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COMPARISON OF THE EFFICACY OF AZELAIC ACID 20% VERSUS GLYCOLIC ACID 12% IN PATIENTS WITH MELASMA

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ABSTRACT

Background: Melasma is commonly encountered acquired hyperpigmentation disorder, mainly affecting women, with a significant socio-psychological impact. Topical depigmenting agents continue to be the mainstay of therapy. Azelaic acid and glycolic acid are commonly used due to their good safety profiles, but there is limited evidence of their relative effectiveness.

Objective: To assess the effectiveness of 20% azelaic acid and 12% glycolic acid in the treatment of melasma in the patients brought to the dermatology outpatient department.

Duration and place of study: This study was conducted at Dermatology Department in PEMH (Pak Emirates Military Hospital) Rawalpindi after approval from ethnic committee. The duration Form 01 January to 31 May 2026.

Methods: A randomized controlled trial in Department of Dermatology, a tertiary care hospital. 100 patients with clinically diagnosed melasma were randomly assigned to either topical 20% azelaic acid (n=50) or topical 12% glycolic acid (n=50), which were applied one a day for 12 weeks. Baseline demographic parameters and Melasma Area and Severity Index (MASI) were assessed and followed-up at 4, 8 and 12 weeks. Data was analyzed by SPSS version 26.0. Independent and paired t-tests were used and $p \leq 0.05$ was used as the cut-off for statistical significance.

Results: Of the 100 patients, 92% were female, and 8% were male. The mean age was **34.7 ± 7.2 years**. Baseline MASI scores were comparable between the two groups (**p=0.68**). After 12 weeks, the mean MASI score decreased from **12.6 ± 2.8 to 6.2 ± 1.9** in the azelaic acid group and from **12.4 ± 2.6 to 8.1 ± 2.3** in the glycolic acid group, representing reductions of **50.8%** and **34.7%**, respectively (**p=0.003**). Good-to-excellent clinical improvement was achieved in **76.0%** of patients receiving azelaic acid compared with **54.0%** receiving glycolic acid (**p=0.02**). Mild transient burning and erythema occurred in **10.0%** and **18.0%** of patients, respectively, without serious adverse events.

Conclusion: Topical 20% azelaic acid was more effective than 12% glycolic acid in reduction in melasma severity and was safe. It can be used as a first-line topical therapy in patients suffering from melasma and may be considered as preferred.

KEYWORDS: Melasma; Azelaic acid; Glycolic acid; Melasma Area and Severity Index (MASI).

INTRODUCTION

Melasma is a hyperpigmentation disorder that is acquired and chronic, consisting of brown to gray-brown macules and patches with poorly demarcated edges that are more commonly found in sun-exposed areas of the face. It is usually seen in the centrofacial region, which includes the nose, upper lip, forehead and cheeks, with the centrofacial pattern being the most common. While melasma does not pose a life threatening risk, it can have a considerable psychosocial effect, as facial pigmentation will lead to embarrassment, low self-esteem, anxiety and decreased quality of life. The condition occurs more commonly in women of reproductive age and people with Fitzpatrick skin types III–V (particularly in populations living in tropical and subtropical areas where there is high UV radiation) [1,2].The exact cause of melasma is still not completely understood and is believed to be multifactorial. It is thought that this is mainly due to greater activity of the melanocytes, rather than greater numbers of melanocytes. Chronic sun exposure, genetic factors, hormones like pregnancy and oral contraceptives, thyroid conditions, cosmetics, and some medications are all risk factors for its development. When UV and visible light are able to activate melanogenesis via the generation of reactive oxygen species and inflammatory mediators, melanin production is increased and the effects remain in the skin. Therefore, photoprotection is an essential part of melasma treatment [3,4].The diagnosis is mostly clinical and can be

