Efficacy and Safety of Topical 5% Azelaic Acid Solution Versus 2% Minoxidil Solution in the Treatment of Female Pattern Hair Loss

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ABSTRACT

Objective: To determine the efficacy and safety of 5% azelaic acid solution in comparison with 2% minoxidil solution in the treatment of FPHL.

Materials and Methods: Twenty-six FPHL patients with Ludwig grade I or II were randomly treated with 5% azelaic acid solution or 2% minoxidil solution twice daily for 6 months. At baseline, 2, 4, and 6 months, hair density and hair shaft diameter were assessed at the targeted fixed area. At 6 months, patient and investigator assessments of hair growth were performed using a 7-point scale.

Results: Hair density and hair shaft diameter in the patients treated with 5% azelaic acid and 2% minoxidil solution were significantly increased compared to the baseline in all cases and visits (P < 0.05). There were no statistically significant differences in hair density and hair shaft diameter changes between both groups (P > 0.05). Both the investigator and patient assessments were comparable between both groups at 6 months. Pruritus was the major adverse effect reported in both groups, but only mild and all could be tolerated.

Conclusion: 5% Azelaic acid solution might be an effective treatment for FPHL, comparable with 2% minoxidil, and could be an alternative treatment for FPHL in minoxidil-allergic patients and pregnant women.

Keywords: Androgenetic alopecia; azelaic acid; female pattern hair loss; minoxidil allergy; pregnancy (Siriraj Med J 2023; 75: 887-893)

INTRODUCTION

Androgenetic alopecia (AGA), also known as pattern hair loss, is the most common form of nonscarring alopecia, affecting up to 80% of men and 50% of women throughout their lifetime. It is characterized by progressive hair loss due to miniaturization of the hair follicles, resulting in vellus transformation of the terminal hairs. Androgens and genetic predisposition appear to play important roles in etiopathogenesis. Current treatments of AGA that

are approved by the US Food and Drug Administration (FDA) consist of oral finasteride (5α -reductase inhibitor) in men, and topical minoxidil and low-level light therapy (LLLT) in both men and women.^{4,5}

Concerning female pattern hair loss (FPHL), the treatment options are limited. Although the roles of androgens and genetic susceptibility are less apparent than in male AGA, oral finasteride and other antiandrogens appear to be helpful in FPHL. However, these medications are

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All material is licensed under terms of the Creative Commons Attribution 4.0 International (CC-BY-NC-ND 4.0) license unless otherwise stated. off-label and restricted, especially in women of childbearing age due to their teratogenicity and the increase in risk of breast cancer.4 Therefore, topical minoxidil is the only FDA-approved first-line medication for FPHL prescribed in general practice. However, concern has been raised in FPHL patients with pregnancy, and so minoxidil should be avoided for pregnant women.^{4,6} There have been reports of neonatal hypertrichosis and fetal malformations (heart, brain, and vascular) related to topical minoxidil use during pregnancy.^{7,8} Although topical minoxidil usage by mothers offers no harm to breastfed children according to expert consensus, minoxidil-induced hypertrichosis in a breastfed infant was recently reported.9 Therefore, minoxidil should be prescribed under supervision, especially when a substantial maternal dosage is part of the therapy and while nursing a premature baby.9

Elevated estrogen levels during pregnancy slow down the hair follicles' normal cycle of shedding. As a result, most pregnant women with FPHL can actually have less hair loss. ¹⁰ However, some of them might also suffer from ongoing hair loss during the gestational period, which may happen as a result of iron deficiency anemia, stopping the oral contraceptive pill, stress, or an imbalance of essential vitamins. ^{11,12} Further hair thinning usually has a negative impact on quality of life and self-esteem.

