Original Article

Comparison of Safety and Efficacy of Topical Mometasone 0.1% Ointment, Calcipotriol 0.005% Ointment, and Tacrolimus 0.1% Ointment in Patients with Localized Alopecia Areata: A Triple-Arm Randomized Clinical Study

Farheen Begum, Sasmita Mishra[1], Ajaya K. Jena[1], Maitreyee Panda[1]

Department of DVL, Kalinga Institute of Medical Sciences, [1]Department of DVL, IMS and SUM Hospital, Bhubaneshwar, Odisha, India

Abstract

Background: Alopecia areata (AA) is an autoimmune, T-cell-mediated disorder manifesting as non-scarring alopecia. Treatment consists of corticosteroids, calcineurin inhibitors, prostaglandin analogs, minoxidil, anthralin, vitamin D analogs, and JAK STAT inhibitors. Despite several treatment options, personal opinions regarding the safety and efficacy of a particular treatment are highly variable. This has led the management of AA to be quite challenging. **Aim:** To compare the efficacy and safety between the three molecules, namely mometasone 0.1% ointment, calcipotriol 0.005% ointment, and tacrolimus 0.1% ointment, in localized AA. **Patients and Methods:** Patients were randomized into three groups, and topical medications were dispensed for each group in unlabeled tubes. Lesional photographs, dermoscopic images, Severity of Alopecia Tool (SALT) scoring, hair pull test, and Dermatology Life Quality Index questionnaires were done at the baseline visit and at every follow-up visit at 4 weeks and 8 weeks from the baseline visit. **Results:** At the end of 8 weeks, both mometasone and calcipotriol groups had a significant decrease in their SALT scores (<0.001), but the tacrolimus group did not show any significant change in parameters at the end of the study. **Limitations:** The main drawback is that there was no control group and the vehicle dispensed was ointment formulation, which may have penetration issues. The lack of long-term follow-up is also a limitation of this study. **Conclusion:** Both mometasone and calcipotriol formulations were found to be effective in the treatment of localized stable AA; however, calcipotriol preparation was associated with minimal side effects.

Keywords: *Alopecia areata, calcipotriol, mometasone, tacrolimus*

Introduction

Alopecia areata (AA) is an autoimmune T-cell-mediated disorder manifesting as a form of non-scarring alopecia involving the scalp, body, or both, and is characterized by hair loss without any clinical indications of inflammation. It represents 0.7% of newly diagnosed dermatological cases in India.[1] It accounts for 25% of all patchy hair loss and is one of the most common types of hair loss.[2]

The diagnosis of AA is mostly clinical. Dermoscopy is useful in doubtful cases and shows a characteristic exclamation mark hair, broken hair, tapering hair, yellow and black dots, and short vellus hairs.[3] The patch may be active and progressing if the hair pull test yields six or more hairs from the periphery. White hairs are initially spared, resulting in an abrupt whitening of the hair (canites subita), whereas in persistent cases, the white hair also falls out.

The most essential step in the management of AA is counseling the patients regarding the nature, course, extent of involvement, prognosis of the disease, and the available therapies for the same. Topical therapy for AA is indicated when there is a solitary lesion that has persisted for more than 6 months, or AA affecting less than 15%–20% of the scalp (95–130 cm^2).[4] The topical modalities available along with their expert consensus as described by the Alopecia Areata Consensus of Experts study are corticosteroids (63%), calcineurin inhibitors (60%), prostaglandin analogs (25%), minoxidil (22%), anthralin, vitamin D analogs, JAK-STAT inhibitors (ruxolitinib, tofacitinib), contact

How to cite this article: Begum F, Mishra S, Jena AK, Panda M. Comparison of safety and efficacy of topical mometasone 0.1% ointment, calcipotriol 0.005% ointment, and tacrolimus 0.1% ointment in patients with localized alopecia areata: A triple-arm randomized clinical study. Indian Dermatol Online J 2025;16:248-57.

Received: 07-Dec-2023. **Revised:** 15-Sep-2024. **Accepted:** 13-Oct-2024. **Published:** 27-Feb-2025.

Address for correspondence:
Dr. Maitreyee Panda, IMS and SUM Hospital, Bhubaneshwar, Odisha, India. E-mail: pandamaitreyee@gmail.com

Access this article online

Website: https://journals.lww.com/idoj

DOI: 10.4103/idoj.idoj_913_23

Quick Response Code:

immunotherapy (diphenylcyclopropenone, squaric acid dibutyl ester, dinitrochlorobenzene) (33%), bexarotene, and photochemotherapy.[5-7] Despite limited evidence for the efficacy of these therapeutic agents, intralesional and topical corticosteroids are considered first-line treatment for most patients with patchy AA. Their use is limited due to lesional atrophy, depigmentation, and folliculitis.[8]

Despite a number of treatment options, personal opinions regarding the safety and efficacy of a particular treatment are highly variable. This has made the management of AA quite challenging. There are numerous studies published in the literature comparing two topical modalities in the treatment of AA (a two-arm study). Our study contains three arms, with each arm containing an established topical therapeutic agent used in the management of patchy AA. We anticipate this study to be of great utility in deciding the topical treatment options in localized AA.

Aim and objectives

The primary objective of this study is to compare the efficacy between the three molecules, namely mometasone 0.1% ointment, calcipotriol 0.005% ointment, and tacrolimus 0.1% ointment, as a better treatment modality in localized AA. The secondary objective is to establish the safety of these molecules.

Patients and Methods

This is a triple-arm, double-blinded, randomized controlled trial. An initial sample of 84 was calculated (28 in each arm) using Raosoft software with a confidence level of 95%. After considering losses, the corrected estimate for sample size was found to be 90 (30 in each arm). Institutional ethical committee approval was taken. The Institutional Ethics Committee, IMS & SUM Hospitals Approval number- Ref.no/DRI/IMS.SH/SOA/2021/165 date of approval 31st August 2021. CTRI registration number was CTRI/2022/04/041728. Informed consent was taken from the patients.

