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Original Research Article

Comparative study of efficacy of minoxidil versus minoxidil with platelet rich plasma versus minoxidil with dermaroller in androgenetic alopecia

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ABSTRACT

Background: Androgenetic alopecia is characterized by progressive hair loss and is recognized as having significant psychological effects on affected patients with a negative impact on QOL. Drug therapies specifically approved by FDA for treating androgenetic alopecia (AGA) are limited to minoxidil and finasteride. There are limited three arm studies comparing treatment modalities in AGA, hence we undertook this study to compare the 3 most common, affordable therapeutic modalities used currently in AGA and their effects.
Methods: This is a prospective comparative parallel group interventional study. 90 subjects recruited into 3 groups, group A treated with minoxidil alone, group B with minoxidil and dermaroller and group C with minoxidil and platelet rich plasma (PRP).
Results: At the end of 5 months 50% patients in group C showed moderate improvement which was found to be superior to the other treatment groups. On the basis of global photographs secondary efficacy analysis was done and all arms were found to have slight improvement. Dermoscopic analysis done at baseline and 5 months showed that group C showed maximum improvement. Pain was the most common side effect noted in group C while pruritus and seborrheic dermatitis was seen more in group A.
Conclusions: Our study showed best results in patients treated with PRP and minoxidil. They have emerged as new non-surgical treatment modalities for AGA, with minimal side effects, good safety profile and patient satisfaction. There are limited three arm studies comparing the efficacy and side effect profile of these 3 modalities in AGA.

Keywords: Minoxidil, PRP with minoxidil, Dermaroller with minoxidil, AGA, Hair follicles

INTRODUCTION

Throughout history, a scalp adorned with luxurious hair has been assigned positive attributes of virility and power. The appearance and disappearance of hair have always symbolized the coming of age and ageing. Above all, the desire to remain permanently youthful explains the common dread of age-associated hair-loss. For human beings, it has been associated with youthfulness and beauty in women and virility and masculinity in men.[1-3] Androgenetic alopecia (AGA) is a genetically determined progressive noncicatricial hair loss usually with a characteristic pattern that affects both genders. The hair thinning begins after puberty and increases in frequency and severity with age.[4] Hair loss can have a significant effect on the quality of life of a person and make him or her feel self-conscious. A prompt diagnosis of different types of alopecia's and early intervention is worthful

when dealing with these patients.[5] We undertook this study to compare minoxidil alone versus minoxidil with platelet-rich plasma (PRP) versus minoxidil with dermaroller in androgenetic alopecia.

METHODS

Male patients between 18 and 45 years with grade II, III or IV AGA (Norwood Hamilton classification) were enrolled in the study between December 2015 and May 2018 and attending outpatient department of Dermatology Venereology and Leprosy in Kempegowda Institute of Medical Sciences, Bangalore. In addition, patients were advised to use the same shampoo, maintain the same hairstyle, hairlength and hair colour during the entire study. Patients excluded from the study included those with any concomitant dermatological disorders on the scalp or serious systemic diseases. In addition, patients with shaved scalp, topical scalp treatment, finasteride treatment or treatment with other investigational hair growth products in the past six months.

After obtaining informed consent, photographic documentation was done both clinically and dermoscopically at baseline, three months and five months. 90 patients were randomly assigned into 3 groups. Group A was asked to apply 1ml of 5% minoxidil twice daily. Group B was asked to apply 1 ml of 5% minoxidil twice daily along with dermaroller once a month for four months. Group C were asked to apply 1ml of 5% minoxidil twice daily along with PRP once a month for four months One hour prior to the procedures anaesthetic cream was applied following which the scalp was surgically cleansed with betadine and normal saline.

In group B, a dermaroller of 1.5 mm sized needles was gently rolled over the affected areas of the scalp in longitudinal, vertical, and diagonal directions until pin point bleeding was noted; this was considered as the end point of the procedure.