Azelaic acid is an effective topical treatment for various dermatologic conditions, such as rosacea, acne, and hyperpigmentation, owing to its anti-inflammatory, antioxidant, and antibacterial properties.¹³ In addition, azelaic acid is also an inhibitor of 5α-reductase, which is a key enzyme in the pathogenesis of AGA.¹⁴ A recent study also showed that azelaic acid could protect hair bulge cells from ultraviolet B damage via an increase in catalase activity, and upregulate Gli1 and Gli2 expression, which could enhance telogen to anagen transition and promote hair growth. 15 Therefore, azelaic acid is believed to be beneficial in the treatment of AGA, and there are many commercial topical preparations containing minoxidil solutions in combination with 5% azelaic acid. Moreover, topical azelaic acid is considered to be safe to apply during pregnancy (pregnancy category B) and breastfeeding.16 However to the best of our knowledge, there has been no previous study on the efficacy of azelaic acid topical solution monotherapy or a controlled study comparing the efficacy of azelaic acid topical solution and the standard treatment of AGA. Thus, the objective of this study was to determine the efficacy and safety of 5% azelaic acid solution in comparison with 2% minoxidil solution in the treatment of FPHL.

MATERIALS AND METHODS

Study design

This prospective, randomized, double-blinded comparative study was conducted at the Department of Dermatology, Faculty of Medicine Siriraj Hospital, Mahidol University. The study was approved by the Siriraj Institutional Review Board and informed consent was obtained from all participants. Overall, 26 FPHL women were enrolled and randomized to receive 5% azelaic acid topical solution or 2% minoxidil topical solution by block randomization (1:1 allocation ratio). The patients were instructed to apply the solution all over their thinning scalp twice daily. The patients were evaluated at months 0 (baseline), 2, 4, and 6.

Participants

FPHL patients aged ≥ 18 years, with a Ludwig classification grade I or II, were recruited in the study. They must not have received any topical or systemic hair loss treatment for at least 6 months prior to the enrollment. The exclusion criteria included patients who had other scalp, systemic, or psychiatric conditions that could be the cause of alopecia. Pregnant or breastfeeding women were also excluded.

Azelaic acid and minoxidil solution

Both 5% azelaic acid and 2% minoxidil solution were formulated by the Pharmacy Department, Faculty of Medicine Siriraj Hospital, Mahidol University. Both solutions used the same vehicles, consisting of 50% ethyl alcohol, 25% propylene glycol, and 25% purified water.

Outcome assessment

Hair density and diameter

On the day of enrollment, each patient was tattooed with 4 dots forming a 1x1 cm square on the vertex area of the scalp, using a brown cosmetic tattoo ink (Micro Pigments, Biotouch Inc., Los Angeles, CA, USA) that would gradually disappear after 6 months. At each visit, hairs in the target area were cut to approximately 1 mm in length and collected. Macrophotographs of the target area on the scalp were taken using a dermoscopic device (Dino-Lite DermaScope®, Dino-Lite, Naarden, the Netherlands) and DinoCapture software. All hairs in the target area were manually counted and reported as the total hair and terminal hair counts. The hair diameter at each visit was calculated by the mean hair diameter of ten representative hairs from the target area. Each hair was measured using an electronic external micrometer (RS PRO External Micrometer, RS Components Ltd., Corby, UK). Both the hair density and hair diameter at

each visit of all the participants were evaluated by the same author (C.P.), who was blinded to the treatment.

Global photographic review (GPR)

Standardized photographs were taken using a digital camera (Digital Canon PowerShot G15, Canon Inc., Tokyo, Japan) at baseline and 6 months. All the photographs at baseline and 6 months were evaluated by two blinded expert dermatologists (K.T. and D.T.) for assessing the improvement in the patient's global hair volume using a 7-point scale (-3 = significant worsening; -2 = moderate worsening; -1 = slight worsening; 0 = no change; +1 = mild improvement; +2 = moderate improvement; +3 = significant improvement).

Patient's own evaluation

After 6 months, patients evaluated their improvement of FPHL compared with the baseline using a 7-point scale, as in the GPR assessment.

Safety assessments

At every patient visit, safety evaluations of 5% azelaic acid solution and 2% minoxidil solution were conducted utilizing the combined information from the history taking, physical examination, and photoimaging. The majority of recorded adverse events were related to scalp irritation, including erythema, itching, scaling, and pruritus. Subjects rated the severity as none, mild,

moderate, or severe. Inspection of the returned container of the designated preparation allowed for the assessment of patient drug compliance.

