

ORIGINAL ARTICLE

The impact of monotherapies for male androgenetic alopecia: A network meta-analysis study

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Abstract

Background: The evidence base pertaining to the efficacy of monotherapies for androgenetic alopecia (AGA), the most common form of hair loss, is ever expanding—and this warrants a formal comparison therapies' effect on a frequent basis.

Aims: The objective of the current study was to determine the comparative effect of relevant monotherapies for male AGA.

Patients/Methods: Our aim was achieved by conducting Bayesian network meta-analysis (NMA), under a random effects model, for two outcomes: 6-month change in (1) total and (2) terminal hair density in adult (i.e., aged 18 years and above) men with AGA; these analyses were preceded by a systematic search of the peer-reviewed literature for suitable data. Interventions' surface under the cumulative ranking curve (SUCRA) and pairwise relative effects (quantified as mean differences) were estimated through the NMAs.

Results: We determined the comparative effect of 20 active comparators and a control (i.e., placebo/vehicle). "Dutasteride 0.5 mg once daily for 24 weeks" was ranked the most effective in terms of 6-month change in (1) total hair density (SUCRA=87%) and terminal hair density (SUCRA=98%). Our results showed that interventions' effectiveness can be dose dependent.

Conclusions: Our updated analyses of the up-to-date evidence regarding monotherapies for male AGA showed that the oral form of 5-alpha reductase inhibitors are more effective than oral minoxidil and other newer agents like Botox, microneedling, and photobiomodulation. Our findings can better inform clinical decision making and design of future research studies.

1 | INTRODUCTION

The relative impact of monotherapeutic regimens for androgenetic alopecia (AGA), the most common form of hair loss in men, have been determined both empirically (through various clinical trials),^{1,2} and statistically (via numerous pairwise and network meta-analysis (NMA) studies).³ The 5-alpha reductase inhibitors (5-ARIs) and

minoxidil are long-standing therapeutic agents for this condition, and their comparative effects were recently determined in NMA studies.^{3,4}

The ever-expanding evidence base for the regimens' effect—as newer empirical results get published—will always warrant updated analyses: the present study's objective was to statistically determine the relative effect of monotherapeutic regimens for male AGA

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by quantitatively synthesizing updated evidence. The current analyses not only compared agents that were investigated in the former analysis (i.e., dutasteride, finasteride and minoxidil),³ but also included other clinically relevant therapeutic agents (e.g., photobiomodulation [low level laser therapy, LLLT] and platelet rich plasma [PRP]). Table 1 demonstrates the potential mechanisms of action of these therapeutic agents.

2 | MATERIALS AND METHODS

The protocol of this work has been officially registered with International Platform of Registered Systematic Review and Meta-analysis Protocols (INPLASY).⁵

2.1 | Search strategy and eligibility criteria for included studies

Data for our quantitative analyses were obtained from studies that were identified through a systematic review of the evidence base. We performed an initial search in August 2023, and a subsequent search in October 2023, using PubMed, EMBASE (Ovid), the Cochrane Central Register of Controlled Trials and [ClinicalTrials.gov](https://www.clinicaltrials.gov) without date restrictions. The following MeSH/search terms were used: "male pattern baldness", "male pattern alopecia", "male type alopecia", "male AGA", "alopecia AND male", "AGA AND male." The reference lists of relevant review articles were screened for any additional eligible studies. As per the

patient-intervention-comparator-outcome (PICO) framework, we analyzed data from trials that were published in English and which had an arm that investigated the impact of a monotherapy in terms two clinically relevant endpoints, namely, 6-month (i.e., 24-week) change in (i) total and (ii) terminal hair density. The steps of (1) deduplication, (2) screening of abstract and/or titles and (3) review of full-text were performed by two authors (TW and MT); conduct of these three steps were managed with Rayyan software,⁶ and any disagreements were resolved through consultation with a third author (AKG). The extraction and collation of data were managed using spreadsheets.

2.2 | Included studies' assessment of evidence quality

Included studies' quality of evidence were evaluated using Cochrane Collaboration's tools for evaluating risk of bias for studies of randomized and observational designs.^{7,8}

2.3 | Statistical analyses

We used network plots to visually depict regimens whose effects had been determined in head-to-head trials. For each network, we conducted "node-splitting analyses of inconsistency" to evaluate statistical consistency across direct and indirect evidence.

