Comparison of Microneedling with Platelet Rich Plasma vs Minoxidil (5%)+Finasteride (0.1%) Topical Therapy in Androgenetic Alopecia: A Randomised Clinical Study

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ABSTRACT

Introduction: Androgenetic Alopecia (AGA) is a progressive loss of hair in a patterned distribution for which treatment selection is limited. Long-term efficacy, safety and cost leads to low compliance rate. Among various treatment modalities (medical and surgical) available, microneedling and Platelet Rich Plasma (PRP) are emerging as a newer, useful and safe non surgical treatment regime.

Aim: To evaluate the effectiveness and safety of microneedling with PRP versus minoxidil (5%) + finasteride (0.1%) topical therapy in AGA.

Materials and Methods: This randomised clinical trial was done at Department of Dermatology, Venereology and Leprology (DVL), Hind Institute of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh, India, from November 2021 to November 2022. Total of 60 adult males clinically diagnosed with AGA were enrolled and randomised into group 1 and group 2. Subjects in group 1 were treated with microneedling+PRP and group 2 were advised minoxidil+finasteride topical therapy. Microneedling alongwith intradermal injection of autologous PRP was done every month for four consecutive months in group 1 (n=30) while 1 mL of minoxidil (5%)+finasteride (0.1%) lotion was advised to be applied over dry scalp twice daily for four months in group 2 (n=30) patients. Both groups were followed-up for next two months. Hair density was assessed by Hamilton Norwood Scale using photographic and dermoscopic images and patients self-assessment scores. Data assessment was done by Chi-square test. Statistical Package for the Social Sciences (SPSS) version 26.0 was used to analyse data and p-value for significance was established at <0.05.

Results: Patients in group 1 with mean age 27.9±4.15 years showed almost similar increase in hair density compared to group 2 with mean age 25.8±3.94 years, as assessed by patient assessment score, photography, dermoscopy, Hamilton Norwood scale at six months of study (p-value >0.05), however onset of action was quicker in group 1. Investigator assessment on improvement in hair density using Hamilton Norwood Scale at three months (p-value=0.920) and six months (p-value=0.995) showed that microneedling+PRP therapy is as effective as minoxidil+finasteride lotion since the difference between results of both groups was not statistically significant.

Conclusion: Microneedling and PRP although safe, effective and promising treatment modality in AGA is comparable to minoxidil+finasteride topical therapy.

INTRODUCTION

The Androgenetic Alopecia (AGA) is an hereditary, male hormone-dependent hair disorder manifesting as thinning of scalp hairs in a patterned distribution [1]. While drug and non drug interventions such as low level light therapy, microneedling, PRP manages to improve density of hair, management of AGA should be aimed to stop the progressive nature of disease [2]. AGA affects social and psychological well-being of young patients, usually beginning at the age of 20 years and affecting 50% of males by 50 years of age [3]. Medical and surgical treatments available include minoxidil, finasteride, dutasteride, oral biotin, low level light therapy and hair transplantation surgery [4]. Among them, only topical minoxidil and oral finasteride are the only Food and Drug Administration (FDA) approved treatment [4]. These conventional modalities may not always be effective, slower in response, expensive, require long-term compliance and may be associated with unacceptable adverse effects [5,6].

Microneedling first described by Orentreich in 1995 is a minimally invasive procedure, which creates percutaneous wounds thereby releasing various growth factors such as platelet-derived growth factor and vascular endothelial growth factor which aids in healing, improvise angiogenesis and arrest or partially alter the fibrotic changes [7]. Previous research has demonstrated that microneedling potentiates therapeutic effects in hair loss disorders by promoting anagen-initiating Wnt/β-catenin signaling pathway and improvising hair stem cell proliferation present in dermal papillae [8,9]. PRP is an autologous concentrate of plasma and a rich source of various growth factors which enhances blood circulation to dermal papilla thereby preventing hair shedding and improving hair density in AGA [10]. There is always a need for new, adjuvant and promising treatment in AGA which gives early patient satisfaction with fewer side-effects.

