

## Review

### **Autologous Micrograft Technology (AMT) and Finasteride for the Management of Androgenic Alopecia – A Systematic Review and Meta-Analysis of Their Efficacy and Safety**

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## **Abstract**

**Introduction:** Present treatment methods for the management of androgenetic alopecia (AGA) have shortcomings. Though recent studies suggest that autologous micrograft technology (AMT) may be an effective alternative, smaller samples sizes in these studies calls for using statistical methods to get pooled effect sizes.

**Objectives:** To compare the efficacy of AMT and finasteride in the management of AGA using a meta-analysis study, comparators being hair count and percentage of patients benefitting from the treatment.

**Methods:** A systematic review and meta-analysis was performed, using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. The protocol was registered in PROSPERO (Reg. No: CRD42024578804). Databases searched for potential articles included PubMed, ScienceDirect, CINAHL, Cochrane, MEDLINE-OVID, Embase-OVID, Web of Science Core Collection, and Bielefeld Academic Search Engine.

**Results:** This study suggests that AMT treatment may be a comparable alternative to  $\geq 1$  mg/day finasteride for the management of AGA. With regards to improvement in hair count, both AMT (Hedges's  $g=0.324$ , 95% confidence interval (CI): 0.198–0.450;  $P<0.001$ ) and finasteride (Hedges's  $g=0.251$ , 95% CI: 0.153–0.349;  $P<0.001$ ) showed small effect sizes. When the percentage of patients who benefitted is considered, AMT had a medium effect size (Hedges's  $g=0.634$ , 95% CI: 0.372–0.896;  $Z\text{-value}=4.736$ ;  $P<0.001$ ), whereas finasteride had a small effect size (Hedges's  $g=0.201$ , 95% CI: 0.153–0.248;  $P<0.001$ ).

**Conclusion:** This study suggests that AMT is an effective method for promoting hair growth in patients with stages 2–5 AGA. This study presents preliminary evidence that the efficacy of AMT is comparable to that of finasteride.

## **Introduction**

Androgenetic alopecia (AGA) is the most prevalent form of nonscarring alopecia, characterized by the gradual conversion of terminal hair to vellus hair and patterned hair loss. Generally, AGA manifests as a result of increased follicular sensitivity to dihydrotestosterone (DHT), which causes the progressive conversion of terminal hairs in the scalp to vellus hair [1-3]. The prevalence of AGA is highest among males, affecting around 80% of males and 50% of females by the age of 70 years. Due to genetic predisposition, the incidence of AGA is highest among the Caucasian population, followed by Asians and African Americans, while AGA is less prevalent among Native Americans and Inuit [4-7].

The US Food and Drug Administration (FDA)-approved treatments for the management of AGA include invasive hair transplant methods (follicular unit transplantation (FUT) and follicular unit excision (FUE)) and noninvasive methods (low-level laser light therapy (LLLT), minoxidil, and finasteride) [4,8-11]. Hair transplant methods are generally more effective and can provide long-lasting effects as compared to noninvasive methods. The hair transplant methods are limited by the need for high amounts of donor hair follicles, which is a major challenge when treating patients with advanced AGA. Further, there are possibilities of developing treatment-related side effects such as numbness, donor hair effluvium, persistent pain, formation of keloid and hypertrophic scars [9,12-14]. On the other hand, noninvasive methods like minoxidil and finasteride need to be administered as a life-long therapy. Further, anti-androgenic treatments like finasteride and

dutasteride can have side effects such as sexual dysfunction, gynecomastia, and mood changes among males, and they are less effective among postmenopausal females [9-11,15]. The autologous micrograft technology (AMT), developed by Rigenera®, shows promise in addressing some of the shortcomings of present AGA treatments. This minimally invasive technique uses autologous stem cells, progenitor cells of hair follicles, and growth factors that are derived from small punch biopsies (2.5 mm to 3 mm size) taken from the same patient, which are processed by specialized kits [16,17].

Though initial studies conducted on the AMT-based management of AGA are promising, sample sizes used in some of these studies are limited, and comprehensive clinical trials in this regard are lacking. Moreover, systematic reviews and meta-analysis on this topic are not available. Therefore, this systematic review (SR) and meta-analysis attempted to comprehend the available studies on AMT in the treatment of AGA. In addition, this study aimed to compare the efficacy of AMT with that of a well-established licensed treatment, finasteride, to better understand its relative efficacy. Consequently, the primary objective of this systematic review and meta-analysis aimed to determine the efficacy of these two treatments of AGA with regards to the changes in hair count and percentage of patients benefitting from the treatment. Further, the percentage of hair growth with regards to the baseline (% of hair prior to treatment) was also assessed.

## **Methods**

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) framework was employed while conducting this systematic review and meta-analysis [18]. The protocol for

the present systematic review and meta-analysis was registered in PROSPERO (ID: CRD42024578804).

### *Literature Search*

An extensive literature search was conducted in the following databases and registers: PubMed, ScienceDirect, CINAHL (Cumulative Index to Nursing and Allied Health Literature), Cochrane Central Register of Controlled Trials, MEDLINE-OVID, Embase-OVID, Web of Science Core Collection, SIGLE (System for Information on Grey Literature in Europe), and BASE Bielefeld Academic Search Engine. The field was set to “title/abstract,” and the publication type was set to “journal article.” Peer-reviewed publications covering the dates from the start of the databases/registers to 15 October 2024 were included in the search. In addition, the ‘reference’ section of the selected articles was also checked for finding potential sources. The following MeSH terms were used to find articles related to AMT in PubMed.

((("micrograft"[All Fields] OR "micrografted"[All Fields] OR "micrografting"[All Fields] OR "micrografts"[All Fields] OR "micro-graft"[All Fields]) AND ("alopecia"[MeSH Terms] OR "alopecia"[All Fields] OR ("androgenic"[All Fields] AND "alopecia"[All Fields]) OR "androgenic alopecia"[All Fields] OR ("alopecia"[MeSH Terms] OR "alopecia"[All Fields] OR ("hair"[All Fields] AND "loss"[All Fields]) OR "hair loss"[All Fields]) OR "pattern"[All Fields] OR "pattern s"[All Fields] OR "patternability"[All Fields] OR "patternable"[All Fields] OR "patterned"[All Fields] OR "patterning"[All Fields] OR "patternings"[All Fields] OR "patterns"[All Fields]) AND ("hair"[MeSH Terms] OR "hair"[All Fields]) AND "loss\*"[All Fields])) OR "rigenera\*"[All Fields].

