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BRIEF REPORT

Efficacy of Skin Patting and Iontophoresis with Dutasteride Gel in Male and Menopausal Female Androgenetic Alopecia: A Pilot Study

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ABSTRACT

Introduction: Androgenetic alopecia (AGA) is a chronic, progressive condition often resistant to conventional treatments. Transdermal delivery systems such as iontophoresis and skin patting (SPi) may enhance drug penetration and follicular targeting. Dutasteride, a potent dual 5α-reductase inhibitor, has shown superior efficacy to finasteride, but topical delivery is limited by variable absorption. In this pilot study, we evaluated the efficacy and safety of dutasteride gel delivered via SPi and iontophoresis in men and postmenopausal women with treatment-resistant AGA.

Methods: In this single-center pilot study, 20 adults (10 males, 10 postmenopausal females) with AGA unresponsive to ≥ 12 months of standard therapy underwent four monthly sessions of SPi and iontophoresis with 6% dutasteride gel. Hair density, shaft diameter, and pull test results were assessed at baseline and 8 weeks post-treatment; patient satisfaction (0–4 scale) and safety were recorded. Paired tests were used to analyze the results, with $p < 0.05$ considered to indicate significance.

Results: Hair density improved significantly in frontal ($p < 0.001$) and vertex ($p < 0.001$) regions. Shaft diameter increased in vertex ($p < 0.001$) and frontal areas ($p = 0.046$). Pull test scores improved ($p < 0.001$). Mean satisfaction was 3.4/4. No adverse events occurred.

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Conclusion: SPi with iontophoresis effectively delivered topical dutasteride, yielding significant clinical improvement and excellent safety in treatment-resistant AGA. Larger randomized trials are warranted to confirm these findings.

Keywords: Dutasteride; Androgenetic alopecia; Skin patting; Iontophoresis; Topical therapy

Key Summary Points
This pilot study evaluated the effects of a compounded 6% dutasteride gel delivered through skin patting (SPi) and iontophoresis in 20 adults (10 males, 10 postmenopausal females) with treatment-resistant androgenetic alopecia (AGA)
Significant improvements were observed in hair density and shaft diameter at both frontal and vertex scalp areas, as well as in pull test scores, indicating enhanced hair regrowth and reduced shedding
Patient satisfaction was high: 70% perceived the treatment as moderately to very effective, 85% found the procedure pleasant, and no side effects were recorded
The combined physical and pharmacological approach (SPi + iontophoresis + dutasteride gel) offers a targeted method to enhance local anti-androgen effects while minimizing systemic exposure
Limitations of this study include the small sample size, open-label non-randomized design, lack of a comparator arm, short follow-up, and use of non-validated outcome measures

INTRODUCTION

Androgenetic alopecia (AGA) is a chronic, progressive, non-scarring form of hair loss that affects up to 80% of men and 50% of women over the course of their lives [1, 2]. Conventional therapies, such as topical minoxidil, often yield limited efficacy in some patients and require continuous, lifelong application. Systemic antiandrogens like finasteride, although effective, may be associated with undesirable side effects, limiting their use [1, 2].

Physical therapies currently considered to be innovative approaches, such as microneedling, platelet-rich plasma (PRP), and mesotherapy, vehiculate their effect through mechanical stimulation. Transdermal drug delivery via iontophoresis or sonophoresis are alternative options to vehiculate growth factors or drugs on the scalp through their high penetration and electronic effect. Tricopat® (APS Srl, Faenza, Italy) is the only medical device that combines the effect of mechanical and electronic action through skin patting (SPi), iontophoresis, and electrostimulation, and it has emerged as promising local treatment option [3–5].

Dutasteride, a 5-alpha-reductase inhibitor, blocks both type I and II enzymes, reducing dihydrotestosterone (DHT) levels by > 90%. Approved for benign prostatic hyperplasia, it is also used off-label for androgenetic alopecia to prevent hair follicle miniaturization. More potent than finasteride (which inhibits only type II enzymes), it has a half-life of approximately 5 weeks [2]. In this context, the use of a dutasteride gel administered through SPi and iontophoresis offers a targeted approach that maximizes local anti-androgenic effects while minimizing systemic exposure and related side effects [1, 2].

