

Original Research Article

Evaluating treatments for male androgenetic alopecia: clinical profile and comparative efficacy of platelet rich plasma and minoxidil with finasteride

Mehak Gupta*, V. K. Garg

Department of Dermatology, Santosh Medical College and Hospital, Ghaziabad, U.P., India

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*Correspondence:

Dr. Mehak Gupta,

E-mail: mehak21gupta@gmail.com

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ABSTRACT

Background: Androgenetic alopecia (AGA) is a common, hereditary, and androgen-dependent disorder characterized by progressive hair thinning on the scalp, affecting both men and women. It arises from follicular miniaturization, leading to the conversion of terminal hair into vellus hair.

Methods: This study is a single-center, prospective, open-label, randomized, placebo-controlled trial with four parallel arms designed to evaluate treatments for male pattern baldness. Eighty patients were randomized into four groups: Group 1 received topical minoxidil and finasteride solution, group 2 received PRP alone, group 3 received PRP with minoxidil and finasteride solution, and group 4 received normal saline (NS). Interventions were administered monthly over three months, followed by a three-month follow-up period. Treatment effects were assessed using measures such as patient self-assessment, global photography, and the hair pull test.

Results: Group 3 (combined treatment) showed the most significant improvement in the hair pull test after six months (73.33% negative tests), followed by group 2 (PRP treatment) with 60% improvement. Patient satisfaction scores were highest in group 3 across all follow-ups (F1 to F5), demonstrating superior treatment response compared to other groups ($p < 0.001$). Global photography assessments indicated varying results among groups, with group 4 recording the highest proportion of fair improvements (58.5%). Group 3 exhibited the highest percentage of patients with above-average improvement.

Conclusions: Our study provides valuable insights into managing AGA, emphasizing the effectiveness of combining PRP with topical treatments compared to individual therapies and placebo.

Keywords: AGA, Minoxidil and finasteride solution, Platelet rich plasma, Hair pull test

INTRODUCTION

Androgenetic alopecia (AGA) is a hereditary, autosomal dominant, and androgen-dependent disorder characterized by progressive hair thinning in a specific pattern on the scalp, affecting both men and women.¹ In India, the prevalence of AGA is significantly higher in men (79%) compared to women (21%).² Among Caucasians, the prevalence increases with age, affecting 30% of men aged 30-39 years, 40% of those aged 40-49 years, and 50% of

those aged 50-59 years.³ In Singaporean males, the prevalence rises from 32% in men aged 17-26 years to 100% in those over 80 years old.⁴ In Korean men, defined as Norwood III or above, the prevalence of AGA is 14.1% across all age groups.⁵

The underlying cause of AGA involves the miniaturization of hair follicles within follicular units, resulting in a gradual reduction in hair shaft diameter, pigmentation, and length.⁶ This process alters the anagen

to telogen hair ratio from 12:1 to 5:1 and changes terminal hair to vellus hair from 8:1 to 4:1.⁷ The progression of hair loss follows well-documented patterns as categorized by the Hamilton and Norwood classifications.^{8,9}

Numerous systemic treatments are available for AGA, including topical therapies such as minoxidil lotion, minoxidil and finasteride lotion, and platelet-rich plasma (PRP).^{10,11} Additionally, other methods such as spironolactone, botulinum toxin, low-level light therapy, and surgical treatments are employed.¹²⁻¹⁵

PRP, originally utilized in cardiac surgery and hematology for its high platelet count, has gained attention for its regenerative and tissue-healing properties across various medical disciplines.^{16,17} Orthopedic surgeons and sports medicine specialists have found PRP particularly promising due to its ability to stimulate tissue repair and modulate inflammation.¹⁹ PRP's growth factors, including epidermal growth factor, transforming growth factor, and platelet-derived growth factor, play crucial roles in regulating follicle growth and differentiation, enhancing its potential as a therapeutic adjunct.²⁰

Recent studies have investigated PRP's efficacy in AGA treatment, often in combination with topical agents like minoxidil. A study in Varanasi compared PRP therapy alone versus PRP with topical 5% minoxidil in male pattern baldness, concluding that the combined therapy was more effective than PRP alone. However, comparative studies evaluating PRP against other modalities remain limited.²¹ Research suggests that combining topical minoxidil with finasteride may yield superior results compared to monotherapy with minoxidil.²²

In a 2020 study conducted by Singh et al in Varanasi, the efficacy of PRP therapy was compared with and without topical 5% minoxidil in male pattern baldness. The study concluded that PRP with topical minoxidil is more effective than PRP alone.²³ However, there is a scarcity of comparative studies evaluating PRP with other treatment modalities. Research suggests that the combination of topical minoxidil and finasteride yields better results than using minoxidil alone.²⁴

Hence because of paucity of literature of comparing various topical modalities prompted us to undertake the study to compare PRP alone and with and without topical minoxidil with finasteride and to compare it with placebo (NS).