In group C, PRP was prepared by drawing 12ml of patients own blood in 2 ACD vials (anticoagulant citrate dextrose) and centrifuging it for 15 minutes, 3600rpm by the single spin method.[6] The supernatant platelet-poor plasma (PPP) was drawn off from the top of the plasma layer leaving 2-3 cc of PRP. With the help of insulin syringe, PRP was injected over affected area by napping technique (multiple small injections in a linear pattern one-cm apart) under proper aseptic precaution.

A target area was selected to provide a stable reference point for photographic imaging throughout the test period. For determination of target area hair counts, hair in a 1×1 cm square at the leading edge of the vertex bald spot was clipped to a length of about 1 mm. Reproducibility of this area was assured by placing two threads one extending from the glabella to the occiput and one between the two helix. The point of intersection is noted, and a line is drawn tangential from it, at a measured distance a square is marked (Figure 1). Photographs of the target area were taken with a polarised Derm Lite DL4 using an iPad attached to the dermoscopy.

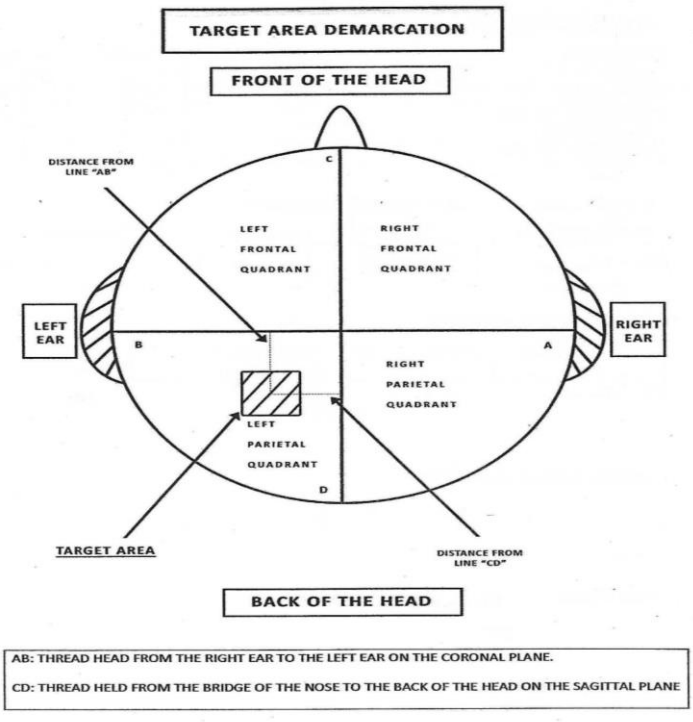

Figure 1: Target area demarcation.

Efficacy evaluation was based on primary efficacy evaluation (investigator asssessment which comprised of a 5-point scale), secondary efficacy evaluation (based on a change in global photographic assessment for hair growth on a 7-point scale) and visual analogue scale.

RESULTS

A total of 90 patients were equally divided into three treatment arms by random allocation. The mean age of the patients was 29.90+5.50 years with minimum 18 and maximum 44 years of age. The distribution of patients in the three treatment arms was found to be similar without a statistical significant difference.

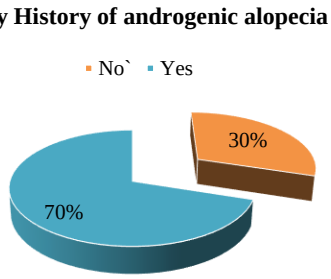

Figure 2: Distribution of the patients according to the family history of AGA.

About 70% of the patients gave a positive family history of AGA whereas only 30% gave a negative history (Figure 2).

As shown in Table 1 there is statistically significant improvement in investigator assessment in the group treated with only 5% minoxidil and PRP when compared to the other two groups using ordinal logistic regression

In secondary efficacy analysis, it was observed that the variation at 5 months as compared to 3 months was significant in all the three treatment arms. Majority of the patients improved only slightly in all the three groups. Worsening of the cases was seen in the treatment arms treated with only 5% minoxidil (Table 2).

