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Research Article

Therapeutic Efficacy of Botulinum Toxin (BOTOX®) and Minoxidil in the Treatment of Androgenetic Alopecia in Males

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Abstract

Background: Androgenetic alopecia is hair loss in men. Minoxidil is an established treatment, whereas botulinum toxin is an uncertain therapeutic option. ***Objective***: To compare the therapeutic efficacy of minoxidil and BOTOX®. ***Methods***: Our randomized, comparative interventional clinical study included male patients with androgenetic alopecia who were randomly allocated to two treatment groups. Group I received topical 5% minoxidil twice daily, while Group II received botulinum toxin type A. Treatment response was assessed next month using vertex hair density and patient-reported hair-growth improvement. ***Results***: The clinical and demographic characteristics were comparable in our two groups at baseline. Vertex hair density is comparable at baseline (84.5 *vs*. 78.5 hairs/cm², p=0.1), at 3 months (84.5 *vs*. 81 hairs/cm², p=0.3), and at 6 months (90 *vs*. 86 hairs/cm², p=0.2) in the minoxidil and BOTOX® groups, respectively. Within-group analysis demonstrated a statistically significant increase in hair density over time in the minoxidil group (p=0.007), with no significant change observed in the BOTOX® group (p=0.6). However, the change in hair density and improvement were not very different in our two study groups (p=0.7 and p=0.5, respectively). At month 6, hair growth was significantly favored by minoxidil (p=0.001), with 86.7% reporting some degree of improvement compared with 73.4% in the BOTOX® group. ***Conclusions***: Topical 5% minoxidil produced a significant improvement in vertex hair density and was associated with greater patient-reported improvement over six months. Botulinum toxin showed less effect.

Keywords: Androgenetic alopecia; Botulinum toxin; Hair density; Minoxidil.

فعالية سموم البوتولينوم والمينوكسيديل في علاج الثعلبة الأندروجينية لدى الذكور

الخلاصة

الخلفية: تساقط الشعر الناتج عن الثعلبة الأندروجينية لدى الرجال. المينوكسيديل علاج معتمد، في حين أن سم البوتولينوم خيار علاجي غير مؤكد. **الهدف**: مقارنة الفعالية العلاجية للمينوكسيديل و سم البوتولينوم. **الطرائق**: شملت دراستنا السريرية التدخلية العشوائية المقارنة مرضى ذكور يعانون من الثعلبة الأندروجينية تم توزيعهم عشوائيا إلى مجموعتين علاجيتين. تلقت المجموعة الأولى مينوكسيديل 5٪ موضعيا مرتين يوميا، بينما تلقت المجموعة الثانية سم البوتولينوم من النوع A. تم تقييم استجابة العلاج الشهر التالي باستخدام كثافة الشعر في الرأس وتحسن نمو الشعر الذي أبلغ عنه المريض. **النتائج**: كانت الخصائص السريرية والديموغرافية قابلة للمقارنة في مجموعتنا عند البداية. كثافة شعر الرؤوس قابلة للمقارنة في الأساس (84.5 مقابل 78.5 شعرة/سم²، p=0.1)، عند 3 أشهر (84.5 مقابل 81 شعرة/سم²، p=0.3)، وعند 6 أشهر (90 مقابل 86 شعرة/سم²، p=0.2) في مجموعتي المينوكسيديل والبوتوكس على التوالي. أظهر تحليل داخل المجموعة زيادة ذات دلالة إحصائية في كثافة الشعر مع مرور الوقت في مجموعة المينوكسيديل (p=0.007)، دون ملاحظة أي تغيير ذي دلالة في مجموعة البوتوكس (p=0.6). ومع ذلك، لم يكن التغير في كثافة الشعر والتحسن مختلفين كثيرا في مجموعتي الدراسة لدينا (p=0.7 و p=0.5 على التوالي). في الشهر السادس، كان نمو الشعر مفضلا بشكل ملحوظ المينوكسيديل (p=0.001)، حيث أبلغ 86.7٪ عن تحسن بدرجة معينة مقارنة ب 73.4٪ في مجموعة البوتوكس. **الاستنتاجات**: أدى المينوكسيديل الموضعي الى 5٪ من تحسين كبير في كثافة الشعر على الرؤوس ومرتبط بتحسن أكبر أبلغ عنه المرضى خلال ستة أشهر. أظهر سم البوتولينوم تأثيرا أقل.

