DOI: https://doi.org/10.53350/pjmhs22166133

ORIGINAL ARTICLE

Efficacy of Topical Clobetasol Propionate 0.05% Ointment and Topical Tacrolimus 0.1% Ointment in Treatment of Alopecia Areata: RCT

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ABSTRACT

Background: Non-scarring hair loss from the scalp or body occurs as a result of alopecia areata. It is the most prevalent autoimmune disorder. **Aims:** To compare the efficacy of topical clobetasol propionate 0.05% ointment and topical tacrolimus 0.1% ointment in the management of localized alopecia areata.
Study design: Randomized control trial.
Methodology: All patients (n=116) having alopecia areata of the scalp were included. SALT Score was calculated at presentation. Group A received topical clobetasol propionate 0.05% ointment applied twice daily over the alopecia patch and group B received topical tacrolimus 0.1% twice daily for 3 months. Patients were followed in OPD at 1month, 2months and 3months interval to ensure compliance. All this information was recorded on Performa. Data was analyzed using SPSS version 26. Efficacy of both groups was compared using Chi square test and keeping P-value of ≤ 0.05 as significant.
Results: As per efficacy, in Group A, 46 (79.31%) patients showed effective results whereas in Group B only 26 (44.82%) patients showed effective results with a significant P-value of 0.00013. **Conclusion:** It was concluded that topical clobetasol propionate 0.05% ointment was more effective as a treatment option in promoting hair re-growth among patients of alopecia areata.
Keywords: Alopecia Areata, Tacrolimus, Clobetasol Propionate and Hair Re-growth.

INTRODUCTION

Non-scarring hair loss from the scalp or body occurs as a result of alopecia areata. It is the most prevalent autoimmune disorder and 2nd most prevalent hair loss disorder after androgenic alopecia and the lifetime risk is estimated to be 2% worldwide[1]. Among Asian population, its prevalence is around 0.7-3.8% among all skin issues[2,3]. A positive family history for 1st degree relatives is found in 21.8% of patients[4]. It usually affects children and young adults[5].

It is a T cell–mediated autoimmune disease of hair follicles. It usually presents as round or oval patches of hair loss with normal underlying skin in the scalp or body. Sometimes it may cause loss of all scalp hair, body hair (alopecia universalis) or band like patches of hair loss may occur around the circumference of the scalp in the occipital, temporal and frontal areas (ophiasis)[5]. Diagnosis is usually easy based upon history and clinical examination. Exclamation mark hair (broken hair that are wider distally and tapper proximally towards the scalp) are highly specific for AA[6].

It does not destroy hair follicles. Hair re-growth potential remains life-long. The course of the disease is very unpredictable. Spontaneous remission occurs is reported among 80% of its sufferers[7]. Poor prognostic factors include early age of onset, long lasting, extensive disease and concomitant autoimmune diseases (atopy, autoimmune thyroid disease and vitiligo). Alopecia areata causes significant changes in appearance of patient and may lead to social phobia, anxiety and depression[8]. Since spontaneous remission is common patients with minimal alopecia areata can be managed by explanation of nature of the disease and advice just to "wait and see"[7]. In patients with progressive or extensive disease the main purpose of treatment is to arrest the disease activity. Commonly used treatment modalities are steroids (intra-lesional, topical or systemic), contact immunotherapy, anthraline, minoxidil, calcineurine inhibitors, topical retinoids, systemic immune modulating agents, photo-chemotherapy, dermatography wigs and hypnotherapy etc[9,10]. Steroids are usually the 1st choice by many dermatologists but there prolonged use can cause scalp atrophy, folliculitis and hypo-pigmentation. One researcher found topical tacrolimus to be ineffective in treatment of alopecia areata after 24 weeks of twice daily application[11]. Due to its increasing prevalence and lack of local data on its management, we designed current study in-order to evaluate its effective treatment option in our setups.

The objective of the study was to compare the efficacy of topical clobetasol propionate 0.05% ointment and topical tacrolimus 0.1% ointment in the management of localized alopecia areata.

Received on 07-10-2021
Accepted on 17-05-2022

METHODOLOGY

After getting permission from ethical review committee, patients (n=116) having alopecia areata of the scalp were included. SALT Score was calculated at presentation. Group A received topical clobetasol propionate 0.05% ointment applied twice daily over the alopecia patch and group B received topical tacrolimus 0.1% twice daily for 3 months. Patients were followed in OPD at 1month, 2 months and 3months interval to ensure compliance. Patients having age (11-50 years), number of patches (≤ 5), no previous treatment for hair loss and duration of alopecia areata (≤ 6months) were enrolled in present study. Patients with pregnancy, lactating mothers, atypical alopecia areata and those who were using immunosuppressive drugs and systemic glucocorticoids were ruled out. Hair re-growth score was calculated from the SALT Score at presentation and SALT Score on follow up after 3 months as follows- 0(re-growth ≤10), 1(11-25%), 2(26-50%), 3(51-75%) and 4(re-growth >75%). Efficacy was considered yes if re-growth ≥3. Written consent was taken.
Statistical Analysis: Data was analyzed by SPSS v.26.0. Frequencies and percentages presented categorical variables like gender & efficacy. Mean±SD presented continuous variables like age of the patients, number of patches, duration of disease, SALT Score and hair RGS. Efficacy of both groups was compared using Chi square test and keeping P-value of ≤ 0.05 as significant.