METHODS

Study design

Study design was single-center, prospective open label,

randomized control trial with four parallel arms

Place of study

Study conducted at department of dermatology, Santosh medical college and hospital, Ghaziabad.

Study period

Study carried out from January 2023 to January 2024.

Study population

Patients with AGA attending the outpatients' clinic of department of dermatology, Santosh medical college and hospital, Ghaziabad will be included in the study after their consent.

Sample size

The 80 patients, 20 patients in each group were included in study.

Inclusion criteria

Patients within age group of 18-50 year, not using topical minoxidil and oral or topical finasteride for at least 6 months, willing to come for regular follow-up, platelet count >1.5 lacs per microliter of blood were included in study.

Exclusion criteria

Uncooperative patients, any dermatological disease of scalp, tendency to form keloid, patients on anticoagulant therapy were excluded.

Registration

Clinical trial registry-India (CTRI) number for the trial was CTRI/2023/04/051903.

Diagnosis of AGA

All patients with AGA attending the outpatient clinic of department of dermatology, Santosh medical college and hospital were included in the study. Detailed demographic data was recorded in a preset proforma. History regarding onset and duration of AGA, medical history, family history and treatment received was taken. Written informed consent was obtained from all the participants in the study.

Assessment of severity of AGA was done using Hamilton and Norwood scale.

Baseline investigations were conducted, encompassing a range of parameters including complete blood count, thyroid function tests (T3, T4, and TSH), blood sugar

levels (fasting and post-prandial), HbA1C levels, screening for HIV I and HIV II, VDRL test for syphilis, and testing for hepatitis B surface antigen (anti-HBsAg) and hepatitis C virus antibodies (anti-HCV).

Cases were randomized into four groups: Group 1 (Minoxidil and finasteride topical solution): Minoxidil 5% solution with 0.1% Finasteride will be applied topically, 1 ml on dry scalp, two times a day throughout the study period. Group 2 (PRP): Intradermal injection of PRP will be administered monthly for 3 months. Group 3 (PRP with minoxidil and finasteride topical solution): Minoxidil 5% solution with 0.1% finasteride will be applied topically, 1 ml on dry scalp, two times a day throughout the study period. Intradermal injection of PRP will be administered monthly for 3 months. Group 4 (NS): Intradermal injection of NS will be given monthly for 3 months.

PRP preparation

PRP was prepared by double spin method in Remi 8C plus machine 17 ml of blood was collected venipuncture in 2 acid citrate dextrose + gel separator + biotin tubes (10 ml/tube) which has 1.5 ml of ACD + gel separator.

Then collected blood was centrifuged by slow spin at 1500 RPM for 15 minutes. Upper supernatant will be pipetted out into a sterile tube. This supernatant was centrifuged by fast spin 3000 RPM for 15 minutes. Upper 2/3rd of PPP (Platelet poor plasma) was removed, and Platelet pellet was suspended in remaining 1/3rd of plasma. The PRP formed was collected into insulin syringe.

Topical LOX 10% spray was applied over the scalp 1hr before the administration of PRP. Areas to be treated were cleaned with 70% alcohol. Patient will be injected with PRP (0.05-0.1 ml/cm²) intradermally by 1ml insulin syringe at a distance of 1cm for 15-20 times.

Furthermore, we calculated the platelet count after preparing PRP with the help of field A and B stain and compared with Baseline and it was always 4 times the value. (2.5 lakhs at the baseline and 9.5-10 lakhs in the PRP) (Figure 1). PRP sessions was given 3 times 1st session at the base line, then 2nd after 1 month and 3rd after 2 months from baseline and then followed up monthly for 3 months after last session.

NS (Placebo) was injected in similar method.

The effect of the treatment was assessed by global photography, hair pull test and by self- designed patient self - assessment score which will be done at baseline and at every follow-up.

Standardized global photographs of the patients were captured at the beginning of the study. Subsequently, paired photographs taken before and after treatment were

evaluated using a standard 7-point assessment scale, which is as follows: Very poor, fair, below average, average, above average, good and excellent.

Patient self-assessment score

Was determined using a scale ranging from 0 to 4, with each score corresponding to a specific range of improvement as follows: Score 0: No improvement, score 1: 1-25% improvement, score 2: 26-50% improvement, score 3: 51-75% improvement and score 4: 75-100% improvement

Patients were asked to assess the degree of improvement in their hair volume, density, and overall satisfaction with the treatment based on this scale.