Few studies were done in past have evaluated the efficacy of microneedling with PRP for hair restoration [11,12] and safety of PRP versus topical minoxidil+finasteride [13]. Although microneedling, PRP, topical minoxidil+finasteride have been individually studied in management of AGA, there is no published literature comparing efficacy of microneedling with PRP versus minoxidil+finasteride topical therapy. Hence, the present study was undertaken to analyse the effectiveness and safety of microneedling with PRP versus minoxidil (5%)+finasteride (0.1%) topical therapy in AGA.

MATERIALS AND METHODS

This hospital-based, prospective, randomised, single-blinded clinical trial was conducted over a period of one year from November 2021 to November 2022 on 60 male patients clinically diagnosed with AGA attending DVL Outpatient Department (OPD), Hind Institute of Medical Sciences, Safedabad, Barabanki, Uttar Pradesh, India. The

study was initiated after getting approval from Institutional Ethical Committee. (IEC Number HIMS/IRB/2021-22/5177).

Inclusion criteria: All male patients aged 18-40 years presenting with patterned baldness grade 2-4, as per Hamilton Norwood scale [14], willing and consenting to participate in the study were enrolled.

Exclusion criteria: Patients with alopecia other than AGA, application of topical lotions like minoxidil, finasteride or any other with antiandrogenic properties during the last six months, uncontrolled systemic disorders like hypertension and diabetes, any history of bleeding diathesis, patients having erythema or swelling over the scalp, previous history of malignancy or any immunocompromised patients were excluded.

Sample size calculation: Sample size was calculated using the following formula:

$$n=\frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2 \{p_1(1-p_1)+p_2(1-p_2)\}}{(p_1-p_2)^2}$$

$Z_{1-\alpha/2}=1.96$ at $\alpha=5\%=0.05$

$Z_{1-\beta}=0.84$ at 80% of power

$p_1=88.2\%=0.882$ [15]

$p_2=47.4\%=0.474$ [15]

$$n=\frac{(1.96+0.84)^2 [0.882 (1-0.882)+0.474 (1-0.474)]}{(0.882-0.474)^2}$$

n=22.28

n=22.28+4.456 (considering 20% dropout)

n=26.736~27

n=30 per group (after round-off)

So, total 60 patients were considered for the study.

Procedure

A detailed medical history was taken for each patient which included duration of hair fall, history of any drug intake, family history, history of any systemic disorder to exclude other causes of diffuse loss of hair. Smoking history was elicited since it can aggravate AGA. A thorough clinical examination was done and AGA was diagnosed. AGA grading as per the Hamilton Norwood scale, baseline clinical photography and dermoscopy (DermLite DL 4) was done in all patients.

Simple randomisation was done by odd and even number and enrolled patients were allotted in two different groups.

Group 1 (n=30): Participants were treated every month with intradermal injection of autologous PRP with microneedling for four months.

Group 2 (n=30): Participants were advised to apply 1 mL of minoxidil (5%)+finasteride (0.1%) lotion over scalp twice daily 12 hours apart for four months. Both groups were followed-up for next two months.

Group 1

The study participants in group 1 were investigated with complete blood picture, hepatic function tests, kidney function tests, thyroid profile, random blood sugar, bleeding time, clotting time, International normalised ratio, hepatitis B, hepatitis C, Enzyme-Linked Immunosorbent Assay (ELISA) for HIV I and II, Rapid Plasma Reagin (RPR) test in dilution.