Dermoscopic analysis showed Maximum improvement in group treated with PRP+minoxidil followed by group treated with Derma roller+minoxidil (Table 3). The difference in the improvement at 3 months and 5 months among the three treatment arms was statistically significant on ANOVA (Figures 3-5).

Most of the patients (n=22) in the group treated with PRP and minoxidil combination gave a VAS score of 4 and above. This number was least (n=9) for the group treated with only 5% minoxidil. A score of zero was given by a total of 8 patients, and most of them were in the groups treated with only 5% minoxidil and with a combination of derma roller and minoxidil (n=3 each)

Table 1: Primary efficacy analysis of the three different treatment type using ordinal logistic regression.

Treatment given	3 Months		5 Months	
	95% CI	P value	95% CI	P value
5% minoxidil	(Reference)		(Reference)	
Dermaroller +minoxidil	-0.43 (-1.3-0.5)	0.36	-0.63 (-1.6 to 0.33)	0.198
PRP+minoxidil	-1.2 (-2.3 to- 0.28)	0.01	-2.03 (-3.1 to -0.96)	<0.001

Table 2: Distribution of the patients according to the secondary efficacy Analysis.

Treatment type	Secondary efficacy grading	At 3 months	At 5 months	P value
Treatment with 5% minoxidil	Greatly decreased	0	1 (3.3)	0.011
	Moderately decreased	1 (3.3)	0	
	Slightly decreased	2 (6.7)	2 (6.7)	
	Unchanged	20 (66.7)	7 (23.3)	
	Slightly increased	7 (23.3)	19 (63.3)	
	Moderately increased	0	1 (3.3)	
	Greatly increased	0	0	
Treatment with - Dermaroller + minoxidil	Greatly decreased	0	0	0.000
	Moderately decreased	0	0	
	Slightly decreased	0	0	
	Unchanged	20 (66.7)	5 (16.7)	
	Slightly increased	10 (33.3)	19 (63.3)	
	Moderately increased	0	5 (16.7)	
	Greatly increased	0	1 (3.3)	
Treatment with PRP + minoxidil	Greatly decreased	0	0	0.001
	Moderately decreased	0	0	

Continued.

Treatment type	Secondary efficacy grading	At 3 months	At 5 months	P value
	Slightly decreased	0	2 (6.7)	
	Unchanged	12 (40.0)	1 (3.3)	
	Slightly increased	13 (43.3)	12 (40.0)	
	Moderately increased	5 (16.7)	10 (33.3)	
	Greatly increased	0	5 (16.7)	

Figure 3: Group A – (A) dermoscopic images (B) clinical images.

