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Research Article

Comparative Efficacy of Topical Tretinoin 0.05% Versus Azelaic Acid 10% in Epidermal Melasma

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ABSTRACT

Background: Melasma is a common acquired disorder of facial hyperpigmentation that predominantly affects women and usually involves sun-exposed areas of the face. Since the pigment is primarily contained in the superficial epidermal layers, epidermal melasma tends to respond well to topical therapy. Topical agents such as tretinoin and azelaic acid are generally used and their relative effectiveness may differ depending on skin type, sun exposure and tolerance.

Objective: To compare the efficacy of topical tretinoin 0.05% and azelaic acid 10% in patients with epidermal melasma.

Methodology: This comparative clinical study was conducted in the Department of Dermatology, Hayatabad Medical Complex, Peshawar, from January 2021 to July 2022. The study compared the efficacy and tolerability of topical tretinoin 0.05% with azelaic acid 10% in patients with epidermal melasma. A total of 77 patients fulfilling the inclusion and exclusion criteria were enrolled. Patients were randomly allocated by lottery method into two groups: the tretinoin group received topical tretinoin 0.05%, while the azelaic acid group received topical azelaic acid 10%. There were 39 patients in the tretinoin group and 38 patients in the azelaic acid group. Melasma severity was evaluated using Melasma Area and Severity Index score at baseline and at 4, 8 and 12 weeks of treatment. The outcomes measured included treatment response, percentage reduction in MASI score, patient satisfaction and local adverse effects. Data were analyzed by SPSS 25 software and p-value was considered significant when ≤ 0.05.

Results: The mean age of patients was 32.64 ± 6.18 years in the tretinoin group and 33.21 ± 5.94 years in the azelaic acid group. Baseline MASI score was comparable between the groups. After 12 weeks, the mean MASI score decreased from 12.46 ± 3.18 to 6.21 ± 2.38 in the tretinoin group and from 12.31 ± 3.06 to 7.82 ± 2.56 in the azelaic acid group. The mean reduction and percentage reduction in MASI score were significantly greater in the tretinoin group. Excellent and good responses were more frequent among patients treated with tretinoin. Mild erythema, dryness, peeling, and burning were more common with tretinoin, whereas azelaic acid showed better tolerability.

Conclusion: Topical tretinoin 0.05% and azelaic acid 10% both improved epidermal melasma after 12 weeks of treatment. However, tretinoin 0.05% showed greater reduction in MASI score and better overall response, while azelaic acid 10% had a more favorable tolerability profile. Regular photoprotection and follow-up are important to maintain response and reduce recurrence.

Keywords: Melasma, epidermal melasma, tretinoin, azelaic acid, MASI score, hyperpigmentation

INTRODUCTION

Melasma is an acquired hyperpigmentary disorder characterized by symmetrical brown to gray-brown macules and patches, most commonly affecting the face. It commonly affects the cheeks, forehead, upper lip, nose, and chin, and is more frequently observed in women of reproductive age. Despite the benign nature of melasma, the condition can significantly affect the patient's appearance, especially on the face, and is recurrent in nature, therefore, having a significant cosmetic and psychological impact. It is especially prevalent in those with darker skin phototypes and in populations exposed to areas with high levels of UV (1-3).

The cause of melasma is complex. There are many factors that have been suggested: increased melanocyte activity, increased melanin synthesis, sun exposure (ultraviolet and visible light), hormonal influences, genetic predisposition, inflammation, vascular factors, and impaired skin barrier function. Epidermal melasma is associated with increased melanin deposition in the epidermis, and typically accentuated under Wood's lamp examination. This type usually is more responsive to topical depigmenting agents than dermal or combined melasma, due to the superficial location of the pigment (4-6).

Current treatment of melasma is difficult as there is often a tendency to recur, and individual variation in response to treatment. The primary aims of treatment are to decrease pigmentation, to avoid aggravation, to enhance cosmetic appearance and to minimize relapse. Topical treatments are the most frequently used in the first line of treatment, particularly in epidermal melasma. These include hydroquinone, retinoids, azelaic acid, kojic acid, tranexamic acid, triple-combination creams and other depigmenting agents. All treatments will require strict photoprotection, whether using the treatment or not, since exposure to UVA/UVB and visible light may exacerbate pigmentation and decrease treatment success (7-9).