PRP preparation: PRP was prepared as per the method described by Singh SK et al., [15]. Under aseptic precautions, 18 mL of whole blood was obtained from the median cubital vein and mixed with 2 mL of 3.8% sodium citrate solution into an autoclaved Falcon tube. Centrifugation machine (Remi model R-8C) was used and 1st spin was done at 1500 revolutions per minute for 10 minutes. It separated the blood components into the following three layers, from bottom to top, containing red blood cell layer followed by PRP layer "buffy coat" and finally topmost acellular plasma layer, Platelet-Poor Plasma (PPP). Finnpipette was used to collect buffy coat with plasma into another Falcon tube and the collected plasma was spinned again at 3500 revolutions per minute for 10 minutes for 2nd spin. This procedure separated the platelets (PRP) at the bottom of the tube. The PPP which got collected at the upper two-third was discarded, and the remaining PRP (lower one-third) was filled in 1 mL Beckton Dickinson syringe which contained calcium gluconate mL (one part calcium gluconate 10% and nine parts of PRP) as an activator. At the end of the procedure, around 3-3.5 mL of PRP having platelet concentration of 3-4 folds higher when compared with whole blood was obtained. About 1 mL of PRP was processed to determine platelet concentrate by Mindray, auto haematology analyser, model: BC-5150 in the first ten participants for standardisation of procedure.

Microneedling+PRP application: Anaesthetic cream, EMLA (eutectic mixture of 2.5% lignocaine+2.5% prilocaine) was applied topically over the treated area of scalp (frontal, parietal and occipital) one hour prior to the procedure. A 70% alcohol was used to disinfect the treated area. A ring block was given at forehead by insulin syringe containing lignocaine hydrochloride 2%. Microneedling with dermapen (model no MYMM-17) at depth of 1.5 mm was done in vertical, horizontal, diagonal directions from frontal to occipital area 6-8 times until mild erythema was obtained. This activation was followed by intradermal injections of PRP 0.05 mL/cm^2 from deeper to superficial layer in receding direction. Remaining PRP was massaged over the treated area to permeate through the epidermis by primary investigator. Similar sessions were done every month for four months.

Group 2

Group 2 patients were advised to apply 1 mL minoxidil (5%)+finasteride (0.1%) lotion twice daily over scalp, 12 hours apart for four months.

Vital signs and adverse events such as instant pain/discomfort, headache, swelling, increase in facial hairs, any allergic reactions observed by the subjects or noticed by the primary investigator were evaluated on follow-up visits in both groups.

Assessment

The study participants were selected, enrolled and assessed by the parameters adopted by similar study done by Singh SK et al., [15]. Both the groups were assessed on socio-demographic factors which included age, duration of hair fall, family history, smoking and grade of alopecia. Hair regrowth was assessed at 3 months intervals by primary investigator on Hamilton Norwood scale by clinical photography and dermoscopy. Photographic images were taken keeping placement, angulation, illumination, magnification fixed using SONY DSC TX -55 camera from frontal, occipital and lateral views of both sides.

Improvement in hair density was assessed by taking dermoscopic pictures at 1cm^2 area from fixed site which was 10 cm above and 3 cm front measured from the upper end of right tragus. Area was fixed with stamp of 1×1 cm. Dermoscopic and photographic images were taken by independent observer.

Patients assessed their scalp hairs at 2nd month, 3rd month, 4th month and 6th month of follow-up (total 6 months of study) on hair growth assessment scale of 0-4 which signify the following:

- A0: No improvement
- A1: 1%-25% improvement
- A2: 26%-50% improvement
- A3: 51%-75% improvement
- A4: 76%-100% improvement

The flow chart of study is depicted in [Table/Fig-1].

