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EVALUATION OF THE EFFICACY AND SAFETY FOR THE COMBINATION USE OF ORAL AND TOPICAL TRANEXAMIC ACID IN THE TREATMENT OF MELASMA AT HO CHI MINH CITY DERMATOLOGY HOSPITAL

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ABSTRACT

Objective: To evaluate the effectiveness and safety of oral and topical tranexamic acid in the treatment of melasma.

Subjects and methods: A descriptive study of a series of cases with longitudinal follow-up was conducted on 28 female patients with melasma at the Ho Chi Minh City Dermatology Hospital from April 2024 to August 2024.

Results: The study subjects had an average age of 47.46 ± 8.23 (34 - 63) years old, 78.57% had a family history of melasma. The assessment of melasma improvement according to the PGA scale showed that 100% of patients had melasma improvement of over 25% (50.00% had good improvement of 51-75%). MASI index had a significant improvement after treatment compared to before treatment with statistical significance with p<0.001. All patients were satisfied after treatment with 57.14% of patients being very satisfied, 92.86% having no side effects.

Conclusion: Oral and topical tranexamic acid is an effective and safe method for treating melasma.

Keywords: tranexamic acid, oral and topical, melasma.

1. INTRODUCTION

Melasma is a common benign hyperpigmentation condition worldwide, characterized by brown to gray-brown or black patches on the face, particularly on both cheeks. The disease frequently occurs in women with darker skin types, such as those from Asia, Latin America, the Middle East, and Africa, with a prevalence ranging from 9-40% of the population [1]. Treating melasma remains a challenge due to its complex pathogenesis, chronic progression, and high recurrence rate. In most cases, combined therapies yield better results than monotherapy. Therefore, many clinicians opt for multimodal treatments for melasma patients. Tranexamic acid is a synthetic lysine derivative that has hemostatic effects and has been FDA-approved for various indications [2]. Tranexamic acid represents a new advancement in melasma treatment and in managing telangiectasia in melasma lesions by inhibiting plasminogen activation, thereby preventing the synthesis of melanin and blood vessel proliferation under UV radiation [3]. Numerous studies worldwide have demonstrated that both oral and topical tranexamic acid are truly effective and safe in treating melasma [4]. In Vietnam, tranexamic acid has been widely used in melasma treatment in recent years. However, there are no comparative data regarding the effectiveness and safety between topical and oral tranexamic acid. Hence, we conducted this study titled, "Evaluation of the efficacy and safety of topical and oral tranexamic acid in the treatment of melasma at Ho Chi Minh City Dermatology Hospital".

2. SUBJECTS AND METHODS

2.1. Study subjects: Female patients over 18 years of age, who visited and were indicated for melasma treatment at the Department of Dermatology and Aesthetic Surgery at Ho Chi Minh City Dermatology Hospital from April 2024 to August 2024 and agreed to participate in the study.

2.2. Study methods:

- Study design: Descriptive study of a series of cases.

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- Sample size and selection: All melasma patients indicated for treatment with 3% tranexamic acid topical application twice daily (morning and evening), combined with 250 mg oral tranexamic acid twice daily (morning and evening). In total, 28 patients were collected.

** Inclusion criteria:*

+ Female patients over 18 years old.

+ No prior melasma treatment in the past 3 months.

+ Patients who agreed to participate in the study.

** Exclusion criteria:*

+ Currently using birth control pills, pregnant, or breast-feeding.

+ Patients undergoing treatment for chronic diseases, with a history of thrombosis, coagulation disorders, photosensitive skin diseases, infections, or malignancies.

+ Patients with other pigmentation disorders on the cheeks.

+ Patients allergic to any components of the medication.

+ Patients who did not adhere to the treatment or missed follow-up appointments.

2.3. Data collection method

Patients visiting the Department of Dermatology and Aesthetic Surgery at Ho Chi Minh City Dermatology Hospital from April 2024 to August 2024, after being diagnosed with melasma and meeting the study's inclusion criteria, were counseled and explained the study objectives and procedures. If the patients agreed to participate, they signed a consent form.

Examinations were performed to determine clinical characteristics.

Assessment of PGA and MASI scores.

Photographs and analysis using the VISIA machine.

Medication dispensing: Patients were given topical and oral medication and instructions on how to apply it.

Follow-up appointments were scheduled after 4 weeks.

At the follow-up visit, clinical examinations were conducted, and data on PGA, MASI scores, VISIA machine analysis parameters, and any side effects during treatment were collected.

Assessment of effectiveness, side effects, and patient satisfaction was done by comparing pre-treatment and post-treatment scores.

2.4. Data analysis:

Data was processed using SPSS 22 software. Descriptive statistics used frequency and percentage. Some quantitative variables were described using mean and standard deviation. For analytical statistics, the Wilcoxon Signed Ranks Test was used with a 95% confidence interval.

2.5. Research ethics:

The study was approved by the Ethics Committee of Pham Ngoc Thach Medical University according to decision No. 402/CN-BVDL, signed on January 29, 2024.

