

The Comparative Efficacy Between Intralesional Steroids and Oral Prednisolone Mini Pulse Therapy in The Treatment of Alopecia Areata (AA).

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Abstract:-

Background: Alopecia areata (AA) is a common auto-immune condition, causing hair loss. This disease has limited treatment modalities. Through this study, comparison between established modalities of treatment such as oral mini pulse therapy, intralesional corticosteroids and platelet-rich plasma (PRP) as a newer modality has been done. The objective of the study was to evaluate the efficacy and safety of various treatment modalities in alopecia areata.

Methods: A total number of one hundred twenty patients with clinical manifestation of alopecia areata attending the dermatology outpatient department of Nalanda Medical College, Patna were included in this study. It was conducted as a randomized prospective study for a period of 16 weeks. After taking informed consent, patients were randomly distributed into three treatment groups. Group 1 patients were treated with Tab. Betamethasone 0.1 mg/kg every Saturday and Sunday, Group 2 was treated with Inj. Triamcinolone acetonide 10 mg/ml for scalp and 2.5 mg/ml for eye brows and face was injected into deep dermis.

Results- The commonest age group was 20 years and below with the total mean age being 24.9 years. Males showed predominance with a ratio of male to female of 2:1. Majority of the patients presented between 2 month to 3 month after the onset. Family history of AA was present in 12% of the subjects. The common patterns of alopecia areata observed in our study was patchy AA .22(18.3%) patients had an association of atopy and 3(2.5%) of the patients had a history of vitiligo. Majority of the patients did not take treatment prior to the onset (93%). Nail changes were observed in 9(7.5%) patients .

Conclusions:Intralesional corticosteroids viz. triamcinolone acetonide still remains the first choice of therapy for AA in adults with limited involvement. Systemic corticosteroids give lower response than intralesional steroids.

Keywords: alopecia areata; mini-pulse therapy; corticosteroids; dexamethasone

INTRODUCTION

Alopecia Areata (AA) is a medical condition caused by the body's immune system attacking hair follicles, resulting in circular or oval areas of hair loss that do not cause permanent scarring. It can affect any part of the body that has hair, however it is most usually found on the scalp.[1]

Alopecia areata (AA) affects approximately 1.7% of the population at some point in their lifetime. The occurrence of alopecia areata (AA) in the overall population is 0.2%, and it does not show any preference for a particular gender. Primarily, it impacts children and young adults, although individuals of any age range may also be affected. Available treatment options include corticosteroids (topical, intralesional, oral), Calcineurin inhibitor (tacrolimus), minoxidil, contact immunotherapies such as squaric acid dibutyl ester, diphenceprone, cyclosporine, Alefacept, sulfasalazine, IVIg, and photo(chemo) therapy using UVA and psoralene.[2]

METHODS

A total number of 120 patients with clinical manifestation of alopecia areata attending the dermatology outpatient department of Nalanda Medical College, Patna were included in this clinico-interventional study. It was a randomized, single blind study of treatment of AA. An informed consent was obtained. Relevant history was taken and clinical examination including general, systemic and local examinations were made. The total number of patches and their locations were noted.

The eligible patients were randomly allocated into group A & group B . The patients of group A received intralesional injection of triamcinolone acetonide 10 mg/ml diluted 1:1 with distilled water being injected at each prick to cover the area of involvement & Group B received 30 mg oral prednisolone for 2 consecutive days in a week. The study protocol was approved by institutional ethics committee.

Data was collected from 12 December 2017 to 12 May 2019 with minimal sample size of one hundred twenty with sixty patients in each group. Patients for each group were selected using purposive sampling technique. Written informed consent was taken from each patient enrolled into the study.

SELECTION CRITERIA

Inclusion criteria:

- Patients willing for the study.
- All the patients presenting with circumscribed patch of hair loss without any signs of inflammation or scarring.
- Patients who have not taken any treatment for alopecia areata during the last six months.
- Patients with age more than 10 years.

Exclusion criteria:

- Patients who are not willing for the study.
- Patients having scarring alopecia.
- Patients with secondary infection.
- Patients with pregnancy or lactation.
- Extensive lesions (more than 5 lesions).

METHOD OF STUDY:

The patients were randomly allocated into two groups namely, group A and group B. The patients of group A received intralesional injection of triamcinolone acetonide 10mg/ml diluted 1:1 with distilled water using insulin syringe, 0.1ml was injected at each prick 1 cm apart, once in three weeks. Group B received 30 mg oral prednisolone for 2 consecutive days in a week. Both the two modalities of treatment were continued for a period of 12 weeks and followed up with three weeks of interval each. Clinical photographs were taken at each visit.

