

A Comparative Study of the Effectiveness of Topical Betamethasone Dipropionate and Tacrolimus in the Treatment of Alopecia Areata

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Received: 15-04-2022 / Revised: 20-05-2022 / Accepted: 05-06-2022

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Conflict of interest: Nil

Abstract

Objective: Alopecia areata (AA) is a typical disorder that results in patchy, non-scarring hair loss at the scalp. To allay the patient's concern over appearance, a variety of treatment approaches have been tried. The current study compares the efficacy of Tacrolimus and topical Betamethasone dipropionate in the management of patchy alopecia areata.

Methodology: It was a prospective, randomized trial conducted over 12 weeks. In this study, 60 patients between the ages of 10 and 50 with alopecia areata of either sex were included. Patients were separated into A and B therapy groups. Group A was administered a lotion containing 0.05 percent betamethasone dipropionate (BMD) twice daily. Group B was administered a topical lotion containing 0.05 percent Tacrolimus twice daily. At the conclusion of 12 weeks, the groups' responses were compared using the alopecia grading scale (AGS) and regrowth score (RGS), and adverse effects were assessed.

Results: We found that 80% of patients in Group A showed statistically significant clinical improvement (RGS 3 and 4) when compared to 10% of patients in Group B. Mean AGS was improved in group A (AGS 4.23) compared to Group b (AGS 10.96) at the end of 12 weeks of treatment. Side-effects encountered with Topical Betamethasone were comparably less than with Topical Tacrolimus.

Conclusion: Betamethasone is more effective than Tacrolimus in promoting hair regrowth in patients with patchy alopecia areata.

Key words: Alopecia Areata, Tacrolimus, Betamethasone.

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Background

Alopecia areata is a type of autoimmune disorder. Clinically, it appears as well-defined, round or oval, fully bald, smooth-surfaced patches of non-scarring alopecia [1]. The condition can affect any hair-

bearing area, although the scalp, brows, eyelashes, and beard are the most usually affected. Hair loss can be spotty or widespread [2]. The condition manifests as a coin-shaped patch anywhere on the body

or a band-like lesion over the occipital (ophiasis) or forehead (reverse ophiasis), and it can proceed to alopecia totalis or universalis [3,4].

The treatment of alopecia areata is a challenge [5]. There is a scarcity of evidence-based data for various alopecia areata treatment techniques. Topical corticosteroids are regarded standard therapy for the treatment of localised alopecia areata among the many treatment alternatives [6].

The present study was conducted to evaluate and compare the efficacy of topical 0.05% Betamethasone dipropionate (BMD) versus topical 0.05% Tacrolimus in patchy Alopecia areata and to compare the adverse effects of both topical treatment modalities.

Material and Methods

A prospective, randomised, comparative, single-blind study was conducted. Patients with localised alopecia areata of either sex in the age range of 10-50 years who attended the outpatient department of Dermatology at Viswabharathi Medical College, Kurnool, were screened for the study. The study was conducted for 3 months.

The inclusion criteria were asymptomatic, non-scarring, patchy hair loss over the scalp and elsewhere, patients age range 10 to 50 years in both genders who never received treatment for hair loss. The exclusion criteria were Extremes of age (<10 and >50 years), Patients with a history of previous treatment of alopecia areata, Pregnant and lactating women, Extensive involvement of the disease (more than 3 patches), Atypical alopecia areata (alopecia totalis,

Universalis, ophiasis), History of allergy to betamethasone or tacrolimus.

Prior to the start of the study, institutional ethics committee approval was acquired. Written informed consent was taken from patients before their participation in the study. Relevant history and clinical examination was done in each patient. Clinical examination of the patches was carried out with respect to number, size and distribution.

People who were eligible for the study were split into two groups at random: Group A and Group B. Patients in each group got a different topical treatment for a total of 12 weeks. Group A patients applied 0.05% Betamethasone dipropionate cream twice daily. Group B patients applied topical 0.05% tacrolimus cream twice daily over the patch.

