

## A CLINICAL STUDY OF ALOPECIA AREATA AND TO EVALUATE OF THE EFFICACY OF 0.03% TOPICAL TACROLIMUS IN ITS TREATMENT

Srinivas M<sup>1</sup>, Ramesh Bhat M<sup>2</sup>, Nanda Kishore B<sup>3</sup>, Sukumar<sup>4</sup>, Narendra J. Shetty<sup>5</sup>, Jacintha Martis<sup>6</sup>, Ganesh Kamath<sup>7</sup>

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**ABSTRACT: BACKGROUND AND OBJECTIVES:** Alopecia Areata refers to a common usually reversible condition in which patchy loss of hair occurs characterized by presence of mononuclear cell infiltrates developing in and around anagen hair follicles and causing circumscribed hair loss. Alopecia Areata has an auto immune pathogenesis mediated by helper T-cells. Since tacrolimus suppresses helper T-cell activity its effect on alopecia areata was studied. **METHODS:** The study was conducted in the dermatology OPD department in Fr. Muller Medical College Hospital, Mangalore. A total of 50 cases of alopecia areata were taken up for the study. The period of study was from October 2004 – April 2006, the study included 33 males and 17 females. An informed consent was obtained from all the patients. Hair root examination, VDRL, haemogram, Liver Function Test (LFT), Renal Function Test (RFT) and other relevant investigations were done. Focal sepsis was ruled out in all patients. Tacrolimus 0.03% cream was applied once daily and reviewed once in two weeks for twelve weeks. Qualitative data wise score analysis was done by using Friedman's test, Mean, Standard Deviation, Chi-Square test and 'p' value (test of significant) was noted. Response was graded as failure, poor, good and excellent objectively. **RESULTS:** 6 (12%) patients with scalp involvement had poor response. 20 (40%) patients of alopecia areata on scalp, 5 (10%) patients on face and 2 (4%) patients each on eyebrow and moustache showed good response. 2 (4%) patients with ophiasis pattern also showed good response. 8 (16%) with scalp and 5 (10%) on face had excellent response. None of the patients had any cutaneous or systemic side effects to 0.03% tacrolimus cream during the study period. **INTERPRETATION AND CONCLUSION:** 10 (20%) patients had associated personal history of atopy and 8 (16%) patients showed exclamation mark hair. 6 (12%) patients who poorly responded to 0.03% tacrolimus cream had nail pitting. Topical tacrolimus is effective and could be the other modality in treating alopecia areata, however higher strength (0.1%) may give a better result. Being non-irritant topical therapy it could be a treatment modality of choice in children. Absence of cutaneous side effects makes it suitable for use on the face.

**KEYWORDS:** Alopecia Areata, auto immunity, tacrolimus.

**INTRODUCTION:** Alopecia Areata refers to a common usually reversible condition representing approximately 2% of the dermatological practice in which patchy loss of hair occurs without any atrophy.<sup>1</sup>

It is characterized by presence of mononuclear cell infiltrates developing in and around anagen hair follicles and causing circumscribed hair loss.<sup>2</sup> Diagnosis is correlated by typical histopathology– peribulbar lymphocytic infiltrate in a 'Swarm of bees' pattern. In long standing cases presence of eosinophils in fibrous tracts and in peribulbar area are helpful diagnostic clues.<sup>3</sup>

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Alopecia Areata is categorized into four types by taking into account the other clinical features in addition to alopecia areata itself.<sup>4</sup>

Type I (common type) accounts for 81% of patients.

Type II (atopic type) accounts for 10% of patients.

Type III (pre-hypertensive type) accounting for 4% of patients.

Type IV (autoimmune type) accounting for 5% of patients.

Currently various treatment options are available which include minoxidil, topical irritants like anthralin, phenol, contact sensitizers like dinitrochlorobenzene

(DNCB), Squaric Acid Dibutyl Ester (SADBE), diphenylprone (DPCP), Psoralen Ultra Violet A (PUVA) therapy, intra-lesional and topical corticosteroids and combination regimens. However topical irritants and sensitizers can cause allergic reaction and corticosteroid treatment may lead to adverse effects such as skin atrophy.<sup>5</sup>

So there is a need for a topical non-steroidal and non-irritant agent which can be effective in the treatment of alopecia areata, thereby overcoming the side effects of other modalities of therapy like allergic reactions or atrophy of skin etc.