The topical retinoid tretinoin has been used in the treatment of melasma, because it stimulates epidermal turnover, helps to disperse melanin granules and aids the removal of the pigment-containing keratinocytes. It could also enhance penetration of other topical medications when used in combination therapy. Local irritation, erythema, peeling, dryness and burning sensation, however, can occur with the use of tretinoin and may contribute to non-compliance. Inflammation plays a key role in clinical importance of irritation in melasma, particularly in darker skin types; where inflammation may lead to post-inflammatory hyperpigmentation (10).

Another topical agent that can be used for pigmentary disorders is azelaic acid. Its primary activity is by blocking tyrosinase activity and abnormal melanocyte function. It also contains anti-inflammatory, keratinization normalizing properties. Azelaic acid is generally well tolerated and safe, and thus useful for those that cannot tolerate more irritating topical agents. The improvement may be less extensive and slower, however, compared to retinoids, and there is not yet a lot of local data to compare(11).

Melasma-area and severity index, a tool for assessment of the severity of melasma and therapeutic response, is widely used. It assesses the involved area, darkness, and homogeneity of pigmentation across different facial regions, allowing objective evaluation of treatment response. It also enables objective comparison of therapeutic response before and after treatment (12).

There is a need for local evidence comparing commonly available topical agents for epidermal melasma in routine dermatology practice. Differences in skin phototype, sun exposure, treatment adherence, and sunscreen use may influence response in Pakistani patients. Therefore, the present study was conducted at Hayatabad Medical Complex, Peshawar, to compare the efficacy and tolerability of topical tretinoin 0.05% versus azelaic acid 10% in patients with epidermal melasma. The objective of the study was to determine which treatment produced greater reduction in MASI score after 12 weeks of therapy.

METHODOLOGY

This randomized comparative clinical study was conducted in the Department of Dermatology, Hayatabad Medical Complex, Peshawar, from January 2021 to July 2022. The study compared the clinical efficacy and tolerability of topical tretinoin 0.05% and azelaic acid 10% among patients with epidermal melasma. A total of 77 patients fulfilling the inclusion and exclusion criteria were enrolled during the study period.

The sample size was calculated using the WHO sample size calculator for comparison of two independent means, as the primary outcome variable was the mean MASI score. A 95% confidence level, 80% power, and expected difference in mean MASI score between the two treatment groups were used based on previous literature (13). The calculated sample size was 77 patients, with 39 patients allocated to the tretinoin group and 38 patients allocated to the azelaic acid group.

Inclusion criteria: Patients of either gender, aged 18 to 50 years, with clinically diagnosed epidermal melasma were included in the study. Epidermal melasma was diagnosed on clinical examination and Wood's lamp assessment, where enhancement of pigmentation under Wood's lamp was considered suggestive of epidermal involvement.

Exclusion criteria: Patients with dermal or mixed melasma, pregnancy or lactation, active facial dermatitis, known hypersensitivity to tretinoin or azelaic acid, recent use of topical

depigmenting agents, chemical peels, laser therapy, systemic retinoids, or hormonal therapy were excluded. Patients who were unwilling to complete follow-up visits were also excluded.

Ethical approval was obtained from the Hospital Ethical Review Committee, Hayatabad Medical Complex, Peshawar. Written informed consent was obtained from all participants before enrollment. Confidentiality of patient information was maintained throughout the study, and no personal identifying information was disclosed. Demographic and clinical details, including age, gender, residence, duration of melasma, family history, sun exposure, sunscreen use, and previous treatment history, were recorded on a predesigned proforma. Before initiation of treatment, a baseline clinical assessment was conducted, including MASI scoring. Group A was referred to as the tretinoin group, and Group B was referred to as the azelaic acid group throughout the manuscript.

