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Original Article

Dermatology Section

Comparative Evaluation of Topical Betamethasone Dipropionate Lotion 0.05% versus its Combination with Intralesional Triamcinolone Acetonide Injection in Alopecia Areata: A Randomised Controlled Trial

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ABSTRACT

Introduction: Alopecia Areata (AA) is non-cicatricial patchy hair loss, which is fairly common and may evoke feelings of vulnerability and loss of self-esteem in patients. Many different treatment modalities have been recommended, including topical, systemic, and intralesional corticosteroids (ILCs). However, no treatment has consistently produced satisfactory results, and various topical therapies used in the past have shown limited effectiveness. ILC is the most commonly used treatment for AA, especially in patients with <50% area involved. Despite this, there is a lack of adequately powered randomised controlled trials assessing the efficacy, safety, and duration of response.

Aim: To compare the efficacy of intralesional triamcinolone acetonide injection, topical betamethasone dipropionate lotion 0.05%, and their combination in treating AA.

Materials and Methods: This randomised controlled trial was conducted at the Department of Dermatology, SMS Medical College, a Tertiary Care Hospital in Jaipur, Rajasthan, India, over a one-year period from August 2012 to July 2013. The study included patients aged 11 to 50 years who were willing to provide informed consent. A total of 120 patients were randomised into two groups (Group A and Group B) of 60 patients each. Twenty patients did not follow-up, leaving 53 patients in Group A and 47 patients in Group B who completed the study were 53 in group A and 47 in group B. Group A received topical betamethasone dipropionate lotion 0.05% with single-night application and intralesional triamcinolone acetonide 10 mg/mL at baseline, 4, 8, and 12 weeks. Group B received topical betamethasone dipropionate lotion 0.05% with single-night application and intralesional normal saline at the same intervals. Patients were followed-up for an additional 12 weeks. Responses were evaluated using the Hair Regrowth Grade (HRG) scale, and statistical analysis was performed using the Chi-square test.

Results: Among the study population, the majority of patients (49, 41%) were in the age group of 21-30 years, with 91 males and 29 females. At the end of the 12-week treatment and 12-week follow-up period, Group A showed greater improvement, with 62% of patients achieving hair regrowth grade scale S-IV (76-100%), and 87% {S-IV (76-100%)} respectively, as compared to only 13% in Group B. Similarly, in the follow-up period, Group A had a higher percentage of patients with S-IV (76-100%) regrowth (87%) compared to Group B (32%).

Conclusion: This study concludes that intralesional triamcinolone acetonide 10 mg/mL is an effective and safe treatment option for AA. The addition of single-night application of betamethasone dipropionate 0.05% lotion yields better results than using either treatment alone.

Keywords: Corticosteroids, Efficacy, Hair regrowth scale, Placebo, Scalp

INTRODUCTION

Hair in humans is largely vestigial; however, maintaining residual hair to meet cultural norms holds significant psychological importance. Alopecia Areata, defined as non-cicatricial patchy hair loss, is a common and easily recognisable condition. The most common form involves isolated, asymptomatic hair loss from a circumscribed area, usually on the scalp, with regrowth occurring within a few months. Severe cases can lead to feelings of vulnerability, loss of self-esteem, and changes in self-identity [1].

The aetiology and prognosis of the disease remain uncertain. While some believe it to be an autoimmune process, others suggest that emotional stress may be a significant triggering factor for AA [2,3]. The only predictable aspect of AA is its unpredictability [4]. Patients often experience multiple episodes of hair loss and regrowth throughout their lifetime, with recovery ranging from complete to partial or none.

Numerous treatment modalities have been recommended, including topical, systemic, or intralesional corticosteroids, topical immunomodulators, topical irritants, minoxidil, cryotherapy, Psoralene Plus Ultraviolet-A radiation (PUVA) therapy, tacrolimus, zinc, dermography tattooing, wigs, and others [5]. Some of these treatments have severe side effects, while others prove to be ineffective. Therefore, it is important to choose a treatment modality that is both effective and safe. Traumatic procedures such as dermabrasion, cryotherapy, needling, and saline injections have also been attempted [5].

Uncontrolled data suggests that intralesional steroids are an excellent treatment option for localised AA, but few studies exist in the literature to prove their efficacy [6,7]. There is no standardised protocol for treatment intervals or duration in AA. Previous studies have typically administered treatment every 3-4 weeks for a period of 3-6 months or until a clinical response is observed. Consequently, this study aims

to conduct a comparative evaluation of intralesional triamcinolone acetonide injection at a concentration of 10 mg/mL versus placebo, as well as the effectiveness of topical betamethasone dipropionate lotion 0.05%, either alone or in combination.

