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Original Article

## Evaluating the Efficacy of Adipose-Derived Stem Cells Exosome (ADSCE) in Treating Androgenetic Hair Loss: An Open-Label Clinical Trial

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### Abstract

**Background and Objectives:** Androgenetic alopecia (AGA) is a common form of hair loss with limited effective treatments. Adipose-derived stem cell exosomes (ADSCE) have emerged as a novel regenerative therapy. This study aimed to evaluate the efficacy and safety of ADSCE compared to standard minoxidil treatment in patients with AGA.

**Methods:** In this randomized controlled trial, 90 adult patients with AGA were assigned to receive either intradermal ADSCE injections or topical minoxidil 5% men and 2% for women for 12 weeks. Hair diameter and count were measured at baseline and at five follow-up visits using Trichoscopy (SIF PRO) and digital image analysis. Patient satisfaction and adverse events were also assessed.

**Results:** Both groups showed improvement in hair diameter and count over time, but the ADSCE group demonstrated significantly greater increases at each follow-up (final visit: hair diameter  $88.8 \pm 15.6 \mu\text{m}$  vs.  $74.2 \pm 23.3 \mu\text{m}$ ,  $p \leq 0.001$ ; hair count  $28.5 \pm 5.8$  vs.  $19.8 \pm 10.4$  (in  $12\mu\text{m}$  of area),  $p \leq 0.001$ ). Patient satisfaction was higher in the ADSCE group (97.8% "very satisfied" vs. 33.3% in the minoxidil group,  $p \leq 0.001$ ). Mild pain and localized swelling were more common in the ADSCE group, but no serious adverse events occurred.

**Conclusion:** ADSCE therapy is more effective than minoxidil in improving hair density and diameter in AGA, with high patient satisfaction and an acceptable safety profile. ADSCE represents a promising alternative for AGA management.

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### 1. Introduction

Androgenetic alopecia (AGA), also known as androgenetic hair loss (AHL), is the most common form of hair loss in both men and women, characterized by progressive thinning and miniaturization of scalp hair follicles (1) The condition is highly prevalent, affecting

approximately 60–70% of the global population, with higher rates observed among Caucasians compared to other ethnic groups (2) The incidence of AGA increases with age, particularly in men, where up to 80% are affected by age 70, and in women, especially after menopause.(3, 4)

AGA is a multifactorial disorder with a strong genetic component, primarily involving polygenic inheritance and key loci such as the androgen receptor gene.(5) Dihydrotestosterone (DHT), which acts on genetically predisposed hair follicles, shortens the anagen (growth) phase while increasing the duration of the telogen (resting) phase of hair shafts, which ultimately compromises the density of hair and contributes to a miniaturisation of hair follicles.(6, 7) Other factors such as inflammation, oxidative stress, and a dysregulation of many signaling pathways, including Wnt/ $\beta$ -catenin, contribute to the development of this disorder.(8)

Diagnosis of AGA remains dependent upon a clinical examination, patient history, and diagnostic tools such as dermatoscopy or scalp biopsy,(9) whereas the treatment options available to the clinician include topical minoxidil, oral finasteride, hair transplantation, low-level laser therapy, and injection of platelet-rich plasma (PRP), all of which vary significantly in terms of efficacy and side effects.(1)

Recent advances in regenerative medicine have introduced a new class of therapeutic modalities for the treatment of AGA. The use of extracellular vesicles derived from adipose-derived stem cells (ADSC), also referred to as adipose-derived stem cell exosomes (ADSCE), has been shown in early research studies to provide many benefits in terms of promoting the health and growth of the hair follicles through modulation of the surrounding tissue microenvironment, stimulation of vascularization and maintenance of dermal papilla cells.(10, 11) Early clinical studies indicate that these Products may help to both increase the rate of hair growth and improve

hair density.(12)

Despite the advancements made through a better understanding of using ADSCE for treating AGA, there still lacks sufficient clinical evidence to demonstrate both its safety and efficacy This study seeks to bridge this evident gap by assessing the clinical outcomes ADSCE employed in AGA Patients, thus providing both a new perspective and an evidence-based source of direction for the use of ADSCE in the clinical setting.

