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Original Research Article

A prospective multicentric real-world evidence study to evaluate the safety and effectiveness of topical Minoxidil (5%) in combination with Procapil, Redensyl, Caffeine & Transcutol vs. plain Minoxidil (5%) topical solution in patients with Androgenetic Alopecia: PRO-ACT

Khyati Patel[1], Hari Kishan Kumar Yadalla[2] , Seema Srinivasa[3], TN Rekha Singh[4], Varsha DV[5], PRO-ACT study group*

[1]Angel Skin Hair Laser Clinic, Ahmedabad, Gujarat, India
[2]Dr Kishan`s Skin Care & Aesthetic Research Centre, Bengaluru, Karnataka, India
[3]Dr Seema's Skin Care and Laser Center, Bengaluru, Karnataka, India
[4]A V Poly Clinic, Hyderabad, Telangana, India
[5]Boss Multispeciality Hospital, Bengaluru, Karnataka, India

***PRO-ACT study group:** Monal Shah (The Smayan Derma Care, Ahmedabad, Gujarat, India); Bansri Mahadevia (B the Change, Ahmedabad, Gujarat, India); Brahmaiah Upputuri (Derma Space Skin and Hair Clinic, Hyderabad, Telangana, India); Deepak Divakar (Dermasculpt Skin and Hair Transplant Clinic, Bengaluru, Karnataka, India); Khyati Patel Vasavada (Raghudeep Eye Hospital (REH), Ahmedabad, Gujarat, India); Namrata Dosapaty Thaker (Dr. Namrata's Swastik Skin Hair and Laser Clinic, Ahmedabad, Gujarat, India); Uzzaif Mansuri (Uzzaif Skin Care, Ahmedabad, Gujarat, India); Alka Makwana (Arista Skin, Hair & Laser clinic, Ahmedabad, Gujarat, India); Bhumi Patel (Noble Hospital, Ahmedabad, Gujarat, India); Monika Chinda, Nimitha Pinto, Ashok Jaiswal (Dept. of Medical and Regulatory Affairs, Zydus Healthcare Limited, Mumbai, Maharashtra, India)

Abstract

Background: Androgenetic alopecia (AGA) is a chronic, progressive condition affecting 60–70% of the global population and is associated with a substantial psychosocial burden. Although topical minoxidil 5% is a well-established treatment, its efficacy may be limited in some individuals.
Aim and objective: To evaluate the safety and effectiveness of a novel formulation of Minoxidil 5% combined with Procapil, Redensyl, caffeine, and Transcutol (Minoxidil PRCT combination) compared to plain Minoxidil 5% in individuals with AGA.
Materials and Methods: In this open-label, prospective, multicenter, real-world study, 400 participants with clinically diagnosed AGA were prescribed either the Minoxidil PRCT combination or plain Minoxidil 5% for 4 months. Primary outcomes included changes in hair diameter, terminal and vellus hair count assessed via trichoscopy. Secondary outcomes were patient satisfaction, compliance, and adverse events.
Results: The Minoxidil PRCT combination group showed a significant increase in hair diameter (+4.8 µm, $p < 0.001$) at 4 month follow-up from baseline compared to non-significant change observed in the plain minoxidil group (+2.7 µm, $p = 0.115$). Terminal hair density also improved significantly in both groups from baseline (+27.5 hairs/cm² in the Minoxidil PRCT group and +24 hairs/cm² in the plain minoxidil group; $p < 0.001$). Patient satisfaction and compliance were higher in the Minoxidil PRCT group. Fewer adverse events were reported in the Minoxidil PRCT group (4%) versus the plain minoxidil group (9.5%).
Conclusion: Minoxidil PRCT demonstrated superior effectiveness, better tolerability, and greater patient satisfaction than plain Minoxidil 5%, supporting its potential as an improved therapeutic option for AGA.