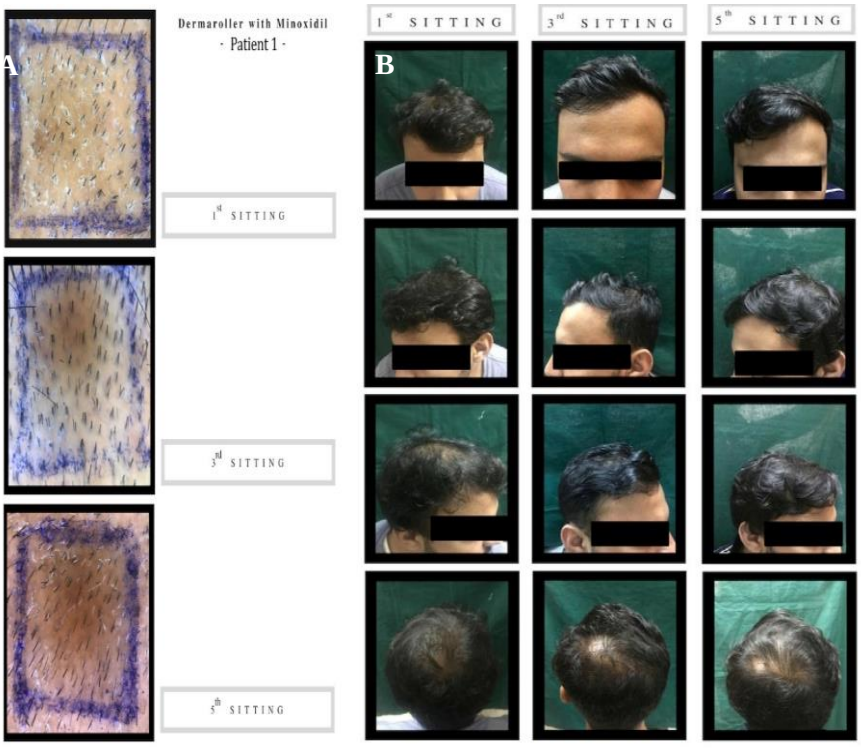

Figure 4: Group B – (A) dermoscopic images (B) clinical images.

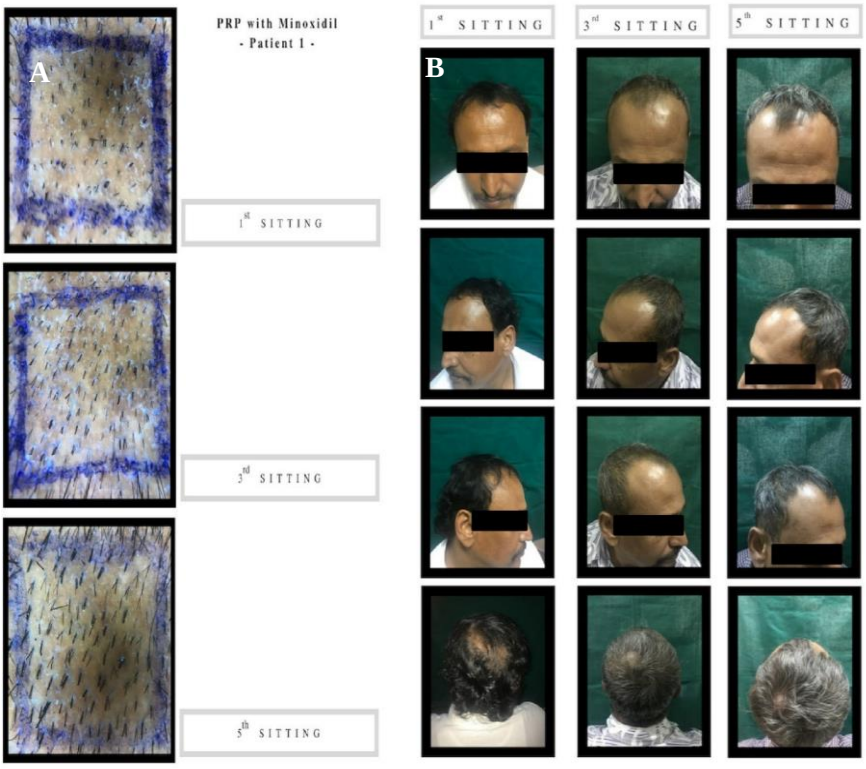

Figure 5: Group C – (A) dermoscopic images (B) clinical images.

Table 3: Comparison of the dermoscopic analysis for improvements in the three groups.

Treatment type	Baseline	At 3 months	At 5 months
Treatment with 5% minoxidil	59.77+13.50	61.53 +13.53	66.83+16.73
Treatment with -Derma roller + minoxidil	69.30+17.97	77.30+21.64	85.73+23.10
Treatment with PRP + minoxidil	64.37+14.42	76.73+12.66	86.13+14.82
P value	0.62	0.000	0.000

Though one third of the patients did not complain of any side effects (n=30), only 6 patients were from the most effective form of treatment i.e. PRP+minoxidil combination. This group also had maximum cases who reported pain, while pruritis, seborrheic dermatitis was maximum observed in group treated with minoxidil only. A fraction of patients also reported more than one side effect.