Statistical analysis

All the data were analyzed using PASW Statistics, version 18.0 (SPSS Inc, Chicago, IL, USA). Descriptive statistics were demonstrated as the frequency, percentage, mean ± standard deviation (SD), median, and range. All the continuous data were evaluated for normality by the Shapiro–Wilk test. The paired t-test and repeated measured ANOVA were used to compare the mean hair density and hair diameter of each visit. The independent t-test was used to compare the means of the two groups. Nonparametric data were compared using the Mann–Whitney U test. Pearson chi-square test and Fisher's exact test were used to compare the categorical data between the two groups. A P-value of <0.05 was considered to be statistically significant.

RESULTS

Demographic data of the patients

This trial enrolled a total of 26 FPHL patients with a mean age of 38.7 years. At baseline, the patients' demographics and hair loss characteristics were similar between both treatment groups (Table 1). Most of them had grade I hair loss severity on the basis of the Ludwig classification.

TABLE 1. Demographic data of patients with female pattern hair loss treated with 5% azelaic acid and 2% minoxidil topical solution.

	5% Azelaic acid solution (n = 13)	2% Minoxidil solution (n = 13)	P-value
Age, y, mean (SD)	40.1 (6.6)	37.3 (4.2)	0.216
Family history of AGA, n (%)	8 (61.5)	5 (38.5)	0.239
Age of onset, y, mean (SD)	33.5 (7.9)	31.5 (6.0)	0.473
Duration of hair loss, months, median (range)	84 (5 to156)	60 (24 to 156)	0.638
Ludwig classification, n (%)			1.000
Grade I	11 (84.6)	10 (76.9)	
Grade II	2 (15.4)	3 (23.1)	
Baseline hair density, per cm², mean (SD)			
Total hair	139.1 (34.3)	158.1 (36.9)	0.419
Terminal hair	109.2 (31.6)	127.7 (34.2)	0.644
Baseline hair diameter, µm, mean (SD)	66.0 (7.7)	65.5 (9.3)	0.548

Hair density and hair diameter

The hair density and hair diameter of the participants treated with 5% azelaic acid and 2% minoxidil solution at each follow-up visit are shown in Table 2. Compared to the baseline, the hair density and hair diameter of both groups significantly increased after two months of treatment. There were no significant differences in the mean percentage of improvement in hair density and diameter between both groups during six months. At the end of the study, the hair density of the 5% azelaic acid solution group and 2% minoxidil solution group increased by 20.4% and 21.1%, respectively. The diameter of the hair improved by 5.3% in the group receiving 5% azelaic acid solution and 7.6% in the group receiving 2% minoxidil solution.

Global photographic review

The investigators assessment of both groups at six months were comparable. Five patients (38.5%) treated with 5% azelaic acid solution showed a mild to moderate improvement in their FPHL (4 mild improvement, 1 moderate improvement), compared with four patients (30.8%) treated with 2% minoxidil solution (1 mild improvement, 3 moderate improvement). Clinical photographs demonstrating the treatment responses

after a 6-month period of using 5% azelaic acid solution and 2% minoxidil solution are shown in Fig 1 and Fig 2, respectively.

Patient's own assessment

Regarding the patient's own assessment, 12 patients (92.3%) treated with 5% azelaic acid solution reported an improvement in their hair loss (5 mild improvement, 7 moderate improvement), while 11 patients (84.6%) treated with 2% minoxidil solution reported an improvement (3 mild improvement, 4 moderate improvement, 4 significant improvement) at the end of the study.

Adverse effects

The major reported adverse effect of both 5% azelaic acid and 2% minoxidil topical solution was pruritus, comprising 46.2% of patients in the azelaic acid group and 23.1% in the minoxidil group (Table 3). Most patients in both groups rated only a mild degree of pruritus, which tended to improve over time. One patient treated with 2% minoxidil solution complained of dryness, while one patient treated with 5% azelaic acid solution reported scaling. No patients reported erythema, or a burning or stinging sensation.