Tacrolimus acts by inhibiting T-cell activation by interfering with production of Interleukin-2 (IL-2). It has got great potential in the treatment of inflammatory skin diseases like atopic dermatitis, psoriasis, pyoderma gangrenosum, lichen planus, contact dermatitis, leg ulcers in rheumatoid arthritis, steroid induced rosacea.<sup>6</sup>

Tacrolimus acts by directly stimulating hair follicles when used topically<sup>7</sup> and it has been observed that topical tacrolimus induces anagen phase of hair growth.<sup>8</sup>

### **MATERIALS AND METHODS:**

**Source of Data:** The study was conducted in the dermatology OPD at Fr. Muller Medical College Hospital, Mangalore during Oct 2004 - April 2006.

**Method of Collection of Data:** After obtaining approval and clearance from the institutional ethical committee, written or informed consent and data was collected from 50 cases of alopecia areata was selected by purposive sampling with the help of a proforma.

Complete physical examination was done and number, size, site and extent of alopecia areata were recorded.

**During their first visit, detailed history was taken with special references to:**

1. Duration of onset
2. Precipitating factors like emotional stress, injury, etc.
3. Personal or family history of associated endocrine, atopy or autoimmune condition.

Base line investigations were done in the form of haemogram, hair root examination, VDRL, LFT, RFT and urine analysis.

### **Inclusion Criteria:**

- Absence of focal sepsis or any other inflammatory conditions over the affected site.
- Patient willing for the required investigations, treatment and follow up.
- All 4 types of alopecia areata described under Ikeda classification.
- Single or multiple patches measuring less than 6x6 cms involving one or more sites.
- More than 2 years of age.

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### Exclusion Criteria:

- Alopecia Totalis and Alopecia Universalis.
- Patients treated with corticosteroids or immune-suppressants in the past 3 months.
- Patients on anti-cancer drugs.
- Pregnancy and lactation

Patients were advised to apply Tacrolimus 0.03% cream once daily and were asked to follow up once in every 2 weeks for 12 weeks.

**Statistical Methods:** On each follow up the clinical response was assessed by texture and density of hair as follows.

Texture	Score
Fine vellus hair	1
Normal coarse hair	2

**Table 1: Scoring of Texture of re-growing Hair**

Area of patch covered with hair	Score
No hair growth	0
1-25%	1
26-50%	2
51-75%	3
76- 100%	4

**Table 2: Scoring for density of hair re-growth**

Scoring of response	Score
Treatment failure	0
Poor	1-3
Good	4-5
Excellent	6

**Table 3: Scoring of overall response (1+2) at end of the study**

Qualitative data wise score analysis was done by using “Friedman’s test” and significance was noted.

**Formula:**

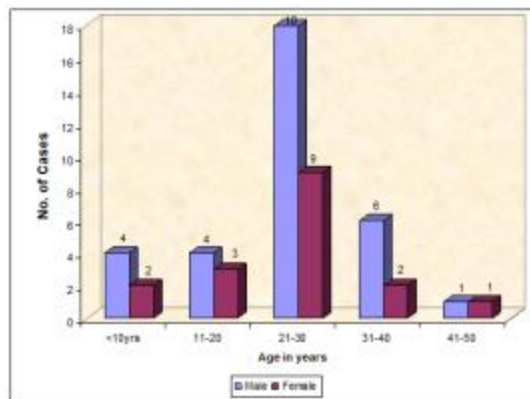
$$S = \frac{12}{NK(K+1)} \left[ R_1^2 + R_2^2 + R_3^2 + R_4^2 \right] - 3N(K+1)$$

K = No of groups

N = Total Sample size

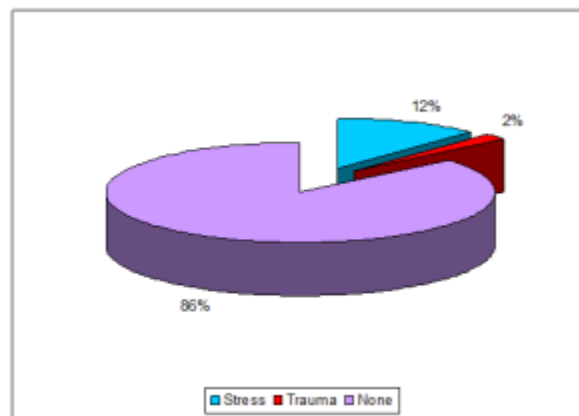
$R_1, R_2$  are the ranks of each groups

**RESULTS:** 50 cases of alopecia areata were studied among those attending the dermatology OPD at Fr. Muller Medical College Hospital, Mangalore during Oct 2004- Apr 2006.



