A Comparative Study between the Efficacy and Safety of 5% Minoxidil Solution and 5% Minoxidil Milky Lotion in the Treatment of Male Androgenic Alopecia†

Rattapon Thuangtong MD*, Kanchalit Thanomkitti MD*, Saroj Suvanasuthi MD, PhD*

** Department of Dermatology, Faculty of Medicine, Siriraj Hospital, Mahidol University, Bangkok, Thailand*
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Background: *5% minoxidil solution is approved for the treatment of male androgenetic alopecia (AGA). However, there have been occasional reports of adverse events that were caused mostly by propylene glycol sensitivity. As an alternative treatment, Siriraj hair team developed a proprietary preparation referred to as "minoxidil milky lotion" that uses butylene glycol as a substitute for propylene glycol.*

Objective: *To compare the efficacy and safety of 5% minoxidil solution with 5% minoxidil milky lotion in the treatment of male AGA.*

Materials and Method: *Twenty males with AGA were recruited for this prospective randomized study. Subjects were randomly treated with 5% minoxidil solution or 5% minoxidil milky lotion. Clinical outcomes and adverse events were recorded at 8, 16, and 24 weeks.*

Results: *The mean age of subjects was 43.5±12.5 years (range, 26-65 years). Percentage increase in hair density at 8 weeks after receiving 5% minoxidil solution and 5% minoxidil milky lotion was 8.8% and 37.4%, respectively (p = 0.01). However, there was no statistically significant difference between the two preparations at the 16 and 24 week visits. Mild irritation was reported in 1 case in the 5% minoxidil milky lotion group.*

Study limitation: *Small sample size.*

Conclusion: *Both formulations were found to be effective and safe in the treatment of male AGA. 5% minoxidil milky lotion may be an alternative treatment in propylene glycol-sensitive patients, with efficacy that is comparable to that of 5% minoxidil solution.*

Keywords: *5% minoxidil solution, 5% minoxidil milky lotion, propylene glycol, butylene glycol, male androgenetic alopecia, contact dermatitis*

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Androgenetic alopecia (AGA), the most common cause of hair loss in both males and females, is the hereditary thinning of hair, which is influenced by androgens, genetic susceptibility, and increasing age. Prevalence of AGA in adults older than 40 years is approximately 50%, with differing gender-specific patterns[1,2]. Although this condition is not a potentially life-threatening disease, it can significantly affect psychological and social aspects of a patient's life. Current treatments for AGA include: topical formulations, oral medications, hair transplantation, hair wig, scalp camouflage agents, and scalp micropigmentation[1-7] . Topical minoxidil solution has become a widely accepted first-line treatment in AGA since its approval by the United States Food and Drug Administration in 1988. However, the action and mechanisms of minoxidil in hair growth promotion remain unclear. It has been postulated that vasodilatory action may directly stimulate dermal papillae or follicular hair matrix cells.

Correspondance to:
Thanomkitti K, Department of Dermatology, Faculty of Medicine Siriraj Hospital, Mahidol University, 2 Prannok Road, Bangkoknoi Bangkok 10700, Thailand.
Phone: +66-80-4406014 Fax. +66-2-4115031
E-mail: kanchalitt@hotmail.com

According to a study in dose-response effect in male-pattern hair loss, 5% minoxidil solution was superior to 2% minoxidil solution and placebo, resulting in approval of 5% minoxidil solution in 2001 for treatment of male AGA[7]. There were, however, occasional reports of adverse events (e.g., contact dermatitis and exacerbation of seborrheic dermatitis), which had greater incidence at higher concentration of minoxidil. In patch testing for allergic contact dermatitis, propylene glycol (PG) was found to be the major allergen (81.8%), not minoxidil itself[8,9]. As a result, alternative solvents, such as butylene glycol or glycerin, need to be combined with minoxidil to treat male AGA in PG-sensitive patients. There have been few placebo-controlled studies to support the efficacy and safety of alternative formulations, although many PG-free minoxidil formulations are commercially available.

Siriraj Hospital, Thailand's largest tertiary referral care center, developed an alternative formulation called "5% minoxidil milky lotion" that uses butylene glycol as a substitute for propylene glycol. Accordingly, this study was designed to compare the efficacy and safety of 5% minoxidil solution (standard formulation consisted of minoxidil USP, ethanol 50%, propylene glycol, and paraben) with 5% minoxidil milky lotion (alternative formulation, a mixture of minoxidil USP, cetyl alcohol, stearyl alcohol, lanolin alcohols, butylene glycol, glyceryl stearate SE, polysorbate, sorbitan monostearte, glycolic acid, and paraben) in the treatment of male AGA.

