

Original Research Article

Study of effect of topical mometasone with intralesional platelet-rich plasma versus topical mometasone alone in the treatment of alopecia areata

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ABSTRACT

Background: Alopecia areata (AA) is an autoimmune disorder and exhibits non scarring alopecia. Currently, there is no definitive cure, platelet rich plasma (PRP) has emerged as a newer modality for non-cicatricial alopecias such as AA. This study was conducted to compare the efficacy and adverse effects of topical mometasone with PRP versus topical mometasone alone in the treatment of patients of AA.

Methods: This study was conducted on a total of 100 clinically diagnosed cases of AA. Patients in group A were subjected to intradermal injection of autologous PRP every 3 weeks along with topical mometasone cream 0.1% daily for 12 weeks. Group B was treated with topical mometasone cream 0.1% once a day locally over affected site for 12 weeks.

Results: Baseline SALT score of group A was 6.05 ± 5.36 while that of group B was 6.62 ± 4.39 . The mean SALT score of group A declined to 0.94 ± 1.69 and that of group B 2.19 ± 1.76 over a period of 20 weeks. Excellent response was observed by 12 and 5 patients of group A and group B respectively. Minor side effects like pain was seen in 10 patients (20%) in group A, while atrophy was seen in 2 patients of group B.

Conclusions: This is the first ever study evaluating the additional benefit of intralesional PRP. In this study, it was found that adding intralesional PRP with topical mometasone 0.1% cream has higher efficacy and early improvement than topical mometasone alone, in the treatment of AA.

Keywords: Alopecia areata, Platelet rich plasma, Non cicatricial alopecia

INTRODUCTION

Alopecia areata (AA) is a common autoimmune disorder among non-scarring alopecias, which presents with patchy loss of hair. AA accounts for 25% of all causes of alopecia.¹ The very first description of the disease was given by Cornelius Celsus and later the term “alopecia areata” was given by Sauvages in 1760.² The prevalence of AA varies from 0.1% to 0.2% and the lifetime risk is about 1.7-2%.³ It shows equal preponderance in males and females.⁴

Exact pathogenesis of AA is still unknown, but currently most important factors known are genetic factors, T cell-mediated autoimmune mechanism and various environmental triggers.⁵ Although there are many therapies that induce hair growth in AA, but currently there is no definitive cure for AA.⁶ Corticosteroids are the mainstay of therapy for AA due to their anti-inflammatory action. Other treatments in the form of oral and topical drugs are given based on severity. Platelet rich plasma (PRP) is being used as a newer modality for non-cicatricial alopecia as it has growth factors which binds to the

corresponding receptors expressed by stem cells in the hair follicle bulge and surrounding tissues which further stimulates the proliferative phase of the hair follicle, giving rise to the anagen follicular unit thus promoting hair growth.⁷ There has been no study which explores the role of PRP in alopecia areata as an adjunct to the first line treatment (topical steroids). This study was conducted to study the efficacy and adverse effects of topical mometasone with intralesional PRP versus topical mometasone in patients of AA.

Objective

The objective of this study was to compare the efficacy and adverse effects of topical mometasone with PRP versus topical mometasone alone in the treatment of patients of AA.

METHODS

Study type, duration and location

This was a hospital based, unblinded randomized controlled trial (RCT) conducted on a total of 100 clinically diagnosed cases of AA attending the outpatient department of dermatology, Jawaharlal Nehru Medical College and Hospital, AMU, Aligarh. The duration of study was two years from January 2021 to December 2022. Written informed consent in a language understandable by the patient was obtained from each patient.

Inclusion criteria

All new clinically diagnosed patients of AA between 12 to 65 years of age group attending OPD during the study period, patients with ≤ 4 patches of AA, patients with $< 50\%$ scalp surface involvement were included in the study.

Exclusion criteria

Patients with < 4 patches but with scalp surface area $> 50\%$, patients with alopecia totalis/universalis, patients who are on immunosuppressive, immunomodulatory or anti-inflammatory drugs or who have taken in past 1 month were excluded from study.

After selection of patient according to inclusion and exclusion criteria, detailed history recording the name, age, sex, address, contact number, marital status, occupation, duration of disease, any previous episodes, family history, drug history and other concomitant diseases was taken. Physical examination for evidence of infections at local sites was done. SALT score was calculated to determine the severity of AA in all patients included in our study. Baseline photographs were taken before starting treatment in each patient. Following baseline investigations were done: thyroid function test (T3, T4, TSH), HIV, HBsAg, HCV serology, serum vitamin D3 and skin biopsy (if needed to confirm biopsy).

