



Research Article

A HOSPITAL BASED COMPARATIVE STUDY TO ASSESS THE SAFETY AND EFFICACY OF VARIOUS ADJUVANT THERAPIES IN ANDROGENETIC ALOPECIA AMONG ADULT MALE

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ARTICLE INFO

Article History:

Received 10th October, 2024

Received in revised form 23rd October, 2024

Accepted 18th Novmber, 2024

Published online 28th Novmber, 2024

Key words:

Androgenetic Alopecia, Platelet Rich Plasma, Injectable – Platelet Rich Fibrin , Randomized Controlled Trial.

ABSTRACT

INTRODUCTION: Androgenetic Alopecia (AGA) is the most common form of hair loss in men. Platelet-rich plasma (PRP) is a source of growth factors derived from a platelet concentrate and is being used in hair regrowth in patients of AGA. Injectable-platelet-rich fibrin (iPRF) is advanced version of platelet-rich fibrin in liquid form which can be injected and contains stem cells with high regenerative potential. **OBJECTIVES:** This study aims to compare the efficacy and safety of platelet rich plasma (PRP) and injectable platelet rich fibrin (i-PRF) as therapeutic options for AGA over conventional therapy assessing improvement in hair density, alopecia grade, and patient satisfaction. **METHODS:** A randomized controlled trial was conducted with 90 male patients diagnosed with AGA, divided equally into three treatment groups: conventional therapy, PRP and i-PRF. Participants received 4 treatment sessions at monthly intervals. Efficacy was evaluated through photographic assessments, hair density and alopecia grade and patient satisfaction score. **RESULTS:** Preliminary findings indicate both PRP and i-PRF significantly improve hair count and alopecia grade compared to baseline measurements ($p < 0.05$). However there is also a significant difference observed in hair density between three groups with i-PRF patients showed maximum 22.39% of increase in hair density while patient with PRP showed 13.09 % improvement and patient with conventional therapy showed 8.5% improvement. **CONCLUSION:** Both PRP and iPRF are effective and safe treatments for AGA, enhancing hair regrowth and achieving high patient satisfaction i-PRF ease of preparation and potential for sustained release of growth factors could make it a preferable choice over conventional treatment.

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INTRODUCTION

Androgenetic alopecia is a type of gradually progressive patterned hair loss which is mediated by androgen results in conversion of susceptible terminal hairs into vellus hairs in genetically predisposed individuals.^[1] It can impact 30% of men by age 30, 50% by age 50, and 80% by age 70. Onset typically occurs at puberty, sometimes as early as 12, with most cases beginning between ages 15 and 25. A family history is usually present, with inheritance pattern being maternal or paternal.^[2] Current therapies for AGA include the use of topical agents like minoxidil, oral medications such as finasteride, and surgical options including hair transplantation. However, each of these treatments has limitations regarding efficacy, side effects, and the necessity of long-term commitment.

^[3] So far, platelet-rich plasma (PRP) has been widely used for hair regeneration. Injectable platelet-rich fibrin (i-PRF), however, differs from traditional PRP by utilizing a low-speed centrifugation process, which yields better results and a significantly higher concentration of leukocytes, platelets, and growth factors, thereby enhancing the regeneration process.^[4] PRP has shown considerable success in treating hair loss, as growth factors released by activated platelets aid in hair growth and PRF is an advanced form of PRP.^[5] Hence the author chose to compare i-PRF with PRP for treating androgenetic alopecia (AGA).

SUBJECTS AND METHODS

Study design

It was a hospital based single blinded interventional prospective study, conducted in the department of dermatology over a period of 12 months from December 2022 to November 2023 after obtaining ethical clearance from the Institutional Ethics Committee.

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Sample size:

Assuming prevalence of Androgenetic alopecia at mean age 30 years is 30%.

p (prevalence of Androgenetic Alopecia) = 30%

q = 70%

d = 0.1%

$Z_{2.5\%} = 1.96$ at $\alpha = 5\%$ level of significance

$n = 90.23$

Therefore, the current study necessitates a minimum sample size of 90.