RESULTS

Table 1: Scoring for density of hair regrowth

Scoring for density of hair regrowth	
Area of Patch covered with air	Score
No hair growth	0
1-25%	1
26-50%	2
51-75%	3
76-100%	4
Scoring of Texture of Regrowing hair	
Fine vellus hair	1
Normal coarse hair	2
Scoring of overall response (1 +2) at the end of the study	
Treatment failure	0
Poor	2-3
Good	4-5
Excellent	6

Table 2: Showing group allotment and drug abbreviations

Name of the Drug	Allotted Group
1/L Triamcinolone	Group A
Oral Prednisolone	Group B

Table 3: Age and Sex distribution

Age	Group A	Group B	Total
20 and below	23(38.3%)	23(38.3%)	46(38.3%)
21-30	24(40%)	21(35%)	45(37.5%)
31-40	9(15%)	11(18.3%)	20(16.7%)
Above 40	4(6.7%)	5(8.3%)	9(7.5%)

Male	44(73.3%)	40(66.7%)	84(70%)
Female	16(26.7%)	20(33.3%)	36(30%)
Total	60 (100%)	60 (100%)	120 (100%)

The majority of patients belonged to the age range of 20 years and younger. The average age in group A is 25.01 years. The duration of time spent in Group B is 24.8 years. In Group A, out of a total of 120 patients, 44 (73.3%) were men and 16 (26.7%) were girls. In Group B, there were 40 (66.7%) male patients and 20 (33.3%) female patients. There is no discernible disparity in gender across the groups.

Table 4: Showing the area of involvement and their abbreviations

Area Involvement	Group A	Group B	Total
BEARD (B)	13 (21.7%)	5 (8.3%)	18(15%)
EYEBROW(E)	1(1.7%)	0 (0%)	1(0.8%)
FRONTAL (F)	4 (6.7%)	5 (8.3%)	9 (7.5%)
OCCIPITAL (O)	28 (46.7%)	36 (60%)	64 (53.3)
PARITAL (P)	8 (13.3)	7 (11.7%)	15 (12.5%)
TEMPORAL OCCIPITAL (TO)	1 (1.7%)	0 (0%)	1 (0.8%)
PARITAL OCCIPITAL (PO)	3 (5%)	2 (3.3%)	5 (4.2)
OCCIPITAL PARITAL & FRONTAL (OPF)	2 (3.3%)	0 (0%)	2 (1.7%)
OPHISIASIS (OPH)	0 (0%)	1(1.7%)	1 (0.8%)
TEMPORAL (T)	0 (0%)	1(1.7%)	1(0.8%)
FRONTAL & PARITAL (FP)	0 (0%)	1(1.7%)	1(0.8%)
PARITAL & TEMPORAL (PT)	0(0%)	2 (3.3%)	2(1.7%)
Number of Lesions			
1	45(75%)	42(70%)	87(72.5%)
2	7(11.7%)	11(18.3%)	18(15%)
3 or > 3	8(13.3%)	7(11.7%)	15(12.5%)
Duration			
1 month and Below	5 (8.3%)	19 (31.7%)	24(20%)
2 month to 3 month	26 (43.3%)	26 (43.3%)	52(43.3%)
4 month to 5 month	15 (25%)	10 (16.7%)	25(20.8%)
6 month and Above	14(23.3%)	5 (8.3%)	19(15.8%)
Treatment History			
NO	51(85%)	42(70%)	93(77.5%)
YES	9(15%)	18(30%)	27(22.5%)
Family History			
NO	51(85%)	57(95%)	108(90%)
YES	9(15%)	3(5%)	12(10%)
History of Vitiligo			
NO	59(98.3%)	58(96.7%)	117(97.5%)
YES	1(1.7%)	2(3.3%)	3(2.5%)
History of Atopy			
NO	50(83.3%)	48(80%)	98(81.7%)
YES	10(16.7%)	12(20%)	22(18.3%)
Nail changes			
NO	55(91.7%)	56(93.3%)	111(92.5%)
YES	5(8.3%)	4(6.7%)	9(7.5%)

A study was conducted on a cohort of 120 patients. Among them, 87 (72.5%) had a single patch, 18 (15%) had 2 patches, and 15 (12.5%) had 3 or more patches. The majority of patients in both groups appeared within a time frame of two to three months after the incident. There were 26 patients (43.3%) in group A and 26 patients (43.3%) in group B. There is no substantial disparity in the duration of the complaints among the categories.