All individuals above 18 years of age diagnosed with localized AA (clinically and dermoscopically), that is, less than five patches of size <5 cm on the scalp or beard, visiting the dermatology outpatient department in a tertiary care hospital in eastern India were included in the study. The study was conducted from October 2020 to October 2022, with the total study duration being 8 weeks for each individual patient.

Exclusion criteria were early age of onset of AA, nail changes, duration >1 year, family history of AA, ophiasis, sisaipho, reticular patterns, active infection at the lesion site, any associated autoimmune disease, pregnancy, any prior treatment within a month, or hormonal association.

A detailed history of all the participants in the study was taken. After obtaining informed consent from the participants, the patients were randomized according to a random number generator and allocated to three interventional groups. Group A was given topical mometasone 0.1% ointment, group B was allotted topical calcipotriol 0.005% ointment, and group C was given topical tacrolimus 0.1% ointment. The medications were dispensed in unlabeled tubes to the respective groups to enable the blinding process. The patients were instructed to apply a thin layer (approx. two finger-tip units) of the allotted medication directly over the patches once daily at night. No oral medications were given during the study period.

Lesional photographs, dermoscopic images, Severity of Alopecia Tool (SALT) scoring, hair pull test, and Dermatology Life Quality Index (DLQI) questionnaires were done at the baseline visit and at every follow-up visit, which was at 4 weeks and at 8 weeks from the baseline visit. Patients were also monitored for any side effects within the study duration.

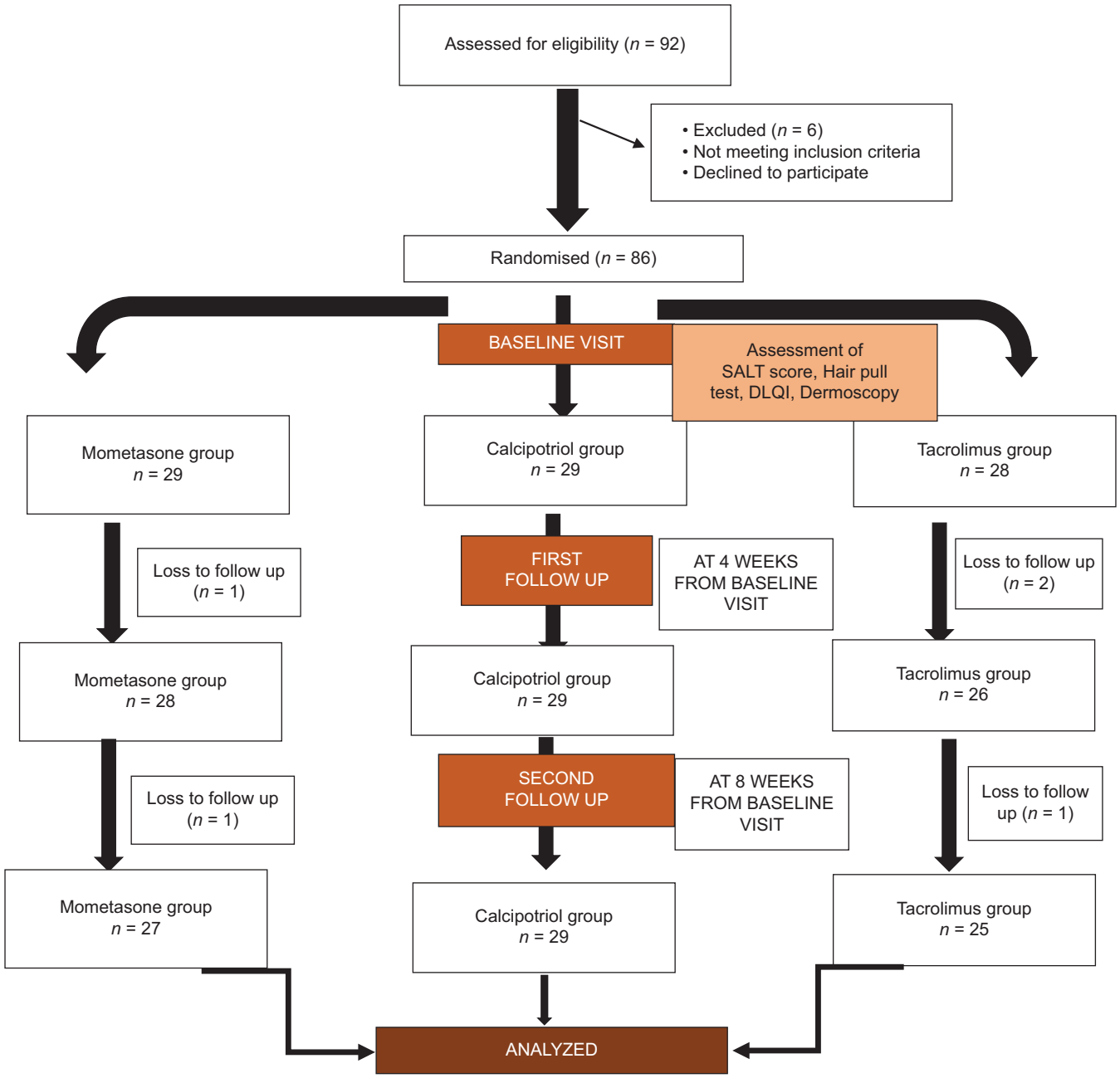
Statistical analysis was performed using the statistical analysis software IBM SPSS version 25.0. All continuous variables were expressed as mean ± SD and median (interquartile range), and categorical variables as frequency and percentage. One-way ANOVA test was used for variables that satisfied the normality test to find out the association of all quantitative variables among the three groups. The Kruskal-Wallis test was used to compare the variables that did not satisfy the normality test. The Chi-square test was used to find out the association between categorical variables. P value < 0.05 was set for the statistical significance.

Flow of the participants in the study is presented in Flowchart 1.