## **2. Materials and Methods**

### **2.1. Study design and setting**

An open-label, randomized controlled clinical trial of this nature was conducted in Sulaimani City through the Shahid Jabar Dermatology and Venereology Teaching Centre and private clinics from January to June 2025, a duration of six months in total.

### **2.2. Participants**

Eligible adults (male or female) were those who had been diagnosed with AGA and were being treated for AGA at Shahid Jabar Dermatology and Venereology Teaching Centre and private clinics in Sulaimani. Eligible subjects were determined by clinical evaluation and confirmation of diagnosis by clinical evaluation using the Norwood-Hamilton or Ludwig Scale. Subjects were recruited from dermatologists' recommendations and through public notice boards in hospitals, and all subjects completed written informed consent before participating in the study.

Eligible patients were randomly selected from the study population, by using computer-generated randomisation and allocation concealment via use of opaque, sealed envelopes. The sample size calculation was

done using an expected medium effect size (Cohen's  $d = 0.6$ ), with a minimum required statistical power of 80% and a maximum alpha level of 0.05. This resulted in 90 subjects, 45 per group.

Inclusion criteria comprised adults aged over 18- 65 years, a confirmed diagnosis of AGA (at least Stage III on the Norwood-Hamilton scale), The Ludwig Scale (stage II, and stage III), and willingness to comply with study procedures. Exclusion criteria included a history of allergic reactions to stem cell or exosome-based therapies, other dermatological or systemic conditions affecting hair growth, recent use of hair loss treatments (within six months), pregnancy or lactation, those who did hair transplantation and contraindications to minor surgical procedures.

### 2.3. Data Collection

The systematic data collection process took place over six-month intervals. The following were collected during the initial assessment: demographics, health history, and digital scalp photos Taken with a high-resolution camera to determine hair density and diameter of the hair shafts (Trichoscopy (SIF PRO)). All eligible participants were assigned randomly to the treatment groups and received either intradermal ADSCE injections (ASCE+, ExoCoBio, Korea) or minoxidil topical solution (5% for men and 2% for women).

The treatment phase lasted 12 weeks, during which patients in both groups received three treatment doses at four-week intervals. Specifically:

- Visit 0 (Baseline): First dose administered, baseline measurements and digital scalp photographs taken.
- Visit 1 (Week 4): Second dose administered; follow-up measurements and photographs obtained.
- Visit 2 (Week 8): Third dose administered which is the final; follow-up measurements and photographs obtained.
- Visit 3 (Week 12): follow-up measurements and photographs obtained post treatments.
- Visit 4 (Week 16) follow-up measurements and photographs obtained post treatments.
- Visit 5 (Week 20) follow-up measurements and photographs obtained post treatments.

During each session, the number of hairs, the average hair thickness, and all patient-reported outcomes (e.g., growth of hair; satisfaction with the procedure; any negative side effects) were recorded. The treatments were administered under sterile conditions by licensed, experienced medical professionals who have received training in the use of intradermal injection and in the assessment of digital images.