Patients were randomly allocated into two treatment groups using the lottery method. The tretinoin group included 39 patients and received topical tretinoin 0.05%, while the azelaic acid group included 38 patients and received topical azelaic acid 10%. Both creams were applied once daily at night as a thin layer over the affected facial areas, avoiding the eyes, lips, and nasolabial folds. All patients were advised to use a broad-spectrum sunscreen regularly during the daytime and to avoid excessive sun exposure. They were also instructed not to use any other topical depigmenting agent, chemical peel, laser treatment, or cosmetic procedure during the study period. Due to differences in treatment preparation and the routine clinical setting, blinding was not performed. However, MASI scoring was performed at predefined follow-up visits to reduce assessment variation.

Follow-up assessments were performed at 4, 8, and 12 weeks after starting treatment. At each visit, MASI score was recorded to assess clinical improvement. Adverse effects, including erythema, burning sensation, dryness, peeling, itching, photosensitivity, and treatment discontinuation, were also documented. Treatment efficacy was assessed by comparing MASI scores from baseline to 12 weeks, while the percentage reduction in MASI score was calculated for each patient. Treatment response was categorized as excellent (>75% reduction), good (51–75% reduction), fair (26–50% reduction), and poor (≤25% reduction).

Data were entered and analyzed using SPSS version 25. Quantitative variables such as age, duration of melasma, and MASI score were presented as mean and standard deviation. Categorical variables such as gender, clinical pattern of melasma, treatment response, and adverse effects were presented as frequency and percentage. Independent sample t-test was used to compare mean MASI scores between the two groups, while paired t-test was applied to assess within-group changes from baseline to follow-up. Chi-square test was used to compare categorical variables between the groups. A p-value of ≤0.05 was considered statistically significant.

RESULTS

The study included 77 patients with epidermal melasma. Patients were randomly allocated by lottery method into two intervention groups. The tretinoin group was treated with topical tretinoin 0.05%, while the azelaic acid group was treated with topical azelaic acid 10%. The response to treatment was determined by the change in the MASI score from baseline to the 12-week follow-up.

The mean age of patients was 32.64 ± 6.18 years in the tretinoin group and 33.21 ± 5.94 years in the azelaic acid group. The difference in the average age of both groups was not statistically significant (p = 0.682). The majority of the patients in both groups were in the 31 – 40 year age group. Both groups had a strong female predominance, with 34 (87.2%) females in the tretinoin group and 32 (84.2%) females in the azelaic acid group.

Table 1. Baseline Demographic Characteristics of Patients, n = 77

Variable	Tretinoin 0.05% n = 39	Azelaic Acid 10% n = 38	p-value
Mean age, years	32.64 ± 6.18	33.21 ± 5.94	0.682
20–30 years	13 (33.3%)	12 (31.6%)	0.873
31–40 years	19 (48.7%)	18 (47.4%)	0.906
>40 years	7 (17.9%)	8 (21.1%)	0.727
Male	5 (12.8%)	6 (15.8%)	0.706
Female	34 (87.2%)	32 (84.2%)	0.706
Urban residence	25 (64.1%)	23 (60.5%)	0.744
Rural residence	14 (35.9%)	15 (39.5%)	0.744

The mean duration of melasma was 14.82 ± 6.47 months in the tretinoin group and 15.36 ± 6.91 months in the azelaic acid group, with no statistically significant difference (p = 0.724). The most common pattern of melasma was centrofacial in both groups, observed in 21 (53.8%) patients in the tretinoin group and 19 (50.0%) patients in the azelaic acid group. Moderate-to-severe sun exposure was reported by most patients in both groups, while regular sunscreen use was low, reported by 12 (30.8%) patients in the tretinoin group and 11 (28.9%) patients in the azelaic acid group.

Table 2. Baseline Clinical Characteristics of Melasma

Variable	**Tretinoin 0.05% n = 39**	**Azelaic Acid 10% n = 38**	**p-value**
Duration of melasma, months	14.82 ± 6.47	15.36 ± 6.91	0.724
Centrofacial pattern	21 (53.8%)	19 (50.0%)	0.737
Malar pattern	14 (35.9%)	15 (39.5%)	0.744
Mandibular pattern	4 (10.3%)	4 (10.5%)	0.972
Positive family history	16 (41.0%)	15 (39.5%)	0.888
Moderate-to-severe sun exposure	27 (69.2%)	26 (68.4%)	0.941
Regular sunscreen use	12 (30.8%)	11 (28.9%)	0.859
Previous treatment history	18 (46.2%)	17 (44.7%)	0.898