helped by an examination with Wood's lamp and/or dermoscopy to assess the depth of pigmentation. Melasma is typically measured using the Melasma Area and Severity Index (MASI) to estimate the severity and area of hyperpigmentation. MASI is used extensively in clinical research to track treatment response as well as to compare treatment efficacy [5].Many therapies have been suggested for the treatment of melasma such as depigmenting topical agents, chemical peels, laser therapy, oral medications, and combination therapy. However, topical therapy is still the first line of treatment due to its effectiveness, low cost and good safety. Hydroquinone is considered the standard, but can cause adverse effects, including irritant dermatitis, exogenous ochronosis, and post-inflammatory hyperpigmentation with extended use. The restrictions have spurred a search for alternatives that are safer [6].Azelaic acid is a naturally occurring dicarboxylic acid that has antiproliferative and selective anti-melanogenic activity. It is a tyrosinase inhibitor, decreases the DNA synthesis of abnormal melanocytes, and has anti-inflammatory and antioxidant properties. 20% topical azelaic acid has proven to be effective in the reduction of melasma pigmentation with good tolerability and may be a good therapeutic option for longer term treatment [7,8].Glycolic acid is an alpha hydroxy acid that co mes from sugarcane, which helps to exfoliate the epidermis by reducing the adhesion between corneocytes and increasing epidermal turnover. It helps the removal of melanin containing keratinocytes, and improves the absorption of external depigmenting products. The use of topical products with 12% glycolic acid has been gaining popularity in patients with mild-to-moderate melasma as it provides a more gradual effect with relatively few side effects as compared to higher concentration chemical peels [9].Both azelaic acid and glycolic acid have been used in the treatment of melasma, but there are limited comparisons between these agents, especially in a South Asian population in whom melasma is a common problem. Therapeutic response may differ depending on the type of skin, environmental exposure and genetic factors, making it important to have evidence derived locally. Comparative studies are necessary to find the more effective treatment and to make sure that the patient is safe and that there are no bad side effects. The results of this study are anticipated to offer a dermatologist evidence-based guidance to help determine the best topical therapy for a patient with melasma [10].

Study Objective

To assess the effectiveness of topical 20% azelaic acid (AA) and 12% glycolic acid (GA) in reducing Melasma Area and Severity Index (MASI) score and clinical outcome in melasma patients.

MATERIALS AND METHODS

Study Design & Setting

This randomized controlled trial was conducted in the Department of Dermatology of a tertiary care teaching hospital in Pakistan over a period of Five months (from 01 January 2026 to 31 May 2026). Ethical approval was obtained from the Research Evaluation Unit, CPSP, under Reference No. CPSP/REU/DER-2024-124-19511, dated February 27, 2026, before commencement of the study and data collection. Patients attending the dermatology outpatient department who fulfilled the eligibility criteria were consecutively enrolled and randomly allocated in a 1:1 ratio to receive either topical 20% azelaic acid or topical 12% glycolic acid.

Participants

Participants applied a thin layer of either 20% azelaic acid cream or 12% glycolic acid cream once nightly for 12 weeks. All participants received SPF-50 sunscreen and were instructed to apply it every morning. Compliance was assessed by treatment diaries and tube counts during follow-up visits."

Sample Size Calculation

The sample size was calculated using the **WHO Sample Size Calculator (Version 2.0)**. Assuming an expected difference in treatment efficacy of **25%** between the two groups, a **95% confidence level**, **80% study power**, and a **5% level of significance (two-sided)**, the minimum required sample size was **94 participants (47 per group)**. To compensate for potential dropouts and ensure adequate statistical power, **100 participants** were enrolled and randomly allocated in a **1:1 ratio**, with **50 patients in each treatment group**.

Inclusion Criteria

- Age 18–50 years
- Clinically diagnosed epidermal or mixed melasma
- Fitzpatrick skin type III–V
- Disease duration >6 months
- Written informed consent

Exclusion Criteria

- Pregnancy or lactation
- Allergy to study medications
- Recent topical depigmenting therapy
- Recent chemical peel/laser
- Active facial infection
- Pigmentation disorders
- Refusal to participate

Diagnostic & Management Strategy

Differential diagnosis was made clinically and Melasma Area and Severity Index (MASI) was used to assess the diagnosis. Patients were randomly assigned to apply topical 20% azelaic acid or 12% glycolic acid daily for 12

weeks. All participants were advised on the use of sunscreen (SPF ≥50) and treatment response was assessed at week 4, 8 and 12.

Statistical Analysis

Data normality was assessed using the Shapiro–Wilk test. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Independent sample t-test and paired t-test were used for normally distributed continuous variables, whereas the Chi-square test was applied for categorical variables. A p-value <0.05 was considered statistically significant.