Results

This study comprised a total of 86 patients, the average age (in years) of the three groups being 31.62 ± 9.38, 31.00 ± 8.19, and 32.18 ± 9.80, respectively. All the demographic and baseline characteristics in the patients of the three groups were comparable [Tables 1 and 2]. The SALT score at baseline was found to be slightly higher in the mometasone group (6.16), followed by the calcipotriol (5.88) and tacrolimus (5.55) groups.

In the mometasone arm [Table 3], there was a decrease in SALT score in the follow-up visits as compared to baseline (6.16), which was found to be statistically significant with P values being 0.017, < 0.001, and < 0.001 for baseline vs. first follow-up, baseline vs. second follow-up, and first vs. second follow-up, respectively. Hair regrowth was seen in about 58.6% of patients at the first follow-up visit, which in the second follow-up increased to 96.3%. This finding was observed to be statistically significant (P = 0.001). The DLQI showed no marked decrease at the first follow-up visit, but in the second follow-up, there was a significant improvement, with P values being < 0.001 and < 0.001 for



Flowchart 1: Flowchart showing the participant flow for the study

baseline vs. second follow-up and first vs. second follow-up, respectively [Figures 1 and 2].

In the subgroup analysis of the calcipotriol group [Table 4], improvement in all parameters was observed in the first follow-up itself, and it was also found to be statistically significant. The average SALT score was also found to have a significant difference from baseline to the first follow-up visit (<0.001) and from the first follow-up to the second follow-up visit (<0.001). Almost all the patients were observed to have hair regrowth by the second follow-up visit. Similarly, DLQI also showed a statistically significant difference in the first follow-up (P = 0.001) and second follow-up visit (P < 0.001) when compared to the baseline visit [Figures 3 and 4].

In the tacrolimus arm [Table 5], there was no statistically significant decrease in the parameters such as the number of patches, SALT score (P = 0.419), hair regrowth, and DLQI [Figures 5 and 6].

Minor side effects such as itching (7.4%), hypopigmentation (14.8%), and folliculitis (7.4%) were seen in the mometasone group [Table 6], whereas in the tacrolimus group, erythema, itching, and burning sensation were observed. In the calcipotriol group, 26 (89.7%) patients did not report any side effects, which

Table 1: Demographic characteristics

		Mometasone	Calcipotriol	Tacrolimus	*P*
Age in completed years		31.62±9.38	31.00±8.19	32.18±9.80	0.888
Gender	Male	14 (48.3%)	16 (55.2%)	19 (67.9%)	0.319
	Female	15 (51.7%)	13 (44.8%)	9 (32.1%)	
No of patches	1	12 (41.4%)	7 (24.1%)	12 (42.9%)	0.604
	2	9 (31.0%)	15 (51.7%)	11 (39.3%)	
	3	7 (24.1%)	5 (17.2%)	4 (14.3%)	
	4	1 (3.4%)	2 (6.9%)	1 (3.6%)	
Duration of the patch (in days)		66.72±35.99	58.34±34.19	66.61±40.71	0.617
Location of patches	Frontal area	9 (31.0%)	4 (13.8%)	6 (21.4%)	0.349
	Temporal area	7 (24.1%)	10 (34.5%)	9 (32.1%)	
	Occipital area	2 (6.9%)	6 (20.7%)	8 (28.6%)	
	Frontal and temporal area	2 (6.9%)	3 (10.3%)	3 (10.7%)	
	Frontal and occipital area	6 (20.7%)	3 (10.3%)	0 (0.0%)	
	Temporal and occipital area	2 (6.9%)	1 (3.4%)	1 (3.6%)	
	Frontal, temporal, and occipital area	1 (3.4%)	2 (6.9%)	1 (3.6%)	
H/o similar patch	Yes	4 (13.8%)	8 (27.6%)	8 (28.6%)	0.332
	No	25 (86.2%)	21 (72.4%)	20 (71.4%)	

Table 2: Baseline characteristics

		Mometasone	Calcipotriol	Tacrolimus	*P*
SALT Score		6.16±3.26	5.88±3.22	5.55±3.45	0.784
Hair pull test	Positive	8 (27.6%)	8 (27.6%)	7 (25.0%)	0.968
	Negative	21 (72.4%)	21 (72.4%)	21 (75.0%)	
Dermoscopic findings	Black dots	4 (13.8%)	2 (13.8%)	7 (25.0%)	0.486
	Yellow dots	5 (17.2%)	7 (17.2%)	6 (21.4%)	
	Broken hairs	1 (3.4%)	3 (3.4%)	0 (0.0%)	
	Exclamation hairs	2 (6.9%)	2 (6.9%)	1 (3.6%)	
	Black and yellow dots	8 (27.6%)	5 (27.6%)	10 (35.7%)	
	Black dots and broken hairs	3 (10.3%)	5 (10.3%)	3 (10.7%)	
	Black dots and exclamation hairs	1 (3.4%)	2 (3.4%)	0 (0.0%)	
	Yellow dots and broken hairs	4 (13.8%)	1 (13.8%)	1 (3.6%)	
	Yellow dots and exclamation hairs	0 (0.0%)	1 (0.0%)	0 (0.0%)	
	Exclamation and broken hairs	1 (3.4%)	1 (3.4%)	0 (0.0%)	
DLQI	1	0 (0.0%)	2 (0.0%)	1 (3.6%)	0.180
	2	12 (41.4%)	8 (41.4%)	16 (57.1%)	
	3	7 (24.1%)	11 (24.1%)	6 (21.4%)	
	4	8 (27.6%)	5 (27.6%)	1 (3.6%)	
	5	1 (3.4%)	3 (3.4%)	3 (10.7%)	
	6	1 (3.4%)	0 (3.4%)	1 (3.6%)	

SALT score - Severity of Alopecia Tool score; DLQI - Dermatology Life Quality Index

was significantly higher than the mometasone (70.3%) and tacrolimus (88.0%) groups. Thus, the calcipotriol group had the least side effects as compared to the other two arms, which was found to be statistically significant (P = 0.048).