For each of the two outcomes, we conducted a random-effects Bayesian NMA with informative priors, four Monte Carlo Markov

TABLE 1 Mechanism of action of drugs or nonsystemic interventions used to treat male androgenetic alopecia.

Drugs or nonsystemic interventions	Mechanism of action
Dutasteride	5- α reductase inhibitor; inhibits the production of DHT ^{18,19}
Finasteride	5- α reductase inhibitor; inhibits the production of DHT ^{18,19}
Minoxidil	Multiple mechanisms have been proposed: vasodilator; Wnt/ β -catenin signaling pathway inducer; anti-inflammatory; anti-androgen (?) ²⁰
PRP	Growth factors and chemokines present in PRP, such as EGF, VEGF, CCL2, IGF, and FGF play key roles in hair follicle growth regulation. ²¹
Cetirizine	Anti-inflammatory and reduces AGA-associated itching. Provides anti-PGD2 effect. PGD2 inhibits hair follicle growth and by reducing its level, cetirizine may enhance hair growth. ²²
LLLT	Not fully understood. A few hypotheses are (a) stimulation of nitric oxide (NO) and reactive oxygen species (ROS) production, activating various signaling pathways that enhance hair growth; (b) modulation of the expression of growth factors, cytokines, and hormones related to hair cycle regulation; (c) increase in the proliferation and differentiation of epidermal stem cells in the hair follicle bulge; (d) stimulation of hair follicle shifting from telogen phase to anagen phase. ²³
Microneedling	Not fully understood. Microneedling induces microtrauma on the scalp, triggering collagen synthesis and promoting neo-angiogenesis as part of the wound-healing response. Microneedling can cause stem cell stimulation and growth factor activation, potentially enhancing hair growth. ²⁴
Botox	Botox may relax scalp muscles and reduce the tension on the hair follicles. This may prevent hair follicle miniaturization and increase blood circulation to the scalp. It may also work as an anti-androgen. ²⁵

Abbreviations: CCL2, chemokine (C-C motif) ligand 2; DHT, dihydrotestosterone; EGF, epidermal growth factor; FGF, fibroblast growth factor; IGF, insulin-like growth factor; LLLT, low-level laser therapy; PGD2, prostaglandin D2; PRP, platelet-rich plasma; VEGF, vascular endothelial growth factor.

Chain (MCMC) chains, 5000 adaptations, and 200 000 iterations. For each outcome, our NMA produced estimates of regimens' surface under the cumulative ranking curve (SUCRA) values—where a regimen's SUCRA can be defined as a “rank metric” for its efficacy. The NMAs also produced estimates of regimens' “relative effect”, that is, the pairwise mean difference (MD) in hair density (in hairs per cm²) along with corresponding 95% credible intervals (CI).

All analyses were conducted using *gemtc* R package in *RStudio*.^{9,10} The cutoff for significance (i.e., alpha) was 5% for all analyses.

3 | RESULTS

3.1 | Included studies

Data from a total of 41 studies—whose details are summarized in Table S1—were used across the two outcomes; schematic of the systematic literature search process is shown in Figure 1, evaluation

of each study's risk of bias are presented in Figure 2 and Table 2. Appendix S1 presents the bibliography of the 41 studies.

Network plots are depicted in Figures 3,4. Across each network, observational (i.e., single-arm) studies were matched to controlled trials using approaches supported by the literature.¹¹ Our node-splitting analyses support that there was statistical consistency between direct and indirect evidence (data not shown).