Material and Method

Patients

Asian males aged 18 years or older who were diagnosed with Hamilton-Norwood classification III vertex, IV, or V male AGA and who were in otherwise good health were prospectively recruited for this study. Candidates with history of sensitivity to minoxidil, history of hair transplantation, or having any chronic active scalp condition were excluded. Study candidates who concomitantly used topical and systemic drugs (e.g., steroids, vasodilators, 5α-reductase inhibitors, antihypertensive agents, anticonvulsant drugs, isotretinoin, and/or herbal medicines) for hair growth within 6 months prior to the start of the study were also excluded.

Study design

The protocol for this 24-week, prospective, randomized, single-blind, comparative study was approved by the Siriraj Institutional Review Board, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand. The 20 enrolled subjects were all patients who sought treatment for hair loss at the Hair Clinic of the Department of Dermatology, Faculty of Medicine Siriraj Hospital during the January 2012 to June 2012 study period. The 20 enrolled participants were randomized using a 1:1 ratio. As such, 10 patients were assigned to the 5% minoxidil solution group and 10 patients were assigned to the 5% minoxidil milky lotion group. Initially, demographic and clinical data were collected and recorded and global photographic images were taken and recorded. Participants were then tattooed with sterile ink to delineate the selected 1 cm^2 target evaluation area in the balding vertex (Fig. 1). Patients were instructed to apply 1 mL of the assigned minoxidil formulation twice daily to all affected areas, including the evaluation area. Moreover, the patients were advised to keep both formulations at proper temperature under 15 degrees Celsius and asked to visit the hair clinic every 8 weeks for clinical evaluation, for a total of 3 follow-up visits over the 24-week trial period.

Efficacy evaluation

Target area hair counts (TAHC)

Target area hair counts (TAHC) were performed at baseline and at weeks 8, 16, and 24 within the tattooed 1 cm^2 evaluation area. The hairs within the tattooed target area were clipped and counted using a Dino-Lite DermaScope® (Dino-Lite, Naarden, the Netherlands) and DinoCapture software was used to record macrophotographs. Terminal and vellus hairs were then counted at every visit by an experienced physician who was blinded to patient clinical data. This data was then used to calculate the terminal to vellus ratio for each patient.

Hair diameter measurement

Ten clipped hairs from the 1 cm^2 target evaluation area were randomly measured by electronic outside micrometer (IP54, Hexagon Metrology, North Kingstown, Rhode Island) at baseline and at weeks 8, 16, and 24. Mean hair diameter thickness for each patient

Table 1. Demographic and clinical data of patients in both treatment groups

Characteristics	5% minoxidil solution (n = 10)	5% minoxidil milky lotion (n = 10)	*p*-value
Age (years; mean±SD)	48.3±11.4	38.7±12.1	0.09
Hamilton-Norwood classification			
• Class III vertex	3 (30.0%)	5 (50.0%)	0.24
• Class IV	7 (70.0%)	3 (30.0%)	
• Class V	0 (0.0%)	2 (20.0%)	
Duration of hair loss (years; mean±SD)	15.5±9.4	10.6±7.0	0.18
Family history of AGA (%)	6 (60.0)	6 (60.0)	1.00
Baseline hair count (hairs/cm^2; mean±SD)	123.0±39.4	114.8±30.4	0.59
Baseline hair diameter (μm; mean±SD)	45.1±11.1	58.0±11.4	0.02
Baseline terminal/vellus ratio (mean±SD)	5.7±3.4	3.7±2.8	0.19

AGA, androgenetic alopecia
p-value <0.05 indicates statistical significance

Table 2. Summary of patient self-assessment at week 24

Characteristics	5% minoxidil solution n (%)	5% minoxidil milky lotion n (%)
-3: Significantly worse	0 (0)	0 (0)
-2: Moderately worse	0 (0)	0 (0)
-1: Slightly worse	0 (0)	0 (0)
0: Not improved	1 (10)	1 (10)
+1: Slightly improved	7 (70)	6 (60)
+2: Moderately improved	2 (20)	3 (30)
+3: Significantly improved	0 (0)	0 (0)

Table 3. Inter-rater reliability of physician reviewer

Observed agreement	53 %
Weight Kappa; quadratic weight (95% CI)	0.52 (0.37-0.67)

was calculated to evaluate improvement at each visit.