The aim of this pilot study was to evaluate the efficacy and safety of topical dutasteride gel administered via SPi and iontophoresis in men and postmenopausal women with treatment-resistant AGA.

METHODS

We conducted an open-label, non-randomized, single-center pilot study, from June 2023 to March 2025, involving adult patients with AGA refractory to at least 1 year of topical minoxidil and/or oral finasteride. Diagnosis was based on

clinical evaluation and trichoscopic findings. Exclusion criteria were significant systemic illness, autoimmune or hematologic disorders, or malignancies and any treatments during and 3 months before the study.

All participants provided written informed consent. The study protocol included three phases: a baseline screening phase, four monthly sessions of SPi and iontophoresis with a compounded dutasteride 6% gel, and an 8-week follow-up after treatment completion. At baseline (T0) and 8 weeks after the end of the treatment (T6), demographic and clinical data were collected, including concomitant medications, results of clinical scalp examination, and standardized trichoscopic images taken using the Fotofinder® system (FotoFinder Systems GmbH, Bad Birnbach, Germany) at 20 × and 40 × magnifications on both the frontal and vertex scalp, evaluating hair density and number of vellus hairs; a pull test was conducted in the same regions at each visit.

Each session followed a standardized protocol with a fixed application grid centered on Kang's V point, defined by the intersection of the midsagittal line and a horizontal line connecting both tragi. From this point, the treatment was applied over an area extending 6 cm toward the frontal hairline, 6 cm toward the vertex, and 4 cm laterally toward each parietal region. No anesthesia was required. The procedure began with controlled microdermabrasion using 0.25-mm microneedles until mild erythema was achieved, stimulating dermal repair. This was followed by radial pressure waves to enhance microcirculation and fibroblast activity, then iontophoresis to facilitate transdermal delivery. Finally, red LED light was applied to promote collagen and elastin production. Each session lasted 20–25 min, with no post-treatment care or restrictions needed.

After 6 months from the baseline, patients completed a structured self-assessment questionnaire designed to evaluate treatment perception. The questionnaire included three domains: (1) perceived effectiveness (5-point Likert scale from "not effective at all" [1] to "very effective" [5]); (2) cosmetic satisfaction (graded from 0 = not satisfied to 4 = very satisfied); and (3) tolerability and comfort during the procedure (rated as unpleasant, neutral, or pleasant). Open-ended questions were also included to capture additional qualitative feedback. This study was conducted in accordance with the Helsinki Declaration of 1964 and its later amendments. Approval from the local ethic committee is not required due to local legislation. The authors attest to obtaining written patient consent for the publication of recognizable patient photographs or other identifiable material, with the understanding that this information may be publicly available.

RESULTS

A total of 20 patients (10 males, and 10 menopausal females) were included in the analysis, with a mean (± standard deviation [SD]) age of 39.0 ± 17.0 years. At baseline (T0), the mean frontal hair density was 113 ± 44.9 hairs/cm^2, while the mean vertex density was 94.7 ± 38.6 hairs/cm^2. The mean number of vellus hairs was 47.8 ± 20.9/cm^2 in the frontal area and 41.1 ± 15.4/cm^2 at the vertex. The average hair shaft diameter measured 0.0508 ± 0.0175 mm in the frontal region and 0.0521 ± 0.0150 mm at the vertex. The pull test showed a mean value of 8.25 ± 3.02. After 6 months (8 weeks after the last session of treatment [T6]), the mean frontal hair density and mean vertex density had increased to 131 ± 51.0 and 109 ± 41.2 hairs/cm^2, respectively; the mean number of vellus hairs had slightly decreased to 40.1 ± 22.3/cm^2 in the frontal area and to 36.1 ± 14.9/cm^2 at the vertex; the average hair diameter had increased to 0.0582 ± 0.0197 mm in the frontal region and to 0.0609 ± 0.0192 mm at the vertex; and the pull test had significantly improved, with a reduction to a mean value of 3.40 ± 1.14. T-test analysis showed a statistically significant increase in frontal ($p < 0.001$) and vertex density ($p < 0.001$) at T6 compared to baseline. No statistically significant changes were observed in the vellus hair counts (frontal $p = 0.112$; vertex $p = 0.113$). A significant increase in hair shaft diameter was detected in both the frontal ($p = 0.046$) and vertex regions ($p < 0.001$). The pull test showed a significant reduction at T6 ($p < 0.001$), indicating