Across the two networks, the relative effect of the following 21 interventions were compared: (1) Botox (i.e., Botulinum toxin administered via intradermal injections for 7 sessions at 4-week intervals), (2) Dutasteride 0.02 mg once daily, (3) Dutasteride 0.1 mg once daily, (4) Dutasteride 0.5 mg once daily, (5) Finasteride 0.2 mg once daily, (6) Finasteride 1 mg once daily, (7) Finasteride 5 mg once daily, (8) low level laser (LLLT) (i.e., cold beam low-level laser light 3 sessions per week), (9) Microneedling (i.e., 12 or 8 sessions at intervals of 2 or 3 weeks), (10) Oral minoxidil 0.25 mg once daily, (11) Oral minoxidil 5 mg once daily, (12) PRP (i.e., 3 or 4 sessions and intervals of 3 weeks or 1 month), (13) Topical cetirizine 1% 1 mL twice daily, (14)

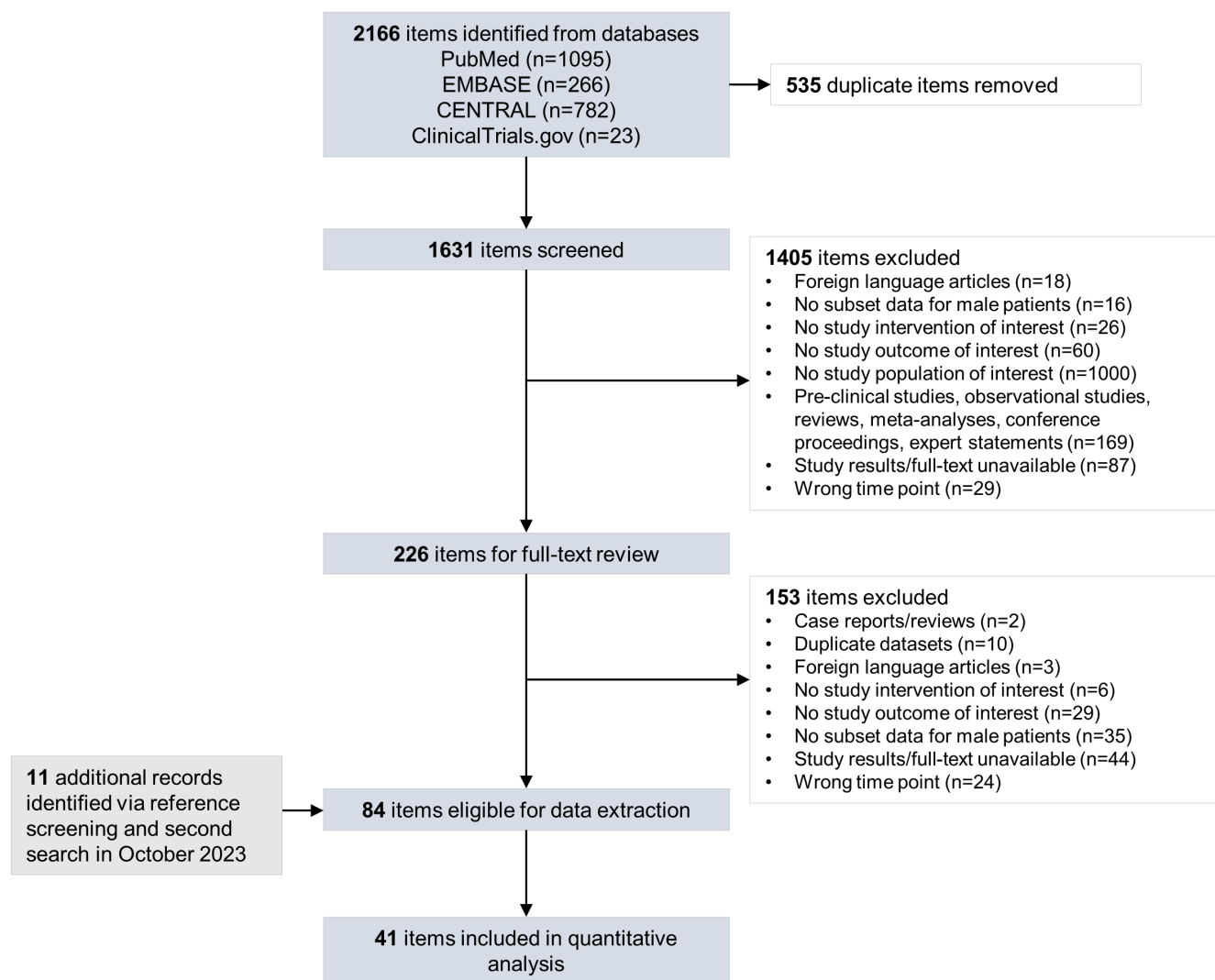


FIGURE 1 Flow chart depicting the systematic literature search and identification of eligible studies for quantitative analysis. CENTRAL, Cochrane central register of controlled trials.