Patient satisfaction

All subjects were asked to evaluate their own hair loss condition, compared to baseline, using a 7-point scale at weeks 8, 16, and 24. The 7-point evaluation scale was scored, as follows: -3 = significantly worse, -2 = moderately worse, -1 = minimally worse, 0 = no change, +1 = minimally improved, +2 = moderately improved, and +3 = significantly improved. To help patients answer this question, they were allowed to compare their current hair condition with baseline photographs of their vertex scalp. At each visit, conditions and factors (e.g., same head position while

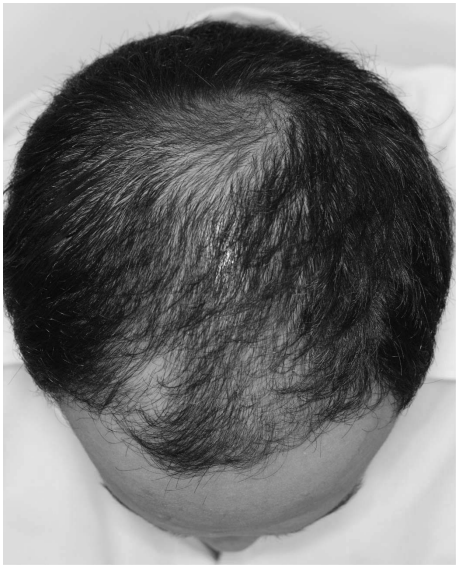

Fig. 1 Target evaluation area was selected in the hair whorl of the balding vertex and then tattooed with sterile ink to outline the area of 1 cm^2.

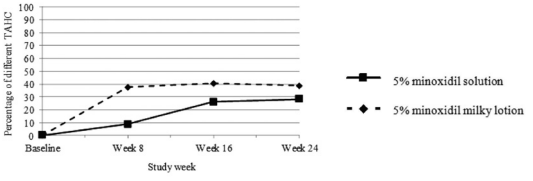

Fig. 2 Hair density at baseline and weeks 8, 16, and 24 (TAHC, target area hair counts).

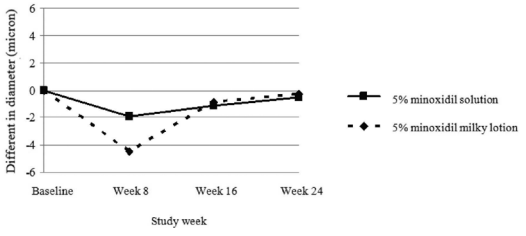

Fig. 3 Hair diameter at baseline and weeks 8, 16, and 24.

sitting, lighting, camera settings, and hair style) were as similar as possible to ensure consistency from one follow-up visit to the next.

Global photographic review

At baseline and weeks 8, 16, and 24, global photographs of the vertex scalp were taken with a Canon D60 60-mm camera (Canon, Inc., Tokyo, Japan). The photographs from each visit were independently rated by 2 blinded, experienced dermatologists. Physician reviewers evaluated individual hair loss condition, compared with baseline, using the same 7-point scale as used by participants. In the case of a different rating, the photograph was discussed until consensus was reached between the two reviewers.

Safety evaluation

Subjects were followed for 24 weeks, with follow-up visits at weeks 8, 16, and 24. Physical examination by dermatologist was performed at each follow-up visit to evaluate for side effects. Adverse events mostly involved scalp irritation, such as erythema, itching, pruritus, and scaling. Degree of severity was rated by subjects as none, mild, moderate, or severe. Patient drug compliance was evaluated by inspection of the returned container of the assigned preparation.

Statistical analysis

Data were analyzed using SPSS Statistics version 17.0 (SPSS, Inc., Chicago, IL, USA). Continuous data were presented as mean±standard deviation and categorical variables were expressed as number and percentage. Proportions were compared using Pearson's chi-square test or Fisher's exact test. *p-value* of <0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 20 Asian males who presented with AGA were enrolled. Subject age ranged from 26 to 65 years, with mean age of 43.5±12.5 years. Ten participants were assigned to the 5% minoxidil solution group and the other 10 participants were assigned to the 5% minoxidil milky lotion group (Table 1). Forty percent of subjects had Hamilton-Norwood hair loss pattern class III vertex, 50% had class IV, and 10% had class V. Sixty percent of subjects had positive family history of androgenetic alopecia. All baseline characteristics in both treatment groups showed no significant difference, except baseline hair diameter. Subjects treated with 5% minoxidil milky lotion had significantly larger hair diameter, as compared to the 5% minoxidil solution group. It is for this reason that we evaluated all differences for each parameter from baseline, instead of using raw data.