MATERIALS AND METHODS

This randomised controlled trial was conducted in the Department of Dermatology, SMS Medical College, a Tertiary Care Hospital, Jaipur, Rajasthan, India, over a period of one year from August 2012 to July 2013, following Ethical Committee approval. A total of 120 patients (60 patients in each group) were randomised using block randomisation into two groups.

Sample size calculation: Sixty patients were included in each group based on an expected regrowth rate of 74% in the intralesional triamcinolone group and 47% in the topical betamethasone group, with an alpha error of 0.05, 80% power, and 95% confidence level. The sampling technique used was non-purposive consecutive sampling.

Inclusion criteria: The study included patients aged 11 to 50 years who were willing to provide informed consent. For minor subjects, parental consent was also obtained. Patients with three or fewer patches of AA, with a total area not exceeding 20% of the scalp/face, and who had not received any treatment in the last three months were included.

Exclusion criteria: Patients with rapidly progressing disease involving >20% of the scalp/face area, patients with a history of allergy to steroids, pregnant and lactating females were excluded.

Study Procedure

Details regarding the familial occurrence of AA were noted, along with a history of associated diseases such as atopy, (allergic rhinitis/asthma/eczema) diabetes mellitus, vitiligo, thyroid disorders, pernicious anemia, Addison's disease, and Down's syndrome were recorded. The total study duration was 24 weeks (12 weeks of treatment and 12 weeks of follow-up). In Group A, patients were treated with topical betamethasone dipropionate lotion 0.05% applied once at night, and intralesional triamcinolone acetonide 10 mg/mL at baseline, 4, 8, and 12 weeks. In Group B, patients received topical betamethasone dipropionate lotion 0.05% applied once at night, and intralesional normal saline at the same intervals. Triamcinolone acetonide at a concentration of 10 mg/mL (maximum volume of 3 mL per session) was injected intradermally with an insulin syringe, using multiple 0.1 mL injections at 1 cm intervals. Baseline pictures and hair regrowth patterns were recorded during treatment (at baseline, 4, 8, and 12 weeks) and at 16, 20, and 24 weeks. Clinical photographs were taken at each visit, and hair regrowth patterns were observed. Hair counting was not performed by the authors, and subjective analysis of hair regrowth was conducted by two independent dermatologists. If AA patches showed approximately up to 25% regrowth, it was graded as Scale I. The responses were analysed using the HRG scale [8]:

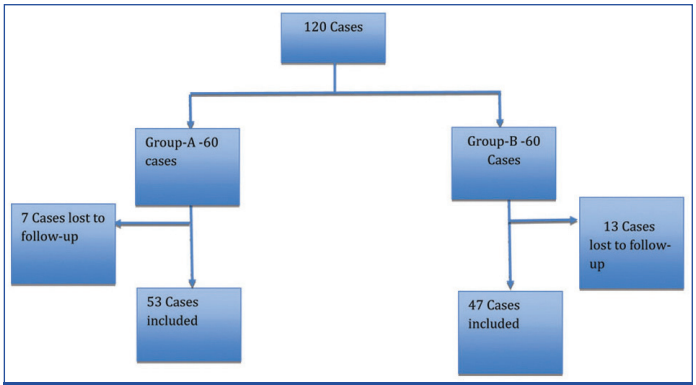
- S-I=0-25%
- S-II=26-50%
- S-III=51-75%
- S-IV and po=76-100%

STATISTICAL ANALYSIS

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS), version 21.0, a statistical software package for Windows (SPSS Inc., Chicago, IL, USA). Categorical data were presented as numbers (percentage proportions) and compared among groups using the Chi-square test. The p-value was calculated using Student's t-test, with a significance level set at $p<0.05$.

RESULTS

A total of 120 cases of AA were enrolled and treated using two different treatment modalities. Twenty patients were lost to follow-up, with 7 from group A and 13 from group B. The remaining patients who completed the study were 53 in group A and 47 in group B [Table/Fig-1]. Among the patients, 31 (25.83%) were in the age group of 11-20 years, 49 (40.83%) were in the age group of 21-30 years, 29 (24.17%) were in the age group of 31-40 years, and 11 (9.17%) were in the age group of 41-50 years [Table/Fig-2]. The largest number of patients (49, 41%) were in the age group of 21-30 years. There was no significant difference observed in the age distributions between the two groups. A total of 91 patients were male, and 29 were female, resulting in a male to female ratio of 3.1:1 [Table/Fig-2].



[Table/Fig-1]: Flowchart depicting study participants.

