ORIGINAL ARTICLE

COMPARISON OF EFFICACY OF VARIOUS TOPICAL TREATMENT MODALITIES IN ALOPECIA AREATA
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HOW TO CITE THIS ARTICLE:

ABSTRACT: BACKGROUND: Alopecia areata is one of the common causes of localized hair loss. Alopecia areata can have spontaneous remission or can follow unpredictable course with exacerbation. Due to which it can be a cause of cosmetic concern for the patient. AIM: To know the efficacy of various topical treatment modalities in Alopecia areata. METHODS: 100 patients presenting with alopecia areata to the dermatology outpatient department of Basaveshwar Teaching and General Hospital and Sangameshwar Hospital, Gulbarga, 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. Patients were randomly distributed into four treatment groups –A, B, C, D. Group. A were treated with 0.05% Betamethasone Dipropionate cream applied twice daily, Group. B were treated with 2% Minoxidil solution applied 1ml twice daily, Group. C was treated with 1.15% Anthralin ointment applied daily for 15 minutes and Group. D were treated with 0.03% Tacrolimus applied twice daily to the affected areas. 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. CONCLUSION: The study concluded that topical 0.05% betamethasone dipropionate is the most effective topical treatment modality in patients with alopecia areata.

KEYWORDS: Alopecia areata; Betamethasone dipropionate; Minoxidil; Anthralin; Tacrolimus.

INTRODUCTION: Alopecia areata (AA) is an autoimmune disease, characterized by non-scarring hair loss of scalp or on any hair bearing surface. It is usually associated with various autoimmune diseases and may be associated with a positive family history. Its lifetime risk is reported to be 1.7%. It is a common cause of localized hair loss in patients of age group 5 to 35 years who attend the outpatient department.

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 emotional problems, various therapeutic modalities have been described and are being used for its treatment. Aim of treatment in alopecia areata is to suppress the activity of the disease as none of them are curative. This randomized prospective study was carried out to compare the treatment outcome and safety profile with various topical treatment modalities in the management of alopecia areata.
AIMS AND OBJECTIVES:
- To study the clinical and epidemiological features of alopecia areata.
- To study the efficacy of different topical treatment modalities in alopecia areata.
- To compare the safety and adverse effects of various topical treatment modalities.

METHODOLOGY: A randomized prospective study was conducted on 100 patients, presenting to the dermatology outpatient department of Basaveshwar Teaching and General Hospital and Sangameshwar Hospital of M. R. Medical College, Gulbarga with features of alopecia areata. Study was conducted for a period of two years, from September 2012 to June 2014.

INCLUSION CRITERIA:
1. Patients attending the skin OPD with features of alopecia areata.
2. Both sexes.
3. Any age group.
4. All types of alopecia areata.
5. AA associated with other autoimmune and systemic illnesses.

EXCLUSION CRITERIA:
1. Patients of AA who are already on treatment.
2. Patients with inflammation and secondary infections over the bald patch.
3. Patients with scars over the bald patch.

Informed consent was taken from the patient or guardian before including them into the study by explaining them the purpose of study. Relevant history was taken and clinical examination was done including general, systemic and local examination in each patient. Relevant investigations were done only when there was a doubt in clinical diagnosis.

Patients were distributed into 4 groups randomly. Each group was given a different topical treatment modality for alopecia areata for duration of 12 weeks.

- **Group A**: topical Steroid that is 0.05% Betamethasone Dipropionate (BMD) cream, applied twice daily over the alopecia patch.
- **Group B**: topical 2% Minoxidil solution, applied twice daily over the patch.
- **Group C**: 1.15% Anthralin ointment, applied once daily over the patch for 10-15mins, followed by washing off the ointment with shampoo. Duration of contact has to be increased subsequently during each follow up if there is no irritation and erythema on the patch.
- **Group D**: 0.03% Tacrolimus ointment, applied twice daily over the alopecia patches.