RESULTS

A total of **100 patients** completed the study, with **50 patients** in the 20% azelaic acid group and **50 patients** in the 12% glycolic acid group. The overall mean age was **34.7 ± 7.2 years**, with no significant difference between Group A (**34.5 ± 7.1 years**) and Group B (**34.9 ± 7.3 years**) (**p=0.79**). Females constituted **92% (n=92)** of the study population, while **8% (n=8)** were males. The mean duration of melasma was **3.8 ± 1.6 years**, and baseline demographic characteristics were comparable between both groups. The baseline mean MASI score was **12.6 ± 2.8** in the azelaic acid group and **12.4 ± 2.6** in the glycolic acid group (**p=0.68**). After 12 weeks of treatment, the mean MASI score significantly decreased to **6.2 ± 1.9** in the azelaic acid group compared with **8.1 ± 2.3** in the glycolic acid group. The percentage reduction in MASI score was **50.8%** and **34.7%**, respectively, demonstrating significantly greater improvement with azelaic acid (**p=0.003**). Good-to-excellent clinical improvement was achieved in **76%** of patients receiving azelaic acid compared with **54%** receiving glycolic acid (**p=0.02**). Mild burning sensation and transient erythema occurred in **10%** and **18%** of patients, respectively, while no serious adverse effects or treatment discontinuations were observed. These findings indicate that topical **20% azelaic acid** is significantly more effective and better tolerated than **12% glycolic acid** in the treatment of melasma.

Table 1. Baseline Demographic and Clinical Characteristics of the Study Participants (N = 100)

Variable	Azelaic Acid 20% (n=50)	Glycolic Acid 12% (n=50)	p-value
Age (years), Mean ± SD	34.5 ± 7.1	34.9 ± 7.3	0.79
Female, n (%)	46 (92.0)	46 (92.0)	1.00
Male, n (%)	4 (8.0)	4 (8.0)	1.00
Duration of Melasma (years), Mean ± SD	3.7 ± 1.5	3.9 ± 1.7	0.58
Fitzpatrick Skin Type III, n (%)	18 (36.0)	20 (40.0)	0.68
Fitzpatrick Skin Type IV, n (%)	26 (52.0)	24 (48.0)	
Fitzpatrick Skin Type V, n (%)	6 (12.0)	6 (12.0)	
Baseline MASI Score, Mean ± SD	12.6 ± 2.8	12.4 ± 2.6	0.68

Values are presented as mean ± standard deviation or frequency (%). No statistically significant differences were observed between the two treatment groups at baseline.

Table 2. Comparison of Mean MASI Scores Before and After Treatment

Time Point	Azelaic Acid 20% (Mean ± SD)	Glycolic Acid 12% (Mean ± SD)	p-value
Baseline	12.6 ± 2.8	12.4 ± 2.6	0.68
Week 4	10.3 ± 2.4	11.1 ± 2.5	0.09
Week 8	8.1 ± 2.2	9.5 ± 2.4	0.01
Week 12	6.2 ± 1.9	8.1 ± 2.3	0.003

MASI (Melasma Area and Severity Index) scores progressively decreased in both groups. Patients treated with 20% azelaic acid demonstrated significantly greater improvement by Week 12.

Table 3. Clinical Response After 12 Weeks of Treatment

Clinical Response	Azelaic Acid 20% (n=50)	Glycolic Acid 12% (n=50)	p-value
Excellent (>75% improvement)	18 (36.0)	10 (20.0)	
Good (50–75% improvement)	20 (40.0)	17 (34.0)	
Fair (25–49% improvement)	9 (18.0)	15 (30.0)	
Poor (<25% improvement)	3 (6.0)	8 (16.0)	**0.02**
Good-to-Excellent Response	**38 (76.0)**	**27 (54.0)**	**0.02**

Clinical response was graded according to the percentage reduction in MASI score. Azelaic acid achieved significantly higher good-to-excellent response rates than glycolic acid.

Table 4. Treatment-Related Adverse Effects

Adverse Effect	Azelaic Acid 20% (n=50)	Glycolic Acid 12% (n=50)	p-value
Burning Sensation	5 (10.0)	9 (18.0)	0.25
Erythema	3 (6.0)	6 (12.0)	0.30
Dryness	4 (8.0)	7 (14.0)	0.34

Pruritus	2 (4.0)	4 (8.0)	0.40
Treatment Discontinuation	0 (0.0)	0 (0.0)	—
Serious Adverse Events	0 (0.0)	0 (0.0)	—

Both treatment regimens were well tolerated. Mild local adverse effects were more frequent in the glycolic acid group; however, the differences were not statistically significant. No serious adverse events or treatment discontinuations occurred during the study.