Patients were allocated into two groups, A and B through randomization. Randomization was done through 'box and chit method', with 50 paper chits each with group A and group B written over them, placed in a box.

PRP preparation method

PRP was prepared by double spin centrifugation using a centrifuge machine (Remi R-8 C, Remiworld India). Twenty milliliters of blood was drawn from each patient under sterile condition and was gently put along the walls into conical tubes (15 ml), that contains 4 drops of EDTA. To isolate plasma, tubes were centrifuged at 3000 rpm for 7 minutes (soft spin). Precipitation of RBC occurred at the bottom of the tube and the plasma containing platelets in rest of the tube. The plasma was then gently transferred to an empty tube and centrifuged again at higher spin at 4000 rpm for 5 minutes (hard spin) leading to separation of plasma into 2 portions: upper portion contain platelet-poor plasma (PPP) and lower portion PRP. Then lower 2 ml of the plasma i.e. PRP concentrate was loaded in 1 ml insulin syringe and was taken for therapy.

PRP injection procedure

The area to be treated was sterilised with povidone-iodine and alcohol and then anaesthetized with topical combined anaesthesia formed of 7% tetracaine + 7% lidocaine for 45-50 minutes before the procedure. Then intralesional PRP was administered intradermally over the center as well as periphery of AA patch with the help of 1 ml insulin syringe (31G). Spacing of 1 cm was kept between injection sites. Patients in group A were subjected to intradermal injection of autologous PRP every 3 weeks over affected patch for a duration of five sessions along with topical mometasone cream 0.1% local application once daily (1 fingertip unit per 2% BSA) for 12 weeks. Group B was treated with topical mometasone cream 0.1% once a day locally over affected site for 12 weeks. At the end of study period 3 patients in group A and 5 patients in group B dropped out of study. The ethical clearance was obtained from the institutional ethical committee of JNMCH, AMU. All the data was tabulated in statistical package for the social sciences (SPSS) software (version 25.0) and statistical analysis included profiling of patients on different demographical parameters. Continuous variables are presented as mean \pm SD and discrete variables as percentages. Student unpaired t-test was used to calculate mean difference two groups and Chi-square test was used to check associations. P value < 0.05 was considered to be statistically significant. The data was analysed using appropriate statistical methods (Chi-square test and student unpaired t-test).

Assessment

All the patients in both group A and B were followed up 3 weekly until 12 weeks for therapy and then at 16 and 20 weeks for the outcome assessment. Regrowth of hairs after the end of last follow-up was graded as given in the table.

Table 1: Global assessment score by patients.

Response	Regrowth (%)
Mild	<25
Moderate	25-50
Good	51-75
Excellent	76-100

RESULTS

Our study was conducted on 100 clinically diagnosed patients of scalp alopecia areata, who were split in to two groups A and B. In our study the patients belonged to the age ranging from 12-65 years. Mean age of group A patients was 24.76 ± 9.70 years, while mean age of group B patients was 22.98 ± 8.42 years. Thirty-four vitiligo patients and 31 patients from control group had history of smoking ($p=0.39$), while 20 vitiligo patients and 21 patients from control group had history of alcohol consumption ($p=0.5$). Hence risk factors such as smoking and alcohol consumption were not significantly different among cases and controls.

Table 2: Patient characteristics.

Parameters	Group A (n=50)	Group B (n=50)	P value
Age (years)			
12-24	31	32	1
25-36	15	16	
37-48	2	1	
49-60	2	1	
Mean age	24.76 ± 9.70	22.98 ± 8.42	1
Gender			
Male	27	30	0.68
Female	23	20	

Maximum prevalence of AA was seen in 12–24 years age group. Out of 100 patients, 57 patients (57%) were males and 43 patients (43%) were females. In this study, maximum number of patients (76%) reported to the hospital with a disease duration of 3 months. In our study, positive family history was present in 8 patients (8%). We found that 49% of patients had involvement of multiple sites over scalp. But on isolated basis, vertex area was most commonly affected (23%), followed by occipital area (12%). The most common clinical pattern seen in our study was focal (86%), followed by reticulate pattern (8%). The pattern least commonly observed was sisaipho and linear, seen in only 1 patient (1%) respectively, out of all 100.