Study ID	D1	D2	D3	D4	D5	Overall	
Anderson 1998	+	+	+	+	+	+	Low risk
Bao 2020	!	+	+	+	+	!	Some concerns
Bao 2022	!	+	+	+	+	!	Some concerns
Berger 2003	!	+	+	+	+	!	Some concerns
Blum 2014	+	+	+	+	+	+	D1 Randomisation process
Brenner 1999	+	+	+	+	+	+	D2 Deviations from the intended interventions
Chuah 2023	+	+	+	+	+	+	D3 Missing outcome data
Civatte 1987	!	+	+	+	+	!	D4 Measurement of the outcome
Connor 1990	+	+	+	+	+	+	D5 Selection of the reported result
DuBois 2021	+	+	+	+	+	+	
Dutrée-Meulenberg 1998	+	+	+	+	+	+	
Eun 2010	+	+	+	+	+	+	
Gubelin Harcha 2014	+	+	+	+	+	+	
Hajheydari 2009	+	+	+	+	+	+	
Jimenez 2014	+	+	+	+	+	+	
Kaufman 1998	+	+	+	+	+	+	
Leyden 1999	+	+	+	+	+	+	
Mostafa 2021	!	+	+	+	+	!	
NCT00441116	+	+	+	+	+	+	
NCT01325337	+	+	+	+	+	+	
Olsen 1986	+	+	+	+	+	+	
Pachar 2022	!	+	+	+	+	!	
Petzoldt 1988	+	+	+	+	+	+	
Piepkorn 1988	+	+	+	+	+	+	
Roberts 1999	+	+	+	+	+	+	
Rossi 2023	-	+	+	+	+	-	
Rushton 1989	+	+	+	+	!	!	
Sakr 2013	+	+	+	+	+	+	
Saraswat 2003	!	+	+	+	+	!	
Shanshanwal 2017	!	+	+	+	+	!	
Shupack 1987	+	+	+	+	+	+	
Singh 2023	+	+	+	+	+	+	
Suchonwanit 2018	!	+	+	+	+	!	
Tsuboi 2009	+	+	+	+	+	+	
Van Neste 2000	!	+	+	+	+	+	
Zhou 2021	+	+	+	+	+	+	

FIGURE 2 Risk of bias assessment of randomized trials included in the quantitative analysis using Cochrane risk-of-bias tool for randomized trials (RoB 2).

TABLE 2 Risk of bias assessment of five non-randomized trials included in the quantitative analysis. The assessment was conducted using the Risk Of Bias In Non-Randomized Studies of Interventions (ROBINS-I) tool.

Study	Bias due to confounding	Bias in selection of participants into the study	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall Bias
Hasanzadeh 2016	Low	Low	Low	Low	Low	Low	Low	Low
Panchaprateep 2020	Low	Low	Moderate	Low	Low	Moderate	Low	Moderate
Primez 2020	Moderate	Moderate	Low	Low	Low	Low	Low	Moderate
Shon 2020	Moderate	Moderate	Low	Low	Low	Low	Low	Moderate
Tsunemi 2016	Moderate	Low	Low	Low	Low	Low	Low	Moderate

Topical finasteride gel 1% twice daily, (15) Topical finasteride spray 0.25% 4 puffs (0.2mL) once daily, (16) Topical minoxidil 0.01% 1mL twice daily, (17) Topical minoxidil 0.1% 1mL twice daily, (18) Topical minoxidil 1% 1mL twice daily, (19) Topical minoxidil 2% 2mL twice daily, (20) Topical minoxidil 5% 1mL twice daily, (21) placebo or vehicle. For our analyses, trial data from placebo and vehicle arms were amalgamated into a single node (Figures 3,4); for each of these 20 active comparators, the treatment duration was 24 weeks.

