*Pakistan Journal of Intensive Care Medicine*
*eISSN: 2708-2261; pISSN: 2958-4728*
www.pjicm.com
DOI: https://doi.org/10.54112/pjicm.v5i02.143
*Pak. J. Inten. Care Med., volume 5(2), **2025**: 143*
*Original Research Article*

# COMPARATIVE EFFICACY OF TOPICAL CLOBETASOL PROPIONATE 0.05% OINTMENT AND TOPICAL TACROLIMUS 0.1% OINTMENT IN THE TREATMENT OF ALOPECIA AREATA

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*(Received, 05th May 2025, Revised 18th June 2025, Accepted 06th July, Published 17th July 2025)*

## ABSTRACT

***Background:*** *Alopecia areata (AA) is a chronic autoimmune disorder characterized by nonscarring hair loss. Various topical therapies are used, yet their relative efficacy remains debated.* ***Objective:*** *To compare the efficacy of topical clobetasol propionate 0.05% and topical tacrolimus 0.1% ointment in the treatment of alopecia areata.* ***Study Design:*** *Randomized controlled trial.* ***Setting:*** *Dermatology Department, Combined Military Hospital (CMH), Nowshera, Pakistan.* ***Duration of Study:*** *11-October-2024 to 11-April-2025.* ***Methods:*** *A total of 62 patients with ≤3 Alopecia areata patches (≤3 cm diameter) and no systemic autoimmune disorders were recruited. Participants were randomized into two equal groups (n = 31 each) using a blocked randomization method. Group A applied clobetasol propionate 0.05% ointment twice daily, while Group B applied tacrolimus 0.1% ointment for three months. Efficacy was assessed using the Severity of Alopecia Tool (SALT) score, with treatment success defined as a SALT score ≤4. Statistical significance was assessed using the chi-square test, with $p < 0.05$ considered statistically significant.* ***Results:*** *The mean age in Group A was 33.06 ± 11.67 years, while in Group B it was 30.45 ± 12.33 years. Treatment success was achieved in 23 patients (74.2%) in the clobetasol group, compared to 14 patients (45.2%) in the tacrolimus group, showing a statistically significant difference ($p = 0.02$).* ***Conclusion:*** *Topical clobetasol propionate 0.05% demonstrated superior efficacy compared to topical tacrolimus 0.1% in the treatment of alopecia areata, highlighting its role as a preferred first-line topical therapy.*

**Keywords:** Alopecia Areata, Clobetasol Propionate, Tacrolimus, SALT Score, Topical Treatment.

## INTRODUCTION

Alopecia areata (AA) is a persistent, immune-mediated autoimmune condition that affects hair follicles and nails (1). This condition affects anagen hair follicles in individuals, leading to hair loss while preserving the integrity of the follicles. AA results from an autoimmune disturbance in the normal hair cycle, leading to loss of immune privilege in hair follicles. AA typically manifests as localized areas of hair loss on the scalp, developing over several weeks. AA is typically presenting as isolated, nonscarring, as well as patchy hair loss on the scalp or any region with hair growth (2-4). AA can present as an acute, self-limiting condition involving one to five patches that typically resolve within 6–12 months, as a chronic condition characterized by numerous patches that relapse and remit over several years, or as total scalp hair loss (5). The annual incidence of AA is reported to be 0.2%, with a lifetime risk estimated to be 1.7% (6).

AA is a prevalent but challenging condition to treat in dermatology. For limited scalp AA, intralesional corticosteroid treatment is regarded as the preferred treatment by numerous experts. Local application of topical corticosteroids is effective in managing moderate-to-severe AA (7). Folliculitis is a widespread negative effect associated with the use of topical corticosteroids. Telangiectasia, as well as atrophy, may occur infrequently (8). However, the main drawbacks of these approaches are their limited efficacy and the occurrence of both local and systemic adverse reactions, especially during long-term therapy, which restrict their application. Tacrolimus, a nonsteroidal topical immune modulator, can be used as an effective treatment for various inflammatory skin disorders, including AA (9, 10). According to a study, the comparative efficacy of topical clobetasol propionate 0.05% ointment was 79.31%, and topical tacrolimus 0.1% ointment was 44.82% for the treatment of alopecia areata (8). AA patients have the option to select from a range of therapeutic approaches. Every strategy possesses distinct benefits and constraints, and its appropriateness differs for each individual. The existing literature on this topic in our local context is scarce; therefore, the goal of this study is to compare the efficacy of topical clobetasol propionate 0.05% ointment and topical tacrolimus 0.1% ointment for the treatment of alopecia areata at our hospital. To our clinicians, investigating the therapeutic effects of these treatments in clinical trials could provide valuable insights into their respective roles as first-line or adjunctive therapies, optimizing treatment approaches, and enhancing patient outcomes in this challenging dermatological condition.