When compared between groups [Table 7], the mean SALT score had a significant decline in all three arms, but when mometasone and calcipotriol groups were compared, there was no statistically significant difference in their mean SALT score (P = 0.63). The mean DLQI score showed statistically significant improvement in the calcipotriol and mometasone groups when compared to the tacrolimus arm, their P values being <0.001 and 0.003, respectively. However, when the mean DLQI was compared between the mometasone and calcipotriol groups, the P value was found to be 0.177, which was not significant.

Discussion

AA has been said to be a T-cell-mediated autoimmune, social, and psychologically challenging disease that affects an individual's quality of daily life. It has been stated that AA preferentially develops before 30 years of age, which may be due to a predilection for dark hair.[9] We observed that age group of the majority of patients in this study were within

Table 3: Changes in different visits among the mometasone group of patients

		Baseline visit	First Follow–up	Second follow-up	Baseline vs. First follow-up	Baseline vs. Second follow-up	First vs. Second follow-up
Number of patches	1	12 (41.4%)	11 (37.9%)	10 (37.0%)	0.326	0.327	0.327
	2	9 (31.0%)	10 (34.5%)	10 (37.0%)			
	3	7 (24.1%)	6 (24.1%)	6 (22.2%)			
	4	1 (3.4%)	1 (3.4%)	1 (3.7%)			
SALT score		6.16±3.26	5.92±3.12	5.05±2.88	0.017	<0.001	<0.001
Hair regrowth	Seen		17 (58.6%)	26 (96.3%)	***	***	0.001
	Not seen		11 (41.4%)	1 (3.7%)			
Hair pull test	Positive	8 (27.6%)	5 (17.2%)	0 (0.0%)	0.264	0.003	0.083
	Negative	21 (72.4%)	23 (82.2%)	27 (100.0%)			
DLQI	1	0 (0.0%)	0 (0.0%)	3 (11.1%)	0.065	<0.001	<0.001
	2	12 (41.4%)	10 (34.5%)	11 (40.7%)			
	3	7 (24.1%)	8 (27.6%)	9 (33.3%)			
	4	8 (27.6%)	8 (31.0%)	3 (11.1%)			
	5	1 (3.4%)	1 (3.4%)	1 (3.7%)			
	6	1 (3.4%)	1 (3.4%)	0 (0.0%)			

***Could not be computed statistically

Table 4: Changes at different visits among the calcipotriol group of patients

		Baseline visit	First follow-up visit	Second follow-up visit	Baseline vs. First follow-up visit	Baseline vs. Second follow-up visit	First vs. Second follow-up visit
Number of patches	1	7 (24.1%)	7 (24.1%)	8 (27.6%)	<0.001	<0.001	<0.001
	2	15 (51.7%)	15 (51.7%)	14 (48.3%)			
	3	5 (17.2%)	5 (17.2%)	7 (24.1%)			
	4	2 (6.9%)	2 (6.9%)	0 (0.0%)			
SALT score		5.88±3.22	5.16±3.03	4.32±2.86	<0.001	<0.001	<0.001
Hair regrowth	Seen		27 (93.1%)	29 (100.0%)	***	***	***
	Not seen		2 (6.9%)	0 (0.0%)			
Hair pull test	Positive	8 (27.6%)	0 (0.0%)	0 (0.0%)	0.003	0.003	***
	Negative	21 (72.4%)	29 (100.0%)	29 (100.0%)			
DLQI	1	2 (0.0%)	3 (10.3%)	12 (41.4%)	0.001	<0.001	<0.001
	2	8 (41.4%)	12 (41.4%)	11 (37.9%)			
	3	11 (24.1%)	9 (31.0%)	5 (17.2%)			
	4	5 (27.6%)	2 (6.9%)	1 (3.4%)			
	5	3 (3.4%)	3 (10.3%)	0 (0.0%)			
	6	0 (3.4%)	0 (0.0%)	0 (0.0%)			

***Could not be computed statistically

or below 30 years of age. This finding was consistent with studies conducted by Sharma *et al*.[1] and Kuldeep *et al*.[10]

We also observed a slight male preponderance in this study (1.3). Similar findings were reported in a study by Kuldeep *et al*., who attributed this majority to biological predisposition,[10] improved health consciousness and access to medical services, and the prevalence of stressful situations among men.[10,11] A comparable depiction in this study supports previous reports that the onset of AA is gradual and mostly affects the temporal region of the scalp.[1]

In this study, we found that mometasone furoate 0.1% showed a statistically significant decrease in SALT scores and DLQI in subsequent visits. Similar results were also reported by Zaher *et al*.[12] in their study on patients with AA with topical mometasone, in which they found a decrease of 2.30 in mean SALT score over a period of 12 weeks. Unal *et al*.[13] also found a similar response with mometasone in AA.

We noticed that in the calcipotriol group, there was a statistically significant decrease in SALT scores, DLQI, and number of patches at the end of 8 weeks ($P < 0.001$), suggesting that calcipotriol is highly efficacious in the treatment of limited AA. This finding supports a retrospective study by Çerman *et al*.,[14] which was done to test the effectiveness and safety of topical calcipotriol cream. Here, a total response was achieved in 69.2% of patients after 12 weeks, and at the end of the trial, the overall SALT score was considerably lower ($P = 0.001$).