DISCUSSION

Androgenetic alopecia (AGA) is a hereditary androgen-dependent disorder of hair that is common among both men and women. Besides being an aesthetic concern for both the patient and the physician, AGA is a common cause of psychosocial stress among both sexes. Various modalities of treatment have been proposed and used for AGA but the efficacy of any modality of treatment varies depending on the age of the patient, grade of hair loss, and compliance with treatment. PRP and dermaroller are the commonly recommended adjuvants for treating AGA. However, three arm comparative studies are limited. Therefore, we conducted this study to compare the role of PRP and microneedling as adjuvants to minoxidil and minoxidil alone in the treatment of AGA

The present, prospective comparative parallel group interventional study was conducted on cases of androgenetic alopecia in the age group 18-45 years. Majority of patients had onset in age group 26-35 (58%), and the average age of onset was 29.9 years. In a study done by Shah et al average age of patients with male pattern baldness was 30.6 years7, while in a study done by Hajheydari et al it was 22.8 years.[8]

Total 63 (70%) patients had a positive family history when compared to 27 (30%) with a negative family history and maximum improvement by dermoscopic analysis was observed in patients with a negative family history, these results were similar to study done by Sharma et al (78% participants had family history) and Nyholt DR et al (80% of the subjects had positive family history of AGA).[9,10] In contrast, to the present study, Vaaruniet al reported positive family history for Androgenic alopecia in 46.66% patients (n=28).[11]

In a study done by Shankar et al 27.27% patients had grade II alopecia, 22.12% patients had grade I alopecia, 21.78% patients had grade III alopecia, 10.8% patients had grade IV alopecia, and 6% patients had Grade V alopecia.[12] In present study about 42% and 37 % patients presented with grade II and grade III of Norwood Hamilton grade at the baseline which increased to 45% and 40 % respectively at end of 5 months.

In our study majority of the patients improved only slightly in the first two groups (Minoxidil5% and dermaroller+minoxidil 5%), while majority of the patients treated by PRP and minoxidil combination improved moderately. This difference was statistically significant when compared to the other two groups. While in a study done by Vaaruni et al excellent improvement was seen in 60% (n=18) patients who were on group B (minoxidil+PRP), it was only 33.33% (n=10) patients of group A (Only minoxidil) at the end of 6 months.[11]

On the basis of global photograph, secondary efficacy analysis was done, and all three arms were found to have a slight improvement. Majority of the patients improved only slightly (+1) in all the three groups. In a study done by Durat et al all patients, who were given microneedling treatment along with minoxidil and finasteride, showed a response of +2 to +3 on standardised 7-point evaluation scale at the end of 6 months of the treatment.[13]

Side effect profile related to treatment showed minimum side effects in patients treated with dermaroller and 5% minoxidil. In a study done by Sharma et al. about 18% of patients treated with PRP had mild side effects like pain, erythema, burning and oedema.[9] These findings were consistent with our study.

Though our study is limited by a small cohort of patients and limited duration of study, from the above discussion it is evident that PRP with minoxidil is a superior treatment modality when compared to minoxidil alone or minoxidil with dermaroller.

CONCLUSION

PRP and dermaroller are exciting new non-surgical therapeutic options for hair growth and stimulation in patients of AGA. Platelet growth factors are probably capable of regulating the life cycle of hair bulbs, thus ensuring a better growth of hair. They are promising treatment options in patients who cannot afford hair transplantation. The effect of once-monthly injections of PRP with minoxidil for four months has shown a considerable increase in hair counts in majority of the subjects of our study when compared to minoxidil alone and dermaroller with minoxidil.

Minoxidil has better efficacy when combined with PRP or dermaroller. PRP and dermaroller stimulate proliferation and differentiation of stem cells in the hair follicles bulge area via multiple molecular mechanisms. Hence, PRP with minoxidil is a simple cost-effective and feasible treatment option in patients with AGA with high overall patient satisfaction.

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Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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