3.2 | Relative effect of monotherapies for male AGA

Figure 5 depicts regimens' SUCRA values as a "kilim plot", the visual tool that is used to present relative outcomes in a visually intuitive manner with the use of a color gradient.¹² The order of regimens' SUCRA values, across the two outcomes, are similar as seen through the very similar color gradients (Figure 5).

"Dutasteride 0.5 mg once daily for 24 weeks" was the top-most ranked regimen for both 6-month change in total (SUCRA=86.9%) and terminal (SUCRA=98.2%) hair densities (Figure 5).

The top-most ranked regimen was significantly more effective than "finasteride 1 mg once daily for 24 weeks" in terms of 24-week change in both total hair density (MD=6.0, 95% CI: 5.7–6.4, $p<0.05$) and terminal hair density (MD=24.5, 95% CI: 18.2–30.8, $p<0.05$).

Though "oral minoxidil 5 mg once daily for 24 weeks" was ranked lower than "dutasteride 0.5 mg once daily for 24 weeks", the difference in these two regimens' effect was not statistically significant for change in total hair density (MD=−5.9, 95% CI: −31.6 to 19.8, $p\geq 0.05$) and terminal hair density (MD=−9.7, 95% CI: −21.9 to 2.7, $p\geq 0.05$) at 6 months.

"Dutasteride 0.5 mg once daily for 24 weeks" was significantly more effective than "dutasteride 0.1 mg once daily for 24 weeks" in terms of change in total hair density at 6 months (MD=5.7, 95% CI: 5.35–6.06, $p<0.05$). Likewise, "dutasteride 0.1 mg once daily for 24 weeks" was significantly more effective than "dutasteride 0.02 mg once daily for 24 weeks" for the same outcome (MD=8.2, 95% CI: 7.86–8.54, $p<0.05$).

The effects of "oral minoxidil 5 mg once daily for 24 weeks" and "oral minoxidil 0.25 mg once daily for 24 weeks" were not significantly different for 24-week change in total hair density (MD=18.06, 95% CI: −11.45 to 47.16, $p\geq 0.05$); however, the former was significantly more effective than the latter for 6-month change in terminal hair density (MD=43.88, 95% CI: 29.99–57.58, $p<0.05$).

The effect of "finasteride 5 mg once daily for 24 weeks" did not significantly differ from that of "finasteride 1 mg once daily for 24 weeks" change in total hair density at 6 months (MD=4.11, 95% CI: −0.93 to 9.15, $p\geq 0.05$).

The effect of "topical cetirizine 1% 1mL twice daily for 24 weeks" was significantly lower than that of "dutasteride 0.5 mg once daily for 24 weeks" for only 6-month change in terminal hair density (MD=−31.8, 95% CI: −47.6 to −16.0, $p<0.05$). As per both outcomes, the effect of the regimens with microneedling, PRP, LLLT and Botox did not significantly ($p\geq 0.05$) vary from those of all other active comparators.

4 | DISCUSSION

Our current NMA study on monotherapeutic regimens for male AGA statistically determined the effects of long-standing agents (such as the 5-ARIs and minoxidil) in relation to five more recent ones, namely, PRP, LLLT, microneedling, cetirizine, and Botox.

As per the present study's two outcomes of choice (i.e., 24-week change in total and terminal hair densities), the effects of the five newer agents did not significantly differ from those of dutasteride, finasteride and minoxidil—with the exception of "dutasteride 0.5 mg once daily for 24 weeks" being significantly more effective than "topical cetirizine 1% 1mL twice daily for 24 weeks" for change in terminal hair density at 6 months. Publication bias¹³ can explain the non-significant point estimates our NMAs produced for these five agents: for each network, we constructed funnel plots, post hoc, and our visual analyses thereof indicate that there was less publication bias across studies that investigated the former agents—as the plots were more symmetrical for those studies (data not shown). Furthermore, the "sheer recency" of studies pertaining to the five newer agents could indirectly result in there being a relatively higher

FIGURE 3 Network plot of monotherapeutic regimens for 24-week change in total hair density across men with AGA.