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INTRODUCTION

Androgenetic alopecia (AGA) is the most common type of nonscarring alopecia and is characterized by patterned reduction in scalp hair density, which happens progressively. AGA occurs because of a combination of genetic predisposition and androgen-related changes in the hair follicle, causing gradual thinning of terminal hair and shortening of the growth phase. In males, hair loss often starts in the frontotemporal and vertex region and may slowly advance to more extensive scalp involvement [1]. AGA is not related to significant physical morbidity, but its visible nature can affect self-image, psychological well-being, and quality of life in a substantial way, especially in young men. The diagnosis is primarily clinical, and it can be supported by trichoscopic findings showing variability in hair shaft diameter, an increase in vellus hairs, and progressive hair follicle miniaturization [2]. The management of AGA aims to stop further hair follicle miniaturization and increase the regrowth of miniaturized hair. Despite the increasing number of therapeutic options, minoxidil (topical) and finasteride (oral) are still the best-established pharmacological treatments for AGA in males. Minoxidil is a potassium-channel opener and a vasodilator that causes hair follicle growth and lengthens the anagen phase, thereby increasing hair density and diameter. Topical 5% minoxidil is widely used in males because of its established efficacy and favorable safety profile. However, this treatment needs continuous use to maintain the therapeutic response, and the improvement is variable among patients. Moreover, local adverse effects such as scalp irritation, pruritus, and dermatitis might affect

adherence [3]. Despite the important role of minoxidil, treatment limitations and variable patient responses have increased interest in adjunctive and alternative therapies. Botulinum toxin type A (BoNT-A) has emerged as a minimally invasive approach for AGA, with its proposed effect related to a temporary relaxation of scalp muscles, changes in local vascular dynamics, and modifying the scalp microenvironment. By reducing scalp muscle tension and improving local tissue perfusion, BoNT-A might create conditions that are more favorable for hair follicle activity. However, the evidence is still less established than those supporting conventional pharmacological treatments, and the variation in dose, injection site, administration techniques, and treatment intervals has led to inconsistent findings across clinical studies [4,5]. So, our study was designed to compare the therapeutic efficacy of topical 5% minoxidil and botulinum toxin type A in male patients with androgenetic alopecia.

METHODS

Study design and setting

This prospective, comparative interventional study included records for history taking and follow-up of male patients with clinically diagnosed androgenetic alopecia who attended the Dermatology Outpatient Private Clinic in the Wasit governorate of Iraq during the study period from January 2025 to June 2025. Eligible patients were randomly allocated into two treatment groups using a computer-generated random sequence with concealed allocation.

Eligibility criteria

Adult male patients aged between 18 and 50 years with clinically confirmed mild-to-moderate androgenetic alopecia were eligible for inclusion. Participants were required to have a stable general medical condition, provide written informed consent, and demonstrate willingness to adhere to the treatment protocol and attend all scheduled follow-up visits. Patients were excluded if they had other causes of nonscarring or scarring alopecia, active inflammatory or infectious scalp disorders, previous hair transplantation, hypersensitivity or contraindications to any of the study treatments, or a history of conditions or medications known to significantly affect hair growth. Patients who had received treatment for androgenetic alopecia within the predefined washout period before enrollment or who failed to attend scheduled follow-up visits were also excluded.

