Comparative Efficacy of Topical Tacrolimus 0.1% and Clobetasol Propionate 0.05% in the Treatment of Alopecia Areata (AA)

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Objective: To assess the effectiveness of topical tacrolimus 0.1% vs. topical clobetasol propionate 0.05% while treating alopecia areata.

Methods: Randomized-controlled trial (Double blind) conducted in Dermatology Department, CMH-Abbottabad, from November 2022 to April 2023. The seventy (70) patients with alopecia areata who attended to OPD of CMH Abbottabad between the ages of 20 and 50 were included. The non-probability consecutive sampling method was used. For up to 3 months, patients in Group A used clobetasol propionate 0.05% twice daily, while patients in Group B used topical tacrolimus 0.1% twice daily. Patients were evaluated at the start of each session, four weeks later, eight weeks later, and twelve weeks later. The SALT score was used to estimate hair loss at presentation and during the 3-month follow-up. The degree of response has been characterized by following hair re-growth as excellent (>75%), marked (51-75%), moderate (26-50%), or mild (25%). A p-value of <0.05 was considered significant.

Results: When the efficacy was compared, 26 (74.3%) patients in group-A (mean age 35.23±7.87 years) shown excellent response, while 14 (40%) patients in group-B (mean age 34.29±7.87 years) with significant p-value was 0.028.

Conclusions: Clobetasol propionate 0.05% was more efficacious as a therapy choice for stimulating hair re-growth in patients.
complication of topical corticosteroids. Telangiectasia and atrophy are uncommon. However, the primary downsides of these techniques are their limited effectiveness, local and systemic adverse effects, particularly in long-term therapy [9]. Tacrolimus might be an effective therapeutic option of management of inflammatory dermatological diseases, including alopecia areata [10]. Alopecia areata patients can choose from a variety of therapy methods. Each method has advantages and limitations, and its suitability varies for each patient. The medical usefulness of topical corticosteroids in AA is yet debatable. This literature on this topic is limited that is why this study is conducted with objective of to compare clobetasol with tacrolimus while treating AA. This study will also help to assess relative effectiveness of clobetasol and tacrolimus in treatment of alopecia areata.

M E T H O D S

A RCT study was conducted in dermatology dept of the CMH, Abbottabad from November 2022 to April 2023 after Ethical Review Board approval dated 01-Nov-2022 (Reg# CMHAd-ETH-56-Derm-22) and RCT (Reg#ClinicalTrials.gov Identifier NCT05885269). The seventy (70) patients who were 20-50 years of age diagnosed as alopecia areata on clinical grounds, confirmed by consultant dermatologist and further examination of plucked hair was done under a microscope. An inform consent was taken. The method of non-probability consecutive sampling was applied. The sample size was estimated using WHO sample size calculator by taking a 95% confidence interval, an 80% power of study, and an expected cure rate of 44.82% for Tacrolimus and 79.31% for Clobetasol propionate. The calculated sample size was 62, with 31 in each group, however a sample size of 79.31% for Clobetasol propionate. The calculated sample size was 62, with 31 in each group, however a sample size of 70 (35 in each group) was used to boost the study’s validity [11]. The study included patients aged between 20-50 years, both gender, who attended the dermatology out-patient department of CMH Abbottabad, had an ailment lasting less than 2 months, and had never had any treatment before. On the other hand, Patients with history of more than 2 months alopecia areata, atypical AA (e.g., Alopecia universalis), a history of hypersensitivity to drugs such as topical corticosteroids and tacrolimus, patients on systemic immune-suppression, and females who are pregnant or on lactation were excluded. Patients before and after the trial, as well as clinical examination by me and by consultant dermatologist. All patients’ findings were assessed at 4th, 8th, and 12th week duration of following therapy completion. The hair re-growth score was determined using the SALT score at presentation and the SALT score(0 to 4) during the 3-month follow-up as follows: 0 (10% re-growth), 1 (11-25% re-growth), 2 (26-50%), 3 (51-75%), and 4 (>75% re-growth). The response was categorized on examining hair re-growth which was labelled excellent upon (>75%), moderate (26% to 50%), or slight (≤ 25%). The statistical program for social sciences (SPSS) version 23.0 was used for analysis. Mean ± SD was determined for continuous data, while frequency percentages were calculated for categorical variables. To evaluate statistical significance for treatment efficacy evaluation, the chi-square test was utilized, with a p-value of 0.05 considered significant.

R E S U L T S

In group-A mean age was 35.23±7.87 years, and in group-B mean age was 34.29±7.87 years. The two groups were well-evaluated in terms of pre-treatment clinical parameters there was significant relations between gender (p=0.034) and number of lesions (p=0.015) in group-A and Group-B. The majority 46(65.7%) patients were greater than 31 years of age, hence 50(71.4%) were males between both groups of Alopecia areata. The 42(60%) patients of single lesions were effectively treated by both the treatment groups (Table 1).