STATISTICAL ANALYSIS

Data presentation was done using mean, standard deviation and percentage. Both groups comparison was done using Chi-square and Fisher's-exact tests for qualitative variables and unpaired t-test
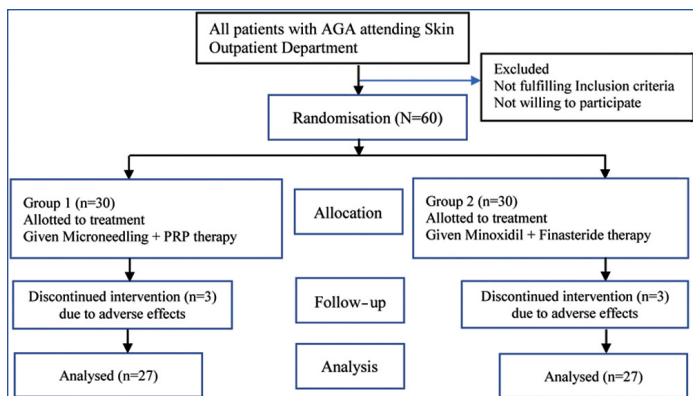
[Table/Fig-1]: Flow chart of study.

for quantitative variables. Level of significance was established at p-value <0.05. Analysis of data was done by Statistical Package for the Social Sciences (SPSS) version 26.0 and advanced Excel.

RESULTS

The study population had mean age of 26.85±4.15 years. Positive family history in group 1 and 2 were seen in 18 (60%) and 11 (36.7%) participants, respectively. Smoking history was present in 15 (50%) and 17 (56.7%) participants in group 1 and group 2, respectively. The most frequent baldness was grade 2 present in 32 (53.3%) patients followed by grade 3 present in 18 (30%) patients. Both groups were almost comparable in terms of clinico-demographic profile except for duration of hair fall as summarised in [Table/Fig-2]. Group 1 patients had longer duration of hair fall.

Parameters	Group 1 (n=30)	Group 2 (n=30)	Test of significance
Age (years) (Mean±SD)	27.9±4.15	25.8±3.94	t=2.01 p=0.05
Duration of hair fall (years) (Mean±SD)	2.83±1.55	1.93±1.19	t=2.5226 p=0.014
Family history n (%)			
Present	18 (60%)	11 (36.7%)	χ^2: 3.27 p=0.0707
Absent	12 (40%)	19 (63.3%)	
Smoking n (%)			
Present	15 (50%)	17 (56.7%)	χ^2: 0.268 p=0.604
Absent	15 (50%)	13 (43.3%)	
Grading of alopecia [14] n (%)			
2	13 (43.3%)	19 (63.3%)	χ^2: 3.12 p=0.21
3	12 (40%)	6 (20%)	
4	5 (16.7%)	5 (16.7%)	

[Table/Fig-2]: Clinico-demographic profile in both groups.

Effect of intervention was studied in both groups by patient self-assessment score as shown in [Table/Fig-3]. The groups were comparable in terms of patient self-assessment score at 2nd month, 3rd month, 4th month and 6th month, respectively and difference was not statistically significant (p-value >0.05). However, patients in group 1 had attained early improvement in hair density.

Investigator assessment of hair density by Hamilton Norwood scale using clinical photographs and dermoscopic images is depicted in [Table/Fig-4,5].

It was observed that both treatment modalities were similarly effective in improving hair density on Hamilton Norwood scale at 3rd and 6th month, respectively and the difference between results of both groups was not statistically significant as shown in [Table/Fig-6].

Overall hair density as analysed by improvement in alopecia grading on Hamilton Norwood scale following 0-3 months and 0-6 months (intragroup analysis) increased significantly in both groups which showed that microneedling and PRP was similarly effective in improving hair density as compared with minoxidil+finasteride topical therapy. A significant increase in hair density after completion of treatment course was demonstrated in group 1 and group 2 with p-value=0.000002 and p-value=0.00002, respectively as depicted in [Table/Fig-7].

Various adverse effects were noted during the study period [Table/Fig-8]. In group 1, 4 (13.3%) patients had instant pain/discomfort on day of procedure which was relieved by ice compression and paracetamol 500 mg. Out of them, 2 (6.7%) patients had swelling, and 1 (3.3%) patient had headache who refused to continue the treatment. In group 2, 2(6.7%) patients had instant pain/discomfort and 4 (13.3%) patients had increase in facial hairs which required reassurance. Among them, 2 (6.7%) patients had swelling, 2 (6.7%) patients had headache and 1 (3.3%) developed allergic reaction to minoxidil.