**Figure 1: Showing Age and Sex Incidence**

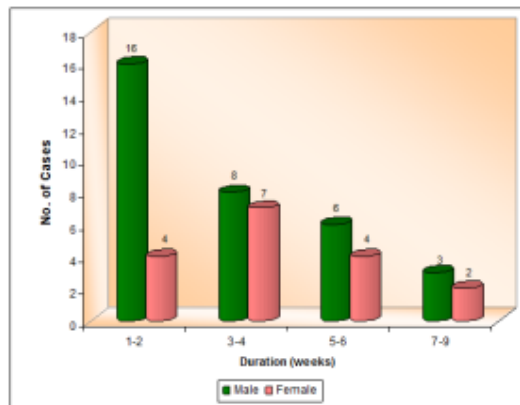
It is evident from the above figure that out of 50 patients 33(66%) were males and 17(34%) were females, majority of the patients (54%) were in the age of group 21-30years. It is also observed from the above figure that 40 (80%) out of 50 patients were less than 30 years of age. The youngest patient was a 6 years old boy and the eldest was a 48 years old woman.



**Figure 2: Showing Precipitating Factors**

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Majority of patients had no known precipitating factors, emotional stress was found to precipitate alopecia areata in a few (12%) patients.



**Figure 3: Duration of Alopecia Areata**

As observed from the figure, in 40% of patients the duration of disease was between 1-2 weeks, 30% of the patients between 3-4 weeks, 20% of patients between 5-6 weeks and 10% of patients between 7-9 weeks.

From the above figure it is evident that the duration of alopecia areata was of less than 3 months.

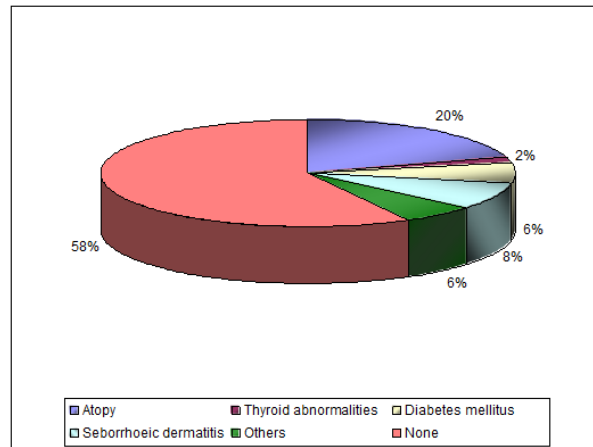
Type	No of lesions	Site		Male	Female	Total	
Patchy	1 lesion	Scalp	Parietal	7	5	32	
			Temporal	2	1		
			Occipital	3	2		
			Frontal	1	2		
		Moustache	2	-			
		Beard	5	-			
	Eyebrow	0	2				
	2 lesions	Scalp	Parietal, Occipital	2	3		14
			Temporal, Occipital	2	2		
			Frontal, Temporal	1	0		
Parietal, Temporal			1	0			
	Beard		3	-			
	Multiple lesions	Beard		2	-	2	
Ophiasis				2	0	2	
<b>Total</b>				<b>33</b>	<b>17</b>	<b>50</b>	

**Table 4: Showing Type and Site of Alopecia Areata**

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In the above table, it is evident that among 50 cases of alopecia areata study group, 48 (96%) cases had patchy type which was distributed as one lesion (32 cases), two lesions (14 cases) and multiple lesions (2 cases). The remaining 2 (4%) cases had ophiasis pattern. Thus the maximum numbers of cases seen were patchy type (96%) with single lesion predominating (64%).