Similarly, the following MeSH terms were used for collecting articles on Finasteride-based treatment for AGA,

("finasteride"[MeSH Terms] OR "finasteride"[All Fields]) AND ("androgen\*"[All Fields] AND ("alopecia"[MeSH Terms] OR "alopecia"[All Fields] OR "alopecias"[All Fields])).

Boolean AND/OR based search strategy was used while searching the other databases as well. To reduce bias and errors, the literature search was performed independently by two reviewers, and the results were compared. If there was a mismatch, then the reason for the inclusion/exclusion was discussed, and the discrepancy was resolved.

### *Inclusion and Exclusion Criteria*

The primary inclusion criteria used while collecting articles include: i) full-length, peer-reviewed research articles related to the treatment of AGA using AMT or finasteride ii) original research studies reporting primary data; iii) well-defined sample population; iv) articles written in English. Table 1 describes the inclusion and exclusion criteria used for present study in the PICO-S format. Two researchers independently scrutinized the collected articles to assess whether they satisfied the inclusion criteria.

### *Data Extraction and Quality Assurance*

Before starting the data extraction process, two reviewers independently verified whether the selected articles met the requirements set as the inclusion criteria. The extracted information included: i) author names and year of publication; ii) study site; iii) study design; iv) sample

population/size; v) inclusion and exclusion criteria used; vi) age and sex ratio; vii) methods of intervention; viii) data analysis methods; ix) duration of follow-up; x) outcome measures; xi) main results; xii) limitations of the study. If there was a mismatch between the data extracted by the two researchers, then the mismatch was reexamined, discussed, and resolved to ensure that the data was error-free. If the disagreement between the two researchers was not solved through discussion, then a third reviewer's opinion (expert opinion) was sought to resolve the disparity. The Cochrane Rob 2 was used for bias assessment of the randomized controlled trials. Further, the National Institutes of Health (NIH) quality tool was used for quality assessment of studies with no control group [19].

### *Meta-Analysis*

The Comprehensive Meta-Analysis Software (CMA) version 3.0 was used for the present meta-analysis. Patients with unconfirmed responses or missing data were not included in the analysis. The present study employed Hedges's  $g$  report the effect sizes because it can account for relatively small sample sizes in the AMT-based studies. Further, Hedges's  $g$  can account for unequal group sizes through its adjustment for the sample variance [20,21]. The effect sizes reported are obtained through a random-effect model. The heterogeneity was assessed using the I-squared (25% and 75% reflects low and high heterogeneity, respectively), and 'between-study variance' was measured using Tau-squared [22-24]. FDA license for Finasteride is a dose of 1mg/day and earlier studies suggest that doses of finasteride <1mg/day is ineffective for the management of AGA [25]. Therefore, data from doses <1 mg/day and finasteride in combination with other treatments were

excluded from the meta-analysis to avoid bias. Similarly, data on AMT in combination with other treatments were not considered.

### *Ethical Concerns*

Ethical approval from Institutional Ethics Committee (IEC) was not necessary for this study because neither were human subjects recruited nor was any personal information of the subjects used in this study. Furthermore, informed consent is not required for this type of study.

## **Results**

### *The Selected Studies*

Out of the 1620 articles obtained through the literature search, 37 research articles 11 articles related to AMT and 26 articles on finasteride) [15-17,25-58] were selected for the systematic review. Two articles from the AMT group were not suitable for quantitative synthesis because they did not report the quantitative information on hair count and percentage of patients benefitting. Therefore, 35 articles were included in the meta-analysis (Figure 1). The data extracted from these studies are available as Supplementary File S1. Key extracts of the systematic review, including the patient distribution in different treatment arms, methods, duration of follow-up, and outcomes, are summarized in Table 2 and Table 3. Meta-analysis was conducted separately to assess the following outcomes: changes in hair count and percentage of patients benefitting. Therefore, separate funnel plots were generated for these analyses (Supplementary Figure S1).

*Primary Endpoint: Changes in Hair Count*

There were six studies that reported changes in hair count after treatment with AMT. The pooled sample size of these six studies was 362. The duration of follow-up in these studies ranged from just over four weeks (30 days) to 58 weeks (Table 2). The assessment of effect size in the AMT-treated group revealed that AMT treatment had a ‘small-to-medium’ effect size (Figure 2A; Hedges’s  $g=0.324$ , 95% CI: 0.198–0.450;  $Z\text{-value}=5.033$ ;  $P<0.001$ ). The heterogeneity was low ( $I\text{-squared}=21.69$ ), and the ‘between-study variance’ was negligible ( $\text{Tau-squared}=0.005$ ). On the other hand, there were 15 studies that reported the effect of finasteride treatment on hair count. These studies had a comparatively high pooled sample size ( $N=1960$ ). The duration of follow-up ranged from 24 weeks to 192 weeks. Interestingly, the effect size of finasteride treatment was found to be lower than that of AMT treatment (Figure 2B; Hedges’s  $g=0.251$ , 95% CI: 0.153–0.349;  $Z\text{-value}=5.024$ ;  $P<0.001$ ). Heterogeneity was comparatively higher in the finasteride-arm ( $I\text{-squared}=64.27$ ), whereas the ‘between-study variance’ was negligible ( $\text{Tau-squared}=0.019$ ).

*Secondary Endpoint: Percentage of Patients Benefitting from the Treatment*

In the AMT-treated arm, we analyzed six studies that reported the rate of success (percentage of patients showing improvement from baseline). Notably, a medium effect size was observed among the AMT-treated group with regards to percentage of improvement (Figure 3A; Hedges’s  $g=0.634$ , 95% CI: 0.372 –0.896;  $Z\text{-value}=4.736$ ;  $P<0.001$ ). The level of heterogeneity was moderate ( $I\text{-squared}=62.84$ ), and the ‘between-study variance’ was low ( $\text{Tau-squared}=0.061$ ). In the

finasteride-treated group, there were 22 studies that reported the percentage of patients showing improvement from baseline. Meta-analysis using the random effects model yielded comparatively smaller effect size than did the AMT-treated group (Figure 3B; Hedges's  $g=0.201$ , 95% CI: 0.153–0.248;  $Z\text{-value}=8.281$ ;  $P<0.001$ ). The level of heterogeneity was moderate ( $I\text{-squared}=57.80$ ), and the between-study variance was negligible ( $\text{Tau-squared}=0.005$ ).

### *Risk of Bias Assessment*

Since seven studies reporting AMT treatment did not use the control/placebo arm, the NIH tool for assessing the risk of bias in studies reporting pre-to-posttreatment changes (without control/placebo) was employed. Four out of seven studies assessed in the AMT arm had low risk of bias, while three had moderate risk of bias. None of them had a high risk of bias. In the finasteride arm, 15 articles were in the “low risk of bias” category, seven were in the “some concerns of bias” category, and four articles were in the “high risk of bias” category (Supplementary Tables S1 and S2).