Mean baseline SALT score of group A patients was found to be 6.05 ± 5.36 , while that of group B patients was 6.62 ± 4.39 . No statistical difference was seen at baseline (Figure 1). At the end of 20 weeks, mean SALT score of group A patients were found to be 0.94, while that for group B patients it was 2.19. Significant difference in decrease in mean of SALT score turned out to be significant at 16 weeks ($p<0.028$) and highly significant at

20 weeks ($p \leq 0.001$) (Table 4). When compared with baseline, there was a significant decrease in SALT score at 20 weeks in each group ($p<0.001$), indicated that the treatment received by patients of both of the groups A and B was effective (Figure 2). The decrease in mean SALT score over a period of 20 weeks in group A patients was found to be 5.11 ± 3.67 , while a decrease of 4.43 ± 2.63 in mean SALT score was seen in the same time duration in group B patients. The superior efficacy of PRP with mometasone compared with only mometasone was statistically significant ($p<0.001$) in terms of decrease in mean SALT score. On evaluating grades of improvement with each treatment excellent (76-100%) hair regrowth was observed in 12 patients of group A when compared to 5 patients of group B. Good regrowth of hairs (50-75% hair regrowth) was perceived in 15 patients of group A and 13 patients of group B (Figure 4). Poor response was noticed in disease duration of more than 6 months in both group A and B. Two patients of Ophiasis pattern showed excellent response at the end of treatment while other 2 patients noticed only mild response while linear and Sisaipho pattern were treatment resistant and showed only mild improvement to patients. On comparing grades of improvement between two groups it came out as statistically non-significant (p value=0.16) (Figure 3).

Table 3: Clinical characteristics of patients.

Characteristics	Group A	Group B	P value
Site			
Multiple	20	29	0.295
Vertex	15	8	
Occipital	6	6	
Temporal	4	2	
Parietal	4	2	
Frontal	1	3	
Number of patches			
1	26	25	0.59
2	11	8	
>2	13	17	
Surface area involvement (%)			
<10	33	28	0.64
11-20	12	17	
21-30	3	3	
31-40	2	1	
>40	0	1	
Pattern of AA			
Focal	42	44	0.12
Reticulate	3	5	
Ophiasis	4	0	
Sisaipho	0	1	
Linear	1	0	
Thyroid function status			
Euthyroid	38	42	0.59
Hypothyroid	8	6	
Hyperthyroid	4	2	
Deranged thyroid status	12	8	20



Figure 1: Group A patient showing excellent response
(a) baseline, (b) at 3 weeks, (c) at 6 weeks, (d) at 9 weeks, (e) at 12 weeks, and (f) at 20 weeks.



Figure 2: Group A patient showing poor response
(a) baseline, (b) at 3 weeks, (c) at 6 weeks, (d) at 9 weeks, (e) at 12 weeks, and (f) at 20 weeks.



Figure 3: Group B patient showing excellent response
(a) baseline, (b) at 3 weeks, (c) at 6 weeks, (d) at 9 weeks, (e) at 12 weeks, and (f) at 20 weeks.



Figure 4: Group B patient showing poor response
(a) baseline, (b) at 3 weeks, (c) at 6 weeks, (d) at 9 weeks, (e) at 12 weeks, and (f) at 20 weeks.

Table 4: Improvement in SALT score during therapy (baseline, three week, six week, nine week, twelve week) in AA patients.

S. no.	Study groups	SALT score baseline	SALT score (3 week)	SALT score (6 week)	SALT score (9 week)	SALT score (12 week)
1	Group A	6.05±5.36	5.49±4.99	4.51±4.30	3.39±3.47	2.58±2.63
2	Group B	6.62±4.39	5.56±3.95	4.87±3.40	4.13±2.61	3.45±2.11
3	P value	0.558	0.933	0.649	0.236	0.07

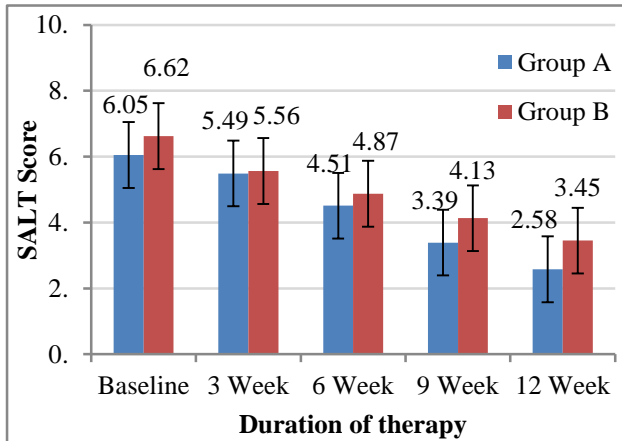


Figure 5: Improvement in SALT score during therapy (baseline, three week, six week, nine week, twelve week) in alopecia areata patients.