## METHODOLOGY

The study was designed as a randomized controlled trial conducted in the Department of Dermatology at Combined Military Hospital (CMH), Nowshera. The study duration spanned from October 11, 2024, to April 11, 2025, following approval from the institute. Sixty-two participants were enrolled and randomly assigned to two groups using a blocked randomization method.

The sample size was determined using the WHO sample size calculator, with efficacy rates of 79.31% for clobetasol propionate and 44.82% for tacrolimus, based on prior research.[11] The study maintained a power of 80% and a confidence level of 95%. Consecutive non-probability sampling was employed. Patients aged 18–60 years of all genders with no history of psychological illness or other autoimmune disorders and presenting with no more than three patches of alopecia areata, each measuring ≤3 Cm in diameter were included. Alopecia areata was diagnosed clinically based on well-demarcated, smooth patches of non-scarring hair loss, characterized by "exclamation mark" hairs within the affected areas. Exclusion protocols comprised patients with alopecia universalis or totalis, hypersensitivity to topical treatments, those on systemic immunosuppression therapy, lactating or pregnant women, and individuals unable to adhere to treatment or follow-up visits. Consent was taken from the patients. Demographic and clinical data, including

age, gender, BMI, education, occupation, socioeconomic status, and medical history (e.g., hypertension, diabetes), were recorded. At baseline, the number and size of patches were documented. Group A (n = 31) received topical clobetasol propionate 0.05% ointment twice daily for 3 months. Group B received topical tacrolimus 0.1% ointment twice daily for a period of three months. Patients were switched to standard treatment as per disease severity if there was a rapid progression. Follow-up assessments were conducted to monitor hair regrowth using the Severity of Alopecia Tool (SALT) score where efficacy was defined based on severity of alopecia tool (SALT) score using score from 0 to 4: 0 represented (10% regrowth), one represented (11 -25% regrowth), two represented (26-50%), three represented (51- 75%) and four represented (>75%re-growth), >75% regrowth (score of 4) after three months was considered effective treatment. A consultant dermatologist with at least five years of post-fellowship experience supervised all evaluations.

Data analysis was done with SPSS 20. Age, height, weight, and BMI were expressed as mean ± SD. Gender, residence, socioeconomic status, education, occupation, efficacy, hypertension, and diabetes were presented as frequencies and percentages. The chi-square test was used to compare efficacy between groups at a 5% significance level. Stratifications were performed for demographic characteristics and comorbidities using the Chi-Square test with a 5% level of significance.

## RESULTS

In Group A, the mean age of the participants was 33.06 ± 11.67 years, with a mean BMI of 25.06 ± 1.65 kg/m². Group B had a mean age of 30.45 ± 12.33 years and a BMI of 24.71 ± 1.31 kg/m². Both groups were balanced in terms of gender distribution, with males comprising 19 (61.3%) in Group A and 18 (58.1%) in Group B. Females accounted for 12 (38.7%) and 13 (41.9%) in Groups A and B, respectively (Table 1).

Comorbidities were comparable, with diabetes present in 4 (12.9%) of Group A and 3 (9.7%) of Group B. Hypertension was reported in 6 (19.4%) and 7 (22.6%) of Groups A and B, respectively (Table 2).

Efficacy analysis demonstrated a significant advantage for clobetasol, with 23 (74.2%) achieving successful treatment outcomes, compared to 14 (45.2%) in the tacrolimus group (p = 0.02) (Table 3). Tables 4 and 5 present the stratifications by comorbidities and demographics.