### *Adverse Events*

No serious side effect (SAE) was reported in any of the studies. The highest percentage of adverse events was reported by Yanagisawa et al. [42], in which 5.6% of the finasteride-treated participants reported decreased libido over a period of 10years. On the other hand, dynamic hair loss in a small portion of AMT-treated patients was reported in two studies [26,30]. Though no SAE was reported,

mild pain and discomfort during the AMT procedure was reported in these studies. Further, there was a chance of minor scarring on the donor site in the case of AMT procedure.

## **Discussion**

The present study suggests that the efficacy of AMT may be comparable to that of finasteride to increase hair count and the percentage of AGA patients experiencing benefit from the treatment. Some of the studies included in the present systematic review suggested that finasteride may not be an effective option for females, especially postmenopausal women [15,38]. An earlier meta-analysis also suggested that finasteride is less effective in females with AGA than in males with AGA. The authors suggested that minoxidil was more effective than finasteride in females with AGA [59].

One worthy point to note here is that at least some of the finasteride-based studies included patients with higher grades of AGA, especially Grade 5 and above per the Norwood-Hamilton classification scale [35,39,40,50]. On the other hand, some of the AMT-based studies did not test the efficacy of treatment in higher grades of AGA. Most of the participants in AMT-based studies had grade 2–5 AGA, while patients with advanced AGA (stages >4) were underrepresented. Therefore, future studies on the efficacy of AMT on larger numbers of patients with advanced stages of AGA (>stage 4) is essential to reaching a conclusion. Further, there is a scarcity of data from clinical trials on AMT at present that are designed with proper controls and randomization to evaluate its efficacy in advanced AGA patients. This highlights potential selection bias due to the low recovery of advanced AGA with most current methods of treatment. Another point to mention here is the secondary endpoint of present study—the percentage of patients benefitting from the

treatment. The definition of "percentage of patients benefitting" may vary from study to study due to subjective heterogeneity. In other words, as there is no gold standard for comparison, this metric may vary between investigators, patient satisfaction reports, and quality of pictures generated through the global photography technique. Consequently, the effect size of the secondary endpoint may be inflated due to subjective bias. Therefore, the effect size reported on the primary endpoint (hair counts) of AMT and finasteride treatment may be more reliable than the effect sizes reported on the secondary endpoint (percentage of patients benefitting) of present study.

Earlier studies suggest that patients with advanced AGA may suffer from psychological stress due to their deteriorated aesthetic appearance and that many of them are in desperate need of improvement [60,61]. Females are psychologically more affected than are males by AGA because of the deleterious effects of AGA on female aesthetics. In premenopausal females with hyperandrogenism, oral antiandrogen therapies such as cyproterone acetate and spironolactone are useful. Further, topical minoxidil can provide good results in mild/early cases of female pattern hair loss (FPHL). However, none of the treatments is effective in postmenopausal women and in females with advanced AGA [62]. Therefore, studies must test the efficacy of AMT not only in patients with advanced AGA but also in postmenopausal women. Notably, only few studies have used secondary measures such as patient satisfaction reports. Though these may be classified as "softer outcomes," they could provide a better reflection of the clinical outcome of the results. These satisfaction reports might provide insight into the "visibly significant results" that are required to help AGA patients.

Furthermore, confounding factors such as age, sex, habits, and ethnicity were not included in most of the AMT-based studies. Only one study (Chunmei et al. 2023) assessed the role of the confounding factors on treatment outcomes [29]. The authors found that females benefitted more

from AMT than did males with regards to improvement in hair density ( $P=0.034$ ). Another significant factor reported in this study is the smoking status of the patient. Nonsmokers have a significantly higher ratio of terminal hairs after the AMT treatment ( $P=0.001$ ). Age was not a significant factor in any of the hair quality-related outcome measures. This study points towards the need to further assess and establish the role of confounding factors in AMT treatment.

Since AMT is a comparatively new technology, there is the possibility that AMT-based studies with significant results have been published while studies with insignificant results/negative results remain unpublished (newness bias). On the other hand, finasteride is a comparatively older regimen, with studies having up to 10 years of follow-up. There is a fair chance that studies reporting negative results of finasteride have also been published during this period. This might have led to regression to the mean values in the case of finasteride. Therefore, the chance of a “newness bias” should be considered while comparing the effect size of AMT with that of finasteride. Further, there is a lack of placebo groups in most of the AMT-based studies. Only three studies [16,26,30] used half-head placebo (saline solution vs AMT-solution) as a control for comparison. These studies suggested that the effect of AMT treatment was significant and that that of placebo was negligible. Notably, all three studies came from the same group. On the other hand, there are many finasteride-based studies with proper controls and much longer follow-up periods. Therefore, more studies from other groups, with true controls, are required to rule out the possibility of a placebo effect and to get a proper understanding on the long-term effect of AMT treatment.

### *Limitations*

Though we have extensively searched various databases for the available literature, there is a chance that some relevant studies were accidentally missed during the electronic database searching. Since articles published in languages other than English were not included in the present meta-analysis, there is a chance of publication bias. The limited number of studies on AMT as well as the lower sample strength in the AMT arm (as compared to the finasteride arm) may have hindered an effective comparison. Finally, the scarcity of studies in the AMT arm with longer follow-up (>1 year) is another limitation of this study. Consequently, there are chances that effect sizes reported in the AMT arm may be inflated.

## **Conclusions**

The present study suggests that the efficacy of AMT may be comparable to finasteride in terms of improving hair count and in the number of patients benefitting from the treatment. At present, hair transplantation is the most widely used treatment to achieve lasting effects in AGA patients, especially when aiming to increase hair count. However, these invasive methods can have side effects and are limited by the availability of hair follicles in the donor site, which is a big challenge in patients with advanced AGA. In such cases, AMT may be regarded as an effective addition to hair transplantation methods like FUT and FUE because AMT is minimally invasive and is unaffected by a depleted donor site. Though “one time” in administration, the cost of AMT is many times more than the cost of one year finasteride administration. On the other hand, the need for life-long treatment and the chance of sexual dysfunction should be considered while using finasteride. To conclude, this study provides preliminary evidence that the efficacy of AMT is comparable to that of finasteride. However, further long-term studies are essential to reach a

conclusion. Therefore, AMT may be preferred over other treatments in some patients for the management of AGA, especially for those who wish for hair regeneration through nonsurgical methods.

