

Retraction

The article "A randomized prospective study to evaluate the efficacy of various topical treatment modalities in patients of alopecia areata" is retracted by the Editor-in-Chief due to violation of the policies and practices of International Journal of Research in Dermatology.¹ The article is retracted due to dispute in authorship. The corresponding author communicated the above article without knowledge of the principal investigator and co researchers involved in the study.

REFERENCES

1. Manthale NS, Raikar DR, Raikar SR. A randomized prospective study to evaluate the efficacy of various topical treatment modalities in patients of alopecia areata. *Int J Res Dermatol.* 2017;3:439-43. DOI: <http://dx.doi.org/10.18203/issn.2455-4529.IntJResDermatol20173927>.

Original Research Article

A randomized prospective study to evaluate the efficacy of various topical treatment modalities in patients of alopecia areata

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ABSTRACT

Background: Alopecia areata (AA) is one of the common causes of localized hair loss among the patients attending the outpatient department. The objective of this study was to know the clinical and epidemiological profile of AA and to compare the efficacy of different topical treatment modalities in AA.

Methods: 100 patients of any age group and of both sexes presenting with AA to the dermatology outpatient department were included in this study. It was conducted as a randomized prospective study for a period of 12 weeks after taking an informed consent from the patient. After studying the clinical profile, patients were randomly distributed, excluding the age and sex bias into four treatment groups. Alopecia grading scale (AGS) was calculated at first visit and 12 weeks. Regrowth score (RGS) was calculated at 12 weeks. Treatment outcome in different groups were compared using mean AGS at 12 weeks and RGS.

Results: Group A patients showed statistically significant clinical improvement when compared to all the other groups. Poorest response was seen in Group D. Intermediate response was seen in Group B and C patients.

Conclusions: The study concluded that topical 0.05% betamethasone dipropionate is the most effective treatment modality in patients with patchy AA (having <25% hair loss).

Keywords: Alopecia areata, Betamethasone dipropionate, Minoxidil, Anthralin, Tacrolimus

INTRODUCTION

Alopecia areata is an autoimmune disease, characterized by non-scarring hair loss of scalp or on any hair bearing surface.¹ It is a chronic inflammatory disease affecting the hair follicles with definite evidence of the role of T lymphocytes.² It is usually associated with various autoimmune diseases and maybe associated with a positive family history.^{3,4} Its lifetime risk is reported to be 1.7%.⁵ It is a common cause of localized hair loss in patients of

age group 5 to 35 years who attend the outpatient department.⁶

Alopecia areata may show a spontaneous remission within few months but it may also follow an unpredictable course of exacerbation. As it causes cosmetic concern for the patient along with stress, various therapeutic modalities have been described and are being used for its treatment.⁷ Aim of treatment in alopecia areata is to suppress the activity of the disease as none of them are curative.⁸

There is paucity of randomized prospective trials, evaluating the efficacy of different treatment modalities in alopecia areata. Thus, evidence based assessment of these therapies is difficult.

Hence, this randomized prospective study was carried out to know the clinico-epidemiological profile of patients with alopecia areata and to compare the treatment outcome with various topical treatment modalities in the management of alopecia areata.

METHODS

A randomized prospective, clinico interventional study, was carried out on 100 patients of any age group presenting to the skin OPD of Basaveshwar Teaching and General Hospital, with the clinical features of AA, during the period of September 2014 to June 2016. In this study, clinico-epidemiological features of AA and the outcome with different topical treatment modalities were assessed.

Informed consent was taken from the patient or guardian. Relevant investigations were done only when there was a doubt in clinical diagnosis. Eligible patients who fulfilled the inclusion criteria were randomly allocated into 4 different treatment groups, and were given treatment for a period of 12 weeks with follow up at regular intervals (15 days). Group A patients were treated with 0.05% BMD cream applied twice daily, Group B with 2% Minoxidil solution applied twice daily, Group C with 1.15% Anthralin ointment applied once daily for 15 minutes and Group D with 0.03% Tacrolimus ointment applied twice daily. The total number of patches and their measurements were noted in all quadrants of scalp. Alopecia Grading Scale (AGS) of each patient was calculated on first visit and at 12 weeks.

Parameters for comparing the treatment response were Regrowth Score (RGS) and mean AGS at 12 weeks. Mean AGS was calculated for each group at 12 weeks to know the degree of improvement with the particular treatment modality. Mean AGS was then compared using chi square test. RGS was calculated as follows- 0 (regrowth <10%), 1 (regrowth 11-25%), 2 (regrowth 26-50%), 3 (regrowth 51-75%) and 4 (regrowth >75%). A patient having RGS of more than or equal to 3 was considered to be improved and those having RGS less

than or equal to 2 were considered not improved. Statistical analysis was done using SPSS 21 version.