Keywords: Androgenetic Alopecia, Hair Loss, Minoxidil, Redensyl, Procapil, Caffeine

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*Corresponding author: Nimitha Pinto
Email: nimitha.l.pinto@zyduslife.com

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1. Introduction

Androgenetic Alopecia (AGA) is a highly prevalent condition affecting 60-70% of the global population at some point in their lives, impacting both men and women.[1] Studies indicate that approximately 67.1% of men experience AGA, while the prevalence among women is significantly lower, ranging from 21% to 23.9%.[2,3] In India, the prevalence among men aged 30-50 is reported at 58%, while rates in East Asian men, such as Chinese and Korean males, are 21.3% and 14.1%, respectively.[4,5] Characterized by progressive hair follicle miniaturization, AGA presents in distinct patterns in men and women, resulting in Male Pattern Hair Loss (MPHL) and Female Pattern Hair Loss (FPHL), respectively. These patterns are classified using the Norwood-Hamilton scale for men and the Ludwig scale for women.[6,7] Beyond the physical appearance, AGA significantly impacts patients' psychological well-being and quality of life.

Current treatment modalities for AGA include topical therapies such as Minoxidil, oral medications like Finasteride, and minimally invasive approaches aimed at promoting hair regrowth and preventing further hair loss.[8] Topical Minoxidil, a widely used and regulatory-approved treatment, is a mainstay therapy for promoting hair regrowth.[9] It works by extending the anagen (growth) phase of hair follicles, enhancing cell proliferation, increasing local blood supply via upregulation of vascular endothelial growth factor (VEGF), and dihydrotestosterone (DHT) levels through suppression of androgen receptors and CYP17A1 activity, thereby preventing follicular miniaturization.[10]

While Minoxidil effectively stimulates hair regrowth by prolonging the anagen phase, its effects can be enhanced with integration of peptides.[11] This involves complementary mechanisms wherein Minoxidil prolongs the anagen phase to promote hair growth, while peptides target DHT-induced follicular miniaturization, a key factor in AGA.[12,13] Many bioactive peptides have shown significant promise in addressing alopecia by targeting various pathways involved in hair growth and follicular health.[14] Redensyl, derived from sustainable wood extracts, activates hair follicle stem cells and promotes the anagen phase, supporting regrowth and reducing hair loss.[15] Procapil, a combination of biotinyl-GHK, apigenin, and oleanolic acid sourced from olive leaves, enhances scalp microcirculation and counteracts DHT, strengthening hair follicles and preventing miniaturization.[16] Caffeine, obtained from coffee beans, stimulates hair follicles by improving blood flow and prolonging the anagen phase.[17]

Due to these combined mechanisms of action, our study investigates the potential of combining Minoxidil with bioactive peptides to enhance hair regrowth and address AGA. This study aims to evaluate the effectiveness and safety of Minoxidil 5% in combination with PRCT (Minoxidil PRCT) (Procapil, Redensyl, caffeine, and Transcutol) compared to plain Minoxidil 5%.

2. Materials and Methods

2.1. Study design

This is an open-label, prospective, multicenter, real-world evidence (RWE) study aimed to compare the safety and effectiveness of Minoxidil PRCT [MPower™ Zydus healthcare Limited, India] versus plain Minoxidil 5% solution over a treatment duration of 4 months. Patients were prescribed one of the two treatment options based on physician discretion: one group received Minoxidil PRCT, while the other group received plain Minoxidil 5% solution.

2.2. Study objectives

2.2.1. Primary objective

To assess changes in hair parameters over the 4-month treatment period through trichoscopic analysis, focusing specifically on hair diameter, vellus hairs (defined as those with a diameter less than 0.03 mm and length shorter than 30 mm), and terminal hair density.

2.2.2. Secondary objective

To evaluate participant satisfaction, tolerability, adherence and adverse events. Patient satisfaction was measured at the end of the study using a validated Subject Satisfaction Questionnaire (SSQ).

2.3. Study patients

The sample size was determined using statistical calculations with 80% power and 95% Confidence Interval accounting for a potential 20% dropout rate. 500 participants were initially screened to achieve the target of 400 completed cases, with 200 patients in each treatment group.

Patients included adults aged 18 years or older who had a clinical diagnosis of AGA confirmed through assessment by their treating physicians. Patients included were those considered suitable for Minoxidil 5% topical treatment by their physicians, with no recent use of other hair loss treatments. Before enrolment, all patients provided informed consent, confirming their understanding of the study requirements. The patients agreed to apply the treatment daily and maintain a treatment diary throughout the study. Individuals were excluded if they were pregnant, breastfeeding, planning to conceive during the study, and had conditions that prevented the use of topical Minoxidil, or had a known allergy to Minoxidil or any ingredients in the PRCT formulation.