**Table 1: Demographics**

| Demographics | | Groups | | | |
|---|---|---|---|---|---|
| | | Group A (Clobetasol) | | Group B (Tacrolimus) | |
| | | n | % | n | % |
| Gender | Male | 19 | 61.3% | 18 | 58.1% |
| | Female | 12 | 38.7% | 13 | 41.9% |
| Education | Literate | 14 | 45.2% | 13 | 41.9% |
| | Illiterate | 17 | 54.8% | 18 | 58.1% |
| Occupation status | Employed | 18 | 58.1% | 15 | 48.4% |
| | Unemployed | 13 | 41.9% | 16 | 51.6% |
| Residence | Urban | 16 | 51.6% | 17 | 54.8% |
| | Rural | 15 | 48.4% | 14 | 45.2% |
| Socioeconomic status | Lower class | 5 | 16.1% | 6 | 19.4% |
| | Middle class | 19 | 61.3% | 17 | 54.8% |
| | Upper class | 7 | 22.6% | 8 | 25.8% |

**Table 2: Comorbidities**

| Comorbidities | | Groups | | | |
|---|---|---|---|---|---|
| | | Group A | | Group B | |
| | | n | % | n | % |
| Diabetes | Yes | 4 | 12.9% | 3 | 9.7% |
| | No | 27 | 87.1% | 28 | 90.3% |
| Hypertension | Yes | 6 | 19.4% | 7 | 22.6% |
| | No | 25 | 80.6% | 24 | 77.4% |

**Table 3: Comparison of efficacy between both groups**

| Efficacy | Groups | | | | P value |
|---|---|---|---|---|---|
| | Group A | | Group B | | |
| | n | % | n | % | |
| Yes | 23 | 74.2% | 14 | 45.2% | 0.02 |
| No | 8 | 25.8% | 17 | 54.8% | |

**Table 4: Stratification of comparison of efficacy between both groups with comorbidities**

| | | | | Groups | | | | P value |
|---|---|---|---|---|---|---|---|---|
| | | | | Group A | | Group B | | |
| | | | | n | % | n | % | |
| Diabetes | Yes | Efficacy | Yes | 2 | 50.0% | 1 | 33.3% | P > 0.05 |
| | | | No | 2 | 50.0% | 2 | 66.7% | |
| | No | Efficacy | Yes | 21 | 77.8% | 13 | 46.4% | **P < 0.05** |
| | | | No | 6 | 22.2% | 15 | 53.6% | |
| Hypertension | Yes | Efficacy | Yes | 5 | 83.3% | 3 | 42.9% | P > 0.05 |
| | | | No | 1 | 16.7% | 4 | 57.1% | |
| | No | Efficacy | Yes | 18 | 72.0% | 11 | 45.8% | P > 0.05 |
| | | | No | 7 | 28.0% | 13 | 54.2% | |

**Table 5: Stratification of comparison of efficacy between both groups with demographics**

| | | | | Groups | | | | P value |
|---|---|---|---|---|---|---|---|---|
| | | | | Group A | | Group B | | |
| | | | | n | % | n | % | |
| Gender | Male | Efficacy | Yes | 13 | 68.4% | 6 | 33.3% | **P < 0.05** |
| | | | No | 6 | 31.6% | 12 | 66.7% | |
| | Female | Efficacy | Yes | 10 | 83.3% | 8 | 61.5% | P > 0.05 |
| | | | No | 2 | 16.7% | 5 | 38.5% | |
| Education | Literate | Efficacy | Yes | 11 | 78.6% | 7 | 53.8% | P > 0.05 |
| | | | No | 3 | 21.4% | 6 | 46.2% | |
| | Illiterate | Efficacy | Yes | 12 | 70.6% | 7 | 38.9% | P > 0.05 |
| | | | No | 5 | 29.4% | 11 | 61.1% | |

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| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Occupation status | Employed | Efficacy | Yes | 14 | 77.8% | 7 | 46.7% | P > 0.05 |
| | | | No | 4 | 22.2% | 8 | 53.3% | |
| | Unemployed | Efficacy | Yes | 9 | 69.2% | 7 | 43.8% | P > 0.05 |
| | | | No | 4 | 30.8% | 9 | 56.2% | |
| Residence | Urban | Efficacy | Yes | 10 | 62.5% | 7 | 41.2% | P > 0.05 |
| | | | No | 6 | 37.5% | 10 | 58.8% | |
| | Rural | Efficacy | Yes | 13 | 86.7% | 7 | 50.0% | **P < 0.05** |
| | | | No | 2 | 13.3% | 7 | 50.0% | |
| Socioeconomic status | Lower class | Efficacy | Yes | 5 | 100.0% | 3 | 50.0% | P > 0.05 |
| | | | No | 0 | 0.0% | 3 | 50.0% | |
| | Middle class | Efficacy | Yes | 14 | 73.7% | 8 | 47.1% | P > 0.05 |
| | | | No | 5 | 26.3% | 9 | 52.9% | |
| | Upper class | Efficacy | Yes | 4 | 57.1% | 3 | 37.5% | P > 0.05 |
| | | | No | 3 | 42.9% | 5 | 62.5% | |
| Age groups (Years) | 18 to 35 | Efficacy | Yes | 15 | 78.9% | 10 | 50.0% | P > 0.05 |
| | | | No | 4 | 21.1% | 10 | 50.0% | |
| | 36 to 50 | Efficacy | Yes | 7 | 77.8% | 2 | 28.6% | **P < 0.05** |
| | | | No | 2 | 22.2% | 5 | 71.4% | |
| | > 50 | Efficacy | Yes | 1 | 33.3% | 2 | 50.0% | P > 0.05 |
| | | | No | 2 | 66.7% | 2 | 50.0% | |
| BMI (Kg/m2) | 18 to 25 | Efficacy | Yes | 14 | 70.0% | 12 | 46.2% | P > 0.05 |
| | | | No | 6 | 30.0% | 14 | 53.8% | |
| | > 25 | Efficacy | Yes | 9 | 81.8% | 2 | 40.0% | P > 0.05 |
| | | | No | 2 | 18.2% | 3 | 60.0% | |