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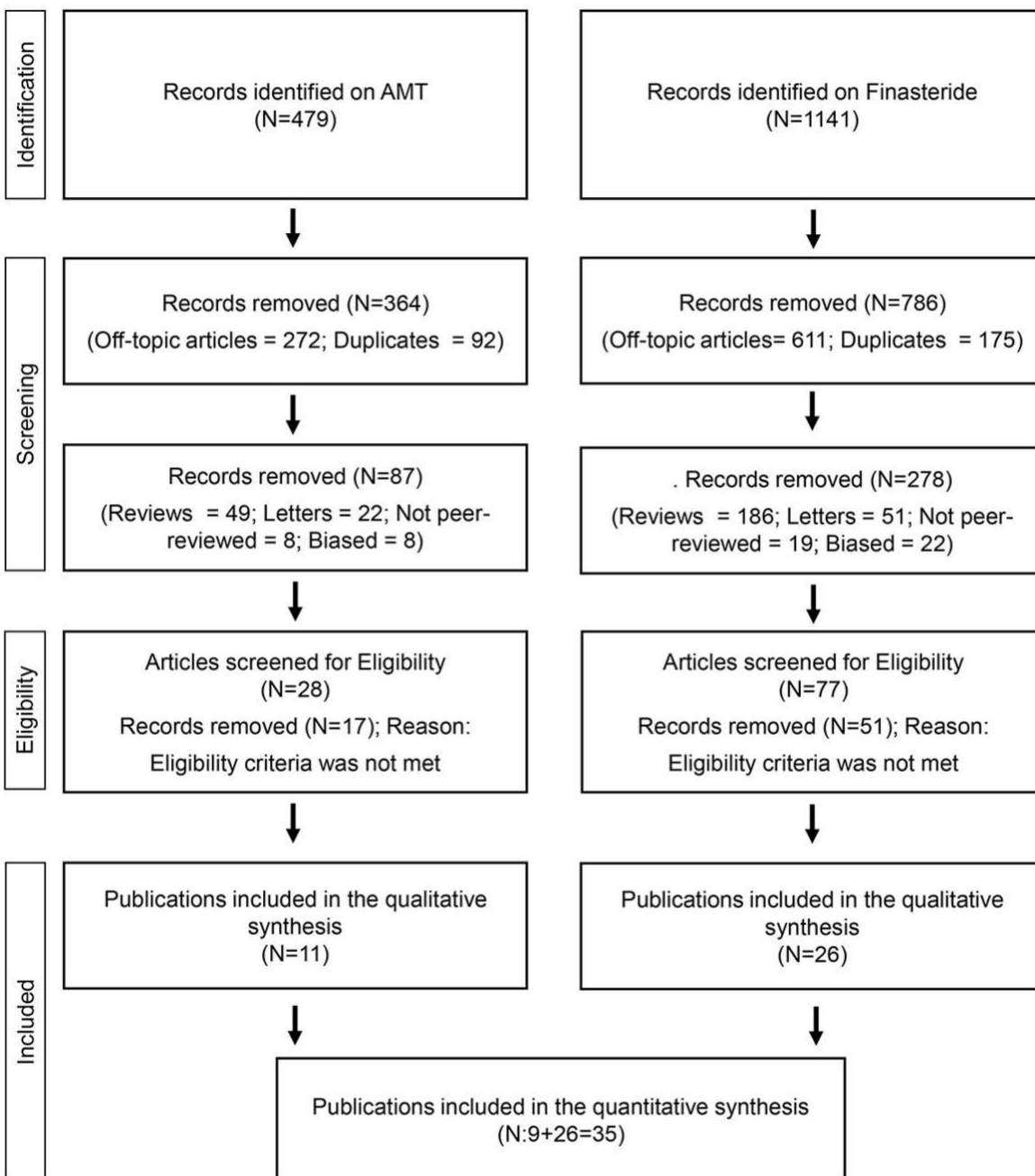
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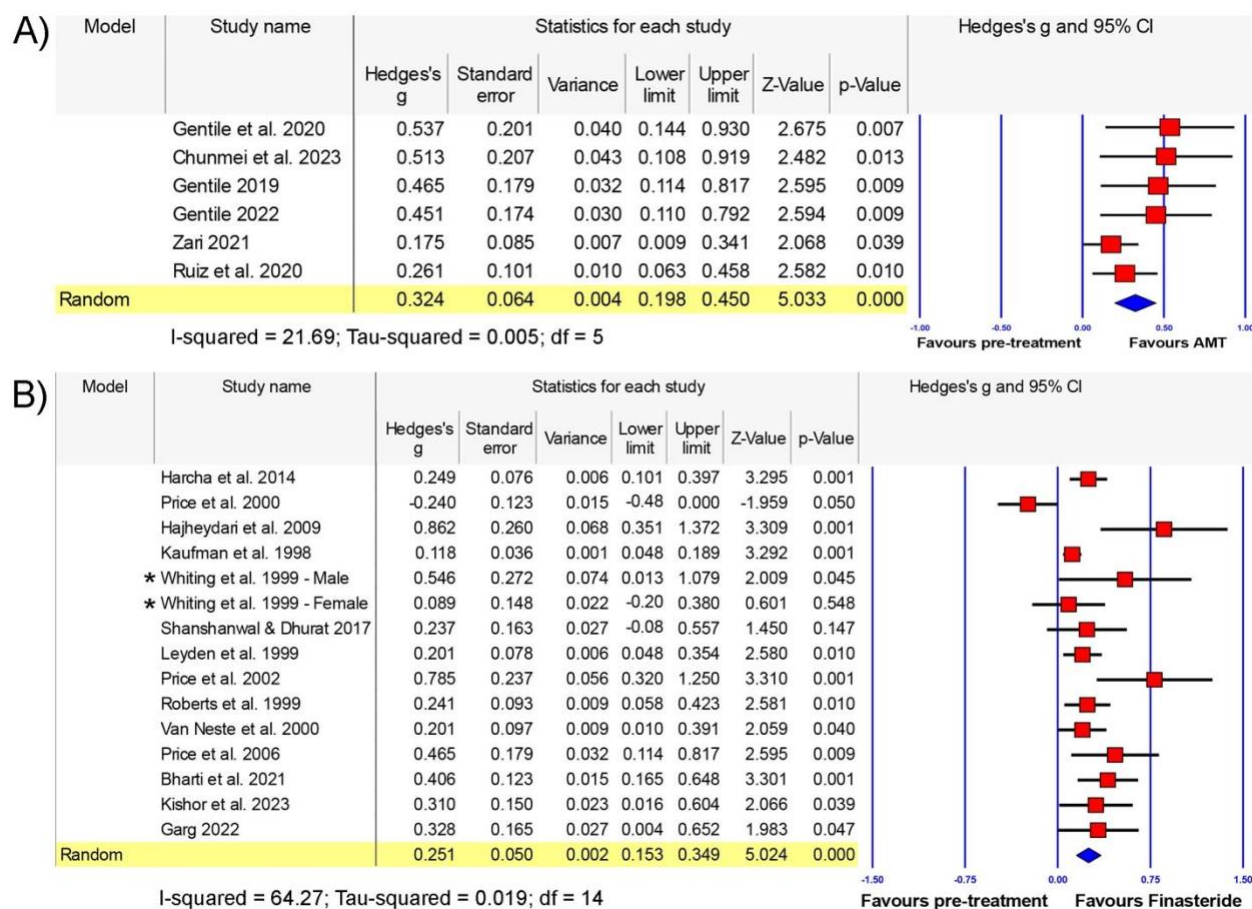
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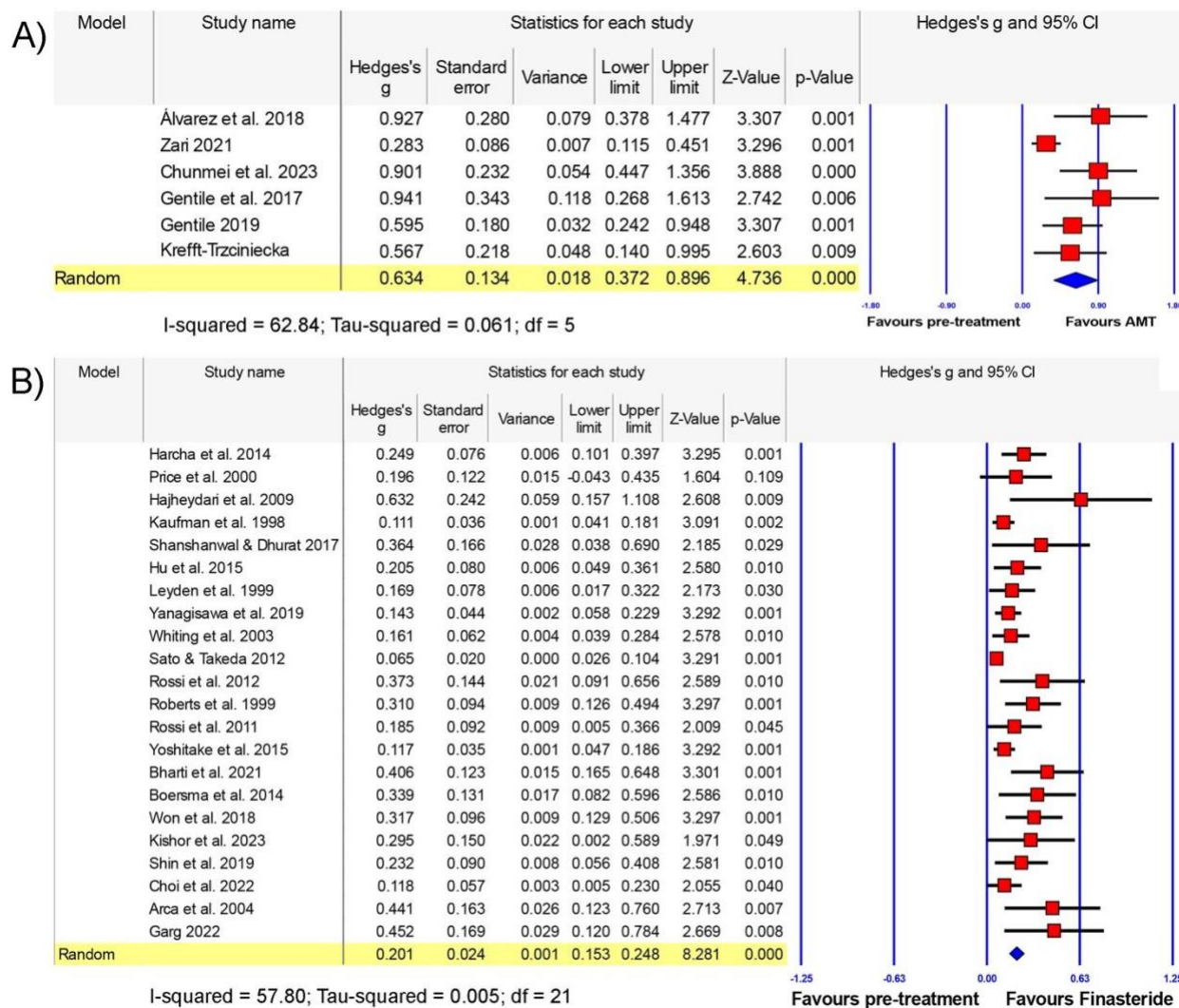
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**Figure 1.** PRISMA flow diagram explaining the process of selecting the studies for the systematic review and meta-analysis.