At baseline, the mean MASI score was 12.46 ± 3.18 (Tretinoin group) and 12.31 ± 3.06 (Azelaic acid group), and the mean was similar (p = 0.835) with both groups having a high degree of severity. After 4 weeks of therapy, the mean MASI score was 10.28 ± 2.91 in the tretinoin group and 10.96 ± 2.84 in the azelaic acid group, at 12 weeks, the mean MASI score was significantly lower in the tretinoin group (6.21 ± 2.38) than in the azelaic acid group (7.82 ± 2.56), with a statistically significant difference (p = 0.006).

Table 3. Comparison of MASI Score Between Both Groups

MASI Score	**Tretinoin 0.05% n = 39**	**Azelaic Acid 10% n = 38**	**p-value**
Baseline MASI score	12.46 ± 3.18	12.31 ± 3.06	0.835
MASI score at 4 weeks	10.28 ± 2.91	10.96 ± 2.84	0.305
MASI score at 8 weeks	8.14 ± 2.63	9.26 ± 2.71	0.070
MASI score at 12 weeks	6.21 ± 2.38	7.82 ± 2.56	0.006
Mean reduction in MASI score	6.25 ± 2.41	4.49 ± 2.28	0.002
Percentage reduction in MASI score	50.16 ± 13.84	36.47 ± 12.96	<0.001

Within-group comparison showed a statistically significant reduction in MASI score from baseline to 12 weeks in both treatment groups. In the tretinoin group, the mean MASI score decreased from 12.46 ± 3.18 to 6.21 ± 2.38, showing a statistically significant reduction (p < 0.001). In the azelaic acid group, the mean MASI score decreased from 12.31 ± 3.06 to 7.82 ± 2.56, also showing a statistically significant reduction (p < 0.001). The reduction was greater in the tretinoin group.

Table 4. Within-Group Reduction in MASI Score

Group	**Baseline MASI**	**12-Week MASI**	**Mean Reduction**	**p-value**
Tretinoin 0.05%	12.46 ± 3.18	6.21 ± 2.38	6.25 ± 2.41	<0.001
Azelaic Acid 10%	12.31 ± 3.06	7.82 ± 2.56	4.49 ± 2.28	<0.001

Treatment response after 12 weeks showed a significantly better response in the tretinoin 0.05% group compared with the azelaic acid 10% group. Excellent response was observed in 9 (23.1%) patients in the tretinoin group and 4 (10.5%) patients in the azelaic acid group. Good response was also higher in the tretinoin group, observed in 18 (46.2%) patients compared with 12 (31.6%) patients in the azelaic acid group.

Fair response was more common in the azelaic acid group 15 (39.5%) compared with the tretinoin group 9 (23.1%). Poor response was also higher among patients using azelaic acid 7 (18.4%) compared with tretinoin 3 (7.7%). The difference in overall treatment response

between the two groups was statistically significant (p = 0.041), showing that topical tretinoin 0.05% produced superior clinical improvement after 12 weeks.

Table 5. Treatment Response After 12 Weeks

Treatment Response	Tretinoin 0.05% n = 39	Azelaic Acid 10% n = 38	p-value
Excellent response >75% reduction	9 (23.1%)	4 (10.5%)	0.041
Good response 51–75% reduction	18 (46.2%)	12 (31.6%)	
Fair response 26–50% reduction	9 (23.1%)	15 (39.5%)	
Poor response ≤25% reduction	3 (7.7%)	7 (18.4%)	

Chi-square test was applied. The p-value represents the overall comparison of treatment response categories between both groups.

With regard to side effects, mild local irritation was more frequent in the tretinoin group. Erythema was observed in 8 (20.5%) patients in the tretinoin group and 4 (10.5%) patients in the azelaic acid group. Patients in the tretinoin group reported burning sensation more frequently (7, 17.9%) than patients in the azelaic acid group (5, 13.2%). Increased dryness and peeling were also reported in the tretinoin group. The majority of side effects were of mild intensity and did not require interruption of the applied treatment. Treatment was discontinued by 2 (5.1%) patients in the tretinoin group and 1 (2.6%) patient in the azelaic acid group. The overall differences in adverse effects were not of statistical significance.