DISCUSSION

The AGA, the most common type of patterned baldness has a high prevalence rate among youth which may adversely affect their Quality of Life (QoL), since hair is an important aspect of one's personality [16]. In the present era, microneedling and PRP is gaining popularity among dermatologists and patients however, there is general lack of controlled trials and no specific criteria have yet been established in regard to total numbers and the interval between sessions required to attain hair regrowth. Overall in the past 5 years, there are few publications favouring microneedling and PRP and this treatment is worth exploring [11,12,17].

Hair density was evaluated in the present study by primary investigator at three months intervals since it takes 90-100 days for new hair growth to become evident over scalp [18]. This methodology was
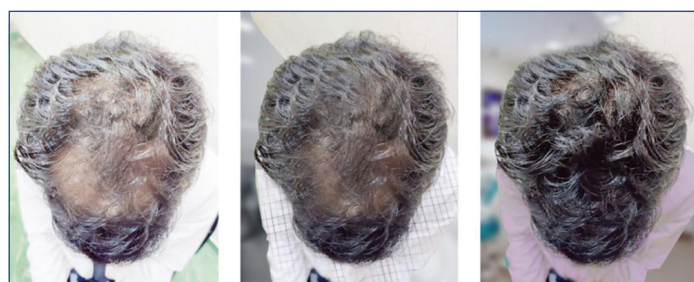
	Patient self-assessment at 2nd month, n (%)						Chi-square value	p-value
	A0	A1	A2	A3	A4	Left the study		
Group 1	11 (36.66%)	17 (56.67%)	0	0	0	2 (6.67%)	1.24	0.931
Group 2	15 (50%)	14 (46.67%)	0	0	0	1 (3.33)		
Total	26	31	0	0	0	3		
	Patient self-assessment at 3rd month, n (%)						Chi-square value	p-value
	A0	A1	A2	A3	A4	Left the study		
Group 1	4 (13.3%)	15 (50%)	8 (26.6%)	0	0	3 (10%)	0.685	0.983
Group 2	6 (20%)	15 (50%)	6 (20%)	0	0	3 (10%)		
Total	10	30	14	0	0	6		
	Patient self-assessment at 4th month, n (%)						Chi-square value	p-value
	A0	A1	A2	A3	A4	Left the study		
Group 1	3 (10%)	5 (16.67%)	11 (36.66%)	6 (20%)	2 (6.66%)	3 (10%)	2.867	0.720
Group 2	3 (10%)	10 (33.3%)	9 (30%)	3 (10%)	2 (6.66%)	3 (10%)		
Total	6	15	20	9	4	6		

	Patient self-assessment at 6th month, n (%)						Chi-square value	p-value
	A0	A1	A2	A3	A4	Left the study		
Group 1	3 (10%)	5 (16.67%)	11 (36.66%)	6 (20%)	2 (6.66%)	3 (10%)	2.867	0.720
Group 2	3 (10%)	10 (33.3%)	9 (30%)	3 (10%)	2 (6.66%)	3 (10%)		
Total	6	15	20	9	4	6		

[Table/Fig-3]: Intergroup analysis of patient self-assessment score, A0: No improvement; A1: 1%-25% improvement; A2: 26%-50% improvement; A3: 51%-75% improvement; A4: 76%-100% improvement.
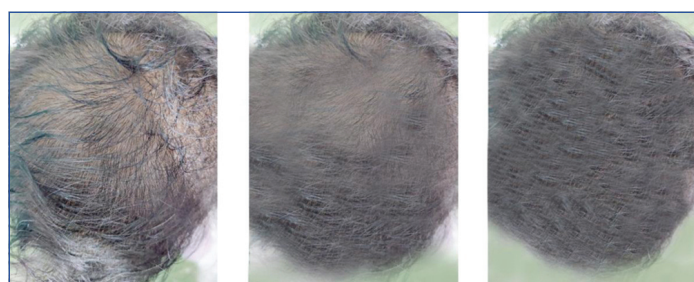
[Table/Fig-4a]: Pictures of subject in group 1 at different time intervals.