RESULTS

Age and sex distribution of patients is presented in Figure 1. Only 9% patients had a family history of alopecia areata. 23% of the patients had an associated history of atopy, 8% had anaemia, 6% had associated focus of infection in the form of otitis media, upper respiratory tract infection, 4% had diabetes mellitus, 3% had hypothyroidism and 3% had vitiligo. Some of the patients had nail changes which is depicted in the Figure 2.

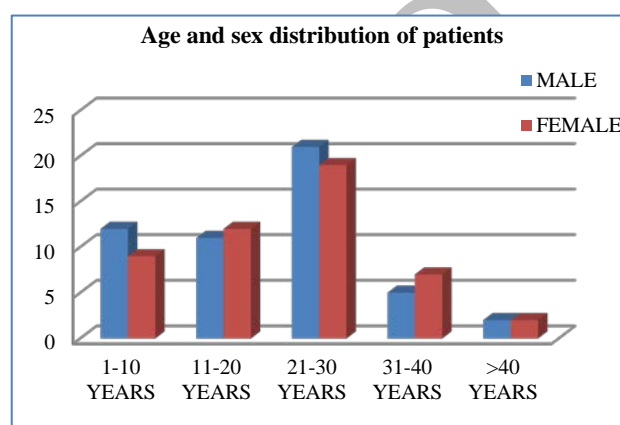


Figure 1: Age and sex distribution of patients with alopecia areata.

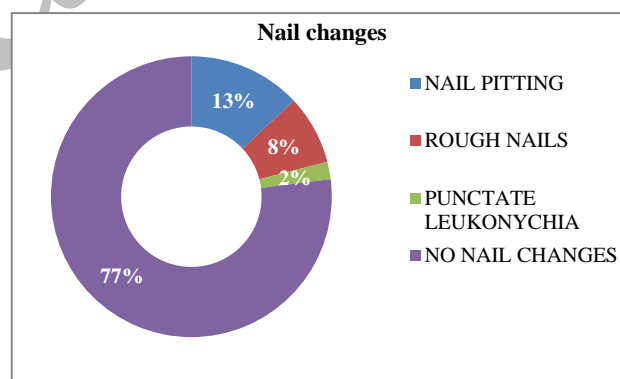


Figure 2: Nail changes in patients with alopecia areata.

Table 1: Mean AGS at first visit and at 12 weeks and mean RGS at 12 weeks.

Treatment group	AGS at first visit (Mean±SD)	AGS at 12 weeks (Mean±SD)	Mean RGS at 12 weeks
Group A (0.05%BMD)	13.19±8.76	4.28±3.65	4
Group B (2% Minoxidil)	12.04±7.34	6.916±3.72	3
Group C (1.15% Anthralin)	13.44±8.12	9.347±3.89	2
Group D (0.03% Tacrolimus)	13.01±8.03	9.347±3.89	1

Table 2: Regrowth score (RGS) and number of patients in each grade at the end of 12 weeks.

RGS	Group A	Group B	Group C	Group D
0	0	0	0	11
1	0	4	6	11
2	5	11	12	1
3	7	8	4	0
4	13	1	1	1

Table 3: Comparison of mean AGS at 12 Weeks.

Groups	T test	P value
GR A v/s GR B	t=2.529	p<0.05
GR A v/s GR C	t=4.6089	p<0.01
GR A v/s GR D	t=6.89	p<0.001
GR B v/s GR C	t=2.21	p<0.05
GR B v/s GR D	t=4.531	p<0.01
GR C v/s GR D	t=2.07	p<0.05

From Table 2, it is apparent that, 80% patients (20 of 25) in Group A showed improvement with a majority of 52% (13) showing excellent response (RGS 4). Around 37% patients (9 of 24) in Group B showed improvement with majority of around 33% (8) showing good response (RGS 3). Around 21.7% patients (5 of 23) in Group C showed improvement, with majority of around 52% (12) showing moderate response (RGS 2). Only 4% patients (1 of 24) in Group D showed improvement with majority 91.6% (22 of 24) showing a poor response (RGS 0 and 1).

By referring to the χ^2 in Table 3, treatment outcome of GR A is better than all the other three groups. Treatment outcome of GR B is better than GR C and D but less than that of GR A. Treatment outcome of GR C is better than GR D and less than that of GR A and GR B. Treatment outcome of GR D is less than all the other three groups.