This study also observed that the number of patches decreased significantly in the calcipotriol group

Table 5: Changes at different visits among the tacrolimus group of patients

		Baseline visit	First follow-up visit	Second follow-up visit	Baseline vs. First follow-up visit	Baseline vs. Second follow-up visit	First vs. Second follow-up visit
Number of patches	1	12 (42.9%)	10 (42.9%)	10 (40.0%)	0.161	0.083	0.161
	2	11 (39.3%)	10 (35.7%)	10 (40.0%)			
	3	4 (14.3%)	5 (17.9%)	4 (16.0%)			
	4	1 (3.6%)	1 (3.6%)	1 (4.0%)			
SALT score		5.55±3.45	5.57±3.58	5.23±3.36	0.791	0.710	0.419
Hair regrowth	Seen		4 (17.9%)	12 (48.0%)	***	***	0.07
	Not seen		22 (82.1%)	13 (52.0%)			
Hair pull test	Positive	7 (25.0%)	6 (25.0%)	4 (16.0%)	1.000	1.000	0.664
	Negative	21 (75.0%)	20 (75.0%)	21 (84.0%)			
DLQI	1	1 (3.6%)	1 (3.6%)	2 (8.0%)	0.573	0.538	0.491
	2	16 (57.1%)	14 (53.6%)	10 (40.0%)			
	3	6 (21.4%)	6 (25.0%)	9 (36.0%)			
	4	1 (3.6%)	1 (3.6%)	1 (4.0%)			
	5	3 (10.7%)	3 (10.7%)	2 (8.0%)			
	6	1 (3.6%)	1 (3.6%)	1 (4.0%)			

***Could not be computed statistically

Table 6: Changes in side effects among all groups

	Side effects	Molecule given			*P*
		Mometasone	Calcipotrol	tacrolimus	
First Visit	Burning sensation	0	0	2	0.202
		0.0%	0.0%	7.6%	
	Burning sensation, itching	0	0	1	
		0.0%	0.0%	3.8%	
	Erythema, itching	0	0	1	
		0.0%	0.0%	3.8%	
	Itching	0	0	1	
		0.0%	0.0%	3.8%	
	None	28	29	21	
		100.0%	100.0%	80.7%	
Second visit	Burning sensation	0	0	2	0.048
		0.0%	0.0%	8.0%	
	Burning sensation, itching	0	1	1	
		0.0%	3.4%	4.0%	
	Erythema, scaling	0	1	0	
		0.0%	3.4%	0.0%	
	Folliculitis	2	0	0	
		7.4%	0.0%	0.0%	
	Hypopigmentation	2	0	0	
		7.4%	0.0%	0.0%	
	Hypopigmentation seen over 1 patch	2	0	0	
		7.4%	0.0%	0.0%	
	Itching	2	0	0	
		7.4%	0.0%	0.0%	
	Itching, erythema	0	1	0	
		0.0%	3.4%	0.0%	
	None	19	26	22	
		70.3%	89.7%	88.0%	

($P < 0.001$) as compared to the mometasone group. The mean SALT score when compared between the mometasone arm and calcipotriol group was not found to be statistically significant. Similar findings were reported by Molinelli *et al*.[15] While comparing calcipotriol 0.005% ointment and clobetasol 0.05% formulation in an intra-subject pilot trial; they concluded that both formulations were efficient and reliable in treating AA