Parameters	Groups	
	Group A	Group B
Age group (in years)		
11-20	18	13
21-30	22	27
31-40	14	15
41-50	5	6
Gender		
Male	47	44
Female	13	16

[Table/Fig-2]: Distribution according to age and sex of patients.

Out of the total patients, 107 (97.5%) presented for treatment within the first six months of the disease. The majority of patients (99, 82.5%) reported between 1-6 months after the onset of the disease, while only three (2.5%) presented after six months [Table/Fig-3]. The progressive type of AA was more common than the stationary type (81% vs 19%) [Table/Fig-4]. Scalp involvement was exclusive in 98 (81%) of patients, A total of while 16 (13%) had patches at sites other than the scalp [Table/Fig-5]. About 72 (60%) of patients presented with more than one patch (2 or 3), while 48 (40%) presented with a single patch [Table/Fig-6].

Duration (in months)	Frequency (n)	Percentage (%)
<1	18	15
1-6	99	82.5
>6	3	2.5

[Table/Fig-3]: Duration of Alopecia Areata (AA).

Spread	Number of cases	Percentage (%)
Progressive	98	81
Stationary	22	19

[Table/Fig-4]: Spread of Alopecia Areata (AA).

The parietal region was the most commonly affected area, found in 49 (40.8%) of cases, followed by the beard in 24 (20%), occipital in 18 (15%), frontal in 10 (8.3%), temporal in 8 (6.7%), vertex in 7 (5.8%), eyebrows in 2 (1.6%), moustache in 2 (1.6%), and no cases involving the arms and legs [Table/Fig-7]. Thirteen (9.2%) cases showed a positive family history of AA [Table/Fig-8]. Nail

Site	Number of cases	Percentage (%)
Scalp	98	81
Non scalp	16	13
Combined	6	6

[Table/Fig-5]: Distribution of the case according to the site of Alopecia Aerata (AA).

Patch	Number of cases	Percentage (%)
One	48	40
Two	45	37.5
Three	27	22.5

[Table/Fig-6]: Distributions of cases according to patches of alopecia.

changes were associated in 14 (11.6%) of the patients, with pitting and longitudinal ridging observed in 11 (9.1%) and 3 (2.5%) patients, respectively [Table/Fig-9].

Site	Number of cases	Percentage (%)
Parietal	49	40.8
Occipital	18	15
Frontal	10	8.3
Vertex	7	5.8
Temporal	8	6.7
Beard	24	20
Moustache	2	1.6
Eyebrows	2	1.6
Disease associated		
Atopic manifestation	11	9.2
Vitiligo	2	1.6
Hypothyroidism	8	6.7
Hypertension	2	1.6

[Table/Fig-7]: Distributions of the cases according to site of body affected.

Family member affected	Number of patients (n)	Percentage (%)
Parents	3	2.5
Brother	5	4.1
Sister	3	2.5
Children	2	1.6

[Table/Fig-8]: Distributions of the cases according to presence of the family history.

Nail change	Number of patients (n)	Percentage (%)
Pitting	11	9.1
Longitudinal ridging	3	2.5

[Table/Fig-9]: Distributions of the cases according to nail changes in Alopecia Aerate (AA).

During treatment, in group A, atrophy and pigmentation were seen in five and three patients, respectively, and one patient each experienced pruritus and bacterial infection. In group B, only one patient developed atrophy [Table/Fig-10].

Side-effects	Group A	Group B
Atrophy	5	1
Pigmentation	3	1
Telangiectasia	0	0
Infections	1	0
Itching	1	1
Pain at injection site	0	1
Acne	0	0

[Table/Fig-10]: Distributions of the cases according to presence of side-effects.

The distribution of cases according to the HRG scale at 4, 8, and 12 weeks of treatment is shown in [Table/Fig-11]. At the end of 12 weeks, group A showed maximal improvement (S-IV, 76-100%) compared to only 13% of cases in group B (S-IV, 76-100%). This difference was significant (p<0.001), indicating a highly significant result. The patients were followed-up at four-week intervals, and their improvement was recorded at each visit. [Table/Fig-11] provides the distribution of cases according to the HRG scale at 4, 8, and 12 weeks of follow-up, with a p-value <0.05 [Table/Fig-11].