Treatment protocol

Group I (Minoxidil group): received topical 5% minoxidil solution as monotherapy. Patients were instructed to apply 1 mL of the solution twice daily to the affected scalp areas throughout the six-month treatment period. Patients received detailed verbal and written instructions regarding the appropriate method of application, treatment adherence, and scalp hygiene. Compliance was reinforced and assessed at each follow-up visit. Group II (Botulinum toxin group): received intradermal botulinum toxin type A injections to the affected scalp areas according to our study protocol. The injections were performed under strict aseptic conditions by the same specialist throughout the study to ensure consistency in the injection technique. Based on the study protocol, the group II (botulinum toxin group) received intradermal botulinum toxin type A injections (botulinum toxin A; BOTOX®, Allergan Aesthetics, an AbbVie company, Irvine, CA, USA). Each 100-U vial was reconstituted with 2.5 mL of preservative-free 0.9% normal saline, yielding a concentration of 4 U per 0.1 mL. A total dose of 50 U was administered per treatment session. The reconstituted solution was administered using a 30-gauge needle as superficial intradermal injections, with approximately 2 U (0.05 mL) per injection site distributed across 25 injection points covering the affected scalp areas. The injection sites were approximately spaced 1–2 cm apart to achieve uniform coverage of the treatment area. Treatment was administered at baseline and a second time at 3 months, for a total of two treatment sessions during the 6-month study period. All injections were performed under strict aseptic conditions by the same specialist using a standardized injection technique throughout the study to minimize procedural variability. A spacing of 1–2 cm between injection sites was selected based on the diffusion radius of the toxin to ensure complete and homogeneous coverage of the affected area without chaotic overlapping. Consequently, 25 injection points were designated to distribute the total dosage precisely across the targeted anatomical region. This regimen was adopted as the study treatment protocol, as there is no universally standardized botulinum toxin regimen for androgenetic alopecia. The 3-month interval allowed assessment before retreatment, while the 6-month follow-up evaluated the sustained response over two treatment cycles.

Data collection

All participants underwent a complete baseline evaluation before starting treatment. Clinical and demographic data, including age, duration of AGA, smoking status, educational level, other relevant medical history, and previous treatment history, were all recorded. A complete dermatological examination was done to confirm the diagnosis of AGA, and we excluded other causes of hair loss. Baseline clinical dermoscopic images were obtained under standardized conditions, including identical patient positioning, scalp preparation, lighting, magnification, and image acquisition settings. The same standardized conditions were maintained during follow-up assessments. Clinical and dermoscopic assessments were performed at the baseline before treatment, three months, and six months after treatment. The primary objective outcome was vertex hair density (hairs/cm²). Hair density was measured using a digital dermatoscope equipped with image-

analysis software. A standardized 1-cm² area of the vertex scalp was selected at baseline and subsequently assessed at the same anatomical location during follow-up visits. The same magnification, illumination, and image-acquisition settings were used throughout the study. Treatment response was additionally evaluated using patient-reported hair growth assessment. At the six-month follow-up visit, participants were asked to compare their current hair growth with baseline and categorize their perceived improvement as no improvement, 1–25% improvement, 26–50% improvement, 51–75% improvement, or 76–100% improvement. This assessment was used to evaluate the patient's subjective perception of therapeutic efficacy. At each follow-up visit, participants were asked regarding any local or systemic adverse events, and a targeted scalp examination was performed. In patients receiving botulinum toxin, any treatment-related systemic or local complications were specifically recorded.

Ethical considerations

The study protocol was conducted in accordance with the principles of the Declaration of Helsinki for research involving human participants. Written informed consent was obtained from all participants before enrollment. A gatekeeper's approval letter was obtained from the recruitment site.

Statistical analysis

The statistical analysis was performed by IBM SPSS Statistics for Windows, Version 26.0 (IBM Corp., Armonk, NY, USA). All the data were checked for completeness and assessed for normality before statistical analysis. Continuous variables were presented as mean ± standard deviation (SD) for normally distributed data or median and interquartile range (IQR) when appropriate. Categorical variables were expressed as frequencies and percentages. Baseline clinical and demographic characteristics were compared between the two treatment groups using the independent-samples Student's t-test for normally distributed continuous variables or the Mann–Whitney U test for non-normally distributed variables. Categorical variables were compared using the chi-square test. Changes in continuous outcomes over time within each treatment group were assessed using appropriate paired statistical tests according to data distribution. Repeated-measures analysis was used when appropriate to evaluate changes across baseline, three-month, and six-month assessments. Between-group differences in treatment response were assessed using appropriate comparative tests. All statistical tests were two-tailed, and a p-value of <0.05 was considered statistically significant.