Statistical analysis

Data was collected on MS excel version 10 and was analyzed using SPSS software version 23. Statistical significance was determined using ANOVA and T-tests.

RESULTS

A total of 80 patients were randomly assigned to four groups: Group 1 (Minoxidil and finasteride topical treatment), group 2 (PRP treatment), group 3 (Combined treatment of minoxidil, finasteride, and PRP), and group 4 (Placebo). Majority of patients (72.5%) were aged between 21-30 years.

Statistical analysis revealed a significant difference in age distribution among the four groups ($p=0.021$). Though the age of onset showed no statistically significant difference ($p=0.067$); duration of male type baldness in a majority of cases was 18 months i.e., 21 patients (26.25%), followed by 18 patients (22.5%) having duration of 2 years.

The remaining patients had duration of 2 to 10 years (34; 42.5%) followed by less 1 year (7; 8.75%). Mean duration for each group is summarized in Table 1.

The mean duration of the disease between the two groups has a $p>0.05$, by applying one way ANOVA test, which is statistically not significant.

Patients in all 4 groups are classified into various categories of Norwood Hamilton Grading as illustrated in Table 4. Maximum number of patients in the study belong to grade 2 (37.5%) followed by grade 3 (Vertex) (23.75%).

Group 3 (Combined treatment) showed the most significant improvement in the hair pull test after 6 months (73.33% negative tests), followed by group 2 (PRP treatment) with 60% improvement. Group 4 (Placebo) showed the least improvement (16.6% negative tests) as shown in Table 2.

Patient satisfaction scores were highest in Group 3 across all follow-ups (F1 to F5), indicating superior treatment response compared to other groups ($p < 0.001$).

At first follow up (Table 3), 35 patients reported no improvement out of which maximum were of group 4 (57.1%) followed by group 2, group 3 and group 1 in decreasing order. Maximum score of 2 was reported by 3 patients, all belonging to group 1. Overall, the treatment response in various groups was significant ($p = 0.001$).

At end of 5th follow up, satisfaction score of 4 was achieved by 8 patients, max of which were from group 3 (75%). No patient of group 4 reported satisfaction score above 2 in any follow up. (Table 3). At 3rd follow up, global photography assessment revealed variable results amongst all groups. Max no. of patients in group 4 (58.5%) recorded as fair improvement, whereas in group 3 it was recorded as average improvement in 50% followed by group 2 and 1 with 38.8% patients recorded as below average improvement. Global photography assessments at follow-ups also showed the highest

percentage of patients with above-average improvement in group 3. After 3 months of last PRP sitting out 80 patients 9 patients were lost to follow-up and 12 (16.90%) patients had above average improvement in which 9 patients were in group 3 (75%). The 23 patients had average improvement (32.39%).

The 36 (50.70%) patients had below average improvement out of which maximum patients were in group 4 (44.4%). Statistical tests (ANOVA, T test) indicated significant differences in treatment outcomes and patient satisfaction scores among the treatment groups ($p < 0.05$).

A significant proportion (63.75%) of patients had a positive family history of AGA. Association of AGA with family history in 1st, 2nd and 3rd generation relatives among all 4 groups was studied. First-generation family history association was most prevalent (49.02%).

Global photography of scalp before treatment and at follow up 5 of groups I, II, III, and IV are shown in (Figure 2-4) respectively.

Table 1: Age distribution, age of onset and duration in different groups.

Variables	Group	Mean	SD	95% CI for mean		P value*	Conclusion
				Lower bound	Upper bound		
Age (in years)	1	24.70	4.054	22.80	26.60	0.021	Significant
	2	30.25	8.944	26.06	34.44		
	3	26.35	4.738	24.13	28.57		
	4	25.80	4.162	23.85	27.75		
	Total	26.78	6.098	25.42	28.13		
Age of onset	1	22.725	3.5187	21.078	24.372	0.067	Not significant
	2	26.425	7.5660	22.884	29.966		
	3	22.925	4.3868	20.872	24.978		
	4	22.775	4.0958	20.858	24.692		
	Total	23.713	5.2818	22.537	24.888		
Duration	1	2.000	1.7014	1.204	2.796	0.189	Not significant
	2	3.340	2.5775	2.134	4.546		
	3	3.375	2.3276	2.286	4.464		
	4	3.025	2.3026	1.947	4.103		
	Total	2.935	2.2773	2.428	3.442		

*One way ANOVA test.