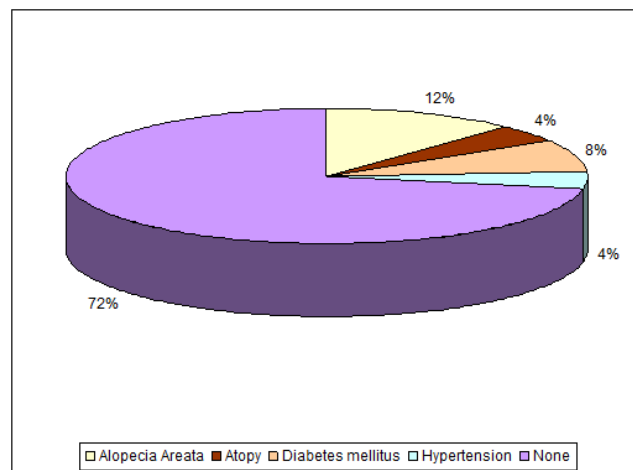
Among the sites 68% of cases had scalp involvement and among sites involved in the scalp, parietal area was maximum (36%) followed by occipital area (28%).



**Figure 4: Showing Personal History**

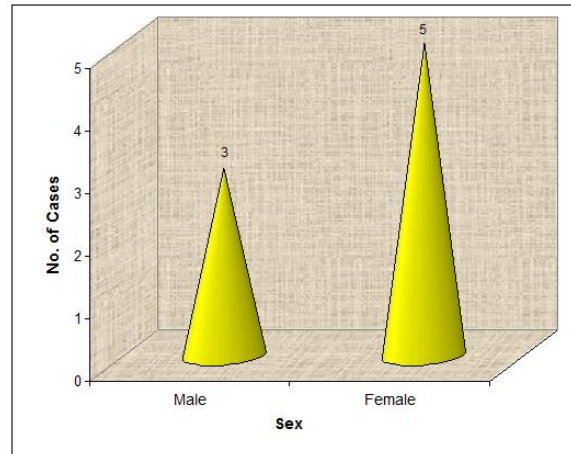
As observed from the above figure, 10 patients had associated atopy, among them 6 patients had bronchial asthma and 4 patients had atopic dermatitis. 3 patients had diabetes mellitus and 4 patients had seborrhoeic dermatitis, one patient had thyroid abnormalities. Among others, 2 patients had caries teeth and 1 patient had urticaria.

Atopy (20%) was found to be the most common associated condition.



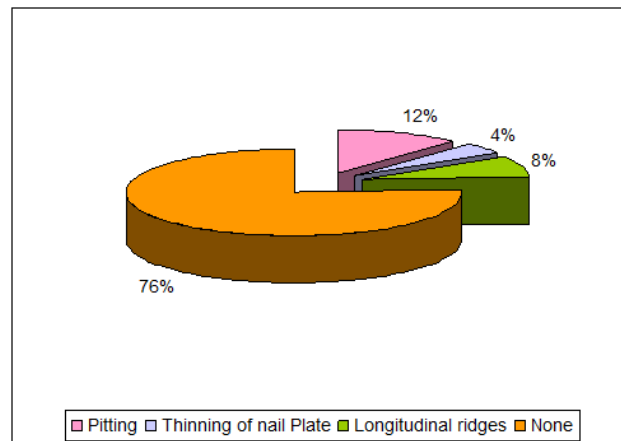
**Figure 5: Showing Family History**

Alopecia Areata (12%) was the most common association in the family, while diabetes mellitus (8%) being next most common.



**Figure 6: Showing Exclamation Mark Hair**

Exclamation mark hair was seen in 8 patients (16%).



**Figure 7: Showing Nail Changes**

As observed from the above graph, nail changes were seen in 12 patients (24%). Pitting was the most frequent finding (12%) in the nail, followed by longitudinal ridges (8%) and thinning of nail plate (4%).

**Evaluation of Clinical Response on Basis of Texture and Density:** All the 50 patients were advised to apply 0.03% tacrolimus cream once daily and were reviewed once in two weeks for twelve weeks. Clinical response was seen in the form of fine vellus hairs which gradually started growing in size and becoming thicker in diameter.