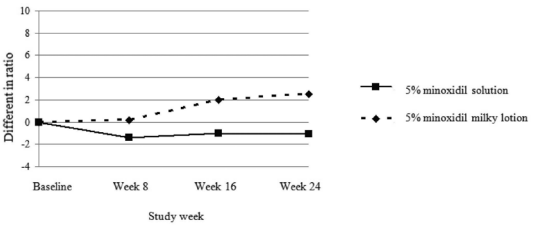

Fig. 4 Terminal:vellus ratio at baseline and weeks 8, 16, and 24.

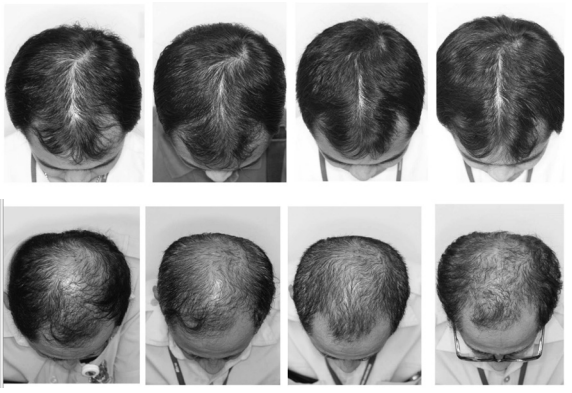

Fig. 5 Global photographs of vertex scalp illustrate gradual clinical improvement in hair loss condition in both groups throughout the 24 week study period; (A) 5% minoxidil milky lotion group, (B) 5% minoxidil solution group.

Efficacy

Target area hair counts (TAHC) and hair diameter measurement

There was significantly greater improvement in hair density in the 5% minoxidil milky lotion group compared to the 5% minoxidil solution group at the 8-week follow-up visit (37.4% *vs*. 8.8%; $p = 0.01$) (Fig. 2). However, there were no significant differences in hair density improvement between groups at either of the two subsequent follow-up visits. There were also no significant differences in either alteration of hair diameter or terminal:vellus ratio between minoxidil formulations at any follow-up visit (Fig. 3 and Fig. 4).

Patient satisfaction

Patient self-assessment revealed gradual clinical improvement throughout the 24-week treatment period in both groups. However, no significant difference was observed between treatment outcomes from the two treatment formulations. Of the 10 subjects in the 5% minoxidil milky lotion, 30% described moderate improvement in their hair loss condition and only 10% felt that their condition was unchanged. Twenty percent of subjects in the 5% minoxidil solution group rated their improvement as moderate (Table 2).

Global photographic review

Patients were clinically evaluated by 2 blinded, experienced dermatologists at each follow-up visit. Over the 24-week course of treatment, patients in both groups showed gradual clinical improvement in their hair loss condition (Fig. 5), with no statistically significant difference between groups. At 24 weeks, 30% (3/10 patients) and 60% (6/10 patients) of patients in the 5% minoxidil milky lotion group had moderate improvement and slight improvement, respectively. For the 5% minoxidil solution group, 20% (2/10 patients) and 70% (7/10 patients) had moderate improvement and slight improvement, respectively. Inter-rater reliability is shown in Table 3.

Safety

One adverse dermatologic event was reported by one patient in the 5% minoxidil milky lotion group at the 8-week follow-up visit. The patient complained of pruritus at a balding area, with no associated erythema, dryness, or scaling reported. He described how the symptoms gradually decreased over one month period. There were no other drug-related adverse events, including headache, palpitation, or angina. During the entire duration of the 24-week study, no subjects discontinued their participation in the study due to intolerable side effects.

Discussion

This comparative study between 5% minoxidil solution and 5% minoxidil milky lotion (butylene glycol base) revealed that 5% minoxidil milky lotion had significantly higher efficacy in hair density improvement at the 8-week visit. No difference in efficacy was noted, however, between the two formulations at 16 and 24 weeks. Although baseline hair diameter of the patients receiving both formulations was significantly different, there was no notable alteration in hair diameter between groups over the course of the

24-week study. The majority of the studies related to AGA were more concerned with the vellus hair count or terminal to vellus ratio than hair diameter[2,7]. It can be explained by the diameter diversity which is the characteristic finding of AGA[10]. Therefore, the average size of 10 randomly selected hairs in this report may not represent the actual hair diameter of the patients.