Study subjects

All male patients diagnosed with AGA were enrolled for the study between the age of 20- 40 years according to the following exclusion criteria: alopecia grade I and VII, no known history of malignant neoplasms, acquired immunodeficiency syndrome, hepatitis B, hepatitis C, or susceptibility to keloid scarring or had active skin lesions in the areas affected by AGA.

A detailed history was taken regarding age, duration of alopecia, duration of hair loss, history of smoking, family history and history of previous intervention. The patients were classified according to Norwood – Hamilton classification in grade II to VI. The baseline platelet count in patients had to be $>140,000$ platelets/ μL .

Study intervention

The patients were selected after counselling regarding the procedure and obtaining a written informed consent. A total of 90 patients were enrolled for the study. The study population was randomly divided into three groups.

Group A: consisted of 30 patients treated with conventional therapy of topical minoxidil.

Group B: consisted of 30 patients treated with injectable-platelet rich plasma with conventional therapy.

Group C: consisted of 30 patients treated with injectable-platelet rich fibrin with conventional therapy.

Procedure

Baseline evaluation of modified Norwood Hamilton grading was made at the first visit by photographic assessment and patients were classified as stage II to stage VI, hair density was measured using trichoscope over an area of 1cm^2 near the vertex 10 cm from glabella. A total of four sittings were administered in each patient at an interval of 30 days. Digital photographs were taken before starting the treatment and periodically thereafter. Results were assessed at the end of 4 months on the basis of change in the density and of hair as measured by trichoscope, by an independent observer evaluation of global photographs and patient's self-satisfaction, as evaluated by a questionnaire.

Preparation of autologous platelet rich plasma

A tube containing 1.5 mL of anticoagulant citrate dextrose A and 10 mL of blood will be prepared. After gently shaking the tube for 15 seconds to ensure thorough mixing, it will be

centrifuged at 1500 revolutions per minute for 15 minutes at room temperature. The resulting supernatant plasma will then undergo a second centrifugation at 2400 revolutions per minute for 10 minutes. The buffy coat and plasma located at the neck of the device will be carefully extracted using a 31G insulin syringe. Subsequently, 2 to 3 mL of this liquid will be injected at 1cm intervals on the scalp, using an insulin syringe.

Preparation of autologous injectable- platelet rich fibrin

10 ml of blood will be drawn into a tube without an anticoagulant. The tube will then be immediately centrifuged at a speed of 700 rotations per minute for a duration of 6 minutes. After centrifugation, the platelet-rich fibrin liquid will be collected using 31G insulin syringes. This liquid will be injected onto the entire scalp through the insulin syringe, penetrating 2-4 mm. A total of 2 to 3ml of the liquid will be injected at intervals of 1 cm apart on the scalp.

Preparation of scalp

Patients were advised to clean their scalp with shampoo at the day of PRP or i-PRF therapy. The scalp is cleaned with betadine and a eutectic mixture of cream containing 2.5% of lignocaine and prilocaine each was applied on the scalp for 40 min, to get the anaesthetic effect. Thereafter, the scalp is cleaned with sterile gauze piece. PRP and i-PRF are filled in insulin syringes and intradermal injections at a distance of 1 cm are given on scalp. Patients were asked not to wash their head for 8 h, and to avoid exposure to sun or dust, and cover their head and restrict heavy weightlifting for 2 days. Paracetamol 650 mg was given if any patient complained of pain at injection site.

Follow up

The patients were followed up after 4 weeks and a total of 4 sessions were done.

Statistical analysis

After collecting information, data was compiled, tabulated and analysed using the SPSS software version 25.0. The parameters of mean, standard deviation ratio, frequency and percentage were used for analysing descriptive statistics. Chi square test and t test were applied. $P < 0.05$ was considered statistically significant. The statistical power of the sample was 80% and type 1 error was 0.05.

RESULTS

The age of patient ranged from 20 to 40 years with mean of 28.48 years. During the history-taking process, participants were asked about the duration of their hair loss condition. The mean duration of Androgenetic Alopecia (AGA) among the patients was found to be 4.45 years. Family history was associated in 76.7 % of the patients. 27.7% of patients had a history of smoking while rest were nonsmokers. 26.6% of selected patients had a history of previous intervention before, that might not have been sufficient. All the selected patients were classified on the basis of Norwood Hamilton classification into grade 1 to 7. Most of the patients are of grade 3 (36.6%) and grade 4 (28.9%) alopecia.