DISCUSSION

Alopecia areata is an autoimmune disease characterized by non-scarring hair loss on the scalp or any hair bearing surface.¹ AA is more common in children and young adults, but it can present at any age.⁹

Age and sex distribution:

In our study, peak age of onset of AA was in 21-30 years of age (40%), followed by 11-20 years of age (23%). It is comparable to the study done by Sardesai et al where the peak age of onset of AA was 21-30 years (>40%) and >30% were aged less than 20 years.¹¹ In another study done by Sharma et al majority of the patients (88%) were below 40 years of age.¹²

There was a slight male preponderance in our study (51%), with male to female ratio being 1.04:1. It is also comparable to the study done by Sardesai et al where male to female ratio was 1.5:1 and to the study done by Sharma et al where M:F ratio was 2:1.^{11,12}

Family history of AA

In our study, family history of AA was present in 9% of the patients. It is comparable to the study done by Sharma et al where in family history of AA was seen in 9% of the patients.¹² In a study done by Das et al, family history of AA was present in 7.5% of patients.¹³

Associated diseases

Majority of the patients (53%) had no associated dermatological or systemic disease. Commonest associated dermatological disease was atopy present in 23% of patients. 8% of the patients had associated history of anaemia and all were females. Focus of infection like upper respiratory tract infection was seen in 6% of the patients and mainly in age group of <15 years. Associated history of diabetes mellitus was present in 4% of the patients. Association of hypothyroidism and vitiligo with AA was seen in 3 patients each (3% each).

Almost similar findings were noted in the study conducted by Das et al on patients aged 6 to 44 years. Atopy was present in 21.2% of the patients. Thyroid disorders were present 3.75% of the patients.¹³ But, history of diabetes mellitus was seen in 8.75% of patients and vitiligo in 7.5% of the patients, unlike in our study where diabetes mellitus was seen in 4% of patients and vitiligo in 3% of the patients.

Nail changes

Majority of the patients (77%) had no associated nail changes. Nail changes were seen in 23% of the patients which was comparable to the study done by Das et al where nail changes was seen in 20% of the patients.¹³ Nail changes were specially seen in those patients with a history of AA of >3 months duration (18 of 23 patients) and in patients where AA was found to be associated with some systemic disease.

Comparison of treatment outcome with different topical modalities:

Efficacy of 0.05% Betamethasone Dipropionate cream

In the study done by Das et al, RGS >3 was seen in 70% of the patients treated with topical Betamethasone dipropionate and topical steroid was declared the most effective treatment modality in AA.¹³ Similar results were obtained in our study, in Group A, 80% of the patients treated with 0.05% Betamethasone Dipropionate cream showed RGS of 3 and 4 at the end of 12 weeks.

Efficacy of topical 2% Minoxidil solution

In a study done by Price, on patients with extensive patchy AA in the age group of 9 to 65 years with 3% topical Minoxidil solution, it was seen that 27.3% of patients had cosmetically acceptable hair growth (RGS>3).¹⁴ Similar findings were also seen in our study in Group B patients, who were treated with topical 2% Minoxidil solution. About 37% of the patients showed improvement or a RGS of 3 and 4 at the end of the 12 weeks of study.

Efficacy of 1.15% Anthralin ointment

In a study done by Fiedler-weiss et al, the efficacy of anthralin cream in the treatment of severe AA in 68 patients was evaluated.¹⁵ Cosmetic response that is RGS >3 was seen in 25% of the patients. Hence, Anthralin was also considered a reasonable therapeutic option for severe AA.

In our study, almost similar findings as that of above studies were seen in Group C patients who were treated with topical 1.15% Anthralin ointment. 21.7% of the patients in Group C showed a RGS of 3 and 4 at the end of 12 weeks.

Efficacy of topical 0.03% Tacrolimus ointment

In a study done by Price et al, no terminal hair regrowth was seen in patients with patchy AA who were treated with 0.1% Tacrolimus ointment.¹⁶

Similar findings were seen in our study also, where in Group D patients treated with topical 0.03% Tacrolimus ointment. In this group, majority (91.6%) of the patients showed no improvement at the end of 12 weeks and only 4% of the patients showed a RGS >3.

CONCLUSION

It can be concluded that 0.05% Betamethasone Dipropionate is most effective and economical topical treatment and superior to other three topical treatment modalities in mild and less extensive forms of AA (less than 25% scalp hair loss).

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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