3. RESULTS

3.1. General characteristics of the study subjects

Table 1. General characteristics of the study subjects

Characteristics		Quantity	Percentage (%)
Mean age (years)		47.46 ± 8.23 (34 – 63)	
Family history of melasma	Yes	22	78.57
	No	6	21.43
Duration of melasma (years)		8.71 ± 6.62 (1-24)	
Sun exposure (hours/day)		1.96 ± 1.20 (1 – 4)	
Sunscreen usage	Yes	21	75.00
	No	7	25.00
Telangiectasia	Yes	19	67.86
	No	9	32.14
Clinical presentation of melasma	Butterfly pattern	18	64.29
	Central facial pattern	10	35.71
	Mandibular pattern	0	0.00
	Mixed pattern	0	0.00

Comment: All study subjects were female, with an average age of 47.46 ± 8.23 years (34 – 63 years). 78.57% had a family history of melasma. The average duration of melasma was 8.71 ± 6.62 years, ranging from 1 to 24 years. 75% of the subjects had the habit of using sunscreen, while 25% did not. 67.86% had telangiectasia, with the most common clinical presentation being the butterfly pattern (64.29%), followed by the central facial pattern (35.71%). No cases of mandibular or mixed pattern were detected.

3.2. Treatment outcomes

Table 2. Assessment of treatment outcomes using the PGA scale after treatment

Score	Improvement level (%)	Quantity	Percentage (%)
0	Minimal improvement (0-25)	0	0.00
1	Moderate improvement (26-50)	4	14.29
2	Good improvement (51-75)	14	50.00
3	Excellent improvement (76-100)	10	35.71
Total	28	100,0	

Comment: The assessment of melasma improvement using the PGA scale showed that 100% of patients had melasma improvement of more than 25%. Among them, 50.00% had good improvement (51-75%), 35.71% had excellent improvement (76-100%), and 14.29% had moderate improvement (26-50%).

Table 3. Comparison of MASI scores before and after treatment

Time point	Mean±SD	Medi-an	Min - Max	p
Before treatment	19.65 ± 8.18	18.60	9.6 - 40.8	<0.001
After treatment	7.46 ± 5.81	6.00	2.4 - 28.8	

Comment: We observed a significant improvement in the MASI score after treatment, with the mean score before treatment being 19.65 ± 8.18, much higher than the post-treatment score of 7.46 ± 5.81. The difference was statistically significant with $p < 0.001$.

Table 4. Patient satisfaction after treatment

Satisfaction level	Quantity	Percentage (%)
Not satisfied	0	0.00
Moderately satisfied	0	0.00
Moderately satisfied	6	21.43
Satisfied	6	21.43
Very satisfied	16	57.14
Total	28	100.00

Comment: Patient satisfaction assessment showed that 57.14% of patients were very satisfied, 21.43% were satisfied, and 21.43% were moderately satisfied. No patients were dissatisfied or slightly satisfied after treatment.

Table 5. Safety of the treatment using topical and oral tranexamic acid

Side effects	Quantity	Percentage (%)
Menstrual disorder	1	3.57
Gastrointestinal distur-bance	1	3.57
None	26	92.86
Total	28	100.0

Comment: After 4 weeks of treatment in 28 patients, we recorded only 1 case of menstrual disorder and 1 case of gastrointestinal disturbance, while 26 patients (92.86%) did not experience any side effects.

4. DISCUSSION

4.1. General characteristics of the study subjects

Our study's participants were all female, with an average age of 47.46 ± 8.23 years, which is similar to the results of Lê Thái Vân Thanh (2023), who studied 32 female patients with an average age of 43.6 ± 9.3 years. In that study, 53.1% of the patients frequently wore face masks [5].

In this study, 67.86% of the patients exhibited telangiectasia, with the most common clinical presentation being the butterfly pattern (64.29%), followed by the central facial pattern (35.71%). No cases of the mandibular pattern were detected. In contrast, in another study by Luu Truc Linh, the central facial pattern accounted for the highest proportion (50.5%), followed by the mixed pattern (22.7%) and the butterfly pattern (21.6%), while the mandibular pattern accounted for the lowest proportion (5.2%) [6].

4.2. Treatment outcomes

The assessment of melasma improvement using the PGA scale in our study showed that 100% of patients experienced more than 25% improvement, with 50.00% showing good improvement (51-75%). These results are similar to those of Aaron Tan, who observed a statistically significant reduction in melasma after 3 months of combined therapy. However, Tan noted that there was a recurrence of melasma in 72% of patients after discontinuing the medication for 2 months [7].

We also found a significant improvement in the MASI score, with the post-treatment mean score being 7.46 ± 5.81, much lower than the pre-treatment score of 19.65 ± 8.18, and the difference was statistically significant ($p < 0.001$). Similarly, J. Na also observed a significant reduction in the MASI score in melasma-affected areas after combined oral and topical tranexamic acid treatment [8].

The majority of our patients (57.14%) were very satisfied with the treatment outcome after 4 weeks, with no patients reporting low satisfaction or dissatisfaction. Tranexamic acid has been shown to be effective not only in melasma treatment but also in treating other pigmentation disorders. In a study by Lee, tranexamic acid was used to treat post-inflammatory hyperpigmentation due to allergic contact dermatitis from henna hair dye, and the results showed significant pigmentation improvement after 10 weeks, with patients expressing high satisfaction [9].

We recorded only 2 cases (7.14%) of side effects (1 case of menstrual disorder and 1 case of gastrointestinal disturbance). The safety of tranexamic acid has also been evaluated in a comprehensive review by Perper, who concluded that tranexamic acid is as effective, or even more effective, than other standard therapies for melasma, with fewer side effects [10].

5. CONCLUSION

Through our research, we found that the combination of topical and oral tranexamic acid is an effective and safe method for treating melasma.

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