The baseline parameters between the three groups were comparable and no statistical difference was observed. Chi square test was used to test the statistical difference in the above parameters.

Dermoscopic analysis

Hair density as assessed by dermoscopic method and was increased by 22.39% (166 to 203.17) in patient treated with i-PRF at the end of three months. The increase was significant and maintained for 3 months after receiving therapy. Patient with PRP showed 13.09% increase in hair density (165.23 to 186.87) the increase was also significant and maintained 3 months after and patient with conventional therapy showed 8.5% improvement (163.33 to 177.3) and the result was significant and persists till therapy continues. The result was statistically significant in all three groups with P value between three groups is <0.01 .

Subjective hair growth assessment questionnaire

Q1 since the start of the study, I can see my bald spot getting smaller. Question 2: Since the start of the study, how would you describe the growth of your hair? Question 3: Since the start of the study, how effective do you think the treatment has been in slowing down your hair loss? Question 4: Compared to the beginning of the study, which statement best describes your satisfaction with the appearance of a) Front of the head: b) Top of the head:

On Hair Growth assessment questionnaire, group-3 patients clearly outmatched the group-2 and group 1 patients in terms of bald size reduction, decrease hair loss, and overall appearance of scalp after four months of treatment.

The patients were asked to grade their satisfaction with the treatment provided, and at the end of treatment they had to give a score on a scale of 1-10 which was 7.25 ± 1.01 in PRF group, 6.07 ± 1.17 in PRP and 4.80 ± 1.06 in group 1 with standard deviation of 1.06.

Side effects of both included tolerable injection site pain during each injection and minimal bleeding

DISCUSSION

We studied the efficacy of autologous i-PRF versus autologous PRP with conventional therapy in androgenetic alopecia in male patients. Our finding revealed increase in hair density from 22.39% (166 to 203.17) in patient treated with i-prf at the end of three months and patient with PRP showed 13.09% (165.23 to 186.87) improvement the increase was also significant and maintained 3 months after. These findings were in agreement with **Ali mohamamad ,safi abbas et al (2022)**^[6], who conducted a comparative evaluation of prp vs I prf in treatment of aga in 30 males. The study was completed by 15 patients in group A (PRP) and 15 patients in group B (PRF). In group A hair density was increased by 18% after 3 months in prp while it was increased by 24% at 3 months in prf group. The study concluded that both PRP and PRF can be used in treatment of hair loss in men. But PRF has significantly better results as compared to prp.

In our study patient satisfaction score with i-PRF by the end of 4 months was 7.25 ± 1.01 which is consistent with the study conducted by **Bhoite KS et al.(2022)**^[7], study enrolled 15 individuals diagnosed with androgenetic alopecia who received injections of PRF along with microneedling every two weeks for a total of four sessions. Participants also followed a background therapy regimen comprising minoxidil, finasteride, and multivitamin supplements. Throughout the study, patients

A hospital based comparative study to assess the safety and efficacy of various adjuvant therapies in androgenetic alopecia

were monitored using clinical photography and dermoscopic evaluation before each session. At the conclusion of the study, a standard assessment questionnaire was administered to evaluate patient satisfaction. Significant improvements in hair growth were clinically noted, evidenced by a favourable satisfaction score of 7.42 on the patient satisfaction scale

A study conducted by **J. Choukroun et al.(2020)**^[8] revealed that employing a low relative centrifugation force resulted in a notably increased quantity of platelets and leukocytes. They hypothesized that this approach, known as the low speed centrifugation concept (LSCC), effectively concentrates leukocytes, platelets, and growth factors within fluid PRF-based matrices.