## DISCUSSION

The mean age of participants in our study (33.06±11.67 years for clobetasol and 30.45±12.33 years for tacrolimus) closely mirrors the age ranges reported in similar trials. Sajjad et al. documented a mean age of 35.23±7.87 years for clobetasol and 34.29±7.87 years for tacrolimus (12). Zarin et al. noted averages of 32.1 ± 7.5 years across both groups (13). This consistency suggests that AA predominantly affects adults in their third to fifth decades, a pattern further supported by Hossain et al., who reported that the majority of participants were aged 15–50 years (14). The slight age disparity between groups in the current study reinforces that age is less predictive of treatment response than the choice of therapy.

The gender distribution in our study, with 61.3% males in the clobetasol group and 58.1% in the tacrolimus group, echoes the male predominance observed by Sajjad et al. (71.4% male) and Nassar et al. (90% male in some subgroups) (12, 15). This aligns with broader epidemiological data indicating a higher AA prevalence in males, possibly due to hormonal or genetic factors.

Educational and employment statuses, which are rarely addressed in prior AA studies, were explored here. Illiteracy rates were high (54.8% in clobetasol and 58.1% in tacrolimus), with unemployment exceeding 40% in both groups. These socioeconomic factors may indirectly affect treatment adherence or access, but did not correlate with efficacy in this trial.

The superior efficacy of clobetasol (74.2% success) over tacrolimus (45.2%) in our study reinforces findings from multiple trials. Sajjad et al. reported that 74.3% of clobetasol patients achieved >75% regrowth, whereas 40% of those using tacrolimus did. In contrast, Zarin et al. (2025) noted that 83% of clobetasol users attained ≥50% regrowth, compared to 33% with tacrolimus (12, 13).

Hossain et al. documented almost equal efficacy for both drugs in the treatment of AA (14). Nassar et al. compared three different treatments for AA in their study. They concluded that Tacrolimus should not be recommended for the treatment of AA, which further affirms our findings (15). The mechanistic superiority of clobetasol likely stems from its potent anti-inflammatory action, suppressing perifollicular T-cell activity more effectively than tacrolimus. This aligns with Nassar et al.'s observation that calcineurin inhibitors, such as tacrolimus, while safer, struggle to penetrate hair follicles due to their molecular size (9).

The collective evidence positions clobetasol as the first-line topical for AA, particularly in adults with patchy lesions. Future research should explore stratified protocols based on disease duration and trichoscopic patterns. Combining tacrolimus with penetration enhancers (e.g., fractional lasers) or immunomodulators could bridge the efficacy gap.

## CONCLUSION

In conclusion, the efficacy of topical clobetasol propionate 0.05% ointment was significantly superior to topical tacrolimus 0.1% ointment for the treatment of alopecia areata.

## DECLARATIONS

**Data Availability Statement**

All data generated or analysed during the study are included in the manuscript.

**Ethics approval and consent to participate**

Approved by the department Concerned. (IRB Ref#08)

**Consent for publication**

Approved

**Funding**

Not applicable

## CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

## AUTHOR CONTRIBUTION

***MOHAMMAD ISHAQ (Trainee Medical Officer)***

*Conception Of Study, Data Collection, Study Design, Manuscript Revisions, Manuscript Drafting, and Final Approval Of Manuscript.*

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***SUMMAYA SALEEM (Assistant Professor)**.*
*Conception of Study, Critical Input, and Final approval of manuscript.*

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