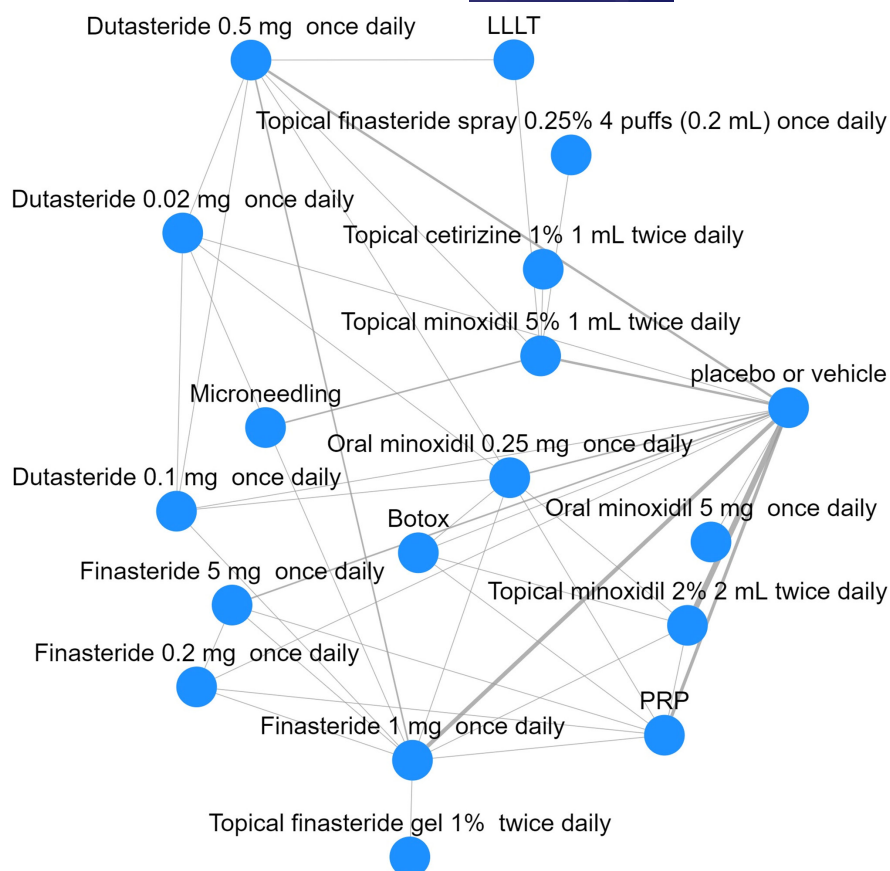
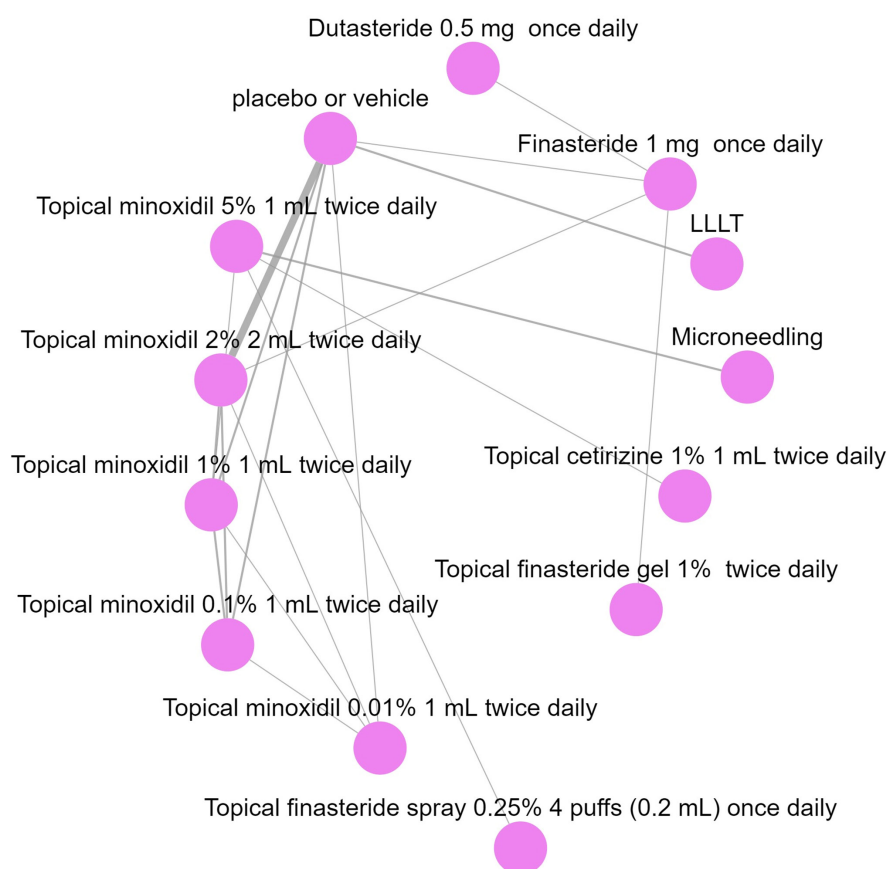