RESULTS

60 patients in total were included in our study. There were no statistically significant differences in baseline demographic or clinical characteristics between the minoxidil and botulinum toxin groups. The mean age was comparable between Group I and Group II (38.5 ± 10.5 vs. 38.2 ± 9.3 years, p= 0.8). Similarly, the mean duration of androgenetic alopecia was not significantly different between the two groups (6.0 ± 2.0 *vs*. 5.4 ± 2.1 years, p= 0.2). Smoking status and educational level were also distributed evenly, with no significant intergroup differences (p= 0.24 and p= 0.9, respectively). Our findings show that our study groups were matched well at baseline, which minimizes the potential confounding effect, allowing for a valid treatment outcome comparison (Table 1).

Table 1: Demographic and clinical characteristics of the patients studied (n=30 in each group)

Variable	Group I (Minoxidil) (n=30)	Group II (Botulinum Toxin) (n=30)	*p*-value
Age (year)			
Mean±SD	38.5±10.5	38.2±9.3	0.8[a]
Range	18–60	21–57	
AGA duration (year)			
Mean ± SD	6±2	5.4±2.1	0.2[a]
Range	2–11	2–10	
Smoking status n(%)			
Non-smoker	4(13.3)	8(26.7)	
Current smoker	9(30)	11(36.7)	0.24[b]
Former smoker	17(56.7)	11(36.7)	
Education level n(%)			
Primary school	5(16.7)	6(20)	0.9[b]
High school	12(40)	13(43.3)	
Bachelor	11(36.7)	10(33.3)	
Master	2(6.7)	1(3.3)	

[a]: Independent t test. [b]: Chi-square test.

At baseline, vertex hair density was a little higher in the minoxidil group compared to the botulinum toxin group; however, the difference is not statistically significant (84.5 *vs*. 78.5 hairs/cm², p= 0.1). And no significant differences were observed between the two groups at Month 3 (84.5 *vs*. 81 hairs/cm², p= 0.3) or Month 6 (90 *vs*. 86 hairs/cm², p= 0.2). Within-group analysis showed a statistically significant increase in hair density over time in the topical minoxidil group (p= 0.007), but no significant change was observed in the botulinum toxin group (p= 0.6). Even with this improvement, the overall change in hair density and percentage improvement were not significantly different between the two groups (p= 0.7 and p= 0.5, respectively). These findings show that topical minoxidil caused a significant improvement in hair density over the study period, while botulinum toxin did not show a similar within-group effect (Table 2).

Table 2: Comparison of Vertex hair density among study groups (n=30 in each group)

Hair Density (hairs/cm²)	Group I (Minoxidil)	Group II (Botulinum Toxin)	*p*-value[a]
Baseline	84.5(31)	78.5(28)	0.1
Month 3	84.5(33)	81(24)	0.3
Month 6	90 (50)	86(26)	0.2
p-value [b]	0.007	0.6	-
Change	4.5(-2.5 -15.2)	0(-1.25 – 16)	0.7
% Improvement	2.9(-2.9 -13.6)	0(-1.7 – 22)	0.5

[a]: Mann Whiney U test. [b]: Friedman test.

Assessment of patient-reported hair growth in Month 6 showed a statistically significant difference between our treatment groups (p= 0.001). In the topical minoxidil group, more than half of the patients (56.7%) reported a 1–25% improvement, while 30% reported a 26–50% improvement and the remaining 13.3% reported no improvement. In contrast, the botulinum toxin group showed a bigger percentage of patients with no improvement (26.7%), whereas 36.7% and 36.7% reported 1–25% and 26–50% improvement, respectively. No patients in either group reported an improvement exceeding 50%. Overall, patient self-assessment was better in the minoxidil treatment group, showing a significantly greater perceived improvement in hair growth compared to botulinum toxin (Table 3).

Table 3: Hair growth self-assessment at month 6 (n=30 in each group)

Improvement	Group I (Minoxidil)	Group II (Botulinum toxin)	*p*-value
No improvement	4(13.3)	8(26.7)	
1–25%	17(56.7)	11(36.7)	
26–50%	9(30)	11(36.7)	0.001
51–75%	0(0.0)	0(0.0)	
76–100%	0(0.0)	0(0.0)	

Values are presented as frequency and percentage.