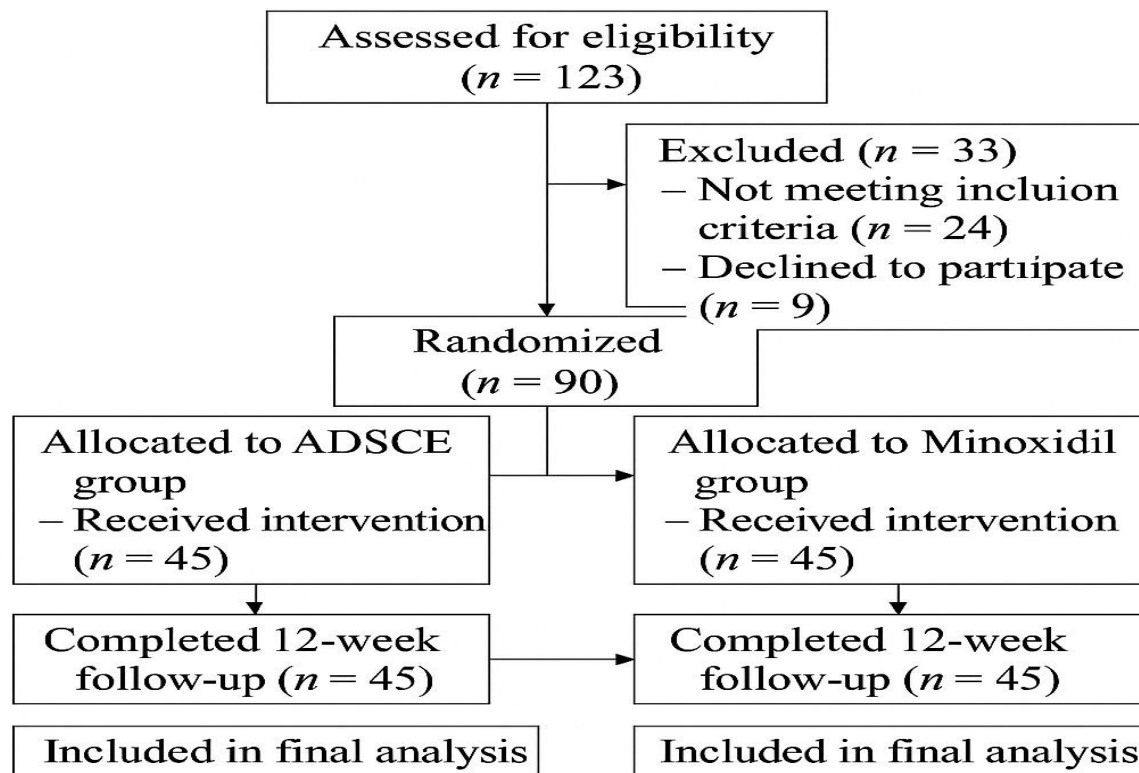
### 2.4. Ethical Considerations

Approval of the Institutional Review Board of the College of Medicine, University of Sulaimani was received for this study (362, 23/10/2024). Written informed consent was acquired from all participants and total confidentiality of all participant identities will be kept in strict accordance with the Declaration of Helsinki as well as local ethical standards.

### 2.5. Statistical Analysis

The SPSS version 28.0 was utilized to assess the data. Descriptive statistics were used to

summarize the baseline characteristics of the participants. The independent Sample t-test and chi-square were used to establish comparisons of the outcomes between the two groups. Hair density at multiple time points was evaluated using repeated measures ANOVA. Statistical significance was established at  $p \leq 0.05$ .



**Figure 1.** Flowchart of participant enrollment, randomization, treatment allocation, and follow-up in the ADSCE versus Minoxidil clinical trial.

### 3. Results

A total of 90 participants were enrolled, with 45 in the Exosome group and 45 in the Minoxidil group. The mean age was comparable between groups (Exosome:  $33.6 \pm 8.8$  years; Minoxidil:  $34.4 \pm 11.9$  years). Females comprised 29 (64.4%) of the Exosome group and 24 (53.3%) of the Minoxidil group. The majority of participants were of Asian

descent (Exosome: 33 (73.3%); Minoxidil: 31 (68.9%)), and nearly all reported a positive family history of hair loss (Table 1).

At baseline, mean hair diameter did not differ significantly between groups (Exosome:  $62.6 \pm 22.3 \mu\text{m}$ ; Minoxidil:  $67.8 \pm 22.8 \mu\text{m}$ ;  $p=0.283$ ). However, the Exosome group had a significantly higher mean hair count ( $14.2 \pm 5.2$ ) compared to the Minoxidil group ( $12.0 \pm$

4.9; p=0.042) (Table 2).