Hair loss is a major source of stress and a leading cause of low self-esteem and depression. Androgenetic alopecia, the most prevalent form of hair loss, results primarily from genetic predisposition and hormonal influences.^[5]

Injectable platelet-rich fibrin (PRF) is classified as a second-generation platelet concentrate, differing from platelet-rich plasma (PRP) due to its capacity to produce a fibrin matrix. This matrix facilitates the sustained release of growth factors over an extended duration^[9]. i-PRF contains a high concentration of growth factors such as platelet-derived growth factor (PDGF), transforming growth factor-beta (TGF- β), vascular endothelial growth factor (VEGF), and epidermal growth factor (EGF)^[10]. The continuous release of these growth factors from the fibrin matrix results in an extended period of stimulating hair follicle regeneration, surpassing the efficacy of PRP^[11]

There are various treatment options available to treat AGA, such as, hair transplant, medications such as finasteride and minoxidil with low-level laser light therapy. All the treatment modalities offer little help except PRP which improves hair growth by constant supply of various growth factors.^[12] However, there is an ever-increasing need for better treatment protocols which can provide patients' satisfaction and redeem his/her self-esteem.

CONCLUSION

It is concluded that preparation of i-PRF requires single spin centrifugation process with no requirement of anti-coagulant whereas PRP is prepared with two spin centrifugation process with use of anticoagulant, thus i-PRF emerges as a more cost-effective and time-efficient option for preparing the concentrate.

From the above study, it can be concluded, that both PRP and iPRF can be used for hair growth in patients with AGA. They both have a good result in, reducing hair fall, increasing hair density and have a good safety profile. Clearly, iPRF has better result than PRP in all the patients, and the results are also sustained for a long time. However, further studies are required to demonstrate its correct efficacy.

Acknowledgement

I would like to thank the patients for their full cooperation.

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Table 1 Demographic data of patients in all three groups

PARAMETERS	GROUP A	GROUP B	GROUP C	P VALUE
AGE(YEARS)	29.27 ± 4.76	28.77 ± 4.06	27.40 ± 3.46	0.199
DURATION (YEARS)	4.70 ± 1.62	4.47 ± 1.63	4.20 ± 1.40	0.465
SMOKING (YES)	9 (30.0%)	7 (23.3%)	9 (30.0%)	0.801
FAMILY HISTORY (YES)	23 (76.7%)	22 (73.3%)	24 (80.0%)	0.830
PREVIOUS INTERVENTION (YES)	7 (23.3%)	9 (30.0%)	8 (26.7%)	0.843
DURATION (YEARS)	4.70 ± 1.62	4.47 ± 1.63	4.20 ± 1.40	0.465

Table 2 Clinical evaluation of patients in all three groups

	GROUP A	GROUP B	GROUP C	P VALUE
ALOPECIA GRADE				
Grade 2	6 (20.0%)	3 (10.0%)	5 (16.7%)	
Grade 3	10 (33.3%)	12 (40.0%)	11 (36.7%)	
Grade 4	6 (20.0%)	10 (33.3%)	10 (33.3%)	
Grade 5	5 (16.7%)	5 (16.7%)	3 (10.0%)	
Grade 6	2 (6.7%)	0 (0.0%)	1 (3.3%)	
INITIAL HAIR DENSITY	163.33 (11.28)	165.23 (11.39)	166.00 (12.64)	0.686

Table 3 Subjective hair growth assessment questionnaire at the end of four months

	GROUP A	GROUP B	GROUP C	
Q1				<0.001
Disagree	7 (23.3%)	3 (10.0%)	0 (0.0%)	
Neutral	13 (43.3%)	9 (30.0%)	4 (13.3%)	
Agree	8 (26.7%)	9 (30.0%)	8 (26.7%)	
Strongly Agree	2 (6.7%)	9 (30.0%)	18 (60.0%)	
Q2				<0.001