Table 6. Comparison of Side Effects Between Both Groups

Side Effect	Tretinoin 0.05% n = 39	Azelaic Acid 10% n = 38	p-value
Erythema	8 (20.5%)	4 (10.5%)	0.224
Burning sensation	7 (17.9%)	5 (13.2%)	0.566
Dryness	9 (23.1%)	5 (13.2%)	0.261
Peeling	6 (15.4%)	3 (7.9%)	0.307
Itching	4 (10.3%)	3 (7.9%)	0.719
Treatment discontinuation	2 (5.1%)	1 (2.6%)	0.573

Satisfaction of tretinoin group patients was more positive. Overall, 27 (69.2%) patients from the tretinoin group were satisfied with the treatment, while 18 (47.4%) patients from the azelaic acid group were satisfied with the treatment. The difference regarding satisfaction between the two groups was statistically significant (p = 0.049). Good compliance was noted in 33 (84.6%) patients in the tretinoin group and 31 (81.6%) patients in the azelaic acid group, with no statistically significant difference between the groups (p = 0.724).

Table 7. Patient Satisfaction and Compliance

Variable	Tretinoin 0.05% n = 39	Azelaic Acid 10% n = 38	p-value
Satisfied with treatment	27 (69.2%)	18 (47.4%)	0.049
Not satisfied	12 (30.8%)	20 (52.6%)	0.049
Good compliance	33 (84.6%)	31 (81.6%)	0.724
Poor compliance	6 (15.4%)	7 (18.4%)	0.724

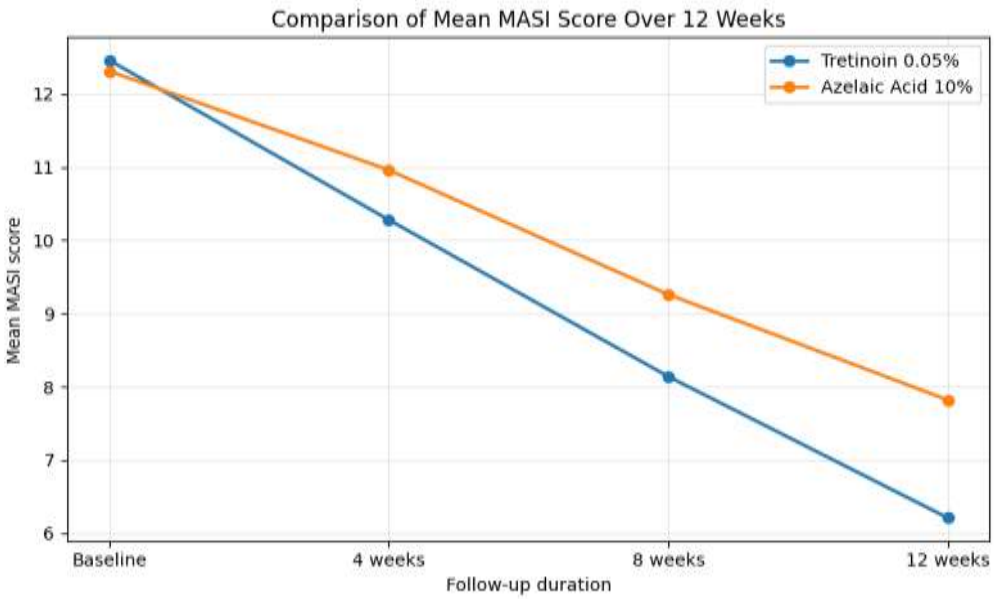

Figure 1. Comparison of mean MASI score over 12 weeks between topical tretinoin 0.05% and azelaic acid 10%.

DISCUSSION

Melasma is a chronic acquired hypermelanosis that commonly affects sun-exposed areas of the face and is influenced by ultraviolet exposure, hormonal factors, genetic predisposition, and epidermal melanocyte activity. In the present study, both topical tretinoin 0.05% and azelaic acid 10% produced improvement in epidermal melasma after 12 weeks of treatment; however, the reduction in MASI score was greater in the tretinoin group. At baseline, both groups were comparable regarding age, gender distribution, duration of disease, clinical pattern, sun exposure, sunscreen use, and baseline MASI score. This baseline similarity strengthens the comparison because the difference observed at follow-up is more likely to be related to treatment effect rather than initial disease imbalance (14-16).