**Table 1.** Baseline sociodemographic characteristics of study participants.

Characteristics	Group	
	Exosome group (n=45)	Minoxidil group (n=45)
Age	33.6 ± 8.8	34.4 ± 11.9
Gender	Male	21 (46.7%)
	Female	24 (53.3%)
Ethnicity	Asian	31 (68.9%)
	European	14 (31.1%)
Family history	Positive	45 (100%)
	Negative	0

**Table 2.** Baseline hair diameter and hair count.

Characteristics	Group		P-value*
	Exosome group (n=45)	Minoxidil group (n=45)	
Hair diameter	62.6 ± 22.3	67.8 ± 22.8	0.283
Hair count	14.2 ± 5.2	12.0 ± 4.9	0.042

Both groups showed increases in hair diameter and count over five follow-up visits, with the Exosome group demonstrating significantly greater improvements at later visits (Table 3). At the fifth visit, the Exosome group had a significantly higher mean hair diameter (88.8 ±

15.6 µm) compared to the Minoxidil group (74.2 ± 23.3 µm; p=0.001). Similarly, mean hair count was higher in the Exosome group (28.5 ± 5.8) than in the Minoxidil group (19.8 ± 10.4; p=0.001).

**Table 3.** Hair diameter and count at baseline and fifth visit.

Characteristics	Group		P-value*	
	Exosome group (n=45)	Minoxidil group (n=45)		
Hair diameter	First visit	72.1 ± 15.9	69.5 ± 17.9	0.461
	Second visit	74.3 ± 15.9	72.8 ± 17.6	0.665
	Third visit	80.8 ± 16.0	74.7 ± 18.4	0.097
	Fourth visit	82.8 ± 15.5	74.8 ± 20.3	0.038
	Fifth visit	88.8 ± 15.6	74.2 ± 23.3	0.001
Hair count	First visit	19.4 ± 5.3	15.2 ± 5.4	0.001
	Second visit	22.0 ± 6.0	18.1 ± 5.8	0.002
	Third visit	24.9 ± 5.6	18.8 ± 6.8	0.001
	Fourth visit	26.9 ± 5.4	19.4 ± 8.8	0.001
	Fifth visit	28.5 ± 5.8	19.8 ± 10.4	0.001

Improvements in hair count were observed in both sexes, but women showed significantly greater increases at later visits. At the fifth

visit, mean hair count was  $26.9 \pm 7.7$  in women versus  $20.2 \pm 10.0$  in men ( $p=0.001$ ) (Table 4).

**Table 4.** Hair characteristics in terms of hair diameter and hair number by gender in the two treatment groups participating in the study.

Characteristics	Group		P-value*	
	Male (n=37)	Female (n=53)		
Hair diameter	Baseline	$64.6 \pm 21.8$	$65.6 \pm 23.3$	0.849
	Visit 1	$68.8 \pm 17.7$	$72.3 \pm 16.3$	0.339
	Visit 2	$72.3 \pm 15.8$	$74.4 \pm 17.3$	0.548
	Visit 3	$74.7 \pm 18.4$	$79.8 \pm 16.5$	0.185
	Visit 4	$74.3 \pm 19.8$	$81.9 \pm 16.9$	0.060
Hair count	Visit 5	$76.5 \pm 22.5$	$84.9 \pm 19.4$	0.066
	Baseline	$12.4 \pm 4.8$	$13.6 \pm 5.4$	0.242
	Visit 1	$16.6 \pm 6.1$	$17.8 \pm 5.5$	0.326
	Visit 2	$18.9 \pm 6.3$	$20.8 \pm 6.1$	0.163
	Visit 3	$19.9 \pm 7.2$	$23.2 \pm 6.4$	0.034
	Visit 4	$20.1 \pm 8.8$	$25.3 \pm 6.9$	0.003
	Visit 5	$20.2 \pm 10.0$	$26.9 \pm 7.7$	0.001

\*P-value based on Independent Sample t-test

Overall satisfaction was significantly higher in the Exosome group, with 97.8% reporting

being "Very Satisfied" compared to 33.3% in the Minoxidil group ( $p=0.001$ ) (Table 5).

**Table 5.** Overall satisfaction with treatment.

Characteristics	Group		P-value*	
	Exosome group (n=45)	Minoxidil group (n=45)		
Overall satisfaction	Very unsatisfied	0	2 (4.4%)	0.001
	Unsatisfied	0	6 (13.3%)	
	Natural	1 (2.2%)	14 (31.1%)	
	Satisfied	0	8 (17.8%)	
	Very Satisfied	44 (97.8%)	15 (33.3%)	

\*P-value based on Chi-square and fisher exact test

Adverse events were generally mild. Mild pain was reported by 97.8% of the Exosome group (none in Minoxidil,  $p=0.001$ ), and localized swelling occurred in 24.4% of the Exosome

group (none in Minoxidil,  $p=0.001$ ). Irritation was more common in the Minoxidil group (11.1% vs. 4.4%), but this was not statistically significant (Table 6).