RESULTS

Age presented as Mean±SD in group-A was 31.71±6.72 while in group-B, it was 30.26±6.66 as shown in table-1. In age wise distribution, in Group A, 27(46.55%) patients were recorded in 11-30 years age group whereas 31(53.44%) patients were recorded in 31-50 years age group. In the same manner, in Group B, 27(46.55%) patients were recorded in 11-30 years age group whereas 31(53.44%) patients were recorded in 31-50 years age group.

Table-1: Variables Presented as Mean ± SD

Variables	Group-A	Group-B
Gender Distribution		
Males	38 (65.51%)	38 (65.51%)
Females	20 (34.48%)	20 (34.48%)
Age Groups		
11-30 Years	27 (46.55%)	27 (46.55%)
31-50 Years	31 (53.44%)	31 (53.44%)
Age	31.71±6.72	30.26±6.66
No of patches	2.26±0.45	2.76±0.65
Duration of Disease	2.29±1.08	2.91±1.08
RGS	3.09±0.66	2.57+0.73

As per efficacy, in Group A, 46(79.31%) patients showed effective results whereas in Group B only 26(44.82%) patients showed effective results with a P-value (0.00013) as shown in table-2.

Table-2: Efficacy of Rx among both groups

Efficacy	Group-A	Group-B	P-value
Yes	46 (79.31%)	26 (44.82%)	0.00013*
No	12 (20.68%)	32 (55.17%)	

*Statistically significant

Stratification of efficacy with respect to age with significant p-values was shown in table-3.

Table-3: Stratification of Efficacy with Age

Age	Efficacy	Group-A	Group-B	P-value
11-30 Years	Yes	21 (36.20%)	09 (15.51%)	0.0010*
	No	06 (10.34%)	18 (31.03%)	
31-50 Years	Yes	25 (43.10%)	17 (29.31%)	0.0914*
	No	06 (10.344%)	11 (18.96%)	

*Statistically significant

Stratification of efficacy with respect to gender with significant p-values was shown in table-4.

Table-4: Stratification of Efficacy with Gender

Gender	Efficacy	Group-A	Group-B	P-value
Males	Yes	28 (48.27%)	16 (27.58%)	0.005*
	No	10 (17.24%)	22 (37.93%)	
Females	Yes	18 (31.03%)	10 (17.24%)	0.005*
	No	02 (3.44%)	10 (17.24%)	

*Statistically significant

DISCUSSION

This disease of short duration is treatable with 75% success rate[12]. Our study compared efficacy of a steroid with immunomodulator in the management of localized alopecia areata. Tacrolimus is a topical immune-modulator that is usually used as treatment option for atopic dermatitis.[13] It has a versatile functions thus can be applied in many other skin disorders including alopecia as demonstrated by previous study.[14] Past many studies illustrated that first line therapy for its treatment is intra-lesional steroids.[15] However, patients have to face few side effects like pain and dermal atrophy during therapy. Secondly, it is an expensive and time consuming treatment. On the other side, many studies showed promising results of steroids when used as its treatment.[14] Present results depicted that when topical corticosteroid, Clobetasol propionate, when used for treatment of mild to moderate alopecia of new onset produced effective outcomes clinically thus findings were in line with many studies. Although different treatment options include both local as well as systemic medicines can be applied for re-growth of hair but all of them have their own adverse effects. The high spontaneous remission rate of alopecia areata sometimes makes it difficult to clearly assess the true efficacy of a given therapy[3].

One study showed that the efficacy of topical tacrolimus treatment is 45% as compared to topical betamethasone which is 70% in the treatment of alopecia areata[12] which as compared to our results where in Group A, 46(79.31%) patients shown effective results whereas in Group B only 26 (44.82%) patients showed effective results with p-value (0.00013) (Table 2). Another study found that steroids as a more effective and safe treatment option[13]. However, one researcher reported 83% efficacy of topical tacrolimus in comparison to clobetasol propionate with 90% efficacy[14] which was comparable to our results.

Limitations: Short sample size with short duration of study and financial constrains were the limitations followed by lack of genetic workup.

CONCLUSION

It was concluded that topical clobetasol propionate 0.05% ointment was more effective as a treatment option in promoting hair re-growth among patients of alopecia areata with mild to moderate disease.

Conflict of Interest: None to declare

Financial Disclosure: None

Authors' Contribution: FU&MD: Conceptualized the study, analyzed the data, and formulated the initial draft, **NN:** Contributed to the proof reading, **SH:** Collected data

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