No Change	7 (23.3%)	3 (10.0%)	0 (0.0%)	
Slightly Increased	13 (43.3%)	7 (23.3%)	4 (13.3%)	
Moderately Increased	6 (20.0%)	8 (26.7%)	7 (23.3%)	
Markedly Increased	4 (13.3%)	12 (40.0%)	19 (63.3%)	
Q3				<0.001
Not Very Effective	12 (40.0%)	9 (30.0%)	0 (0.0%)	
Somewhat Effective	16 (53.3%)	15 (50.0%)	13 (43.3%)	
Very Effective	2 (6.7%)	6 (20.0%)	17 (56.7%)	
Q4A				<0.001
Dissatisfied	7 (23.3%)	3 (10.0%)	0 (0.0%)	
Neutral	13 (43.3%)	6 (20.0%)	5 (16.7%)	
Satisfied	8 (26.7%)	13 (43.3%)	8 (26.7%)	
Very Satisfied	2 (6.7%)	8 (26.7%)	17 (56.7%)	
Q4B				0.009
Dissatisfied	8 (26.7%)	2 (6.7%)	0 (0.0%)	
Neutral	12 (40.0%)	11 (36.7%)	8 (26.7%)	
Satisfied	8 (26.7%)	10 (33.3%)	12 (40.0%)	
Very Satisfied	2 (6.7%)	7 (23.3%)	10 (33.3%)	
Patient Satisfaction Score	4.80 ± 1.06	6.07 ± 1.17	7.25 ± 1.01	<0.001

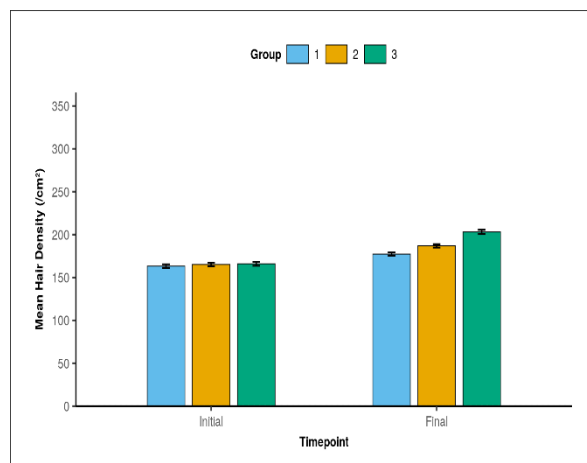
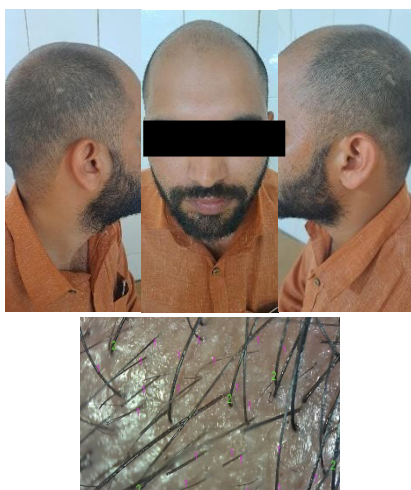


Figure 1 Comparison in improvement of hair density among all three groups



(A),(B),(C),(D)

Figure 2 Patient in Group A at baseline



FIGURE 3 (A),(B),(C),(D)

Figure 3 Patient in Group A after 4 months of conventional



(A),(B),(C),(D)

Figure 4 Patient in Group B at baseline



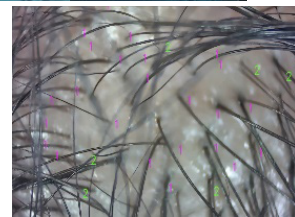
(A),(B),(C),(D)

Figure 5 Patient in Group B after 4 sessions of injectable platelet rich plasma



(A),(B),(C),(D)

Figure 6 Patient in Group C at baseline



(A),(B),(C),(D)

figure 7 Patient in Group c after 4 sessions of injectable platelet rich fibrin

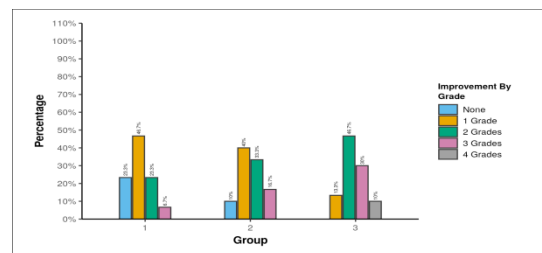


Figure 8 Improvement in alopecia grade among all three groups

How to cite this article:

Tanya Goyal .,Yatendra Singh Chahar., Karamvir Singh and Vartika.(2024) A hospital based comparative study to assess the safety and efficacy of various adjuvant therapies in androgenetic alopecia, *International Journal of Current Advanced Research*, 13(11), pp.3334-3339.