**Table 6.** Adverse events in both treatment groups.

Characteristics	Group		P-value*
	Exosome group (n=45)	Minoxidil group (n=45)	

Side effects	Headache	2 (4.4%)	0	0.494
	Negative	43 (65.6%)	45 (100%)	
Pain	Mild pain	44 (97.8%)	0	0.001
	Negative	1 (2.2%)	45 (100%)	
Irritation	Positive	2 (4.4%)	5 (11.1%)	0.434
	Negative	43 (95.6%)	40 (88.9%)	
Swelling	Localized	11 (24.4%)	0	0.001
	Negative	34 (75.6%)	45 (100%)	

\*P-value based on Chi-square and fisher exact test.

Representative clinical photographs illustrating treatment responses are shown in Figure 1 (ADSCE group) and Figure 2 (Minoxidil group).

Top-down scalp images of a female patient with androgenetic alopecia treated with intradermal adipose-derived stem cell exosome (ADSCE) therapy. Images represent: (A)

Baseline before treatment; (B) Visit 1 (Week 4); (C) Visit 2 (Week 8); (D) Visit 3 (Week 12); (E) Visit 4 (Week 16, post-treatment follow-up); (F) Visit 5 (Week 20, post-treatment follow-up). Progressive improvement in hair density and scalp coverage is visible over the 6-month period figure 2.



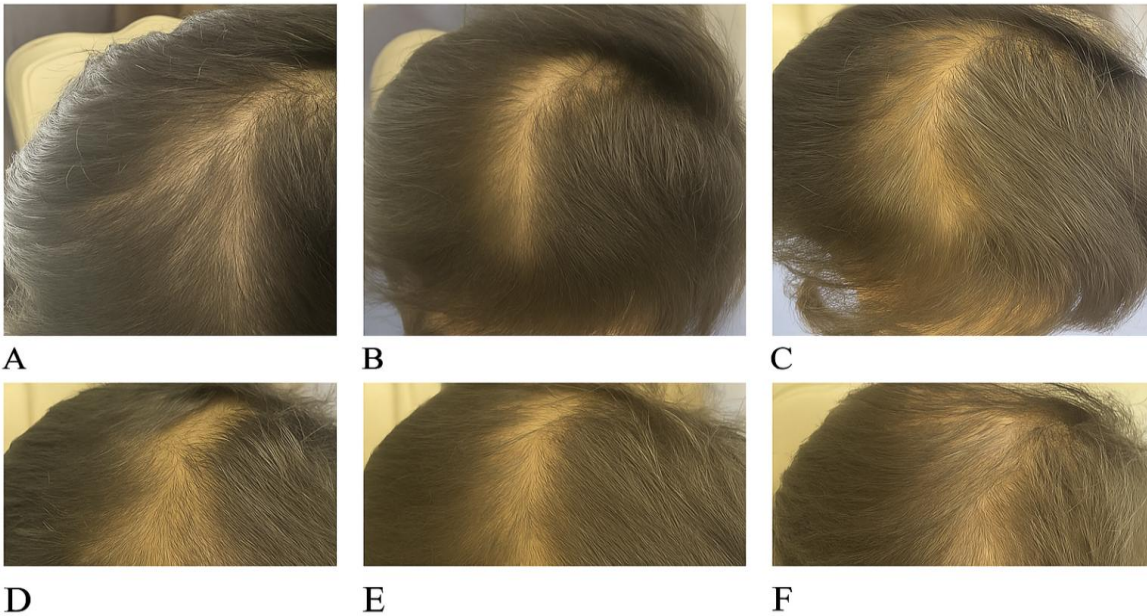
**Figure 1.** Serial Clinical Photographs of a Patient Treated with ADSCE Therapy Over Six Months

Sequential top-view scalp photographs of a female patient with androgenetic alopecia treated with topical minoxidil. Images

represent: (A) Baseline before treatment; (B) Visit 1 (Week 4); (C) Visit 2 (Week 8); (D) Visit 3 (Week 12); (E) Visit 4 (Week 16, post-

treatment follow-up); (F) Visit 5 (Week 20, post-treatment follow-up). The progression shows mild improvement in hair coverage over

time, though less pronounced than in the ADSCE group figure 3.