DISCUSSION

Androgenetic alopecia is the most common progressive hair-loss disorder that can have a significant impact on patients' appearance and life quality. Our study compares the effectiveness of topical minoxidil and botulinum toxin in male patients with AGA, concentrating on the objective changes in hair density and the improvements reported by patients over a six-month period. Baseline clinical and demographic characteristics were similar in the topical minoxidil and botulinum toxin groups, with no significant differences in age, smoking status, or educational level. This baseline homogeneity minimizes potential confounding and supports the validity of the treatment comparison results. Regarding the vertex hair density, baseline values were slightly higher in the topical minoxidil group compared to the botulinum toxin group, but the differences were not significant. At Month 3, densities were 84.5 *vs*. 81 hairs/cm² (p= 0.3), increasing at Month 6 to 90 vs. 86 hairs/cm² (p= 0.2), respectively. Even though both groups showed numerical improvement, only the topical minoxidil group expressed a significant within-group increase over the six-month period (p= 0.007), while significant change was not observed with botulinum toxin (p= 0.6). However, the percentage improvement and overall change were similar between groups, showing that topical minoxidil improved hair density over time and is statistically comparable to botulinum toxin regarding overall change. The significant increase in vertex hair density with topical minoxidil is consistent with those of [12], who demonstrated significant improvements in both vertex terminal and vellus hair density following a minoxidil-containing regimen, as well as significant improvements [6], which indicated significantly bigger increases in non-vellus hair counts with 5% minoxidil (topical) compared with 2% minoxidil (topical) and placebo in 393 men. Similarly, they found significant increases in target-area hair count and cumulative hair width with 5% minoxidil foam in men with vertex AGA [7]. Further demonstrated sustained improvements in hair density, hair width, and scalp coverage over 104 weeks, supporting the efficacy of minoxidil in the vertex region [8]. More recent evidence also supports these findings. Reported increased vertex hair density after 24 weeks with both oral and topical minoxidil [9], although without significant differences between treatment modalities. Similarly, it demonstrated significant improvement in hair counts following 24 weeks of oral minoxidil [10]. Also found significant improvement with both oral and topical minoxidil, with no significant difference between the two approaches [11]. Collectively, these findings support the effectiveness of minoxidil in increasing hair density regardless of its route of administration. Our findings are also consistent with those of [12], who demonstrated significant improvements in both vertex terminal and vellus hair density following a minoxidil-containing regimen, as well as significant improvements in vertex terminal and vellus hair density following a minoxidil-containing regimen, and who reported significant improvements in hair-growth parameters among men receiving topical minoxidil [13]. Although Bassiouny studied women, their findings further support the responsiveness of the vertex region to minoxidil-based treatment. Studies evaluating combination therapies provide further evidence that the response to minoxidil may be influenced by treatment modality. The combination of minoxidil and microneedling resulted in a greater increase in hair count compared to minoxidil alone [14]. Reported significant increases in hair density with combined minoxidil and finasteride therapy [15]. These findings suggest that although minoxidil is effective as monotherapy, treatment response may