FIGURE 4 Network plot of monotherapeutic regimens for 24-week change in terminal hair density across men with AGA.



degree publication bias vis-à-vis the longer standing agents whose evidence base is far greater (as a function of time).

Our systematic review identified regimens that were eventually excluded from our analyses such as "niosomal kopexil 1% lotion 1 mL twice daily for 24 weeks",¹⁴ and 1% pyrithione zinc shampoo at least once daily for half a year,¹⁵ among others. Our reason for this exclusion was that such are not as clinically relevant; moreover, including any more active comparators over the 20 could consequently reduce statistical power of our analyses.

Many of the results from the analyses of the current study resonate with those of our former work. For instance, the previous NMA study by Gupta et al. (2022) also showed that, for 6-month change in total hair density, "dutasteride 0.5 mg once daily for 24 weeks" was significantly more effective than "dutasteride 0.1 mg once daily for 24 weeks" (authors reported a MD of 6.2 and a 95% CI of 3.8–8.6); the authors also found that "dutasteride 0.1 mg once daily for 24 weeks", in turn, was significantly more effective than "dutasteride 0.02 mg once daily for 24 weeks" for the same endpoint (authors reported a MD of 8.2 and 95% CI of 5.7–10.7).³ Hence, the former and the updated analyses support that the therapeutic impact of these agents can be dose dependent. Notwithstanding this, a dose-dependent effect is not always observed—as evident through findings of the former and previous analyses: for instance, Gupta et al. (2022) also found that the effect "oral minoxidil 0.25 mg once daily for 24 weeks" did not significantly differ from that of "oral minoxidil 5 mg once daily for 24 weeks" for 6-month change in total hair density (authors reported a MD of 8.7 and a 95% CI of –9.2 to 26.5).³ However, just like our current study, the previous study did find the impact of "oral minoxidil 5 mg once daily for 24 weeks" to be greater than the effect of "oral minoxidil 0.25 mg once daily for 24 weeks" on change in terminal hair

density at 6 months (previous study showed a MD of 43.6 and a 95% CI of 29.7–57.7). This is in contrast to the fact that many physicians find that the effect of minoxidil is dose-dependent and the upper dose for males in many clinics maybe up to 5.0 mg/day to obtain an optimal balance between efficacy and safety.

Due to potential side effects such as erectile dysfunction associated with oral finasteride¹⁶; researchers have explored topical finasteride preparations for AGA treatment. The SUCRA plot suggests that topical finasteride's efficacy is comparable to, or slightly less than, that of oral finasteride (Figure 5). The study by Piraccini et al. indicates that the efficacy of oral finasteride at 1 mg/day and daily application of 0.25% (w/w) topical finasteride spray (50–200 µL) were numerically similar.¹⁷ Over 24 weeks of treatment, oral finasteride increased hair density by 21.1 ± 3.9 hair/cm², while topical finasteride spray increased it by 20.2 ± 3.9 hair/cm² in the vertex. Further work needs to be done in the development of topical finasteride preparations which are effective and safe.