Table 1: Clinical Parameters of both treatment Groups(n=70)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Categories</th>
<th>Group-A N (%)</th>
<th>Group-B N (%)</th>
<th>Total N (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Early Adulthood</td>
<td>11 (31.4%)</td>
<td>13 (37.1%)</td>
<td>24 (34.3%)</td>
<td>0.615</td>
</tr>
<tr>
<td></td>
<td>Middle Adulthood</td>
<td>24 (88.6%)</td>
<td>22 (62.9%)</td>
<td>46 (65.7%)</td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td>Mean ± SD</td>
<td>35.23±7.87</td>
<td>34.29±7.87</td>
<td>-</td>
<td>0.034</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>24(80%)</td>
<td>26(82.9%)</td>
<td>50(71.4%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>14(40%)</td>
<td>12(37.1%)</td>
<td>26(37.1%)</td>
<td>0.015</td>
</tr>
<tr>
<td>Number Of Lesions</td>
<td>Single</td>
<td>16(45.7%)</td>
<td>21(45.5%)</td>
<td>37(52.8%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Multiple</td>
<td>19(54.3%)</td>
<td>25(54.5%)</td>
<td>44(67.2%)</td>
<td></td>
</tr>
</tbody>
</table>

In Table 2, while comparing the efficacy, in group-A
26 (74.3%) patients showed excellent response as compared to 14 (40%) patients in Group-B (p=0.05), whereas remaining patients of Group A showed 5 (14.3%) marked, 3 (8.6%) moderate, 1 (2.8%) slight dose response. The rest of group B showed marked, moderate and slight response to the dose as 15 (42.9%), 4 (11.4%) 2 (5.7%) respectively. There is significant relationship between both the treatment group which showed that clobetasol propionate of group A had significant difference than the group B topical Tacrolimus 0.01% (p=0.028).

Table 2: Treatment efficacy between both Groups at end of treatment (n=70)

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group A vs. Group B</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grades of response</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excellent (&gt;75% re-growth)</td>
<td>26 (74.3%)</td>
<td>14 (40%)</td>
</tr>
<tr>
<td>Marked (51-75% re-growth)</td>
<td>5 (14.3%)</td>
<td>15 (42.9%)</td>
</tr>
<tr>
<td>Moderate (26-50% re-growth)</td>
<td>3 (8.6%)</td>
<td>4 (11.4%)</td>
</tr>
<tr>
<td>Slight (≤ 25% re-growth)</td>
<td>2 (5.7%)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>35 (100%)</td>
<td>39 (100%)</td>
</tr>
</tbody>
</table>

**Discussion**

In our study, topical clobetasol propionate 0.05% was used to treat 35 patients in group-A while topical tacrolimus 0.1% was used to treat 35 patients in group-B. In terms of age distribution, both groups included a majority of people who were 31 to 50 years of age. The duration of sickness was essentially comparable across the two groups as majority of the patients had less than 2 months of illness duration. The study showed that topical clobetasol propionate 0.05% had 74.3% excellent response as compared to the topical tacrolimus 0.1% i.e., 40% which is similar to the study conducted in 2022 by Ullah et al., [11]. Sotiriou et al., studied the effect of topical tacrolimus 0.1% as 45% for active patchy alopecia areata which is quite close to our 40% excellent response in adult patients [12]. Thus, another study by Rokhsar et al., find out 70% topical efficacy of clobetasol propionate while treating alopecia areata but in this study we find out 74% efficacy which is better than the study conducted by Rokhsar et al., [13]. In this study only 4 (11.43%) patients treated with clobetasol propionate Vs. 6(17.14%) patients treated with Tacrolimus 0.1% reported less than 50% improvement during this trial, opposed to 79.4% patients treated with clobetasol and 76.5% patients in the study of Hossain et al., [14, 15]. The determinants of the study were age, gender and number of lesions. There was insignificant difference for age [16] between both groups except gender, number of lesions which showed significant difference which is similar to the study conducted by You et al., [17]. On the contrary, in a meta-analysis suggests that AA is also associated with systemic and psychiatric diseases also. Therefore, Physicians are highly encouraged to assess and manage co-morbidities to get better outcomes [18, 19]. Chanprapaph et al., studied that gender male was the risk factor of alopecia areata which is similar to our study in which most of the patients were male and statistically significant difference was seen as p-value 0.034 [20], but in some studies reported that both genders are equally diagnosed with AA. In group-A 28(40%) patients suffered multiple number of lesions as compared to group-A 09(25.7%) patients. Despite large number of patients suffering multiple lesions in group-A, Clobetasol propionate's efficacy is markedly more than the topical tacrolimus to treat multiple lesions effectively. This comparative efficacy advantage of using clobetasol is more support use of in clinical practice in severe AA. Thereby this study was conducted to compare the efficacy of both groups in order to better treat alopecia (AA) patients and provide informed treatment by following evidence-based practice.

**Conclusions**

Topical clobetasol propionate 0.05% was more efficacious as a therapy choice for stimulating hair re-growth among patients of alopecia areata. It also treats multiple lesions effectively as compared to tacrolimus. The treatment is compliant to all patients.

**Authors Contribution**

Conceptualization: DS, BM
Methodology: SA, HF
Formal analysis: DS, MAS, MH
Writing-review and editing: DS, SA, HF

All authors have read and agreed to the published version of the manuscript.

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**Conflicts of Interest**

The authors declare no conflict of interest.

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