Regarding significant difference finding between formulations at week 8, the factors affecting percutaneous absorption is the basic knowledge to explain the result. Generally, there are various factors including skin age and site, temperature and peripheral circulation, state of the skin (normal or abraded), contact time and frequency of re-application, degree of hydration of the skin, physical characteristics of the penetrant, vehicle, and the penetrant-vehicle relationship[11]. However, both formulations in our study had no in vitro test to estimate drug penetration previously. After reviewing previous literatures, we propose two possible explanations. The first of which may be the lower pH of the 5% minoxidil milky lotion formulation. The preceding study revealed that minoxidil was more soluble in acidic solution than in basic solution[12,13]. Specifically, our developed formulation 5% minoxidil milky lotion has a pH of 4, whereas 5% minoxidil solution has a pH of 9. Therefore, lower pH condition of 5% minoxidil milky lotion provides better dissolution, generating early hair condition improvement. The second possible explanation is the non-crystalline form of minoxidil milky lotion that makes it easier to absorb. A previous study reported that the insoluble crystalline form of minoxidil solution after evaporation of ethanol was insufficient for uptake. This is different from minoxidil milky lotion, which is viscous and leaves the scalp moist providing easily absorption through the skin[13].

Regarding physician reviewer use of the 7-point scale, both minoxidil formulations showed improvement at 8 weeks, 16 weeks, and 24 weeks, compared with baseline. The majority of the patients had slight improvement. At 24 weeks, 5% minoxidil solution had better overall results. However, there was moderate interobserver agreement in this study. Regarding patient self-assessment using the 7-point scale, gradual improvement was reported by both groups, but no significant difference was found between minoxidil formulations. The majority of the patients rated slight to moderate improvement.

Observed adverse effects from both formulas was very low (1 of 20 patients; 5%). One patient reported pruritus after applying 5% minoxidil milky lotion. However, that patient's symptoms continuously subsided over a period of one month. Generally, topical minoxidil formulations can cause pruritus and scaling of the scalp due to allergic contact dermatitis, irritant contact dermatitis, or an aggravation of seborrheic dermatitis. Although the use of topical minoxidil formulations is remained, the last two conditions may be alleviated when treated with anti-inflammatory agents including tar shampoo. Previous study revealed that propylene glycol was the most frequent allergens from patch testing results in these populations,[9] but there was no comparative data of the incidence of irritant contact dermatitis and seborrheic dermatitis exacerbation between propylene and butylene glycol. Therefore, the knowledge from further studies will ensure the safety information of both minoxidil preparations.

Our study was limited by the small sample size which may account for non-significant results. Moreover, the greatest outcome after using topical minoxidil preparation is at 48 weeks. Future long-term studies in larger AGA patients are necessary to clarify the efficacy data and better understand the safety information between both formulations.

In conclusion, both of the topical minoxidil formulas were found to be effective and safe in the treatment of male androgenetic alopecia. The efficacy of 5% minoxidil milky lotion was comparable to that of 5% minoxidil solution. As such, 5% minoxidil milky lotion should be considered as an alternative topical treatment in propylene glycol-sensitive patients. However an acknowledging the small sample size in this study, further studies with larger sample populations should be conducted to verify and further elucidate these findings.

What is already known on this topic?

- 5% minoxidil solution is approved for the treatment of male androgenetic alopecia (AGA), with occasional reports of adverse events that were caused mostly by propylene glycol.
- 5% minoxidil milky lotion is one of alternative treatment in propylene glycol-sensitive patients, which uses butylene glycol as a solvent.

● There were only studies of the efficacy of 5% minoxidil milky lotion in the treatment of male AGA.that compare with baseline condition.

What is this study adds?

● Based on the findings from the present study, both 5% minoxidil solution and 5% minoxidil milky lotion were found to be effective and safe in the treatment of male AGA.

● 5% minoxidil milky lotion may be as an alternative treatment in propylene glycol-sensitive patients, with efficacy that is comparable to that of 5% minoxidil solution.

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Potential conflicts of interest

None.