Table 2: Comparison of hair pull test in every group before and after treatment at every follow-up.

Follow-up	Hair pull test	Group				Total
		1	2	3	4	
BT	Negative	8	5	5	8	26
	Positive	12	15	15	12	54
F1	Negative	8	5	12	8	33
	Positive	12	15	8	12	47
F2	Negative	11	10	14	9	44
	Positive	9	10	6	9	34
F3	Negative	11	12	15	10	48
	Positive	7	6	5	7	25
F4	Negative	14	13	16	10	53
	Positive	4	5	3	7	19
F5	Negative	13	14	16	10	53
	Positive	4	4	3	7	18

Table 3: Evaluation of treatment response at every follow up in different groups based on patient's satisfaction score.

Variables		Group				Total	P value
		1	2	3	4		
Follow up 1							
0	N	1	8	6	20	35	0.001
	%	2.9	22.9	17.1	57.1	100.0	
1	N	18	12	14	0	44	
	%	40.9	27.7	31.81	0.0	100.0	
2	N	1	0	0	0	1	
	%	0.0	0.0	0.0	0.0	100.0	
Follow up 5							
0	N	0	0	0	3	3	0.001
	%	0.0	0.0	0.0	100.0	100.0	
1	N	0	3	1	8	12	
	%	0.0	25.0	8.3	66.7	100.0	
2	N	18	5	5	6	34	
	%						

Table 4: Comparison of hair pull test in different groups before and after months of treatment.

Group	Negative hair pull test at end of 6 months	P value
1	6 (46.1%)	<0.05 (significant)
2	9 (60%)	<0.05 (significant)
3	11(73.3%)	<0.05 (significant)
4	2 (16.6%)	>0.05 (Insignificant)
P value	<0.05 (significant)	

Table 5: Evaluation of treatment response on the basis of patient's satisfaction score.

Group	Follow up (Mean±SD)				
	F1	F2	F3	F4	F5
1 (n=20)	12.75±5.730	14.75±4.993	27.50±6.697	31.11±3.660	37.50±7.717
2 (n=20)	7.00±6.156	12.75±8.025	25.00±11.757	32.22±12.973	48.89±18.986
3 (n=20)	13.25±7.993	20.00±7.609	34.25±10.672	45.79±16.605	61.05±17.995
4 (n=20)	0.00±0.000	0.00±0.000	5.00±5.590	7.81±5.764	8.44±6.250
Total (Mean± SD)	8.25±7.839	11.88±9.493	23.49±14.061	30.07±17.43	40.14±23.73
P value	0.001	0.001	0.001	0.001	0.001

**Figure 1: Platelet count on field A and B stain.****Figure 2 (A and B): Group 1 (Minoxidil and finasteride topical solution).**



Figure 3 (A and B): Group 2, PRP.



Figure 4 (A and B): Group 3, PRP with minoxidil and finasteride topical solution.

DISCUSSION

AGA is a dermatological condition characterized by hereditary and androgen-dependent factors, with a higher prevalence in men.²⁵

In India, the prevalence rate of AGA varies, among males aged 30 to 50 years was found to be 58%.²⁶

Numerous topical and oral medications have been developed to treat AGA. However, it's only topical minoxidil and oral finasteride have received approval from the FDA.

We were unable to find any previous study comparing four arms of PRP alone, topical minoxidil + finasteride alone, PRP with topical minoxidil + finasteride, and NS. We conducted a randomized placebo-controlled trial, enrolling 80 cases in total.

In this study, the most common age group among patients was 21-30 years, comprising 58 (72.5%) individuals. The second most common age group was 31-40 years, with 12 (15%) patients. The mean age across all participants was

26.78 years. While the mean age of patients in Gupta et al study was 28.3 years and in Verma et al was 29 years and in Agarwal et al 32 study 26.78 years.²⁷⁻²⁹

In our study the average age of onset is 23.7 years while in a study by Verma et al study it was 29 years, in Gupta et al 24 years, and in Agarwal et al 23.2 years.²⁷⁻²⁹

The mean age group varies because studies have been carried out in different places and time.

Regarding the duration of the disease at presentation, the average duration observed in this study was 2.93 years (equivalent to 35.18 months). In comparison, the average duration reported in the study by Hajheydari et al was 23.10 months, Gupta et al reported an average duration of 66.04 months, and Shah et al reported an average duration of 54.54 months.^{27,30,31}

The average duration of disease was compared across four study groups. In group 1, the average duration was 2 years, while in group 2, it was 3.34 years. Group 3 had an average duration of 3.38 years, and group 4 had an average duration of 3.03 years. The calculated $p > 0.05$, indicating that the difference was not statistically significant.