2.4. Procedure

At the first visit baseline demographic information, including age, sex, height, and weight, was collected, and vital signs (pulse rate, blood pressure, respiratory rate, and temperature) were recorded. Each patient's trichoscopic measurements were taken to determine hair diameter, vellus hair, and terminal hair density.

Patients were prescribed either Minoxidil PRCT or plain Minoxidil 5% solution, applied at a dose of 1 mL directly to the affected areas of the scalp. Patients were advised to record each application in a diary, including the time of application and any adverse events or reactions observed. They were instructed to avoid applying the solution if the scalp was inflamed, infected, or otherwise irritated.

At the first follow-up visit at 2 months (±7 days) from baseline, each participant's vital signs were checked, and trichoscopic measurements were repeated to evaluate changes in hair parameters from baseline. Compliance with the treatment regimen was assessed by reviewing entries in the participant's diary, and any adverse events reported were documented and evaluated for severity and potential causality. Patients were reminded to continue the treatment application as prescribed and to maintain diary entries daily.

At the final follow-up visit at 4-month (±7 days), patients underwent the same assessments as the baseline and 2-month visits, including vital signs and trichoscopic evaluation. The patients' satisfaction with the treatment was assessed through SSQ. Both the investigator and participant also provided an overall tolerability rating, considering the frequency and severity of any adverse events experienced.

2.5. Data collection and statistical analysis

Data were collected through standardized electronic Case Report Forms (eCRFs) and participant diaries. The diaries recorded daily treatment application, adverse events, and self-reported compliance, which were reviewed and verified at each follow-up visit.

Descriptive statistics were calculated for baseline characteristics. An independent t-test was used for comparing continuous (quantitative) variables, while the chi-square test was applied for categorical (qualitative) variables to assess inter-group differences. For longitudinal trichoscopic parameters, repeated measures ANOVA was used to evaluate changes over time within each group. All statistical analyses were conducted using SPSS® (Version 21.0), with significance set at $p < 0.05$.

2.6. Ethical considerations

The study received approval from the ACEAS - Independent Ethics Committee. The approval was granted under Ethics Committee Registration No. ECR/281/Indt/GJ/2017/RR-21 and OHRP US DHHS Registration No. IRB00011046.

2.7. Clinical trial registry

The study was registered under the ISRCTN registry with registration number ISRCTN65325698.

3. Results

3.1. Baseline demographics

A total of 200 patients were included in each group. The mean age in the Minoxidil PRCT group was 32 ± 8 years, while in the plain Minoxidil group it was 32.5 ± 8.21 years. Both groups had comparable gender distributions, with 66.5% males in the Minoxidil PRCT group and 63.5% males in the plain Minoxidil group. Further baseline demographics, including height, weight, vital signs, and AGA grading, are detailed in **Table 1**.

3.2. Primary outcomes: Trichoscopic assessments

3.2.1. Hair diameter

The Minoxidil PRCT group exhibited a statistically significant increase in mean hair diameter, showing an improvement of approximately 4.8 µm from baseline to the 4-month ($p < 0.001$). In contrast, the plain Minoxidil group saw a smaller increase of 2.7 µm over the same period ($p = 0.115$) (**Table 2**).

3.2.2. Terminal hair density

Increases in terminal hair density were observed within each group. The Minoxidil PRCT group had a mean increase of 27.5 hairs/cm² from baseline to 4 months ($p < 0.001$), while the plain Minoxidil group saw an increase of 24 hairs/cm² over the same period ($p < 0.001$) (**Table 2**).

3.2.3. Vellus hair percentage

Over the 4-month treatment period, both groups demonstrated a statistically significant mean increase in vellus hair density from baseline. In the Minoxidil PRCT group, mean vellus hair density increased from 32.2 ± 9.57 hairs/cm² at baseline to 41.5 ± 12.49 hairs/cm² at month 4, reflecting a mean increase of 9.3 hairs/cm² ($p < 0.001$). Similarly, the plain Minoxidil group showed an increase from 31.3 ± 10.5 to 39.3 ± 13.6 hairs/cm², with a mean increase of 8.0 hairs/cm² ($p < 0.001$) (**Table 3**).