Regarding the past treatment received by the patients, a significant majority (77.5%) in both groups did not undergo any form of treatment. 9 patients (15%) in Group A and 3 patients (5%) in Group B exhibited a familial history. Out of the patients in Group A, 1 (1.7%) had a history of vitiligo, while in Group B, 2 (3.3%) had a history of vitiligo. The vast majority, specifically 98 patients (81.7%), did not have any association with Atopy. Out of the patients in Group A, 5 (8.3%) had nail changes. Similarly, in Group B, 4 (6.7%) patients had nail abnormalities.

Table 5: Shows the RGS readings at 3rd week

	Group A	Group B	Total
3rd Week			
II	40 (66.7%)	11 (18.3%)	51 (42.5%)
0	20 (33.3%)	49 (81.7%)	69 (57.5%)
6th Week			
II	12 (20%)	40 (66.7%)	52 (43.3%)
III	34 (56.6%)	16 (26.6%)	50 (41.7%)
IV	14 (23.3%)	4 (6.7%)	18 (15%)
9th Week			
III	12 (20%)	45 (75%)	57 (47.5%)
IV	38 (63.3%)	12 (20%)	50 (41.7%)
V	10 (16.7%)	3 (5%)	13 (10.8%)
12th Week			
IV	14 (23.3%)	37 (61.7%)	51 (42.6%)
V	24 (40%)	16 (26.6%)	40 (33.3%)
VI	22 (36.7%)	7 (11.7%)	29 (24.1%)

Table 6: Showing a side effect

Atrophy Of skin	Group A	Group B	Total
NO	53 (88.3%)	60 (100%)	113 (94.1%)
YES	7 (11.7%)	0 (0%)	7 (5.9%)
Pain			
NO	48 (80%)	60 (100%)	108 (90%)
YES	12 (20%)	0 (0%)	12 (10%)
Hypopigmentation			
NO	55 (91.7%)	60 (100%)	115 (95.8%)
YES	5 (8.3%)	0 (0%)	5 (4.2%)
Gastric upset			
NO	60 (100%)	47 (78.3%)	107 (89.2%)
YES	0 (0%)	13 (21.7%)	13 (10.8%)
Acneiform eruption			
NO	60 (100%)	49 (81.7%)	109 (90.8%)
YES	0 (0%)	11 (18.3%)	11 (9.2%)
Weight gain			
NO	60 (100%)	55 (91.7%)	115 (95.8%)
YES	0 (0%)	5 (8.3%)	5 (4.2%)
Cushingoid features			
NO	60 (100%)	59 (98.4%)	119 (99.2%)
YES	0 (0%)	1 (1.6%)	1 (0.8%)

DISCUSSION

Alopecia areata is a frequently occurring condition in dermatology, accounting for about 2% of cases. It is characterised by the non-permanent loss of hair in patches, without any accompanying tissue shrinkage. This

study examined 120 individuals with alopecia areata who were seen in the dermatology outpatient department of Nalanda Medical College Hospital, Patna. Demographic breakdown by age and gender: The survey found that the majority of patients (38.3%) were aged 20 and below, while 37.5% of patients were aged between 21 and 30. These findings were comparable to the study conducted by Rivitti.[3] The youngest patient was 11 years old, while the oldest patient was 50 years old.

In our study, there was a predominance of males (73.3%), with a higher number of males compared to females. The ratio is 2:1, which is similar to the ratio found in Rivitti's study. [3] Possible contributing causes for these outcomes may involve the prompt identification of alopecia diseases in guys due to their shorter hair length. The hairdressers acknowledged this and brought it to their attention.

The majority of patients had just scalp involvement, however a few cases demonstrated concurrent involvement of the scalp and face. The occipital area was most impacted in these cases. The percentage of cases (53.3%) is higher in comparison to other sites. Beards were affected in 18 cases, accounting for 15% of the total. Eyebrows were affected in 1 case, representing 0.8% of the total.

A total of 120 individuals were examined, and among them, 87 patients (72.5%) had a solitary patch. Out of the total number of patients, 18 (15%) had 2 patches, whereas 15 (12.5%) had 3 or more patches.