Texture	2 <sup>nd</sup> week	4 <sup>th</sup> week	6 <sup>th</sup> week	8 <sup>th</sup> week	10 <sup>th</sup> week	12 <sup>th</sup> week
Fine vellus hair	24	35	13	7	6	8
Normal coarse hair	0	0	26	32	38	42

**Table 5: Texture of hair growth**

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Ordinal by ordinal Gamma	<b>Value</b>	<b>Asymp. Std. Error</b>	<b>Approx. T</b>	<b>P</b>
	0.656	0.037	17.961	0.001

**Table 6: Symmetric Measures**

Out of 50 patients, 24 (48%) patients showed initial clinical response with the growth of vellus hair by the end of the 2<sup>nd</sup> week. By the end of the 8<sup>th</sup> week, the vellus hair had gradually transformed into normal coarse hair in 32 patients (62%).

At the end of 12 weeks 42 (84%) patients had showed normal coarse hair growth.

<b>Scoring</b>	<b>2<sup>nd</sup> week</b>	<b>4<sup>th</sup> week</b>	<b>6<sup>th</sup> week</b>	<b>8<sup>th</sup> week</b>	<b>10<sup>th</sup> week</b>	<b>12<sup>th</sup> week</b>
Minimal (1-25%)	23	41	21	12	4	1
Moderate (26-50%)	0	2	21	26	19	5
Good (51-75%)	0	0	10	5	20	31
Excellent (76-100%)	0	0	1	1	1	13

**Table 7: Density of hair growth**

Ordinal by ordinal Gamma	<b>Value</b>	<b>Asymp. Std. Error</b>	<b>Approx. T</b>	<b>P</b>
	0.751	0.033	19.468	0.001

**Table 8: Symmetric Measures**

Out of 50 patients, 23 (46%) patients showed initiation of clinical response in the form of hair growth by the end of the 2<sup>nd</sup> week.

By the end of the 8<sup>th</sup> week, 26 patients (52%) showed moderate (26-50%) hair growth.

Good density of hair growth was seen in 31(62%) patients and excellent density of hair growth was seen in 13 (26%) patients by the end of the 12<sup>th</sup> week.

<b>Follow up</b>	<b>Paired Differences</b>		<b>t</b>	<b>p (test of significant)</b>
	<b>Mean</b>	<b>Std. Deviation</b>		
2 <sup>nd</sup> – 4 <sup>th</sup> week	-0.9600	0.94675	-7.170	0.001
2 <sup>nd</sup> – 6 <sup>th</sup> week	-1.8000	1.03016	-12.355	0.001
2 <sup>nd</sup> – 8 <sup>th</sup> week	-2.6400	1.02539	-18.205	0.001
2 <sup>nd</sup> – 10 <sup>th</sup> week	-3.1600	0.91160	-24.511	0.001
2 <sup>nd</sup> – 12 <sup>th</sup> week	-3.6800	1.11465	-23.345	0.001

**Table 9: Qualitative data wise score analysis from 2<sup>nd</sup> week to 12<sup>th</sup> week follow up by using “Friedman’s test”**



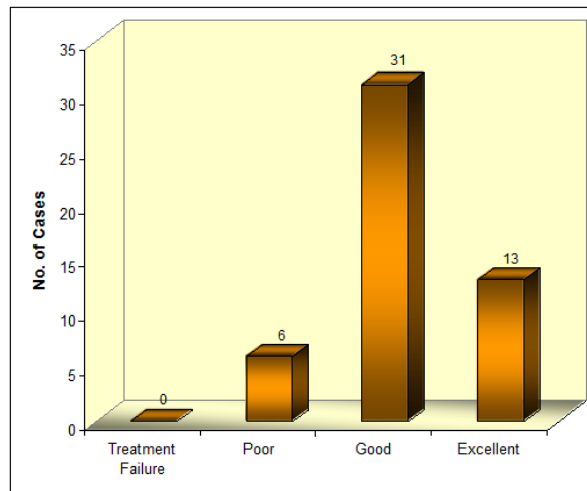
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N	50
Chi - Square	228.991
P	0.001

**Table 10: Test Statistics**

### Friedman Test

By using 'Friedman's Test' qualitative data-wise score changes from 2<sup>nd</sup> to 12<sup>th</sup> week follow up was done and was found to be very significant indicating the efficacy of topical tacrolimus in alopecia areata.