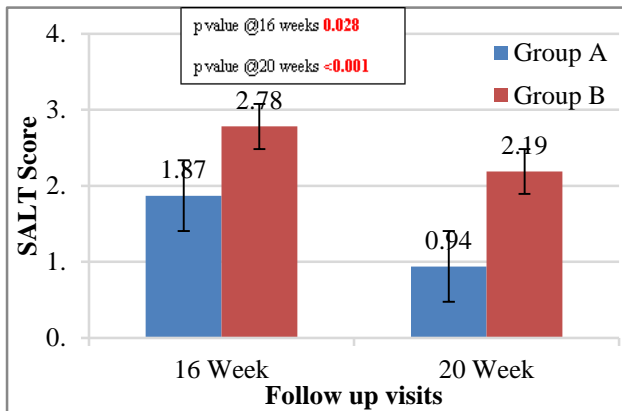


Figure 6: Improvement in SALT score during follow-up (16 week and 20 week) in AA patients.

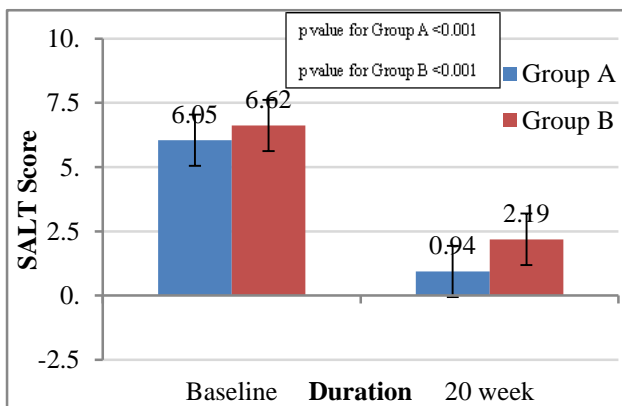


Figure 7: Comparison of SALT score from baseline to last follow up (twenty weeks).

The mean SALT score in group A decreased from 6.05 ± 5.36 before treatment to 0.94 ± 1.69 after treatment and was compared to group B where mean SALT score decreased from 6.62 ± 4.39 to 2.19 ± 1.76 after treatment. This decrease was statistically significant. Pain was complained by 10 patients (20%) in group A due to

injection of PRP at affected site. 9 out of 10 patients complained of mild pain while 1 patient felt moderate pain (Figure 9).

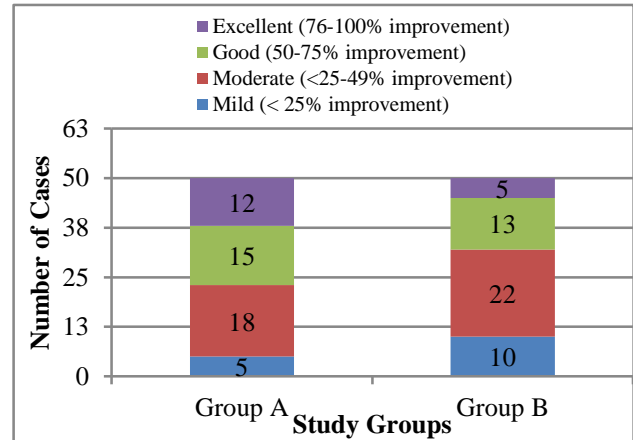


Figure 8: Percentage of hair regrowth score.

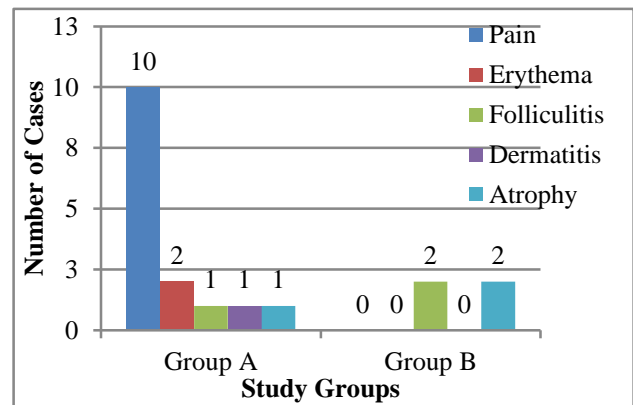


Figure 9: Adverse effects due to treatment.