3.3. Secondary outcomes

3.3.1. Drug tolerability

Tolerability ratings indicated a preference for Minoxidil PRCT based on participant assessment at the end of the treatment. The tolerability was rated as excellent to good by 91.9% of the patients in Minoxidil PRCT, whereas it was 54% in the plain Minoxidil. [**Figure 1**]

3.4. Patient satisfaction and compliance

Patient satisfaction was rated as very satisfied to satisfied by 95.90% of the patients in Minoxidil PRCT; whereas it was 27.5% with plain Minoxidil [**Figure 2**]. Compliance of >80% was reported in more than 95.90% patients in the Minoxidil PRCT group as compared to 52.2% patients with plain Minoxidil.

Table 1: Sociodemographic and clinical profile of the patients

Variables	Minoxidil PRCT (N= 200)	Plain Minoxidil (5%) (N= 200)	t-test p-value
Age (years) (Mean + SD)	32 ± 8	32.5 ± 8.21	0.528
Height (cm) (Mean + SD)	168 ± 8.96	168 ± 8.76	0.514
Weight (kg)(Mean + SD)	68.8 ± 10.9	68 ± 11.3	0.504
SBP (mm-Hg)	122 ± 5.03	121 ± 5.33	0.052
DBP (mm-Hg)	82.8 ± 8.45	81.7 ± 6.8	0.137
Respiratory Rate (Breaths/minute)	16 ± 2.35	15.7 ± 2.2	0.104
Temperature (F)	98.2 ± 0.55	98.3 ± 0.54	0.654
Gender n (%)			
Male	134 (66.5%)	126 (63.5%)	Chi-square test P= 0.536
Female	66 (33.5%)	74 (36.5%)	
Frequency of medications n (%)			
Once Daily	66 (33.5%)	74 (36.5%)	Chi-square test P= 0.145
Twice Daily	134 (66.5%)	126 (63.5%)	

Table 2: Change in the Trichoscopy parameters from the baseline to the end of the treatment

	Minoxidil PRCT			ANOVA	Minoxidil plain 5%			ANOVA
Trichoscopy Parameters	**Baseline**	**2 months**	**4 months**	**(p-value)**	**Baseline**	**2 months**	**4 months**	**(p-value)**
Hair diameter (µm)	69.2±12.2	71.3±12.46	74±12.41	**<0.001**	69.1±13.7	70.3 ± 13.8	71.8±13.5	0.115
Terminal hair density (hairs/cm2)	101±31.57	115.7±36.14	128.5±40.48	**<0.001**	104.5±31.9	116.9±35.4	128.5±38.4	**<0.001**
Vellus hairs (hairs/cm2)	32.2±9.57	37±11.37	41.5±12.49	**<0.001**	31.3±10.5	35.6±12.3	39.3±13.6	**<0.001**

Data presented are mean ± SD

Table 3: Adverse events observed in each group (N=200)

Type of Adverse events	Minoxidil PRCT (5%)	Plain Minoxidil (5%)
Solicited Adverse Events- Local		
Pruritus	3 (1.5%)	6 (3.0%)
Dryness	1 (0.5%)	6 (3.0%)
Scaling/ flaking	2 (1.0%)	4 (2.0%)
Local irritation/ burning	2 (1.0%)	2 (1.0%)
Solicited Adverse Events- Systemic		
Tachycardia	0	1 (0.5%)

Data presented are n (%).

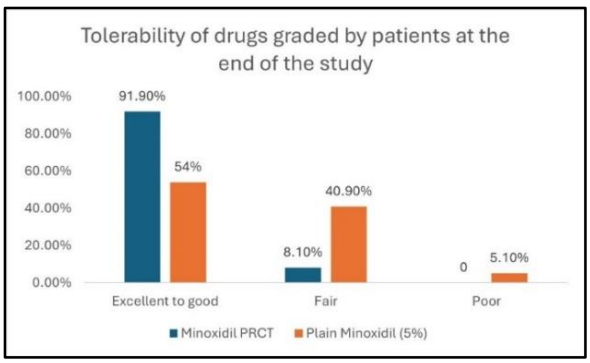

Figure 1: Drug tolerability graded by patients

3.5. Adverse events

The incidence of adverse events was slightly lower in the Minoxidil PRCT group (4.0%) compared to the plain Minoxidil group (7.5%), though this difference was not statistically significant (p = 0.133). Common adverse events in both groups included pruritus, dryness, scaling/flaking, and local irritation/burning. Only one case of tachycardia was reported in the plain Minoxidil group. All adverse events were managed successfully, except for one instance of persistent dryness in the plain Minoxidil group.