Patients were advised to come for follow up at every 15 days for a period of 12 weeks. AGS - Alopecia grading scale and RGS - Regrowth score were used to compare the treatment response on patients in different groups. AGS was calculated for each patient at the first visit (Baseline AGS) and finally at 12 weeks or the last visit. Chi-Square test was used for the statistical analysis of the data.
RESULTS: Peak age of onset was 21-30 yrs (40%). Mean age of onset was 21.1 years. There was a slight male preponderance in our study with male to female ratio of 1.04:1. A positive family history of AA was seen in 9% of the patients. Majority of the patients (45%) presented within 1 to 3 months after the onset of the disease. Majority (89%) of the patients had patchy type of AA, 6% had reticulate pattern and 4% had ophiasis pattern. Only 1 patient presented with alopecia totalis. In this study, no patient presented with alopecia universalis or with sisaipho pattern.

The response in each group was graded by assessment of mean Alopecia Grading Score (AGS) at baseline and at 12 weeks. A total of 96 patients completed the study at 12 weeks. 25 in group A, 24 in group B, 23 in group C and 24 in group D.

Patient profile and decrease in mean AGS at end of 12 weeks in different treatment groups is summarized in Table 1. Response to treatment was best in betamethasone dipropionate group and least in tacrolimus group [p<0.05]. GR A and GR C had 2 patients each of reticulate pattern of AA whereas GR B and GR D had only 1 patient each of reticulate pattern. Each group had 1 patient each of ophiasis pattern of AA. In both the groups best response and improvement at 12 weeks was seen in Group A treated with 0.05% BMD cream followed by Group C treated with 1.15% Anthralin ointment.[table 2].

A RGS of 0 and 1 is taken as Poor response, 2 as Moderate response, 3 as Good response and 4 as Excellent response. At the end of 12 weeks, a RGS of more than or equal to 3 was considered as improved and a RGS of less than or equal to 2 was considered as not improved. In our study;

- 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 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 & 1).

No major side effects were noted during the study. Folliculitis was seen in 1 patient treated with 0.05% Betamethasone dipropionate cream. Generalized hypertrichosis and scaling were seen in 1 patient each in 2% Minoxidil treated group, which reversed gradually and completely after stopping the treatment. Erythema with burning sensation was seen in only 1 patient treated with 1.15% Anthralin ointment. No side effects were seen in patients treated with 0.03% Tacrolimus ointment.

DISCUSSION: In our study, the patient profile, male predominance and positive family history were similar to findings of other studies. Various studies are available which have evaluated the efficacy of topical drugs in alopecia areata.

In the study done by Das S 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. In another study done by Mancuso G et al, a RGS>3 was observed in 61% of the patients treated with Betamethasone valerate foam. And a RGS>3 was seen in 27% of patients treated with
betamethasone dipropionate lotion. These findings are similar to our study. 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 and only one patient in the group developed folliculitis as side effect. Thus, topical steroid was found to be the best treatment modality in patchy AA.

In a study done by Price VH, on patients with extensive patchy AA in the age group of 9 to 65 years with 3% topical Minoxidil solution, it was seen that minoxidil application was generally well tolerated except for scalp itching in 3 patients. Hair growth was seen in 63.6% of the patients in the minoxidil treated group but cosmetically acceptable hair growth (RGS > 3) was seen in only 27.3% of patients in the minoxidil treated group. Examination of vital signs and lab measurements revealed no evidence of systemic effects of minoxidil. In another study done by Fiedler – Weiss, a dose response efficacy comparing 1% and 5% topical minoxidil was demonstrated. Patients with extensive scalp hair loss showed a response rate of 38% with 1% minoxidil. 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. And only one patient each showed the side effect of scaling and hypertrichosis which also reversed after the stoppage of treatment.