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การศึกษาเปรียบเทียบประสิทธิภาพและความปลอดภัยระหว่างยาไมน็อกซิดิลโซลูชั่น 5% และยาไมน็อกซิดิลมิลค์กี้โลชั่น 5% ในการรักษาผู้ป่วยเพศชายที่มีภาวะผมบางแบบพันธุกรรม

รัฐพล ตวงทอง, กัณห์ชลิต ถนอมกิตติ, สาโรช สุวรรณสุทธิ

ภูมิหลัง: *ยาทาไมน็อกซิดิลขนาดความเข้มข้น 5% เป็นยาที่ได้รับการรับรองให้ใช้เพื่อรักษาผู้ป่วยเพศชายที่มีภาวะผมบางแบบพันธุกรรมมานานนับสิบปี อย่างไรก็ตาม มีการศึกษาหลายฉบับที่พบผลข้างเคียงจากยาดังกล่าวในเวลาต่อมา ซึ่งส่วนมากมีสาเหตุจากตัวทำละลายคือสารโพรพิลีนไกลคอล และล่าสุดโรงพยาบาลศิริราชได้ผลิตยาทาไมน็อกซิดิลสูตรใหม่ชื่อว่าไมน็อกซิดิลมิลค์กี้โลชั่น ซึ่งใช้สารบิวทิลีนไกลคอลเป็นตัวทำละลาย เพื่อหวังลดปัญหาผลข้างเคียงดังกล่าว*

วัตถุประสงค์: *เพื่อศึกษาประสิทธิภาพและความปลอดภัยของยาไมน็อกซิดิลโซลูชั่น 5% และยาไมน็อกซิดิลมิลค์กี้โลชั่น 5% ในการรักษาผู้ป่วยเพศชายที่มีภาวะผมบางแบบพันธุกรรม*

วัสดุและวิธีการ: *การศึกษานี้เป็นการทดลองเปรียบเทียบยาทาไมน็อกซิดิล 2 ชนิดดังกล่าว ในการรักษาผู้ป่วยเพศชายที่มีภาวะผมบางแบบพันธุกรรมแบบสุ่ม มีอาสาสมัครชายชาวเอเชียที่เข้าร่วมโครงการทั้งสิ้น 20 ราย โดยแต่ละรายจะได้รับการรักษาด้วยยาชนิดใดชนิดหนึ่งเป็นระยะเวลา 24 สัปดาห์ และมีการประเมินผลการรักษาและผลข้างเคียงที่ระยะเวลา 8 สัปดาห์ 16 สัปดาห์ และ 24 สัปดาห์*

ผลการศึกษา: *ผู้ป่วยมีอายุเฉลี่ย 43.5±12.5 ปี (26-65 ปี) จากการศึกษานี้พบว่าความหนาแน่นเส้นผมที่เพิ่มขึ้น ณ เวลา 8 สัปดาห์ หลังรักษาด้วยยาไมน็อกซิดิลโซลูชั่น 5% และยาไมน็อกซิดิลมิลค์กี้โลชั่น 5% เท่ากับ 8.8% และ 37.4% ตามลำดับ ($p = 0.01$) อย่างไรก็ตามไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติในการเปลี่ยนแปลงความหนาแน่นเส้นผม ณ เวลา 16 และ 24 สัปดาห์จากการเปรียบเทียบผู้ป่วยทั้งสองกลุ่ม นอกจากนี้ยังพบว่ามีผู้ป่วย 1 รายซึ่งได้รับการรักษาด้วยยาไมน็อกซิดิลมิลค์กี้โลชั่น 5% มีอาการระคายเคืองเล็กน้อยในช่วงเดือนแรกของการใช้ยาและอาการดังกล่าวค่อย ๆ ดีขึ้นเอง*

สรุป: *ยาไมน็อกซิดิลโซลูชั่น 5% และยาไมน็อกซิดิลมิลค์กี้โลชั่น 5% ถือเป็นยาทาที่มีประสิทธิภาพและความปลอดภัยในการรักษาผู้ป่วยเพศชายที่มีภาวะผมบางแบบพันธุกรรม โดยยาไมน็อกซิดิลมิลค์กี้โลชั่น 5% ถือว่าเป็นทางเลือกหนึ่งในผู้ป่วยที่มีอาการแพ้สัมผัสจากสารโพรพิลีนไกลคอล โดยให้ผลในการรักษาได้ดีเทียบเคียงกับการรักษามาตรฐานคือยาไมน็อกซิดิลโซลูชั่น 5%*