**Figure 2.** Forest plot showing comparison of AMT (A) with finasteride (B) in terms of changes in hair count (number of hairs/cm<sup>2</sup>). \*The study by Whiting et al. (1999) reported the male and female cohorts separately (combined data were not provided), hence the analysis was done separately.



**Figure 3.** Forest plot showing comparison of AMT (A) with finasteride (B), depicting percentage of patients benefitting from the treatment.

**Table 1.** Inclusion and exclusion criteria for the present study, depicted using the PICO-S format.

	<b>Inclusion Criteria</b>	<b>Exclusion criteria</b>
<b>P - Patients</b>	Patients with androgenetic alopecia of any age and sex	Patients with conditions other than androgenetic alopecia
<b>I - Intervention</b>	<b>AMT</b> - Subdermal injection of AMT solution into the scalp. AMT is defined as a stem cell suspension produced through the processing of a small tissue sample from the same patient. <b>Finasteride – Treatment with oral finasteride pills (<math>\geq 1</math> mg/day)</b>	Usage of techniques other than AMT/finasteride
<b>C - Comparators</b>	Any type of control, including placebo or pretreatment (baseline)-posttreatment comparisons.	Not applicable
<b>O - Outcomes</b>	Quantitative and/or qualitative improvement with regards to hair thickness, hair density, and follicular unit count; improved aesthetic appearance in global photographic assessment.	Not applicable
<b>S - Study design</b>	Intervention studies (randomized controlled trials, controlled clinical trials, pilot trials), observational studies (cohort, case-control, and cross-sectional), prospective and retrospective studies	Expert opinion, case reports, comments, letters to the editor, reviews, conference presentations/poster presentations, systematic reviews and articles with bias (treatments not correctly defined and/or mixed usage of treatments; ambiguous reporting of the outcomes).