A strength of the current study is that the analyses of outcome data was done for a particular time point (i.e., half a year), which rules out selection bias due to time-varying confounding—unlike other studies that may not demarcate time points. We did not conduct sensitivity analyses as our previous work found disease severity to not be impactful in modifying effect³; moreover, given that the five newer agents were reported only in a few studies, such sensitivity analyses were not feasible. Our results justify the conduct of trials that investigate the effect of the newer agents using standardized procedures: for instance, the administration protocol for PRP can vary widely in trial studies—and even clinical practice. Hence standardization of protocols will aid comparative effectiveness research. Through the findings of the current study, clinicians can make more

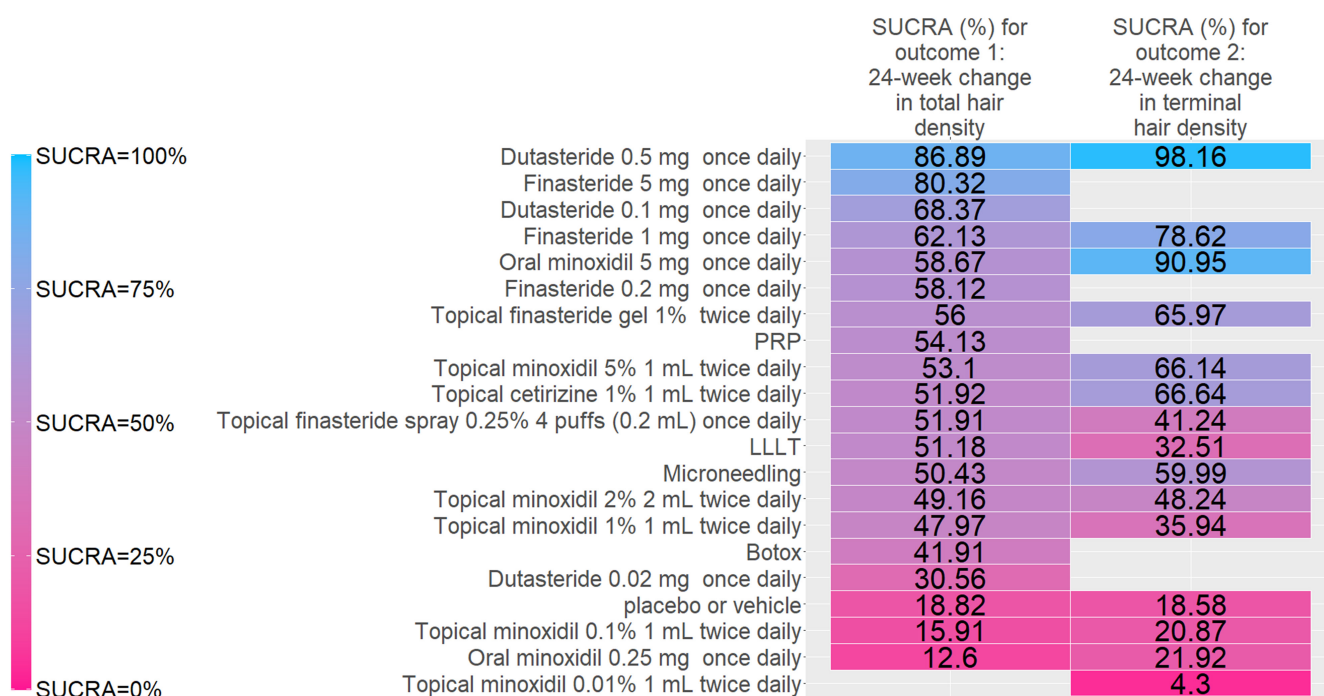


FIGURE 5 Regimens' surface under the cumulative ranking curve (SUCRA).

informed decisions and scientists can better design studies on the impact of monotherapies for male AGA.

AUTHOR CONTRIBUTIONS

Aditya K. Gupta mainly contributed to the conceptualization of the study, and critically revised the manuscript. Mary A. Bamimore conducted all statistical analyses and contributed to manuscript writing. Tong Wang collected and collated data. Mesbah Talukder also contributed to data collection and collation, and mainly supervised the study.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflict of interest to declare.

DATA AVAILABILITY STATEMENT

Data will be made available upon reasonable request.

ETHICS STATEMENT

Not applicable. The authors declare that human ethics approval was not required for this article.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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