[Table/Fig-4b]: Standardised dermoscopic pictures of subject in group 1 at different time intervals.

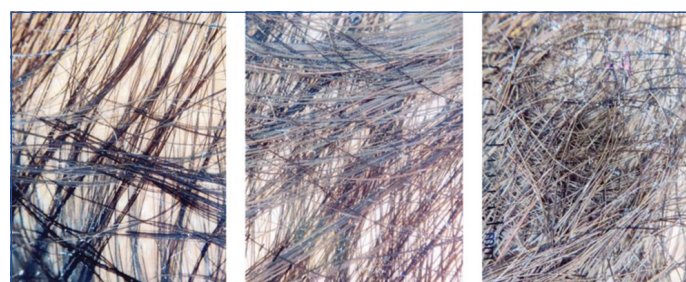[Table/Fig-5a]: Standardised pictures of subject in group 2 at different time intervals.

[Table/Fig-5b]: Standardised dermoscopic pictures of subject in group 2 at different time intervals.

	Investigator assessment at 3rd month, n (%)						
Grade	1	2	3	4	Left the study	Chi-square	p-value
Group 1 (n=30)	11 (36.7%)	11 (36.7%)	5 (16.7%)	0 (0)	3 (10%)	0.927	0.920
Group 2 (n=30)	14 (46.7%)	7 (23.3%)	5 (16.7%)	1 (3.3%)	3 (10%)		
	Investigator assessment at 6th month, n (%)						
Grade	1	2	3	4	Left the study	Chi-square	p-value
Group 1 (n=30)	20 (66.7%)	5 (16.7%)	2 (6.7%)	0 (0)	3 (10%)	0.193	0.995
Group 2 (n=30)	18 (60%)	6 (20%)	3 (10%)	0 (0)	3 (10%)		

[Table/Fig-6]: Intergroup analysis to assess hair density using Hamilton Norwood scale by investigator.
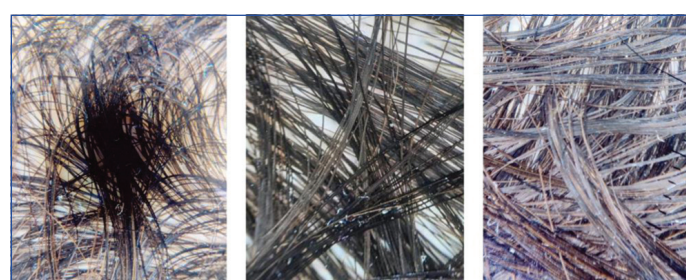
	Assessment of hair density Test of significance		
Groups	0-3 months	3-6 months	0-6 months
Group 1 [27 (90%)]	χ^2=15.784 p=0.003	χ^2=4.365 p=0.358	χ^2=31.091 p=0.000002
Group 2 [27 (90%)]	χ^2=19.559 p=0.0006	χ^2=0.573 p=0.966	χ^2=26.793 p=0.00002

[Table/Fig-7]: Intragroup analysis to assess hair density on Hamilton Norwood scale; Fisher-exact test was applied when more than 20% of cells had expected frequencies <5.
p-value <0.05 considered significant