TABLE 2. Comparison of hair density and hair diameter at each follow-up visit after treatment with 5% azelaic acid and 2% minoxidil topical solution

	5% Azelaic acid solution (n = 13)		2% Minoxidil solution (n = 13)		Azelaic acid vs. Minoxidil	of improvement	
	Mean (SD)	P-value (compared to baseline)	Mean (SD)	P-value (compared to baseline)	P-value	Mean difference	P-value
Total hair density, per cm ²	2						
Baseline	139.1 (34.3)		158.1 (36.9)		0.186		
2 months	154.7 (37.1)	0.001	180.5 (45.9)	0.001	0.129	-2.4	0.592
4 months	161.2 (35.5)	<0.001	187.0 (45.0)	<0.001	0.118	-2.1	0.718
6 months	167.5 (35.0)	<0.001	191.5 (39.6)	<0.001	0.115	-0.4	0.947
Hair diameter, µm							
Baseline	66.0 (7.7)		65.5 (9.3)				
2 months	68.0 (9.3)	0.017	68.1 (8.4)	0.043	0.968	-1.5	0.475
4 months	69.4 (7.9)	0.001	69.1 (8.0)	0.010	0.939	-0.8	0.735
6 months	69.5 (7.9)	<0.001	70.5 (9.3)	0.004	0.760	-2.6	0.282

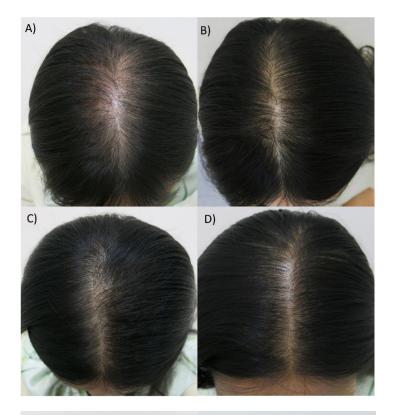


Fig 1. Female pattern hair loss patients (Ludwig grade I) who received 5% azelaic acid solution twice daily for 6 months. Patient No. 1 (**A** baseline, **B** 6 months) and patient No. 2 (**C** baseline, **D** 6months).

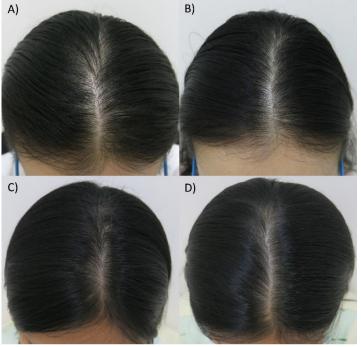


Fig 2. Female pattern hair loss patients (Ludwig grade I) who received 2% minoxidil solution twice daily for 6 months. Patient No. 3 (**A** baseline, **B** 6 months) and patient No. 4 (**C** baseline, **D** 6 months).

TABLE 3. Reported adverse effects from 5% azelaic acid and 2% minoxidil topical solution.

	5% Azelaic acid solution	2% Minoxidil solution		
	(n = 13)	(n = 13)		
Dryness, n (%)	0 (0)	1 (7.7)		
Pruritus, n (%)	6 (46.2)	3 (23.1)		
Scaling, n (%)	1 (7.7)	0 (0)		

DISCUSSION

According to Stamatiadis et al.'s study, azelaic acid was proved to be a potent inhibitor of 5α -reductase.¹⁴ Moreover, a recent study also demonstrated that azelaic acid could improve telogen to anagen transition and promote hair growth by upregulating Gli1 and Gli2 expression and protecting hair bulge cells from ultraviolet B damage. 15 Therefore, azelaic acid might be an effective treatment for AGA. There are many commercial topical preparations containing various concentrations of minoxidil in combination with 5% azelaic acid. A previous randomized controlled study on the efficacy of 5% minoxidil topical solution monotherapy and a combination of 12.5% minoxidil, 5% azelaic acid, and 0.025% betamethasone-17-valerate showed a similar outcome in increasing hair growth between both treatments, but the combination solution significantly decreased hair shedding compared to 5% minoxidil monotherapy. $^{\! 17}$ However, evidence of the efficacy of azelaic acid topical solution as a monotherapy for AGA is lacking. Our study was the first randomized clinical study of the efficacy and safety of 5% azelaic acid topical solution in comparison with 2% minoxidil solution in the treatment of FPHL.

Both 5% azelaic acid and 2% minoxidil topical solution significantly increased both hair density and hair diameter at 2, 4, and 6 months of treatment. There were no statistically significant differences between both solutions in every follow-up visit (Table 2). Nonetheless, the increases in hair density and the hair diameter of FPHL patients treated with 5% azelaic acid solution were slightly lower than those with 2% minoxidil solution, which is one of the standard treatments for FPHL. The investigators and patient's own assessments also correlated with both clinical parameters. Regarding GPR, slightly more FPHL patients treated with 5% azelaic acid solution than 2% minoxidil solution were considered to demonstrate mild to moderate improvement at the end of the study. More than half of the patients in both groups rated themselves at least showing a moderate improvement from the baseline condition.