HRG scale	Group A n (%)	Group B n (%)	Chi-square test	p-value
4 weeks				
S-I (0-25%)	21 (40%)	43 (91%)	26.87 at 1 DF	p<0.001 HS
S-II (26-50%)	18 (34%)	4 (9%)	7.979 at 1 DF	p=0.005 S
S-III (51-75%)	6 (11%)	0	NA	NA
S-IV (76-100%)	8 (15%)	0	NA	NA
8 weeks				
S-I (0-25%)	8 (15%)	34 (72%)	31.20 at 1 DF	p<0.001 HS
S-II (26-50%)	11 (21%)	9 (19%)	0.0 at 1 DF	p=0.960 NS
S-III (51-75%)	18 (34%)	3 (7%)	9.81 at 1 DF	p=0.002 S
S-IV (76-100%)	16 (30%)	1 (2%)	12.27 at 1 DF	p<0.001 HS
12 weeks				
S-I (0-25%)	2 (4%)	15 (32%)	12.05 at 1 DF	p<0.001 HS
S-II (26-50%)	7 (13%)	19 (40%)	8.22 at 1 DF	p=0.004 S
S-III (51-75%)	11 (21%)	7 (15%)	0.25 at 1 DF	p=0.617 NS
S-IV (76-100%)	33 (62%)	6 (13%)	23.61 at 1 DF	p<0.001 HS

[Table/Fig-11]: Distribution of cases according to HRG scale during treatment at 4, 8, and 12 weeks.
A: Group A, received intralesional triamcinolone acetonide, and topical betamethasone dipropionate lotion 0.05% single night time application
B: Group B, received intralesional normal saline, and topical betamethasone dipropionate lotion 0.05% single nighttime application
Chi-square test applied
p-value-<0.05 which is significant
DF: Degree of freedom; HRG: Hair regrowth grading; HS: Highly significant; S: Significant; NS: Not significant

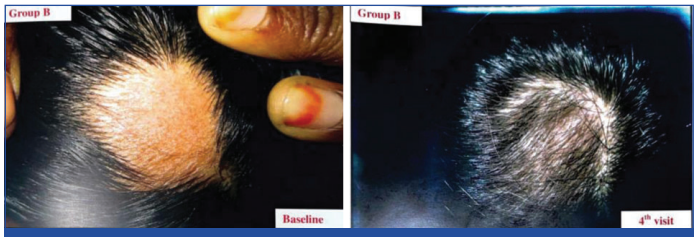
The patients were followed-up at four-week intervals, and their improvement was recorded at each visit. [Table/Fig-12] presents the distribution of cases according to the HRG scale at 4, 8, and

HRG scale	Group A (n=53)	Group B (n=47)	Chi-square test	p-value
4 week follow-up				
S-I (0-25%)	2 (4%)	13 (28%)	9.35 at1 DF	p=0.002 HS
S-II (26-50%)	3 (6%)	15 (32%)	9.92 at 1DF	p=0.002 S
S-III (51-75%)	8 (15%)	10 (21%)	NA	NA
S-IV (76-100%)	40 (65%)	9 (19%)	NA	NA
8 week follow-up				
S-I (0-25%)	1 (2%)	11 (23%)	8.979 at 1 DF	p=0.003 S
S-II (26-50%)	3 (6%)	10 (21%)	4.079 at 1 DF	p=0.043 S
S-III (51-75%)	5 (9%)	12 (26%)	3.505 at 1 DF	p=0.061 NS
S-IV (76-100%)	44 (83%)	14 (30%)	12.27 at 1 DF	p<0.001HS
12 week follow-up				
S -I (0-25%)	1 (2%)	9 (19%)	6.441 at 1 DF	p=0.01 S
S-II (26-50%)	2 (4%)	10 (21%)	5.66 at 1 DF	p=0.017 S
S-III (51-75%)	4 (7%)	13 (28%)	0.007 at 1 DF	p=0.932 NS
S-IV (76-100%)	46 (87%)	15 (32%)	29.26 at 1 DF	p<0.001 HS

[Table/Fig-12]: Distribution of cases according to HRG scale at 4, 8, 12 follow-up weeks.
A*: Group A, received intralesional triamcinolone acetonide, and topical betamethasone dipropionate lotion 0.05% single nighttime application
B*: Group B, received intralesional normal saline, and topical betamethasone dipropionate lotion 0.05% single nighttime application
Chi-square test applied
p-value-<0.05 which is significant
DF: Degree of freedom; HRG: Hair regrowth grading; HS: Highly significant; S: Significant; NS: Not significant

12 weeks of follow-up. The maximal growth (S-4, 75%-100%) was observed at the 4th and 16th weeks of therapy [Table/Fig-13]. At 16th week of therapy maximal growth S-4 (75%-100%) was seen [Table/Fig-14].

[Table/Fig-13]: Results at 4th week of therapy.



[Table/Fig-14]: Results at 16th week of therapy.