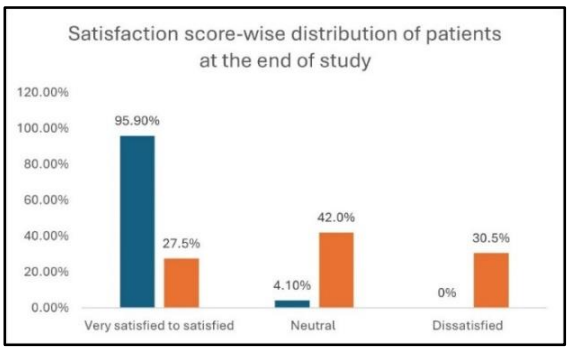

Figure 2: Satisfaction score-wise distribution of patients after 4 months of treatment with Minoxidil in combination with PRCT and Plain Minoxidil (5%)

4. Discussion

This study demonstrated that Minoxidil PRCT provides advantages over plain 5% Minoxidil in the treatment of androgenetic alopecia (AGA). Participants in the Minoxidil PRCT group exhibited statistically significant improvements in trichoscopic parameters.

Incorporating bioactive peptides into Minoxidil-based formulations offers additional advantages by targeting key mechanisms underlying AGA. Procapil, which combines oleanolic acid, apigenin, and biotinyl-GHK, has been shown to inhibit 5α-reductase, a critical enzyme in the conversion of testosterone to DHT, thereby reducing follicular miniaturization. A study by Khoso et al. (2024) demonstrated that the addition of Procapil to Minoxidil observed a mean hair count increase of 36.92 hairs/cm² ($p < 0.0001$). The combination therapy also resulted in higher patient satisfaction ($p = 0.011$) and dermatologist assessment scores ($p = 0.0054$).[18] Similarly, Redensyl targets dermal papilla stem cells and outer root sheath cells, promoting follicular regeneration. A study by Karaca and Akpolat (2019) compared the effectiveness of Minoxidil 5% to a combination of Redensyl, Procapil, and Capixyl (RCP) in men with AGA. After 24 weeks, 64.7% of patients in the RCP group exhibited significant or moderate recovery compared to 25.5% in the Minoxidil group ($p = 0.0006$).[12] Fischer et al. (2012) demonstrated that caffeine counteracts testosterone-induced suppression of hair follicle growth by promoting cellular metabolism and increasing hair shaft elongation in an in vitro model. Additionally, caffeine's ability to inhibit phosphodiesterase activity enhances cyclic adenosine monophosphate levels, which stimulate keratinocyte proliferation.[19]

Transcutol acts as a skin penetration enhancer which interpenetrates the phospholipid bilayer, thus improving the vesicular bilayer fluidity, and reduces the barrier function. Subedi et al. (2022) demonstrated that a Transcutol-based formulation increased drug penetration by up to 7.6-fold compared to conventional ethanol-based vehicles, facilitating deeper dermal delivery and improved therapeutic outcomes.[20] Similarly, Mura et al. (2011) highlighted that Transcutol enhances Minoxidil deposition in the deeper layers of the skin without significant transdermal delivery, ensuring localized action while minimizing systemic absorption.[21]

The significant improvement in trichoscopic parameters observed with Minoxidil in combination with PRCT aligns with existing evidence supporting the enhanced efficacy of combining Minoxidil with additional therapeutic agents. Study by, Khoso et al. (2024) observed a mean hair count improvement of 36.92 hairs/cm² with Minoxidil and Procapil, compared to Minoxidil alone (16.06 hairs/cm²) ($p < 0.0001$).[18] Minoxidil in combination with PRCT demonstrated fewer adverse events (4% vs. 9.5%) and higher compliance compared to plain Minoxidil, offering a safer and more tolerable alternative to other combination therapies.[22] This emphasizes the added advantage of Minoxidil in combination with PRCT formulation, which integrates bioactive peptides, targeting multiple pathways in AGA management while maintaining a favourable safety profile.