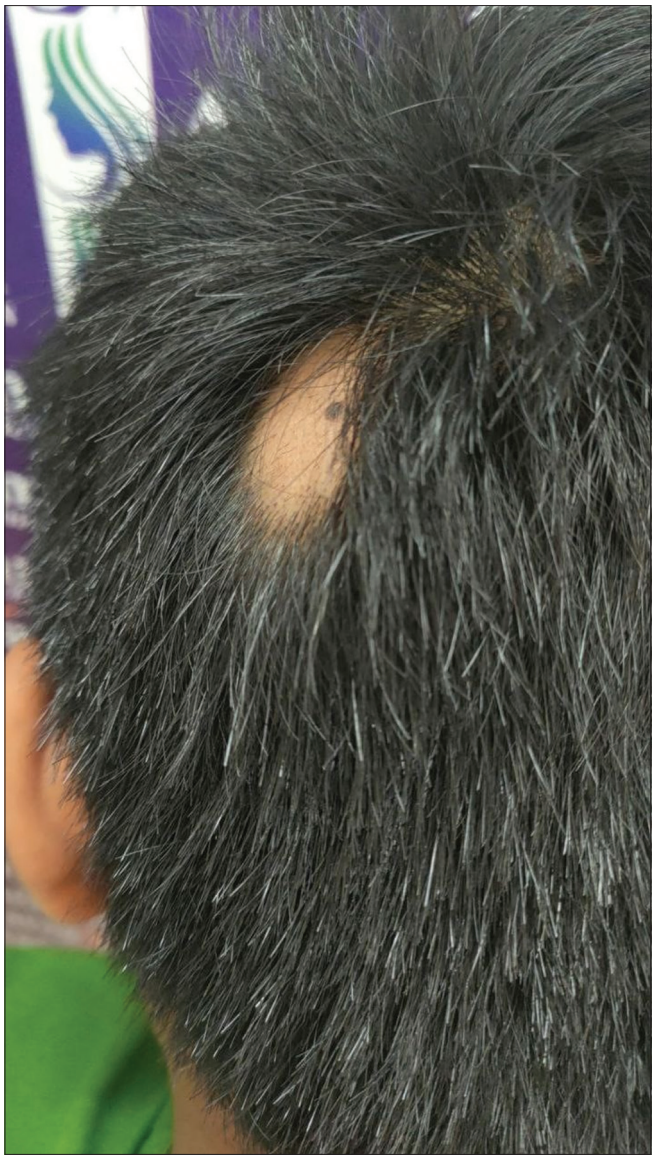


Figure 1: Baseline visit: A single patch measuring 3 × 3 cm

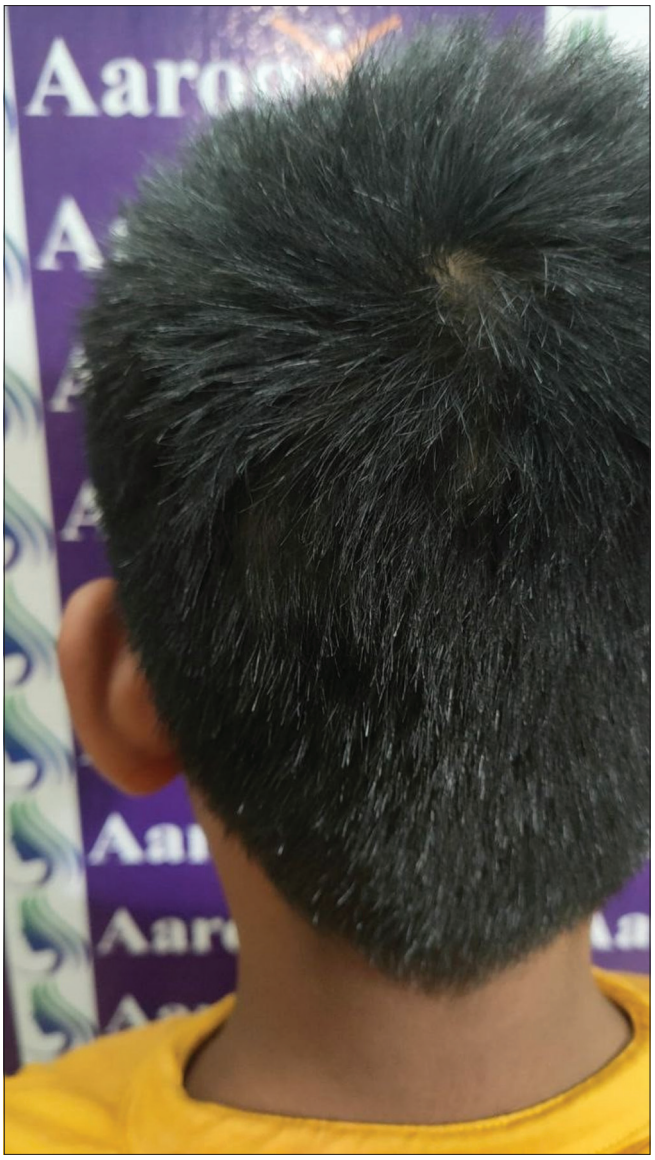


Figure 2: Second follow-up: Hair regrowth present after mometasone therapy for 8 weeks

with no significant variation. Narang *et al*.[16] conducted a pilot study to observe the efficacy and safety of topical calcipotriol in the treatment of AA and observed a high response rate of 59.1%.

We observed that topical tacrolimus managed to cause hair regrowth in about 48% of the patients by the second follow-up visit. However, altogether, it did not have any remarkable change in the SALT scores, number of AA patches, or DLQI. These findings correspond to a study by Price *et al*.,[17] which observed the efficacy of tacrolimus in the treatment of AA. Here, 17 patients with AA were treated with topical tacrolimus twice daily for 24 weeks. At the conclusion of the research, the patients either showed no change in hair growth or further hair loss. Only one patient in the study showed terminal hair growth, which could be speculated as a probable spontaneous phenomenon.

In another study**,** Kuldeep *et al*.[10] examined the effects of tacrolimus cream, intralesional triamcinolone acetonide, and topical betamethasone valerate foam on hair growth in localized AA. They noted that tacrolimus showed a very poor response as compared to the other two groups ($P < 0.001$). Topical tacrolimus's inability to promote hair growth in AA may be due to the existing ointment formulation's insufficient depth of penetration. Patients with extensive peribulbar T-cell infiltrates and active, progressing patchy AA may respond more favorably to topical tacrolimus, a medication that suppresses the cytokines that cause the disease, than patients with stable, persistent patchy AA.[17]

In the mometasone arm, patients experienced side effects in the form of itching, folliculitis, and hypopigmentation on the lesion, but adverse effects such as skin atrophy

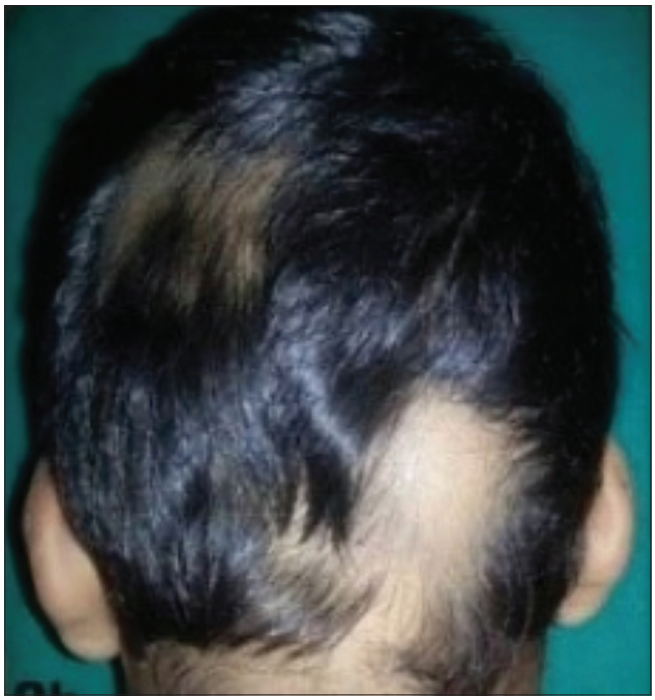


Figure 3: Baseline visit: A patch measuring 4 cm × 3 cm present on the occipital region

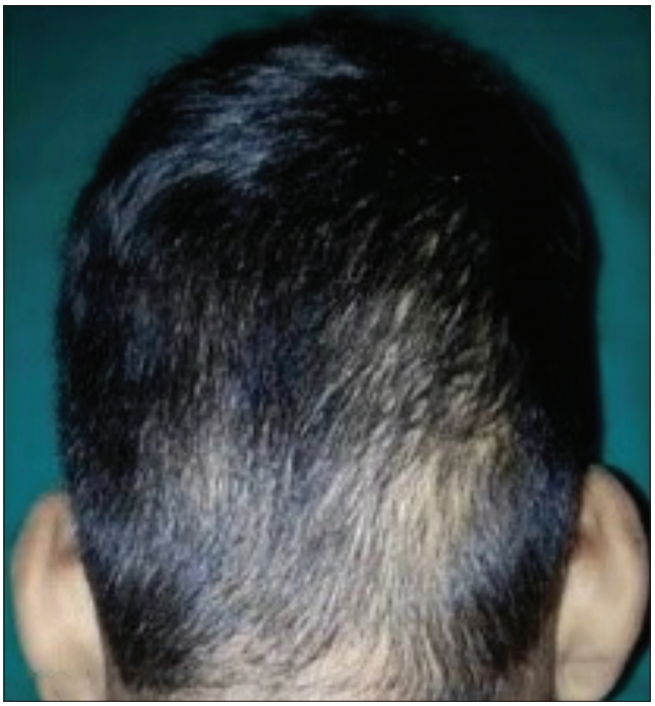


Figure 4: A patch on the occipital region treated with calcipotriol showed hair regrowth after 8 weeks