clinical improvement. All results and comparisons are shown in Table 1.

The mean global clinical improvement score was + 1.9 on the 7-point scale, corresponding to moderate regrowth and reduction in shedding. Patient-reported outcomes reinforced the objective findings. On the effectiveness domain, 70% of participants rated the treatment as either "moderately effective" or "very effective." In terms of cosmetic satisfaction, the mean score was 3.4/4, indicating a high level of approval. Tolerability was equally favorable, with 85% of patients describing the procedure as pleasant and no reports of discomfort or side effects. No adverse events were recorded during the treatment or follow-up. All statistical analyses were performed using Jamovi (Version 2.6).

DISCUSSION

Androgenetic alopecia is the most common form of hair loss [1, 2]. Recently, physical transdermal delivery technologies, such as iontophoresis and microneedling, have been explored to enhance the effectiveness of topical therapies while minimizing systemic exposure [3–5].

Tricopat® is a novel medical device combining skin patting, iontophoresis, and electrostimulation with red LED light therapy [3–5]. Treatments that combine controlled microdermal incisions, radial pressure waves, and iontophoresis have shown potential in enhancing scalp drug penetration, stimulating microcirculation, and promoting follicular activity. These effects are further amplified by the application of red LED light at the end of each session, known for its regenerative and anti-inflammatory properties [3–5]. In comparison to these treatments, dutasteride, which is a dual 5α-reductase inhibitor with a prolonged half-life and higher potency than finasteride, has shown promise as a topical agent in the treatment of AGA [2]. Dutasteride is preferred over finasteride in the protocol described here due to its longer half-life (approximately 5 weeks), which aligns well with the treatment schedule. Our findings support the utility of SPi and iontophoresis with a dutasteride gel as an effective, well-tolerated option for AGA in both sexes. The combination of physical and pharmacologic modalities appears to enhance follicular penetration and stimulate regrowth, even in previously treatment-resistant cases. These results align with earlier data on combination therapy of SPi-facilitated delivery of growth factors and corticosteroids (Fig. 1a-h) [3, 4]. This study has some limitations inherent to its pilot nature. First, the small sample size ($n = 20$) limits the statistical power and generalizability of the findings. Furthermore, no formal power calculation was conducted due to the exploratory design of the study. Second, the study design was open-label and non-randomized, without a control or comparator arm (e.g., sham device,

Table 1 Clinical and trichoscopic parameters at baseline (T0) and at 8 weeks after the end of the treatment (T6)

Parameter	T0 (mean ± SD)	T6 (mean ± SD)	*p*-value
Frontal hair density (hairs/cm^2)	113 ± 44.9	131 ± 51.0	< 0.001*
Vertex hair density (hairs/cm^2)	94.7 ± 38.6	109 ± 41.2	< 0.001*
Frontal vellus hair (hairs/cm^2)	47.8 ± 20.9	40.1 ± 22.3	0.112
Vertex vellus hair (hairs/cm^2)	41.1 ± 15.4	36.1 ± 14.9	0.113
Frontal hair shaft diameter (mm)	0.0508 ± 0.0175	0.0582 ± 0.0197	0.046
Vertex hair shaft diameter (mm)	0.0521 ± 0.0150	0.0609 ± 0.0192	< 0.001*
Pull test (hair)	8.25 ± 3.02	3.40 ± 1.14	< 0.001*