The findings of this study demonstrate the efficacy of Minoxidil in combination with PRCT, a novel formulation integrating Minoxidil with bioactive peptides and penetration enhancers, in improving hair density and overall treatment satisfaction. By targeting multiple pathways implicated in AGA, Minoxidil in combination with PRCT addresses limitations of traditional Minoxidil therapy. However, the short duration of the study and its open-label design present limitations in assessing the formulation's long-term effectiveness and safety, warranting further investigation through extended and randomized trials.

5. Conclusion

Minoxidil PRCT demonstrated superior efficacy in terms of hair diameter and tolerability compared to plain Minoxidil 5% in managing Androgenetic Alopecia (AGA). Significant improvements were observed in various trichoscopic parameters and patient satisfaction, and compliance, alongside fewer adverse events. These findings highlight the potential of advantages of topical minoxidil 5% in combination with bioactive peptides.

6. Author Contributions

Conceptualization / Study design

Khyati Patel, Alka Makwana, Seema Srinivasa, Bhumi Patel, T N Rekha Singh, Monal Shah, Bansri Mahadevia, Hari Kishan Kumar Yadalla, Upputuri Brahmaiah, Deepak Divakar, Khyati Patel Vasavada, Namrata Dosapaty Thaker, Uzzaif Mansuri, Varsha D V, Monika Chinda, Nimitha Pinto, Ashok Jaiswal.

Data acquisition

Khyati Patel, Alka Makwana, Seema Srinivasa, Bhumi Patel, T N Rekha Singh, Monal Shah, Bansri Mahadevia, Hari Kishan Kumar Yadalla, Upputuri Brahmaiah, Deepak Divakar, Khyati Patel Vasavada, Namrata Dosapaty Thaker, Uzzaif Mansuri, Varsha D V.

Drafting of manuscript

Khyati Patel, Alka Makwana, Seema Srinivasa, Bhumi Patel, T N Rekha Singh, Monal Shah, Bansri Mahadevia, Hari Kishan Kumar Yadalla, Upputuri Brahmaiah, Deepak Divakar, Khyati Patel Vasavada, Namrata Dosapaty Thaker, Uzzaif Mansuri, Varsha D V.

Critical revision of manuscript

Khyati patel, Alka Makwana, Seema Srinivasa, Bhumi Patel, T N Rekha Singh, Monal Shah, Bansri Mahadevia, Hari Kishan Kumar Yadalla, Upputuri Brahmaiah, Deepak Divakar, Khyati Patel Vasavada, Namrata Dosapaty Thaker, Uzzaif Mansuri, Varsha D V

Final approval of the version to be published

Khyati Patel, Alka Makwana, Seema Srinivasa, Bhumi Patel, T N Rekha Singh, Monal Shah, Bansri Mahadevia, Hari Kishan Kumar Yadalla, Upputuri Brahmaiah, Deepak Divakar, Khyati Patel Vasavada, Namrata Dosapaty Thaker, Uzzaif Mansuri, Varsha D V, Nimitha Pinto, Ashok Jaiswal.

Accountability for all aspects of the work

Khyati Patel, Alka Makwana, Seema Srinivasa, Bhumi Patel, T N Rekha Singh, Monal Shah, Bansri Mahadevia, Hari Kishan Kumar Yadalla, Upputuri Brahmaiah, Deepak Divakar, Khyati Patel Vasavada, Namrata Dosapaty Thaker, Uzzaif Mansuri, Varsha D V.

Data analysis & interpretation

Nimitha Pinto, Ashok Jaiswal.

Statistical analysis

Nimitha Pinto, Ashok Jaiswal.

Administrative / technical / material support

Monika Chinda, Nimitha Pinto, Ashok Jaiswal.

Supervision

Monika Chinda, Nimitha Pinto, Ashok Jaiswal.

7. Source of Funding

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8. Conflict of Interest

The authors declare no conflicts of interest.

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