**Figure 2.** Serial Clinical Photographs of a Patient Treated with Topical Minoxidil Over Six Months

#### 4. Discussion

Androgenetic alopecia (AGA) is a common condition with significant psychosocial impact, and current treatments such as minoxidil and finasteride often yield suboptimal results or cause adverse effects, highlighting the need for novel therapies.(13, 14) ADSCE can be used in clinical practice as an effective and safe approach to treating AGA.(15) The effectiveness of ADSCE was demonstrated in this current study where both hair density and diameter were significantly improved compared to minoxidil, which was also indicated by the high level of satisfaction associated with the use of ADSCE by the study participants. These results are comparable with previous studies, clinical and preclinical alike, demonstrating how exosome therapies can enhance hair growth and quality and, in many instances, be superior to standard therapies.(16, 17)

The increase in effectiveness of ADSCE can be due to its activation of the Wnt/ $\beta$ -catenin pathway, its effects on dermal papilla cell proliferation, and its ability to increase angiogenesis.(18, 19) The present study showed an increase in hair shaft diameter with ADSCE cumulatively and over time. This is consistent with the results reported by Shimizu et al. (2022).(20) It seems that exosome therapy has longer-lasting effects than minoxidil. Despite a difference in the number of hairs at the start of the study, the ADSCE-treated group had a consistent and statistically significant increase in the number of hairs produced. This supports data from Ersan et al. (2024),(16) and Li et al. (2022),(21) showing the superior ability of exosome-based therapy to promote hair growth.

Analyses of sex demonstrated that, as compared to men, women in this study demonstrated a greater increase in the number

of hairs. Biologically based variables may account for the difference between men and women, consistent with findings of Grymowicz et al. (2020),(22) and Ho et al. (2023).(23) Reports of mild and transient adverse effects provide support for the favorable safety profile of ADSCE, consistent with the reports of others providing evidence for the safety of this treatment.(24, 25)

### **Study Limitations and Recommendations**

The study's clinical outcomes could be impacted by the study design because the study only had one control group. In addition, there are shortcomings in the follow-up period. This was just three months (12 weeks). Therefore, it was too short to fully evaluate the long-term process of hair growth, maintenance, and durability of ADSCE's abilities.

Future research should examine extended follow-up periods to evaluate the durability and long-term safety of ADSCE; as well as conduct large multicenter double-blinded trials to confirm effectiveness and control for bias. Future research should evaluate optimal dosing regimens and administration intervals for ADSCE; examine combination therapies involving ADSCE with other approved AGA treatments; conduct mechanistic studies using biological markers to better understand how ADSCE affects hair growth; investigate sex-specific responses to ADSCE and develop personalized treatment protocols based on these differences; and conduct cost-effectiveness analyses to assess the practical utility of ADSCE in the healthcare system.

### **5. Conclusions**

In this study, we found that ADSCE Therapy significantly increased Hair Density and Diameter of each Hair Shaft in AGA Patients

compared to Topical Minoxidil, and that as the amounts of each increased, the Greater the improvement observed. The findings are consistent with the various Regenerative Mechanisms associated with Exosomes, and patients reported a very high level of Satisfaction with the treatment. Women had significantly Greater Increases in Hair Count than men, indicating the potential for the development of individualized therapeutic options. Our findings support the use of ADSCE to treat AGA, so larger and longer-term clinical studies should be done to better understand how and why ADSCE can be used effectively to treat this condition.

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**Conflict of interest:** The authors declare no competing interests.

**Data availability:** Upon reasonable request, the data from the research may be obtained from the corresponding author.

**Authors' contributions:** Each author made an equal contribution to this research work.

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