The azelaic acid concentration in commercially available hair formulations, combined with minoxidil solution, varies between 1.5% to 5%. However, the 5% azelaic acid used in our study was lower than typical concentrations used for other dermatologic conditions, such as rosacea, acne, and melasma, which range from 10% to 20%. A higher concentration of azelaic acid might be more effective in improving hair thinning but may also incur an increased risk of adverse events, like pruritus, dryness, stinging, and burning sensation. Further investigations are needed to establish the optimal

concentration of azelaic acid for the treatment of FPHL. As mentioned above, the possible mechanisms of azelaic acid in the improvement of FPHL could be that azelaic acid may inhibit 5α -reductase¹⁴ and promote telogen to anagen transition.¹⁵ Its anti-inflammatory property might also be another explanation. In a recent study, it was reported that the pathophysiology of both male pattern hair loss (MPHL) and FPHL may be influenced by the presence of perifollicular inflammation.¹⁸ Azelaic acid could reduce the synthesis of pro-inflammatory cytokines and reactive oxygen species, thus it might be capable of improving PHL.¹³

The US Food and Drug Administration (FDA) has classified azelaic acid as pregnancy category B and can be used in pregnant and breastfeeding women, whereas minoxidil is not recommended due to several reports of fetal abnormalities. 16 According to our study, azelaic acid could be a treatment option for pregnant women with pre-existing FPHL, particularly in patients who have previously received anti-hair loss treatments, in particular, because discontinuation of those treatments in patients who were trying to conceive could further result in a deterioration of hair thinning and finally lead to a negative impact on their quality of life and self-esteem. Thus, 5% azelaic acid topical solution might be a valuable alternative to 2% minoxidil solution for the treatment of FPHL in pregnancy, as not only would it improve FPHL, but it would also relieve stress and be beneficial to the quality of life of patients during pregnancy, as minoxidil is restricted in these patients.

Topical minoxidil could cause transient telogen hair shedding in some patients in the first 8 weeks of treatment.² In this study, we expected to find no change or perhaps a slightly worsening in hair density in patients treated with 2% minoxidil at 2 months after treatment. However, our study showed that the hair density in patients treated with 2% minoxidil increased at 2 months and continued increasing throughout the study, similar to a previous study.¹⁹ This suggested that hair shedding following minoxidil therapy might actually resolve before 8 weeks, or the quantity of hair growth might outnumber hair shedding.

In our study, the most common adverse effect was pruritus in both groups of patients. The explanation for this might be due to the inclusion of propylene glycol in both solutions or the active ingredient itself. Propylene glycol is a well-known allergen and irritant that can cause contact dermatitis. ²⁰ Other vehicles or solvents may be used instead of propylene glycol to avoid skin irritation. A previous study showed that the rates of pruritus and dandruff were significantly lower in patients treated

with 5% minoxidil topical foam (propylene glycol-free preparation) than in those treated with 2% minoxidil topical solution.²¹ Further investigations are needed to assess the efficacy and safety of different vehicles used in azelaic acid topical preparations in the treatment of FPHL. In our study, pruritus was more commonly observed in patients treated with 5% azelaic acid solution than in those treated with 2% minoxidil solution. This might be because azelaic acid is also a skin irritant and probably causes additional pruritus.

Even though this study was a randomized, double-blind, comparative study, our sample size of 26 patients can be regarded as being relatively small. To accurately determine the effectiveness and long-term safety of topical azelaic acid for the treatment of both MPHL and FPHL patients, a larger sample size with longer research periods is needed in the future.

In conclusion, 5% azelaic acid topical solution might be an effective treatment for FPHL, comparable to 2% minoxidil solution. Furthermore, it could be an alternative treatment for FPHL in pregnant and breastfeeding women. More research on azelaic acid solution is needed to determine the optimal concentration of azelaic acid and the proper vehicles to use in FPHL preparations.

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