI scores for each group was consistent, there were no appreciable variations in the magnitude of this improvement between the two groups.

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