Each patient was followed up every two weeks for a total of 12 weeks, and their response to treatment was assessed both subjectively and objectively. A history of any side effects owing to treatment mode, the appearance of any new patches, a decrease in the size of existing patches, and patient compliance were all recorded at each appointment. Each patient's alopecia grading scale (AGS) was calculated at the first visit (baseline) and again at 12 weeks. Each group's mean AGS at baseline and 12 weeks was then determined. At 12 weeks, the regrowth score (RGS) was calculated. The response in both groups was then compared using the mean AGS and RGS at 12 weeks. A RGS of 3 or higher was considered a better and statistically meaningful response. The Chi-square test was used to analyse the data. A P-value of ≤ 0.05 was considered as statistically significant.

Results

Table 1: Comparison of age group and sex distribution between the two groups

	11-20 years		21-30years		31-40 years		41-50 years		Total
	M	F	M	F	M	F	M	F	
Group A	10	2	4	2	8	2	1	1	30
Group B	6	6	8	2	2	4	1	1	30

In Topical Betamethasone group, 12, 6, 10 and 2 patients were in age group of 11-20yr, 21-30yrs, 31-40 and 41-50 yrs respectively. In Tacrolimus group, 12, 10, 6 and 2 patients were in age group of 11-20yrs, 21-30 yrs, 31-40 and 41-50 yrs respectively.

Table 2: Comparison of mean alopecia grading scores (AGS) in two groups

Group A		Group B	
Baseline	12 weeks	Baseline	12 weeks
13.19	4.23	13.01	10.96

Mean Alopecia Grading Score (AGS) has improved in Group A compared to Group B

Table 4: Regrowth score (RGS) at the end of 12 weeks

RGS	0	1	2	3	4
GROUP A	0	1	5	9	15
GROUP B	12	13	2	2	1

A RGS of 0 and 1 are taken as Poor, 2 is taken as Moderate improvement, 3 is taken as Good and RGS of 4 as Excellent improvement. At the end of 12 weeks, 15 patients in Group A had excellent improvement in RGS, whereas 1 patient in Group B had excellent improvement in RGS

Table 5: Comparative improvement of both the group

	Improved (RGS \geq 3)	Not improved (RGS<3)	Total	P Value (chi-square test)
Gr A	24	6	30	<0.001
Gr B	3	27	30	
TOTAL	27	33	60	

Table 6: Comparison of incidence of side effects between groups

	Group A	Group B
Atrophy	1	-
Folliculitis	1	-
Burning sensation	-	5

Discussion

This was a comparative study that assessed the efficacy of Betamethasone and tacrolimus increasing hair growth among the patients with alopecia areata. In our study, thirty of group A patients were treated by topical betamethasone and thirty of group B patients were treated by topical tacrolimus. It showed that topical Tacrolimus (0.05%) is less effective than topical Betamethasone (0.05%). In our study 85% of patients in the Betamethasone group and 10% of patients in Group Tacrolimus improved respectively.

Tacrolimus is a steroid-free topical immunomodulator that was designed to

treat atopic dermatitis [6]. It is used to treat a variety of dermatological conditions, including alopecia areata [7]. For alopecia areata, intralesional glucocorticoids are considered first-line therapy [8]. However, pain during injections and dermal atrophy are common, transient side effects. In addition, intralesional steroids are time and cost-consuming.

Alopecia areata treatment with topical corticosteroids has yielded encouraging clinical effects, according to some authors [9]. However, most writers believe that monotherapy with topical corticosteroids is ineffective for treating alopecia areata [10].

Our findings imply that Betamethasone valerate, a topical corticosteroid, could be utilised as first-line therapy in alopecia areata. Our findings also suggest that Betamethasone ointment is still a superior option than Tacrolimus ointment for stimulating hair regrowth in patchy alopecia areata. Though various therapy techniques, both local and systemic, have been utilised to induce hair regeneration, each has its own set of problems and efficacies. The high spontaneous remission rate of alopecia areata makes determining the genuine success of a given medication difficult at times [11].

Conclusion

By comparing topical Betamethasone to the new steroid-free immunomodulator topical Tacrolimus, it can be concluded from this study that topical Betamethasone is the most effective and well-tolerated therapy choice for alopecia areata.

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