SD Standard deviation

*Significant difference ($p = 0.046$) between T0 and T6

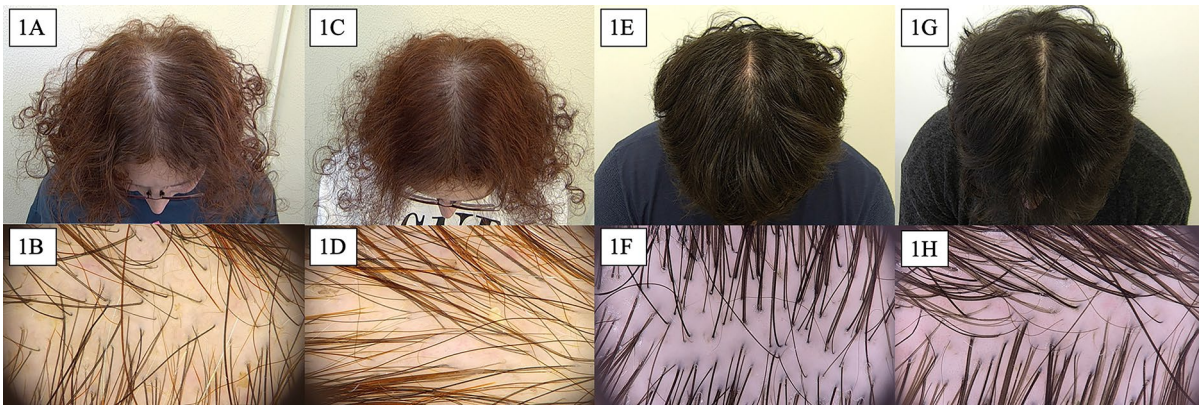

Fig. 1 Baseline and post-treatment global and trichoscopic images of two patients with androgenetic alopecia. **a–d** A 52-year-old female, **e–h** a 24 year-old male. **a**, **e** Global photographs at baseline (T0); **c**, **g** global photographs at the final visit after 4 therapeutic sessions. **b**, **f** trichoscopic images at baseline corresponding to **a** and **e**, respectively; **d**, **h** trichoscopic images at the final visit corresponding to **c** and **g**, respectively

topical dutasteride alone, or placebo), making it impossible to isolate the effects of the individual components of the combined treatment or to rule out placebo response. Third, outcome assessment relied partly on subjective and non-validated tools, including a custom patient satisfaction questionnaire and a non-blinded clinical improvement scale. Additionally, the lack of standardization in trichoscopic imaging and measurement protocols may have introduced variability. Finally, the follow-up period was relatively short (8 weeks after the final session), which may be insufficient to fully capture the long-term effects of a drug with a prolonged half-life like dutasteride. Future randomized, controlled trials with larger cohorts, validated outcome measures, and extended follow-up are needed to confirm and expand upon these preliminary observations.

CONCLUSION

In conclusion, delivery of dutasteride gel through SPi and iontophoresis appears to be a promising therapeutic option for AGA in treatment-resistant men and menopausal women. The combination of physical and pharmacological mechanisms produced meaningful clinical and trichoscopic improvements with excellent patient satisfaction and no adverse effects. Larger, controlled trials are warranted to validate these preliminary findings and refine treatment protocols.

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Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of interest. Michela Starace is an Editorial Board member of *Dermatology and Therapy*. Michela Starace was not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions. Michela Starace is currently a speaker for Tricopat®. Stephano Cedirian, Francesca Pampaloni, Luca Rapparini, Federico Quadrelli, Francesca Bruni, Ginevra Martelli, and Bianca Maria Piraccini have no conflict of interest to disclose.

Ethical Approval. This study was conducted in accordance with the Helsinki Declaration of 1964 and its later amendments. Approval from the local ethic committee is not required due to local legislation. The authors attest to obtaining written patient consent for the publication of recognizable patient photographs or other identifiable material, with the understanding that this information may be publicly available.

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