In this study, a family history of AGA was present in 63.75% (51) of patients, while 36.25% had no such family history. The percentage of family history positivity observed in this study was higher compared to the findings in Shah et al (54%), but lower compared to Hajheydari et al (81.6%) and Gowda et al (73.35%).^{24,30,31} Association of AGA with family history in 1st, 2nd and 3rd generation relatives among all 4 groups was studied. A significant proportion of patients (49.02%) had 1st generation association of family history.

Patients in all 4 groups are classified into various categories of Norwood Hamilton grading as illustrated in Table 5. Maximum number of patients in the study belongs to Norwood Hamilton grade 2 (37.5%) followed by grade 3 (vertex) (23.75%).

In the review done by Shankar et al grade 2 is the most well-known stage with 27.27%, grade 1-22.12%, grade 3-21.78%, grade 4-10.8% and grade 5-6% of patients.³²

In the review done by Shah et al grade 3 is the most well-known grade with half of patients, trailed by grade 4 with 32% of patients, grade 5, 18% of patients.³¹

The hair pull test was conducted to assess the condition's severity at treatment initiation and after six months. Patients refrained from shampooing for 24 hours before the test. Approximately 60 strands of hair were grasped between the thumb, index, and middle fingers and gently pulled. A positive result, indicating hair loss, was defined as extracting more than six hairs or 10% of the total

pulled. Conversely, a negative result indicated pulling six or fewer hairs, or less than 10% of the total.

In our study hair pull test after 6 months of treatment 6 patients of group 1, 9 patients in group 2, 11 patients of group 3 and 2 patients of group 4 had negative hair pull test after 6 months of treatment (Table 4). In another study by Verma et al.²⁸ At the end of the 6-month treatment period, 12 patients in group A (PRP) (75%) exhibited a negative hair pull test, whereas only 6 patients in group B (minoxidil) (42.8%) showed the same result. However, the calculated $p=0.135$ indicated that this difference was not statistically significant.

In a study by Khatu et al all the patients (100%) tested positive on the hair pull test.²² Following the fourth session of PRP, the test results showed a negative result in 9 patients (81.81%).

In our study at the end of treatment group 1 had a mean value of 37.50 with SD of 7.717, mean value of group 2-48.89 with SD 18.986. In group 3 mean value is 61.05 with SD 17.995 and in group 4 the mean is 8.44 and SD 6.250 and p value was found to be the significant (Table 5).

In Verma et al patients in group A exhibited a mean satisfaction score of 6.56 with a standard deviation of 1.09, whereas patients in group B had a mean satisfaction score of 4.85 with a standard deviation of 1.46.²⁸ The calculated p value indicated a highly significant difference between the two groups.

In our research, 67.1% of patients exhibited minimal improvement after a 3-month treatment period, while 50.70% showed little progress even after 5 months of treatment. In Agarwal et al study, 72.2% of patients showed no change at the conclusion of a 3-month period, with 33.3% still showing no improvement after 6 months.²⁹ Mild improvement was observed in 22.2% and 26.6% of patients at the 3-month and 6-month marks, respectively. Notably, there were no patients showing significant improvement after 3 months. By the end of the 6-month PRP therapy, only ten out of thirty patients experienced excellent improvement.

Global photography is currently accepted even throughout clinical trials for biologicals in psoriasis.²⁹

Evaluation methods used in our study were global photography, patient satisfaction score and hair pull test. Our study demonstrates a significant improvement in hair volume and quality as evidenced by global pictures, overall patient satisfaction, and the hair pull test.

We found that PRP combined with topical minoxidil and finasteride was the most effective treatment modality, while both PRP alone and topical minoxidil and finasteride alone were more effective than placebo.

Limitations

The study's limitations include the relatively short follow-up period and the lack of long-term data on the sustainability of treatment effects. Additionally, the study was conducted at a single center, which may affect the generalizability of the findings.

CONCLUSION

Our study provides valuable insights into managing AGA. Combining PRP with topical minoxidil and finasteride yielded superior results compared to other treatments, with notable improvements in hair volume, patient satisfaction, and global photography scores. This combination therapy offers a promising approach for AGA management and highlights the importance of personalized treatment strategies.

Recommendations

Long-term studies with larger sample sizes are recommended to validate the sustainability of treatment effects and generalizability of the findings. Incorporating combination therapies involving PRP, minoxidil, and finasteride should be considered for more effective management of AGA. Emphasize the importance of early intervention and adherence to prescribed treatments for better outcomes in AGA management.

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