**Table 2.** Key extracts of the studies which reported the treatment of AGA with AMT.

Ref. No.	Study	Sample size (N)	Male: female ratio	Age (Range in years)	Duration of follow-up and percentage of patients showing improvement/no change/deterioration	Mean change in hair count (from baseline or as compared to placebo)	Limitations
26	Gentile et al. 2020	27	17:10	NA	Follow-up - 58 weeks; NA	The AMT treated group showed a mean increase of 23.3 hairs/cm <sup>2</sup> ; Placebo group showed a mean decrease of 0.7 hairs/cm <sup>2</sup> (control vs. treatment: $P < 0.0001$ ).	Demographic data on how many patients had improvements/no change/deterioration were not provided
27	Álvarez et al. 2018	17	9:8	21 - 58	Follow-up: 30 days; Improvement: 70.58%; No change: 29.42%; Deterioration: 0%	NA	Comparatively small sample size (N=17); Short duration of follow-up (only for 30 days); change in hair count not provided.
28	Álvarez et al. 2017	3	3:0	>18 years	Follow-up: 30 days; Improvement: 100%	NA	Very small sample size (N=3); Short duration of follow-up (only for 30 days); change in hair count and hair density per unit area not provided.
29	Chunmei et al. 2023	25	15:10	23 - 64	Follow-up: 6 months; Improvement: 96%; No change: 4%; Deterioration: 0%	Baseline: 120.72 hairs/cm <sup>2</sup> ; Outcome: 162.28 hairs/cm <sup>2</sup> ( $P < 0.001$ ).	Lack of continuous evaluation (single assessment was done at 6 months posttreatment)
16	Gentile et al. 2017	11	11:0	38 - 61	Follow-up: 23 weeks; Improvement: 63.64%; No change: NA; Deterioration: NA	NA	Demographics on how many patients had no change/deterioration were not provided; Change in vellus hair and terminal hair was not provided.

30	Gentile 2019	35	25:10	NA	Follow-up: 44 weeks; Improvement: 100%	Baseline: 114.43 hairs/cm <sup>2</sup> ; AMT treated group: 145.32/cm <sup>2</sup> ; Placebo: 115.23 hairs/cm <sup>2</sup> ( <i>P</i> <0.05)	Age and patient demographics of the cohort are missing.
31	Gentile 2022	35	25:10	18 - 72	Follow-up: 44 weeks; Improvement: NA; No change: NA; Deterioration: NA	Baseline: 114.4 hairs/cm <sup>2</sup> ; Placebo = 115.54 hairs/cm <sup>2</sup> ; AMT treated group (23 weeks): 152.19 hairs/cm <sup>2</sup> ; A-PRP treated group (12 weeks): 149.90 hairs/cm <sup>2</sup> (placebo vs. AMT: <i>P</i> <0.01; AMT Vs A-PRP: <i>P</i> >0.05)	Data were collected at different time points for A- PRP (12 weeks) and AMT (23 and 44 weeks), which made the comparisons ineffective.
32	Kreff- Trzcieniecka 2024a	23	0:23	18 - 65	Follow-up: 6 months; Improvement: 95.65%; No change: 4.35%; Deterioration: 0%	NA	Numerical data relating to the increase in hair count or density were not provided.
33	Kreff- Trzcieniecka 2024b	23	0:23	19 - 65	Follow-up: 6 months; Improvement: NA; No change: NA; Deterioration; NA	NA	Numerical data related to the increase in hair count or density were not provided.
34	Zari 2021	140	27:113	18 - 65	Follow-up: 6 months; Improvement: 66.4%; No change: NA; Deterioration: NA	Control = 162.12/cm <sup>2</sup> ; AMT treated = 167.83/cm <sup>2</sup> ; <i>P</i> <0.05	Demographics on how many patients had no change/deterioration was not provided;
17	Ruiz et al. 2020	100	NA	NA	Follow-up: 12 months. Improvement: NA; No change: NA; Deterioration: NA	Baseline = 15.2/cm <sup>2</sup> ; AMT treated group = 48.5/cm <sup>2</sup> ( <i>P</i> <0.001)	Though the methods section described assessment at 4, 6, and 12 months, the hair quality- related data, which is associated with these time points are not provided

Abbreviation: NA = not available.

**Table 3.** Key extracts of the studies which reported the treatment of AGA with finasteride.

Ref. No	Study	Sample size (N)	Male: Female ratio	Age (Range in years)	Duration of follow-up and percentage of patients showing improvement/no change/deterioration from baseline	Change in hair count or change in the percentage of hair density in the target area (from baseline)	Limitations
35	Harcha et al. 2014	360 (finasteride 179; placebo 181)	360: 0	20 - 50	Follow-up: 24 weeks. <u>Finasteride:</u> Improvement: 35.36%; No change: NA; Deterioration: NA. <u>Placebo:</u> Improvement: 6.97%; No change: NA; Deterioration: NA.	Baseline: 130.97/cm <sup>2</sup> . Post-finasteride: 142.04/cm <sup>2</sup> ( $P<0.01$ )	Demographic data on how many patients had no change/ deterioration are not provided; short duration of follow-up; Incomplete patient satisfaction report.
15	Price et al. 2000	137 (finasteride 67; placebo 70)	0: 137	41 - 60	Follow-up: 12 months. <u>Finasteride:</u> Improvement: 18%; No change: 77%; Deterioration: 5%. <u>Placebo:</u> Improvement: 23%; No change: 77%; Deterioration: 0%.	Finasteride, Baseline: 151 hairs/cm <sup>2</sup> ; Outcome: 142.3/cm <sup>2</sup> . Placebo, Baseline: 164/cm <sup>2</sup> ; outcome: 157.4/cm <sup>2</sup> . ( $P<0.05$ , significant decrease of hair count in the finasteride arm)	Nil
36	Hajheydari et al. 2009	38 (finasteride pill 19, finasteride gel 19)	38:0	18 - 30	Follow-up: 6 months. <u>Finasteride pill:</u> Improvement: 56%; No change: NA; Deterioration: NA . <u>Finasteride gel:</u> Improvement: 54.5%; No change: NA; Deterioration: NA .	Baseline: 137.89/cm <sup>2</sup> ; Posttreatment: 153.56/cm <sup>2</sup> ( $P<0.001$ )	Small sample size (N=19) and comparatively short duration of the follow-up (6 months)