**Figure 8: Overall assessment of test area by the end of the study (texture + density)**

As evident in the figure, all patients showed response to the treatment. Majority of the patients (62%) showed good response while 12% of the patients showed poor response, where as 26% patients showed excellent response.

None of the patients had any side effects to tacrolimus (0.03%) cream during the study period.

**DISCUSSION:** Alopecia Areata is a common usually reversible condition representing approximately 2% of the dermatological practice characterized by patchy loss of hair without any atrophy.

In the present study 50 patients of alopecia areata were studied in the out-patient department of dermatology of Fr. Muller Medical College Hospital, Mangalore.

**AGE AND SEX:** In the present study, 40(80%) patients were under the age of 30 years. Among these, the maximum number of patients were in the age group of 21 - 30 years (54%) and 13 patients (26%) were under the age of 20.

Sharma et al.<sup>9</sup> reported that 24% of the patients were children and young adults which is compatible with the present study in which 26% of the patients were under the age of 20.

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In this study the youngest patient was a 6 year old boy and eldest was 48 year old woman. Thirty three cases were male and seventeen were females with a male to female ratio of nearly 2:1. This was found to be similar to the studies conducted by Sharma et al.<sup>9</sup>

**Precipitating Factors:** Studies conducted by various workers have stressed that precipitating factors are the causative factors in many cases of alopecia areata.

In this study precipitating factors were observed in 7 patients with 6 cases (12%) having emotional stress and 1 patient having trauma.

This is compatible with the study conducted by Muller and Winkelmann<sup>10</sup> in which 12% of alopecia areata patients were associated with emotional disturbances.

**Duration of Alopecia Areata:** In the present study, the duration of alopecia areata varied from 8 days to 9 weeks.

In 40% of patients the duration was between 1 – 2 weeks, between 3 – 4 weeks in 30% of the patients, 5 – 6 weeks in 20% of patients and in 10% of patients between 7 – 9 weeks.

**Personal History:** In our study, personal history of atopy was seen in 10 patients (20%) among which bronchial asthma was seen in 6 patients and atopic dermatitis in 4 patients. This is accordance to the study conducted by Sharma et al.<sup>9</sup> in which atopy was reported in 18% of alopecia areata patients.

The incidence of atopy varied from 10% to 52% in studies conducted by Ikeda,<sup>4</sup> Muller and Winkelmann.<sup>10</sup>

Alopecia areata is known to be associated with thyroid disease, vitiligo, pernicious anaemia, lichen planus, Addison's disease and SLE.<sup>11,12</sup>

In the present study, 4 patients had seborrhoeic dermatitis, 4 patients had diabetes mellitus, and 1 patient had thyroid abnormalities. Among others, 2 patients had caries teeth and 1 patient had urticaria.

Sharma et al.<sup>9</sup> in their study found association of auto immune disease in 5%, thyroid disease in 1%, diabetes mellitus in 0.4% and vitiligo in 1.8% of cases.

Muller and Winkelmann<sup>10</sup> found thyroid diseases in 8% of the patients, collagen vascular disease in 2% and psychiatric disorders in 12% of the patients.

In our study, atopy was found to be the most commonly associated (20%) condition.

**Family History:** In our study, family history of alopecia areata was seen in 12% of the patients, which is in accordance with the study conducted by Sharma et al.<sup>9</sup> and Muller and Winkelmann.<sup>10</sup>

Family history of atopy was seen in 4%, diabetes mellitus was seen in 8% and hypertension was seen in 4% of alopecia areata patients. These studies are compatible with the findings of Sharma et al.<sup>9</sup>

**Clinical Features:** In our study, almost all the patients had an insidious onset. 68% of cases had scalp involvement, parietal (36%) and occipital (28%) areas were the most common site of initial involvement. 96% of the cases were patchy type with single lesion predominating (64%) followed by two lesions (28%) and multiple lesions (4%). 4% of the cases had ophiasis pattern.

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The exclamatory mark hair is the diagnostic sign which is found in the active lesions of alopecia areata.

In the present study exclamation mark hair was seen in 8 patients.

**Nail Changes:** Nail changes are most commonly associated with extensive alopecia areata.

In the present study, nail changes were seen in 24% of the cases. Among these 12% of the cases showed pitting, nail plate thinning in 4% of the cases and longitudinal ridges in 8% of the cases. Six patients (12%) who poorly responded to tacrolimus 0.03% ointment had nail pitting.