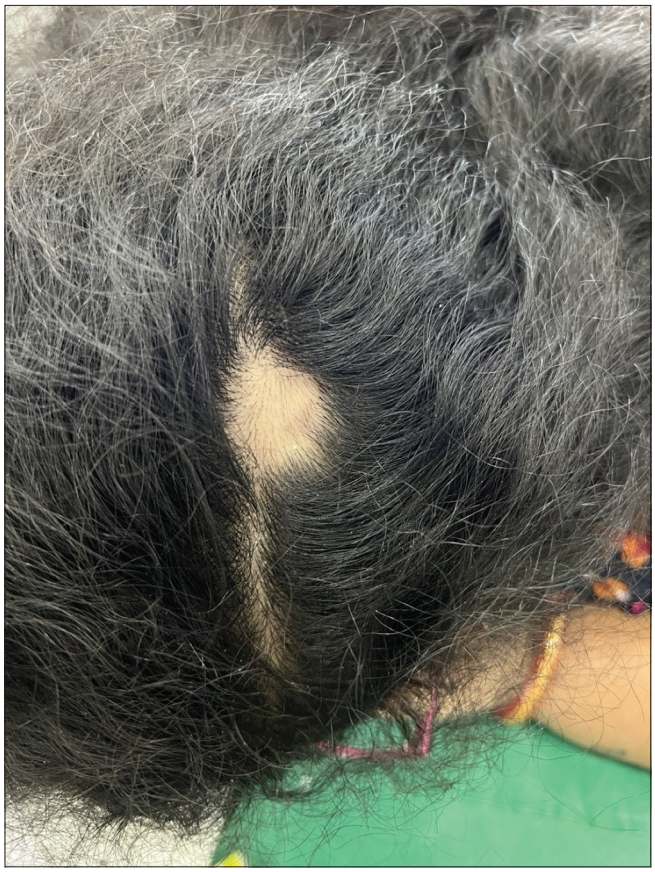


Figure 5: Baseline visit- a patch of 3x2cm present on the vertex region

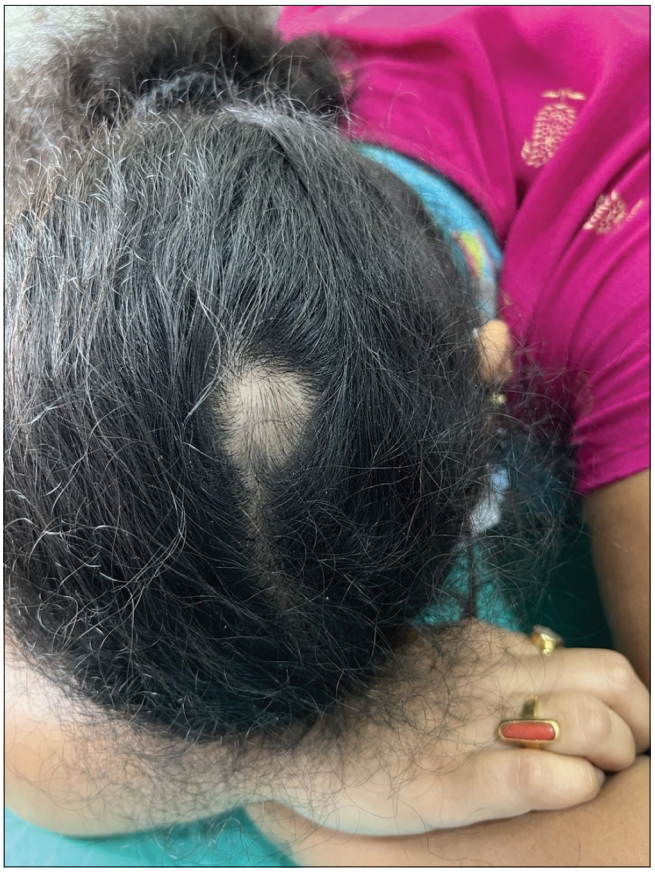


Figure 6: Second follow-up: Partial hair regrowth seen with tacrolimus

or telangiectasias were not reported. In the Australian expert consensus statement for the management of AA by Cranwell *et al*.,[4] corticosteroids are widely used in the treatment of patchy alopecia, but are frequently associated

Table 7: Intergroup comparison (A and B)

Variables	Mometasone			Calcipotrol			Tacrolimus			*P*
	Median	IQR		Median	IQR		Median	IQR		
Salt Score_1st visit	5.40	3.90	8.80	4.80	3.80	7.20	4.80	2.93	8.00	0.63
DLQI_1st Visit	3.00	2.00	4.00	3.00	2.00	4.00	2.00	2.00	3.00	0.28
Salt Score_2nd visit	5.40	3.60	8.54	4.50	3.22	6.55	4.44	2.88	8.00	0.41
DLQI_2nd Visit	3.00	2.00	4.00	2.00	2.00	3.00	2.00	2.00	3.00	0.00

			Molecule given			*P*
			Momatasone	Calcipotrol	Tacrolimus	
DLQI_3rd visit	1	Count	3	12	2	0.070
		% within molecule given	11.1%	41.4%	8.0%	
	2	Count	11	11	10	
		% within molecule given	40.7%	37.9%	40.0%	
	3	Count	9	5	9	
		% within molecule given	33.3%	17.2%	36.0%	
	4	Count	3	1	1	
		% within molecule given	11.1%	3.4%	4.0%	
	5	Count	1	0	2	
		% within molecule given	3.7%	0.0%	8.0%	
	6	Count	0	0	1	
		% within molecule given	0.0%	0.0%	4.0%	

with undesirable side effects, such as telangiectasia, skin atrophy, and acneiform eruptions. Side effects in the calcipotriol group were in the form of erythema, burning sensation, and itching (10.2%). Similar observations were made by Narang *et al*.,[16] where 31.8% of patients applying calcipotriol experienced side effects such as itchiness, scaling, erythema, pruritus, pigmentation, and folliculitis. The patients in the tacrolimus group developed burning sensation, erythema, and itching (30%). Similar findings were seen by Price *et al*.,[17] where they observed mild-to-moderate scalp itching, mild transient stinging, and burning.