37	<b>Kaufman et al. 1998</b>	1553 (finasteride 779; placebo 774)	1153:0	18 - 41	Follow-up: 12 months. <u>Finasteride:</u> Improvement: 65%; No change: NA; Deterioration: NA. <u>Placebo:</u> Improvement: 37%; No change: NA; Deterioration: NA.	Baseline: 171.76/cm <sup>2</sup> Finasteride showed a mean increase of 16.86 hairs/cm <sup>2</sup> from baseline; Placebo had a mean decrease of 4.12 hairs/cm <sup>2</sup> ( $P<0.01$ )	According to global photographic assessments, 37% of the placebo-treated patients showed hair growth/reduction in the size of bald area, which is not explained by the authors.
38	<b>Whiting et al. 1999</b>	120 finasteride 58 (14 in the male arm and 44 in the female arm); placebo 62 (12 in the male arm and 50 in the female arm)	26:94	18 - 60	Follow-up: 12 months. Improvement: NA; No change: NA; Deterioration: NA	<b>Male arm:</b> Finasteride, Baseline: 15.5/cm <sup>2</sup> ; Outcome: 20.9/cm <sup>2</sup> . Placebo, Baseline: 17.3/cm <sup>2</sup> ; outcome: 18.3/cm <sup>2</sup> ( $P<0.05$ ). <b>Female arm:</b> Finasteride, Baseline: 20.5/cm <sup>2</sup> ; Outcome: 20.7/cm <sup>2</sup> . Placebo, Baseline: 20.9/cm <sup>2</sup> ; outcome: 21.9/cm <sup>2</sup> ( $P>0.05$ ).	The number of finasteride-treated patients in the male arm is comparatively small (N=14).
39	<b>Shanshanwal &amp; Dhurat 2017</b>	90 (finasteride 45; dutasteride 45)	90:0	18 - 40	Follow-up: 24 weeks. <u>Finasteride:</u> Improvement: 54.1%; No change: 32.4%; Deterioration: 13.5%. <u>Dutasteride:</u> Improvement: 91.4%; No change: 8.6; Deterioration: 0%.	Finasteride group, baseline: 226.78±48.8 hairs/cm <sup>2</sup> ; outcome: 231.08±51.08 hairs/cm <sup>2</sup> Dutasteride group, baseline: 222.83±50.68 hairs/cm <sup>2</sup> ; outcome: 245.97± 49.86 hairs/cm <sup>2</sup> (change in total hair count - Finasteride Vs Dutasteride: $P<0.001$ )	Open label (non-blinded) study and short duration (6 months). Statistical significance on the change from baseline in each group was not provided

40	<b>Hu et al. 2015</b>	450 (1 mg/day finasteride 160; 5% minoxidil 130; and finasteride + minoxidil combined 160)	450:0	18 - 50	Follow-up: 12 months. <u>Finasteride:</u> Improvement: 80.5%; No change: 14.93%; Deterioration: 4.55%. <u>Minoxidil:</u> Improvement: 59.02%; No change: 23.77%; Deterioration: 17.21%. <u>Combination:</u> Improvement: 94.08%; No change: 3.95%; Deterioration: 1.97%.	NA	Open label (non-blinded) study. Further, the authors have mentioned chi-square test in the procedures, but results of the statistical analysis, including the p-values, were not reported.
41	<b>Leyden et al. 1999</b>	326 (finasteride 166; placebo 160)	326:0	18 - 40	Follow-up: 12 months. <u>Finasteride:</u> Improvement: 37%; No change: 33%; Deterioration: 30%. <u>Placebo:</u> Improvement: 7%; No change: 37%; Deterioration: 56%.	Finasteride, Baseline: 211±4 hairs/cm <sup>2</sup> ; Outcome = 220.6±5.2 hairs/cm <sup>2</sup> . Placebo, Baseline: 219±4 hairs/cm <sup>2</sup> ; outcome = 216.9±2.6 hairs/cm <sup>2</sup> (P<0.001).	Though the study mentions continuous improvements in hair growth during second year extension, the data are not reported. Further, change in the number of vellus hairs/telogen hairs/anagen hairs etc. from baseline in each group are not reported.
42	<b>Yanagisawa et al. 2019</b>	532 (All patients were treated with finasteride)	532:0	20 - 69	Follow-up: 10 years; Improvement: 91.5%; No change: NA; Deterioration: NA.	NA	Trichoscopy-related reports are not provided and numerical data on the change in hair numbers/vellus hair are not reported.
43	<b>Whiting et al. 2003</b>	424 (finasteride = 286 and placebo 138)	424:0	41 - 60	Follow-up: 24 months. <u>Finasteride:</u> Improvement: 39%;	NA	Numerical data on the changes in hair growth were not reported. Demographics on how

					<u>Placebo</u> : Improvement: 4%; (No change/Deterioration: NA)		many patients had no change/ deterioration was not provided
44	<b>Boersma et al. 2014</b>	120 (60 women in finasteride group and 60 women in Dutasteride group)	0:120	16 - 84	Follow-up: 36 months. <u>Finasteride</u> : Improvement: 68.9%; No change: 12.8%; Deterioration: 18.3%. <u>Dutasteride</u> : Improvement: 65.6%; No change: 17.7%; Deterioration: 16.7%.	NA	No major drawbacks
45	<b>Sato &amp; Takeda 2012</b>	3177 (All patients were treated with finasteride)	3177:0	NA (Mean: 37.5 ± 11.9)	Follow-up: 36 months. Improvement: 87.1%; No change: NA; Deterioration: NA.	NA	Changes in hair growth were not reported in real numbers (that is, changes in the count of terminal hairs, telogen, anagen, and vellus hairs were not reported).
46	<b>Won et al. 2018</b>	112 (All patients were treated with finasteride)	0:112	30 - 73	Follow-up: up to 59 months. Improvement: 94.6%; No change: NA; Deterioration: NA.	NA	Lack of placebo group. Further, changes in the count of terminal hairs, telogen, anagen, and vellus hairs were not reported.
47	<b>Price et al. 2002</b>	66 (Finasteride = 33 and placebo 33)	66:0	22 - 40	Follow-up: 96 weeks. Improvement: NA; No change: NA; Deterioration: NA.	Finasteride group, Baseline: 255±48; Outcome: 278.2±5.6); Placebo group, Baseline: 236±67; outcome: 221.2±62; $P<0.05$	Comparatively small sample number (N=33 per arm). Percentage or number of patients who are benefitted from the treatment is not reported.
48	<b>Rossi et al. 2012</b>	100 (50 men in the Finasteride arm and 50 men in Serenoa repens arm)	100:0	20 - 40	Follow-up: 24 months. <u>Finasteride</u> : Improvement: 68%; No change: NA; Deterioration: NA.	NA	Numerical data on the changes in hair growth were not reported.