In a study done by Fiedler-weiß VC et al, the efficacy of anthralin cream in the treatment of severe AA in 68 patients was evaluated. Cosmetic response that is RGS > 3 was seen in 25% of the patients. In another study done by Das S et al, 35% of the patients treated with topical anthralin (Dithranol paste) showed >60% regrowth at the end of study in patchy AA. In our study, 21.7% of the patients in Group C showed a RGS of 3 and 4 at the end of 12 weeks. Erythema with burning sensation was seen in only 1 patient of the group.

In our study, Group D patients were 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. And no side effects were observed among patients in this group. This was similar to study done by Price VH et al.

Best treatment response was seen in Group A who were treated with 0.05% Betamethasone Dipropionate cream when compared with the other three groups. Least response was seen in Group D who were treated with 0.03% Tacrolimus ointment. Patients treated with 2% minoxidil and 1.15% anthralin ointment showed a response better than Group D but less than that of Group A patients.

In our study, best response at 12 weeks among cases with Reticulate type of AA was seen in Group A treated with 0.05% BMD cream followed by Group C treated with 1.15% Anthralin ointment. Among ophiasis pattern, best response was seen in Group A treated with 0.05% BMD cream followed by Group C treated with 1.15% Anthralin ointment. Side effects with various treatment modalities were mild, minimal, temporary and reversed as soon as the treatment was stopped. Patient compliance was good in all the four groups.

**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).
BIBLIOGRAPHY:

<table>
<thead>
<tr>
<th></th>
<th>Group A Steroid (0.05% BMD)</th>
<th>Group B (2% Minoxidil)</th>
<th>Group C (Anthralin 1.15%)</th>
<th>Group D (0.03% Tacrolimus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total No. of patients</td>
<td>26</td>
<td>25</td>
<td>25</td>
<td>24</td>
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<tr>
<td>Remained in study</td>
<td>25 (96.15%)</td>
<td>24 (96%)</td>
<td>23 (92%)</td>
<td>24 (100%)</td>
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<tr>
<td>Left the study</td>
<td>1 (3.8%)</td>
<td>1 (4%)</td>
<td>2 (8%)</td>
<td>0</td>
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<td>Mean age in years</td>
<td>20.42</td>
<td>21.92</td>
<td>20.04</td>
<td>22.20</td>
</tr>
</tbody>
</table>

GENDER
- Male: 15, 11, 14, 11
- Female: 11, 14, 11, 13

MEAN AGS
- Baseline AGS: 13.19, 12.04, 13.44, 13.01
- AGS at 12 weeks: 4.28, 6.916, 9.347, 11.45

TABLE 1
**ORIGINAL ARTICLE**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number of ophiasis patients</th>
<th>Improvement at 12 weeks</th>
<th>Number of reticulate patients</th>
<th>Improvement at 12 weeks</th>
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<tbody>
<tr>
<td>GROUP A</td>
<td>1</td>
<td>52%</td>
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<td>50%</td>
</tr>
<tr>
<td>GROUP B</td>
<td>1</td>
<td>20%</td>
<td>1</td>
<td>17%</td>
</tr>
<tr>
<td>GROUP C</td>
<td>1</td>
<td>27%</td>
<td>2</td>
<td>23%</td>
</tr>
<tr>
<td>GROUP D</td>
<td>1</td>
<td>12%</td>
<td>1</td>
<td>7%</td>
</tr>
</tbody>
</table>

**TABLE 2**

![Graph](image)

**Fig. 1:** Shows number of patients with different RGS in the various treatment groups

X-Axis = Regrowth Score; Y-Axis = Number of Patients

![Before treatment](image)

**Fig. 2:** Patient on 0.05% BMD—before treatment

![After treatment](image)

**Fig. 3:** Patient on 0.05% BMD—after treatment
Fig. 4: Patient on 2% Minoxidil – before treatment

Fig. 5: Patient on 2% Minoxidil – after treatment

Fig. 6: Patient on 1.15% Anthralin – before treatment

Fig. 7: Patient on 1.15% Anthralin – after treatment

Fig. 8: Patient on 0.03% Tacrolimus – before treatment
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Fig. 9: Patient on 0.03% Tacrolimus – after treatment