vary according to the therapeutic regimen and patient characteristics. Finally, our finding that the overall change in hair density did not differ significantly between treatments is consistent with [16], which showed improvement in hair density in both low-level laser therapy and minoxidil, without a significant between-group difference. These findings emphasize that a significant within-group improvement does not necessarily indicate superiority over another active treatment, which is consistent with the present study. Regarding botulinum toxin, the absence of a significant increase in vertex hair density in our study differs from several studies. Reported good-to-excellent photographic improvement in 80% of patients and similar improvement by self-assessment in 70% after 24 weeks of botulinum toxin treatment. However, their small sample size and no control group limit a direct comparison [17]. Also reported significant increases in hair count, with effectiveness rates of 73.3% for botulinum toxin alone and 84.8% when it got combined with finasteride [18]. Their repeated injection every three months for four sessions, compared with the six-month protocol in our study, may partly explain the difference in findings. Similarly, they found significantly increased hair density following botulinum toxin treatment at three and six months. But botulinum toxin was used alongside finasteride and minoxidil, making it difficult to know its independent effect [19]. Also reported greater hair growth, satisfaction, and quality-of-life improvement when botulinum toxin was added to topical minoxidil [20]. The more favorable results in these studies may therefore be related to combination therapy rather than botulinum toxin alone. In contrast, our findings are supported by recent evidence questioning the effect of botulinum toxin on objective hair parameters. Found no significant changes in hair density or the vellus-to-terminal hair ratio six months after botulinum toxin treatment, regardless of injection technique [21], which closely agrees with our findings. Also highlighted the limited quality of available evidence, mainly due to small samples, inadequate controls, and methodological heterogeneity [22]. Conversely, [23] reported a significant pooled increase in hair density following botulinum toxin treatment in a recent meta-analysis, although substantial heterogeneity related to treatment dose and protocols was noted. These variations may explain the different results across studies and the absence of a significant effect in our study. The difference between our findings and the other previous positive studies may be related to variations in botulinum toxin dose, injection technique, treatment frequency, concomitant therapy, and outcome assessment. As our study evaluated botulinum toxin monotherapy using objective vertex hair density, the absence of a significant improvement may reflect the specific treatment protocol rather than complete therapeutic ineffectiveness. Overall, minoxidil showed a more consistent within-group improvement, although the difference in overall hair-density change was not statistically significant. Regarding patient-reported hair growth at Month 6, a significant difference was observed between the minoxidil and botulinum toxin groups. In the minoxidil group, 56.7% of patients reported 1–25% improvement, 30.0% reported 26–50% improvement, and 13.3% reported no improvement. In comparison, 26.7% of patients receiving botulinum toxin reported no improvement, while 36.7% reported 1–25% and 36.7% reported 26–50% improvement. No patient in either group reported improvement exceeding 50%. These findings indicate a more favorable subjective response to minoxidil. Our findings are consistent with [6], which showed improvements in both hair counts and patient-perceived scalp coverage with 5% topical minoxidil. Similarly, it demonstrated significant patient-perceived improvement in scalp coverage after 24 weeks of 5% minoxidil foam, supporting the subjective benefit observed in our minoxidil group [7]. Patient-reported improvement might not always directly correspond to real objective hair density, as it can also reflect changes in hair thickness, scalp coverage, and cosmetic appearance. Thus, the greater subjective improvement with topical minoxidil in our study may show both an observed increase in hair density and qualitative changes in hair characteristics. The absence of improvements of more than 50% in either group also suggests that the overall perceived benefit stayed modest during our six-month follow-up. Overall, the patient-reported findings support our objective results, with minoxidil demonstrating a consistently higher clinical response. Although a substantial number of patients receiving botulinum toxin reported some improvement, the subjective improvement was not accompanied by a significant increase in objective hair density.

Study Strengths

The main strengths of our study include its prospective randomized comparative design and the direct comparison of topical minoxidil with botulinum toxin. The treatment groups were balanced well at baseline, minimizing potential confounding. In addition, treatment response was evaluated using both objective vertex hair density and patient-reported improvement, providing complementary measures of therapeutic efficacy. The standardized follow-up at baseline, three months, and six months also allowed for the assessment of treatment response over time.

Study Limitations

Several limitations should be considered. The relatively small sample size may have limited the ability to detect modest differences between groups. The six-month follow-up may also have been insufficient to fully assess the long-term efficacy and durability of botulinum toxin, particularly with repeated treatment sessions. In addition, only one botulinum toxin treatment protocol was evaluated, limiting generalizability to other doses or injection techniques. Assessment was primarily focused on vertex hair density, which may not reflect changes in other scalp regions. Finally, patient-reported improvement was based on percentage categories rather than a validated disease-specific questionnaire,

and long-term adherence, safety, and persistence of treatment effects were not evaluated. Larger randomized studies with longer follow-up time and standardized botulinum toxin protocols are therefore warranted.

Conclusion

Minoxidil significantly improved the vertex hair density and patient-reported hair growth over the six months, whereas botulinum toxin showed no significant within-group improvement in hair density. However, the overall change in hair density did not differ significantly between treatments. Minoxidil therefore demonstrated a more consistent clinical response, while botulinum toxin may represent a potential alternative treatment requiring further investigation.

Conflict of interests

The authors declared no conflict of interest.

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Data sharing statement

The data that supports the findings of this study are available from the corresponding author upon a reasonable request.

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