					<u>S. repens</u> : Improvement: 38%; No change: NA; Deterioration: NA.		
25	<b>Roberts et al. 1999</b>	693 (patient allocation as per Finasteride dosages: 5mg/day = 111; 1mg/day = 117; 0.2mg/day = 115; 0.01mg/day = 117; Placebo = 233).	693:0	18 - 36	Follow-up: 12 months. per ICA, improvement was found: 5 mg/day finasteride: 77%; 1 mg/day finasteride: 91%; placebo: 46%. per GPA, improvement was found in: 5 mg/day finasteride – 48%; 1 mg/day finasteride - 54%; placebo – 3%. Patients with no change/deterioration: not reported.	Mean changes in hair count - Finasteride, Baseline: 185.29 hairs/cm <sup>2</sup> ; outcome: 201.96 hairs/cm <sup>2</sup> ; Placebo, Baseline: 177.65 hairs/cm <sup>2</sup> ; outcome: 173.72 hairs/cm <sup>2</sup> . Placebo vs Finasteride: $P < 0.001$	There is a huge disparity between global photographic assessments and investigators clinical assessments. Further, improved hair growth was found among 46% of the placebo-treated patients (per ICA), which is not explained by the authors.
49	<b>Rossi et al. 2011</b>	118 (All patients were treated with Finasteride)	118:0	20 - 61	Follow-up: up to 10 years. Improvement: 47.78%; No change: 42.48; Deterioration: 9.73%.	NA	No major drawbacks.
50	<b>Van Neste et al. 2000</b>	212 (Finasteride 106: placebo 106)	212:0	18 - 40	Follow-up: 48 weeks. Improvement: NA; No change: NA; Deterioration: NA.	Mean changes in hair count - Finasteride, Baseline: 198±5 hairs/cm <sup>2</sup> ; outcome: 205.3±5 hairs/cm <sup>2</sup> ; Placebo, Baseline: 197±5 hairs/cm <sup>2</sup> ; outcome: 186.9±5 hairs/cm <sup>2</sup> . Placebo vs Finasteride: $P < 0.001$	Comparatively short duration (48 weeks follow-up)
51	<b>Yoshitake et al. 2015</b>	903 (All patients were treated with Finasteride)	903:0	NA (Mean: 37.9 ± 10.8)	Follow-up: 60 months. Improvement: 86.64%; No change/Deterioration: 13.36%.	NA	Numerical data on the changes in hair growth were not reported

52	<b>Price et al. 2006</b>	66 (Finasteride = 33 and placebo 33)	66:0	22 - 40	Follow-up: 192 weeks. Improvement: NA; No change: NA; Deterioration: NA.	Mean changes in hair count - Finasteride, Baseline: 255±48 hairs/cm <sup>2</sup> ; outcome: 268.6±53.6 hairs/cm <sup>2</sup> ; Placebo, Baseline: 236±67 hairs/cm <sup>2</sup> ; outcome: 213.2±62 hairs/cm <sup>2</sup> . Placebo vs Finasteride: $P<0.01$	Final data are from a small sample number because only 22 patients completed the trial (finasteride arm = 15; placebo arm = 7).
53	<b>Kishor et al. 2023</b>	90 (Finasteride =45; 1ml of 5% Minoxidil, twice a day = 45)	90:0	NA	Follow-up:6 months. <u>Finasteride</u> : Improvement: 57.77%; No change: 33.33%; Deterioration: 8.9%. <u>Minoxidil</u> : Improvement: 51.11%; No change: 48.89%; Deterioration: 0%.	Mean changes in hair count - Finasteride, Baseline: 97.68 hairs/cm <sup>2</sup> ; outcome: 108.96 hairs/cm <sup>2</sup> ; Minoxidil, Baseline: 95.85 hairs/cm <sup>2</sup> ; outcome: 118.58 hairs/cm <sup>2</sup> . (Minoxidil vs Finasteride: $P<0.05$ )	Results of global photography and data from hair counts on the scalp are contradictory. Further, changes in the count of telogen, anagen, and vellus hairs were not reported.
54	<b>Bharti et al. 2021</b>	146 (Finasteride 1mg/day = 70; 1ml of 5% Minoxidil, twice a day = 76)	146:0	18 - 40	Follow-up: 12 months. <u>Finasteride</u> : Improvement: 72.52%; No change: 24.19%; Deterioration: 3.29%. <u>Minoxidil</u> : Improvement: 66.67%; No change: 33.33%; Deterioration: 0%.	Mean changes in hair count - Finasteride, Baseline: 96.52 hairs/cm <sup>2</sup> ; outcome: 136.79 hairs/cm <sup>2</sup> ; Minoxidil, Baseline: 95.18 hairs/cm <sup>2</sup> ; outcome: 116.5 hairs/cm <sup>2</sup> . (Minoxidil vs Finasteride: $P<0.007$ )	No major drawbacks.
55	<b>Shin et al. 2019</b>	126 (All patients were treated with Finasteride)	126:0	18 - 40	Follow-up: 60 months. Improvement: 85.7%; No change: NA; Deterioration: NA.	NA	No major drawbacks.

56	<b>Choi et al. 2022</b>	600 (Finasteride = 305; Dutasteride = 295)	600:0	NA	Follow-up: 36 months. <u>Finasteride</u> : Improvement: 51.67%. <u>Dutasteride</u> : Improvement: 84.71%; No change /Deterioration: NA.	NA	No major drawbacks.
57	<b>Arca et al. 2004</b>	65 (Finasteride = 40; Minoxidil = 25)	65:0	18 - 50	Follow-up: 12 months. <u>Finasteride</u> : Improvement: 79%; No change: 18%; Deterioration:3%. <u>Minoxidil</u> : Improvement: 52%; No change: 20%; Deterioration: 28%.	NA	No major drawbacks apart from the comparatively small sample size
58	<b>Garg 2022</b>	74 (Finasteride = 37; Minoxidil = 37)	74:0	NA	Follow-up: NA. <u>Finasteride</u> : Improvement – 64.88%; No change:27.02%; Deterioration: 8.1% <u>Minoxidil</u> : Improvement: 54.05; No change: 45.95%; Deterioration: 0%.	Mean changes in hair count - Finasteride, Baseline: 96.4 hairs/cm <sup>2</sup> ; outcome: 106.2 hairs/cm <sup>2</sup> ; Minoxidil, Baseline: 94.2 hairs/cm <sup>2</sup> ; outcome: 116.4 hairs/cm <sup>2</sup> . (Minoxidil vs Finasteride: <i>P</i> <0.05)	Open-label study; Comparatively small sample size.

Abbreviation: NA = not available.