DISCUSSION

This current study evaluated effect of PRP along with mometasone versus mometasone alone in case of AA. Since, AA is a common autoimmune disease of hair, thence an unpredictable course. Most of the patients with a single patch of AA usually have regrowth of hair within a year of its onset, even without treatment. Potent topical corticosteroids and contact sensitizers have been the cornerstone for the management of AA since long time. Intralesional corticosteroids are one of the widely used therapy for AA. But, they have their own disadvantages. In recent times PRP has drawn attention due to the virtue of abundant growth factors. These growth factors act on the dermal papilla via GSK and Akt pathway. Additionally, PRP also increases expression of Bcl-2 which prevents apoptosis, prolongs anagen phase and delays catagen by proliferation and differentiation of stem cells. PRP also increases angiogenesis and has an immunomodulatory effect in AA. So, PRP can have additional advantage in cases of AA. Mean age of group A patients was 24.76 ± 9.70 years, while mean age of group B patients was 22.98 ± 8.42 years. Kumar et al in their study

have found mean age of patients to be 29.27.⁸ Unal et al reported the mean age of patients of alopecia areata in their study as 27.4±9.2 years.⁹

Similarly, Kapoor et al in their study reported mean age of 27.1±7.08 years.¹⁰ In this study, males outnumbered females in terms of prevalence of AA. Out of 100 patients, 57 patients (57%) were males and 43 patients (43%) were females. Similar result was supported by Kumar et al who found 74.7% males and 25.3% females, out of 75 patients included in his study.⁸ Zaher et al found 18 males (60%) out of 30 patients.¹¹ Rinaldiet al in their study found 37 males (61.67%) out of 60 patients.¹² Lower frequency of AA in females may be due to non-reporting to the hospitals and also due to long hairs which in turn makes patchy loss of hairs less noticeable.

In this study, maximum number of patients (76%) reported to the hospital with disease duration of 3 months. Several studies have shown a wide diversity in the duration of AA among their patients. Balakrishnan et al in his study found that 60% of the patients had a disease duration of less than 3 months.¹³ In a study conducted by Unal et al. it was found to be 5.8±3.2 months.¹⁰ Zaher et al showed that disease duration ranged between 6 to 9 months (mean 7.7±2.89).¹¹ This early reporting is probably due to association of AA with psychological stress, depression and anxiety.

Scoring of severity for AA using SALT score was also done by Zaher et al.¹¹ They reported a mean baseline SALT score of 7.6 in a study on 30 patients of AA. Significant difference in decrease in mean of SALT score turned out to be significant at 16 weeks ($p<0.028$) and highly significant at 20 weeks ($p\leq0.001$).¹¹ The decrease in mean SALT score over a period of 20 weeks in group A patients was found to be 5.11±3.67, while a decrease of 4.43±2.63 in mean SALT score was seen in the same time duration in group B patients. Similar results were also reported by Zaher et al who in their study of treatment of patients of AA with topical mometasone found a significant decrease of 2.30 in mean SALT score over a period of 12 weeks.¹¹ Unal et al in his study of treatment of AA with topical mometasone found similar results.¹⁰ In a study done by Trink et al PRP was found to have a better efficacy than intralesional corticosteroids.¹⁴

There was a significant difference of SALT score with better hair regrowth and better SALT score after treatment in group A. The improvement in alopecia occurred over a period of 20 weeks. This shows that PRP has a slower mode of action and when combined with topical corticosteroids, which acts at halting the inflammatory process by inhibiting inflammatory cells and cytokines, it increases the efficacy as an adjuvant by release of its growth factors like fibroblast growth factors, transforming growth factor, insulin like growth factor, hepatocyte growth factor and prevents apoptosis by increasing expression of anti-apoptotic factor Bcl-2. PRP has an anti-inflammatory action by preventing MCP-1 and various chemotactic cytokines.

In addition, it promotes angiogenesis by secretion of VEGF. Therefore, intralesional PRP seems to provide additional efficacy, when combined with topical mometasone in the treatment of AA.

Limitations

The limitations of the study were small sample size and long term follow up of cases was not done in view of relapse.

CONCLUSION

AA is a common cause of hair loss, especially in young adults. Steroids remain the first line of treatment due to their action on inflammatory cells, thus halting further progression of disease. The main drawback of using steroids is atrophy and telangiectasia due to prolonged application requirement. This requires need of additional options which can either decrease duration of topical steroid use or additionally increases the effectiveness of treatment thereby improving the outcome. PRP is that additional intervention which accelerates the response, decreases therapy duration and adverse effects. In this study, we found that adding intralesional PRP with topical mometasone 0.1% cream has higher efficacy and early improvement than topical mometasone alone, in the treatment of AA.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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