We observed that there was a remarkable decrease in the SALT score in the arms receiving mometasone and calcipotriol, but patients in the mometasone group faced more side effects, which was statistically significant ($P < 0.013$). This corresponds to a study by Alam *et al*.,[18] where the effectiveness of topical mometasone with calcipotriol was compared with mometasone alone in the management of AA. They found a statistically significant decrease in the mean SALT score ($P < 0.001$) at 24 weeks in the patients receiving the combination treatment. They concluded that the treatment of AA is more effective when topical calcipotriol 0.005% ointment is combined with topical mometasone 0.1% cream as they work synergistically. Moreover, calcipotriol may reduce the total cumulative dose of steroid required.

Limitations

The main limitations of this study are that there was no control group and the vehicle dispensed was ointment formulation, which may have penetration issues. Moreover, there was a lack of long-term evaluation. We did not follow up with the patients after the study completion to check for any relapse of AA patches. Therefore, additional research using large cohorts, carefully chosen patients, and a clinically significant outcome such as long-term overall regrowth is required to support these findings.

Conclusion

Our study highlights that both mometasone and calcipotriol formulations are effective in the treatment of localized stable AA. However, we found that calcipotriol preparation was associated with minimal side effects, which were mostly reversible as compared to the other interventional arms. Calcipotriol showed early and persistent hair regrowth in patchy AA and can be considered a safe and effective topical modality. Topical tacrolimus did not have any marked effect over the AA patches in our study; thus, it should not be preferred as a first-line treatment over the above two formulations.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. Sharma VK, Dawn G, Kumar B. Profile of alopecia areata in Northern India. Int J Dermatol 1996;35:22-7.
2. McMichael AJ, Pearce DJ, Wasserman D, Camacho FT, Fleischer AB Jr, Feldman SR, *et al*. Alopecia in the United States: Outpatient utilization and common prescribing patterns. J Am Acad Dermatol 2007;57:S49-51.
3. Tosti A, Whiting D, Iorizzo M, Pazzaglia M, Misciali C,

Vincenzi C, *et al*. The role of scalp dermoscopy in the diagnosis of alopecia areata incognita. J Am Acad Dermatol 2008;59:64-7.

4. Cranwell WC, Lai VW, Photiou L, Meah N, Wall D, Rathnayake D, *et al*. Treatment of alopecia areata: An Australian expert consensus statement. Australas J Dermatol 2019;60:163-70.
5. Meah N, Wall D, York K, Bhoyrul B, Bokhari L, Sigall DA, *et al*. The Alopecia Areata Consensus of Experts (ACE) study: Results of an international expert opinion on treatments for alopecia areata. J Am Acad Dermatol 2020;83:123-30.
6. Yan D, Fan H, Chen M, Xia L, Wang S, Dong W, *et al*. The efficacy and safety of JAK inhibitors for alopecia areata: A systematic review and meta-analysis of prospective studies. Front Pharmacol 2022;13:950450.
7. Rajiv M, Singh N. Bexarotene gel: A new topical therapy for alopecia areata. Int J Trichology 2010;2:66-7.
8. Lepe K, Zito PM. Alopecia areata. In: StatPearls. Treasure Island (FL): StatPearls Publishing; 2022.
9. Burns T, Neilcox SB, Griffith C, editors. Rook's Text Book of Dermatology. 7th ed. Massachusetts: Blackwell Publishers; 2004. p. 63.36-46.
10. Kuldeep CM, Singhal H, Khare AK, Mittal A, Gupta LK, Garg A. Randomized comparison of topical betamethasone valerate foam, intralesional triamcinolone acetonide and tacrolimus ointment in management of localized alopecia areata. Int J Trichol 2011;3:20-4.
11. Van der Steen P, Troupe H, Happle R, Boenzeman J, Strater R, Hamm H. The genetic risk for alopecia areata in first degree relatives of severely affected patients. An estimate. Acta Derm Venereol 1992;72:373-5.
12. Zaher H, Gawdat HI, Hegazy RA, Hassan M. Bimatoprost versus mometasone furoate in the treatment of scalp alopecia areata: A pilot study. Dermatology 2015;230:308–13.
13. Unal M. Use of adapalene in alopecia areata: Efficacy and safety of mometasone furoate 0.1% cream versus combination of mometasone furoate 0.1% cream and adapalene 0.1% gel in alopecia areata. Dermatol Ther 2018;31:e12574.
14. Çerman AA, Solak SS, Altunay İ, Küçükünal NA. Topical calcipotriol therapy for mild-to-moderate alopecia areata: A retrospective study. J Drugs Dermatol 2015;14:616-20.
15. Molinelli E, Campanati A, Brisigotti V, Sapigni C, Paolinelli M, Offidani A. Efficacy and safety of topical calcipotriol 0.005% versus topical clobetasol 0.05% in the management of alopecia areata: An intrasubject pilot study. Dermatol Ther (Heidelb) 2020;10:515-21.
16. Narang T, Daroach M, Kumaran MS. Efficacy and safety of topical calcipotriol in management of alopecia areata: A pilot study. Dermatol Ther 2017;30:e12464.
17. Price VH, Willey A, Chen BK. Topical tacrolimus in alopecia areata. J Am Acad Dermatol 2005;52:138-9.
18. Alam M, Amin SS, Adil M, Arif T, Zahra FT, Varshney I. Comparative study of efficacy of topical mometasone with calcipotriol versus mometasone alone in the treatment of alopecia areata. Int J Trichology 2019;11:123-7.