DISCUSSION

AA is a unique disorder characterised by patches of asymptomatic, non-scarring, non-inflammatory hair loss, most commonly on the scalp, with regrowth occurring within a few months. This benign form may gradually progress to more severe forms, sometimes resulting in universal alopecia. In a large study by Miller SA and Winkelman RK, the peak incidence of AA was found to be between 31 and 40 years [9]. Shallow reported that 48% of AA patients present before the age of 20 years [2]. In the present study, the maximum prevalence was observed in the third decade. The development of AA in the age group of 21-40 years might be due to proposed etiological factors such as stress and strain [3].

The reported sex incidence in AA patients has varied widely. Lowy M et al. reported an equal incidence among males and females (1:1) [10]. Bastos AA et al. found a male predominance (3:1), while Friedmann observed a higher number of females with a male to female ratio of 1:2 [11,12]. AA is considered an autoimmune disease and has been reported in association with several well-recognised autoimmune disorders such as thyroid disease, Hashimoto's disease, pernicious anemia, vitiligo, and Addison's disease. Muller SA and Winkelmann RK reported a 10% association of atopic manifestations with AA [9].

Nail changes have been found to be associated with a wide range of AA patients. In their series, Muller SA and Winkelmann RK reported that 7% of AA cases had associated nail changes, while Klingmuller G found nail changes in 66% of AA patients [9,13]. The most common manifestations of nail changes are pitting and trachyonychia. Other commonly reported findings include red spotted lunulae, onycholysis, and punctate leukonychia. Various treatment modalities have been recommended for AA, including topical use of corticosteroids, irritants such as phenol anthraline and liquid nitrogen, contact sensitisers like dinitrochlorobenzene, squaric acid dibutyl esters, diphencyprone, PUVA, minoxidil, and tacrolimus. Systemic use of corticosteroids and cyclosporin, as well as intralesional use of corticosteroids, have also been used with satisfactory results [14-17].

The use of corticosteroids has inherent disadvantages. Improper use of topical and intralesional steroids can lead to atrophy and pigmentation issues. Systemic steroids may cause serious side effects such as hypertension, edema, pseudotumor cerebri, peptic ulceration, gastritis, weight gain, Cushingoid facies, diabetic ketoacidosis, tuberculosis reactivation, avascular necrosis, osteoporosis, cataract, glaucoma, stillbirth, growth suppression, and hypothalamo-pituitary-axis suppression [18]. Cochrane Database (2008) reported that although ILCs have been used in the treatment of AA for about 50 years; there are no published randomised controlled trials for intralesional corticosteroids in the treatment of alopecia areata (AA) [19]. Kumaresan M observed that ILCs are most suitable and preferred method of treatment for patchy, relatively stable hair loss, of limited extent. But this modality is not appropriate in rapidly progressive AA or alopecia totalis/universalis, intralesional corticosteroids are not appropriate [20].

Porter D and Burton JL showed hair regrowth in 64% and 97% of treated AA sites using intralesional triamcinolone acetonide and triamcinolone hexacetonide, respectively [18]. Abell E and Munro DD reported that 52 of 84 patients (62%) showed regrowth of hair at 12 weeks after three injections of triamcinolone acetonide, using the Porto J et needleless device, compared to one of 1 5 (7%) control subjects [21]. Kuldeep CM et al. concluded that intralesional triamcinolone acetonide (60%) and betamethasone valerate foam (53.6%) were effective in treating localised AA, while tacrolimus showed no improvement [7]. These results are consistent with the present study.

The National Guidelines from the British Association of Dermatologists (2012) recommend intralesional corticosteroid therapy as the first-line treatment for localised patchy AA, with success rates of approximately 60-75%. Prospective studies using triamcinolone acetonide (5-10 mg/mL), administered intradermally at 2-6 week intervals, reported localised hair regrowth in 60-70% of injection sites [22].

Limitation(s)

Long-term follow-up was not conducted to assess the recurrence of alopecia patches after complete remission.

CONCLUSION(S)

The present study concluded that intralesional triamcinolone acetonide at a concentration of 10 mg/dL is a good treatment option. Additionally, the addition of betamethasone dipropionate 0.05% lotion as a single nighttime application resulted in better outcomes compared to using intralesional triamcinolone acetonide alone. The study observed a significant improvement in the group treated with intralesional triamcinolone acetonide compared to the group treated with intralesional normal saline. The slightly increased incidence of side effects in the intralesional triamcinolone acetonide group was attributed to the use of both intralesional and topical steroids. The combination of intralesional triamcinolone acetonide and topical betamethasone yielded better results compared to betamethasone alone.

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