Sharma et al.<sup>9</sup> found associated nail changes in 20% of the patients and more frequent in severe forms of alopecia areata.

**Evaluation of Clinical Response to 0.03% Tacrolimus Cream on the Basis of Texture and Density of hair Growth:** In this study, clinical response was in the form of fine vellus hair which gradually started growing in size and became thicker in diameter. At the end of the 2<sup>nd</sup> week, 24 patients (48%) showed growth of vellus hair. This vellus hair by the end of the 8<sup>th</sup> week had gradually transformed into normal coarse hair in 32 patients (62%). At the end of 12 weeks, 42 (84%) patients had showed normal coarse hair growth.

Density of hair growth started increasing at the end of the 6<sup>th</sup> week and maximum at 12 weeks. 46% patients showed initiation of clinical response in the form of hair growth by the end of the 2<sup>nd</sup> week. By the end of the 8<sup>th</sup> week 26 patients had shown moderate hair growth. Good density and excellent density of hair growth was seen in 31 and 13 patients respectively by the end of the study. The qualitative data-wise score analysis from the 2<sup>nd</sup> week to the 12<sup>th</sup> week follow up was found to be very significant, establishing efficacy of tacrolimus cream.

On assessing the overall response (texture and density of hair growth) at the end of the study, all patients showed response to the treatment.

**RESULTS:** 8 (16%) patients with scalp involvement and 5 (10%) with involvement of beard had excellent response. 20 (40%) patients with alopecia areata on the scalp and 5 (10%) patients on the beard had good response. 6 (12%) patients with scalp involvement had poor response. 2(4%) patients each with lesions on the eyebrows and moustache showed good response. The clinical response of 2 (4%) patients with ophiasis pattern was good.

**Limitations of the Study:** Alopecia Areata going for alopecia totalis or alopecia universalis was not included and the efficacy of topical tacrolimus in its treatment was not studied.

**CONCLUSION:** In this clinical study of alopecia areata including 50 cases the following analysis is made after analyzing the data:

- Atopy (20%) was found to be the most common associated condition in alopecia areata.
- Family history of alopecia areata was present in 12% of the subjects.
- Nail changes were seen in 24% subjects. Pitting was the most frequent finding (12%) in the nail, followed by longitudinal ridges (8%) and thinning of nail plate (4%).
- Only 12% subjects showed poor response to topical tacrolimus(0.03%) treatment, while remaining 88% subjects showed good(62%) to excellent(26%) response.

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- Topical tacrolimus is effective and could be the other modality in treating alopecia areata. However, higher strength (0.1%) may give better results.
- Being a non-irritant topical therapy it could be a treatment modality of choice in children.
- Absence of cutaneous side effects (as evident in corticosteroids) makes it suitable for use on the face.
- Nail pitting is associated with poor prognosis in treating alopecia areata.
- None of the patients had any side effects to tacrolimus (0.03%) cream during the study period.

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### **AUTHORS:**

1. Srinivas M
2. Ramesh Bhat M
3. Nanda Kishore B
4. Sukumar
5. Narendra J. Shetty
6. Jacintha Martis
7. Ganesh Kamath

### **PARTICULARS OF CONTRIBUTORS:**

1. Assistant Professor, Department of Dermatology, Akash Institute of Medical Sciences & RC, Devanahalli, Bengaluru.
2. Professor and HOD, Department of Dermatology, FR. Muller Medical College & Hospital, Mangalore.
3. Professor, Department of DVL, FR. Muller Medical College & Hospital, Mangalore.
4. Professor, Department of DVL, FR. Muller Medical College & Hospital, Mangalore.

5. Professor and HOD, Department of Dermatology, AJ Institute of Medical Sciences, Mangalore.
6. Professor, Department of DVL, FR. Muller Medical College & Hospital, Mangalore.
7. Professor, Department of DVL, FR. Muller Medical College & Hospital, Mangalore.

### **NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:**

Dr. Srinivas M,  
Bloom Super Speciality Skin Cosmetic  
Surgery Clinic,  
#19, 1<sup>st</sup> Main, Judge's Layout,  
Ganga Nagar, R. T. Nagar, Bangalore -32.  
Email: drshreeniderm@gmail.com

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