In this study, the mean MASI score decreased from 12.46 ± 3.18 to 6.21 ± 2.38 in the tretinoin group, while it decreased from 12.31 ± 3.06 to 7.82 ± 2.56 in the azelaic acid group after 12 weeks. Although both agents produced significant improvement, the magnitude of reduction was higher with tretinoin 0.05%. This may be explained by the pharmacological action of tretinoin, which promotes epidermal turnover, facilitates dispersion of melanin granules, and enhances removal of pigment-containing keratinocytes. Previous studies have also demonstrated that topical retinoids improve epidermal pigmentation by increasing keratinocyte turnover and promoting clearance of melanin-containing cells (17, 18).

Azelaic acid also demonstrated clinical benefit, although its response was comparatively lower than that observed with tretinoin. Azelaic acid acts mainly by inhibiting tyrosinase activity and suppressing abnormal melanocyte function. It also has anti-inflammatory and keratinization-normalizing properties, which may contribute to its role in pigmentary disorders. However, its depigmenting effect may be slower and less pronounced than topical retinoids, particularly over a 12-week treatment period (19).

Treatment response categories further supported the superior clinical response in the tretinoin group. Excellent and good responses were more frequent among patients using tretinoin, whereas fair and poor responses were more common in the azelaic acid group. These findings suggest that tretinoin may provide greater pigment reduction and more rapid improvement in epidermal melasma compared with azelaic acid. However, melasma is a chronic and relapsing condition; therefore, short-term improvement should not be interpreted as permanent clearance. Long-term maintenance, regular photoprotection, and avoidance of triggering factors remain essential (20).

Regarding tolerability, local adverse effects were more frequently reported in the tretinoin group. Erythema, dryness, peeling, and burning sensation were more common among patients using tretinoin 0.05%, although most reactions were mild and did not require treatment discontinuation. This pattern is consistent with the known irritant potential of topical retinoids, especially during the early phase of therapy. In contrast, azelaic acid demonstrated a more favorable tolerability profile, with fewer complaints of dryness and peeling. This makes

azelaic acid a useful option for patients with sensitive skin or intolerance to retinoids (21).

Patient satisfaction was higher in the tretinoin group, which may be related to the greater visible reduction in pigmentation at 12 weeks. Nevertheless, satisfaction is influenced by several factors, including cosmetic expectations, treatment tolerance, adherence, cost, and perceived improvement. In the present study, all patients were advised to use sunscreen regularly, as photoprotection is a key component of melasma management. Without consistent sunscreen use, recurrence and incomplete response may occur despite topical depigmenting therapy.

LIMITATIONS

This study has some limitations. It was conducted at a single tertiary-care hospital, and the sample size was modest. The follow-up period was limited to 12 weeks; therefore, recurrence, relapse pattern, and long-term maintenance response could not be assessed. The study relied on MASI scoring and clinical assessment; objective tools such as colorimetry or standardized digital photography may have improved measurement accuracy. In addition, blinding was not performed due to differences in treatment preparation and routine clinical setting, which may have introduced assessment bias.

Overall, the findings indicate that topical tretinoin 0.05% is more effective than azelaic acid 10% in reducing MASI score over 12 weeks in patients with epidermal melasma, while azelaic acid offers better tolerability. Future randomized blinded studies with larger sample sizes, longer follow-up, and objective pigmentation assessment are recommended to confirm these findings.

CONCLUSION

Topical tretinoin 0.05% and azelaic acid 10% both produced clinical improvement in patients with epidermal melasma after 12 weeks of treatment. However, tretinoin 0.05% demonstrated a greater reduction in MASI score, higher percentage improvement, and better overall treatment response compared with azelaic acid 10%. Azelaic acid 10% showed a more favorable tolerability profile, with fewer local adverse effects, and may be considered a suitable alternative for patients with sensitive skin or intolerance to retinoids. Regular photoprotection and continued follow-up remain essential to maintain therapeutic response and minimize recurrence.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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