The duration of alopecia areata ranged from 2 to 3 months in the current study. 43.3% of the patients in group A and 43.3% of the patients in group B. There is no significant difference in the duration of the complaints between the groups. Ancestral lineage: In this investigation, 12 patients (10% of the total) exhibited a positive family history. Similar to the research conducted by Jabbari A et al.[4]

Regarding the previous treatment received by the patients, a significant majority of them (77.5%) did not undergo any treatment in any of the categories.

Out of the total number of patients in this study, 22 individuals (18.3%) were found to have atopy, a condition that is similar to The study conducted by Alkhalifah et al. indicates a correlation between atopy.[5]

Out of the 120 individuals included in this study, a total of 3 patients (2.5%) were found to have vitiligo. which is similar in magnitude to the study conducted by Messenger.2Nail alterations were seen in 9 (7.5%) of the individuals in this investigation. The vast majority of patients, specifically 111 individuals (92.5%), did not exhibit any nail alterations.

A comparative analysis was conducted to examine the effectiveness of intralesional steroid treatment against oral steroid treatment.No comparative studies have been discovered in the literature that assess the effectiveness and safety of the two most commonly used intralesional medications for treating alopecia areata. This study is the first to compare both treatment techniques in alopecia areata.

Although intralesional corticosteroids are commonly used as an initial treatment for patchy alopecia areata, there is a lack of published randomised controlled trials investigating their efficacy in this condition.Triamcinolone acetonide injections administered three times every 2 weeks have resulted in hair regeneration in 71% of patients with subtotal AA. In contrast, only 7% of control participants who received isotonic saline injections saw hair regrowth. Porter and Burton demonstrated that hair regrowth occurred in 64% and 97% of alopecia areata (AA) sites treated with intralesional injections of triamcinolone acetonide and its less soluble derivative, triamcinolone hexa-acetonide, respectively. A non-randomized trial including 62 individuals diagnosed with AA who had monthly injections of triamcinolone acetonide directly into the affected areas demonstrated total hair regrowth in 40 patients, accounting for 63% of the study population, after 4 months of treatment. Young individuals with a small number of lesions (less than five patches), lesions that have been present for a short period of time (less than 1 month), and patches that are smaller than 3cm in diameter are likely to see regrowth. In a single case, it was found that 60% of individuals with significant alopecia areata (more than 50% involvement) showed a positive response to intralesional triamcinolone acetonide treatment.[6]

This study involved the division of 120 patients into two groups, with each group consisting of 60 patients. Although both groups had a notable clinical improvement, group A exhibited the quickest therapeutic response, with 40 individuals (66.7%) showing a reaction with RGS II and 20 individuals (33.3%) showing a response with RGS 0. Among the patients in group B, 18.3% exhibited RGS II, while 81.7% showed RGS 0.During the third week, a highly significant P value of 0.0001 (HS) was observed.

During the 6th week, grade IV (good) was observed in 14 patients (23.3%) in group A and 4 patients (6.7%) in group B. The difference between the two groups was highly significant, with a P value of 0.001 (HS). During the 9th week, a positive response was observed in 10 patients (16.7%) in group A and 3 patients (5%) in group B. Among the patients in group A, a Grade IV (excellent) response was observed in 38 individuals, which accounts for 63.3% of the total. The statistical analysis revealed a very significant P value of 0.0001, indicating a strong association. During the 12th week, a favourable response was observed in 22 patients (36.7%) in group A and in 7 patients (11.7%) in group B, both of whom were classified as grade VI (excellent). Group A achieved a Grade V (good) response in 24 cases, which accounts for 40% of the total. 16 patients, which accounts for 26.6% of the group B patients.

Adverse effects: Among the patients who received intralesional steroids, 12 had pain, 7 experienced atrophy, and 5 experienced hypopigmentation. These findings align with the results of a study conducted by Kumaresan M.[7] Thirteen patients experienced gastric discomfort, eleven patients had an acneiform eruption, and five patients gained weight when treated with oral steroids. These findings are consistent with a research conducted by Bajaj et al.[8]

CONCLUSION

The onset of therapeutic response was earlier in participants treated with intralesional steroids compared to those treated with oral steroids. This outcome persisted throughout the course of the treatment. Following the treatment, 22 patients who got intralesional steroid demonstrated an outstanding clinical reaction, while 38 patients showed a decent response. In contrast, only 7 patients who received oral steroid exhibited an exceptional response. Adverse reactions were more prevalent in patients taking oral prednisolone compared to those receiving intralesional steroid. Hence, intralesional triamcinolone is more efficacious than oral mini pulse in treating Alopecia Areata.

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