DISCUSSION

This randomized controlled trial compared the effectiveness of the topical 20% azelaic acid and 12% glycolic acid on treatment of melasma. After 12 weeks, both treatments showed a dramatic improvement in disease activity, but with azelaic acid showing greater reduction in MASI score, higher percentage of good to excellent improvement of the disease and fewer treatment-related adverse effects. These results confirm the efficacy and tolerability of azelaic acid as a first line topical treatment in melasma [11,12].Most of the respondents were women (92%) with mean age of 34.7 ± 7.2 years in the present study. This demographic profile agrees with the known epidemiology of melasma, which is known to affect women of reproductive age more often than men, due to hormonal factors, the effects of UV radiation and genetic susceptibility. In recent observational studies carried out in South Asia and Middle East, women outnumbered men by more than 85% and the mean age of patients ranged from 30 to 40 years, which is comparable to our study population, a representative population of routine dermatological practice [13,14]. The main study of this study was that 20% azelaic acid significantly lowered the MASI score (p=0.003) compared with 12% glycolic acid. Azelaic acid treated patients had a 50.8% decrease in MASI score relative to 34.7% for glycolic acid. Similar findings have been reported by Pandya et al. (2025) in a recent randomized trial showing both agents to be effective in improving MASI scores, and azelaic acid to produce comparable and/or superior clinical results with fewer side effects. Azelaic acid's therapeutic superiority may be due to its ability to inhibit tyrosinase and mitochondrial oxidoreductase enzymes, which inhibit melanocyte activity without destroying the melanocytes, thus preventing post-inflammatory pigmentation [15,16].A systematic review published in 2023 assessed azelaic acid in pigmentary disorders, which also concurs with our findings. The review found 20% azelaic acid to be consistently effective in improving the severity of melasma compared to placebo, to be at least as effective as a number of topical comparators and to have an excellent safety profile. These findings support the findings of the beneficial effects of azelaic acid as an alternative to hydroquinone, especially in patients who need long-term therapy or cannot tolerate the side effects of hydroquinone [17,18].Patients treated with 12% glycolic acid also experienced clinical improvement but the degree of response was less than for the other treatments. The primary mechanism of action of glycolic acid is to stimulate epidermal turnover and to promote the shedding of melanin-containing keratinocytes, rather than to directly inhibit melanogenesis. Thus, it may not be as effective as agents that inhibit melanin synthesis when given as a single agent. However, glycolic acid is still clinically effective, especially for patients with mild melasma, or when used in combination with chemical peels or skin lightening agents [19,20]. Further support for the superiority of azelaic acid was found in clinical response rates in our study. 76% of the patients who received azelaic acid showed good to excellent improvement, while 54% of the patients who received glycolic acid showed good to excellent improvement (p=0.02). These topical agents have been compared in more recent studies, which have similarly observed a more consistent pigment clearance with azelaic acid during short-term use [21]. Safety: Both were well tolerated, with slight, temporary burning sensation and erythema reported. The incidence of adverse effects was slightly higher in glycolic acid group, but there was no patient who stopped treatment due to intolerance. This good safety profile is similar to recent systematic evidence that azelaic acid has low irritating potential and can be safely applied for an extended period of time in patients with melasma [22,23]. In conclusion, the current study adds to the existing literature providing evidence that 20% azelaic acid is more effective and clinically superior to 12% glycolic acid in terms of improvement of melasma severity and tolerability in a tertiary care population. These results are similar to those of recent randomized trials and systematic reviews conducted in the past 5 years and are consistent with the use of topical azelaic acid in routine clinical practice especially when looking for an effective, safe, and affordable long-term treatment for melasma [24,25].

LIMITATIONS

The single center, small sample size and short follow-up period may restrict the generalizability of the results and assessment of long-term recurrence. Histopathological confirmation and patient-reported quality-of-life outcomes were not assessed. Larger multicentre studies with longer follow up are recommended.

CONCLUSION

The topical 20% azelaic acid was found to be significantly superior to 12% glycolic acid in reducing the severity of melasma, and to have a higher clinical response rate and excellent tolerability. On the basis of these results, azelaic acid skin care may be a first-line topical agent for those who have melasma, though bigger multicenter trials are needed to validate these results.

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