similarly adopted by Schiavone G et al., [19]. In the present study, both treatments were well tolerated and equally effective in attaining hair regrowth but results in microneedling and PRP group was attained early. In similar study done by Yepuri V and Venkataram M, in 2021, PRP with microneedling was found to be effective treatment which augments the effect of conventional treatment [12]. Jha AK et al., studied 93 AGA patients which were randomised into three: groups A (31 patients treated with minoxidil 5% lotion twice daily), group B (31 patients advised twice a day application of minoxidil 5% topically and PRP), and group C (31 patients given minoxidil 5% topically twice a day along with PRP and microneedling). Effect of intervention was studied by baseline and post-treatment photographic and dermoscopic images, hair pull test, patient's self-satisfaction score on Likert scale. Final observation post-treatment showed that hair pull test became negative in 27 (87.1%, p-value <0.01), 20 (64.5%, p-value <0.05) and 15 (48.4%) participants in groups C, B, A, respectively. Hair regrowth as analysed by photographic and dermoscopic images showed better outcome in group C (26/31) participants than group B (17/31) and group A (10/31) participants. Patients self-satisfaction score evaluated on Likert scale showed higher score in group C (24/31) and hence, the study concluded that PRP in adjuvant with microneedling was more effective than PRP or minoxidil monotherapy in AGA [17].

Shah KB et al., in 2017 evaluated 50 AGA patients aged 18-50 years with Hamilton Norwood scale (3-5) who were grouped

Adverse effects	1st month n (%)	2nd month n (%)	3rd month n (%)	4th month n (%)	5th month n (%)	6th month n (%)	Test of significance
Group 1 (n=30)							
Instant pain/discomfort	1 (3.3%)	2 (6.7%)	4 (13.3%)	4 (13.3%)	-	-	t=0.894 p=0.397
Swelling	1 (3.3%)	1 (3.3%)	-	-	-	-	
Headache	1 (3.3%)	-	-	-	-	-	
Increase facial hair	-	-	-	-	-	-	
Any allergic reaction	-	-	-	-	-	-	

Group 2 (n=30)					
Instant pain/discomfort	1 (3.3%)	2 (6.7%)	2 (6.7%)	2 (6.7%)	-	-
Swelling	-	1 (3.3%)	2 (6.7%)	-	-	-
Headache	1 (3.3%)	1 (3.3%)	2 (6.7%)	-	-	-
Increase facial hair	-	2 (6.7%)	3 (10%)	4 (13.3%)	-	-
Any allergic reaction	-	1 (3.3%)	-	-	-	-

[Table/Fig-8]: Adverse effects in both groups.
Unpaired t-test was applied; p-value <0.05 considered statistically significant

into group A and B; group A (25 patients received minoxidil 5% topically and group B (25 patients treated with minoxidil 5% lotion, PRP and microneedling). At the end of study period of 6 months, group B participants had significant improvement in both patient and investigator's assessment than group A with p-value <0.05, thereby concluding that microneedling and PRP was safer, efficacious and encouraging modality of treatment in AGA [11].

Sharma HK et al., studied 60 AGA patients which were divided into: group A participants who were treated with PRP therapy and group B were advised topical application of minoxidil plus finasteride therapy. Assessment was done by photography, standardised hair growth questionnaire and patient satisfaction score. The final assessment after 12 months of study period showed that PRP group had better result on investigator satisfaction scale score (p-value <0.001) and hence concluded that PRP acts as an adjunctive therapy in AGA [13].

Rai PB et al., found that topical minoxidil and finasteride had significantly improved the QoL and the assessment was done according to the male AGA QoL questionnaire [20].

To the best of our knowledge, no literature has been published comparing microneedling and PRP versus minoxidil+finasteride. The study concluded that microneedling and PRP although comparable with minoxidil+finasteride regime yielded early onset of action on patient and investigator assessment scale and should be offered to patients along with existing treatment modalities for faster hair regrowth and better patient compliance.

Limitation(s)

The limitations of the present study were small sample size and follow-up of patients for six months only. The duration of hairfall was not comparable between groups also limits the study. The study participants included only male gender hence results cannot be generalised to the entire population.

CONCLUSION(S)

Both forms of therapies are equally effective in improving hair density in AGA. However, microneedling and PRP therapy had early improvement in hair regrowth and hence had a slight edge over minoxidil+finasteride lotion. This may require reconfirmation in future with more studies including larger sample size, done on more varied population and for longer period of time before it is used extensively.

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