Topical Betamethasone Valerate 0.1% W/V vs. Topical Ketoconazole 2% W/V: A Comparison of Efficacy in Patients of Seborrheic Dermatitis

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ABSTRACT

Objective: To compare the efficacy of topical Betamethasone valerate 0.1% w/v and topical Ketoconazole 2% w/v in patients of seborrheic dermatitis.

Study Design: Comparative prospective study.

Place and Duration of Study: Department of Dermatology, Pak Emirates Military Hospital Rawalpindi Pakistan from Feb to Aug 2019.

Methodology: A total of 80 patients of both genders with seborrheic dermatitis were included. Patients were divided into two groups randomly, with 40 patients in each group. Group-A patients were given topical Betamethasone valerate 0.1% w/v, while patients in Group-B were given topical Ketoconazole 2% w/v for 12 weeks. Data regarding efficacy was assessed after 12 weeks per operational definition from both groups and noted.

Results: The mean age of patients in group A was 34.45 ± 6.73 years, and in the Group-B was 32.18 ± 6.07 years. The majority of the patients, 54 (67.50%), were between 15 to 35 years of age. Efficacy of Group-A (topical Betamethasone valerate 0.1%) was seen in 35 (87.50%) patients while in Group-B (topical Ketoconazole 2%) efficacy was seen in 25 (62.50%) patients (*p*-value = 0.010).

Conclusion: This study concluded that the efficacy of topical Betamethasone valerate 0.1% w/v is higher than topical Ketoconazole 2% w/v in patients with seborrheic dermatitis.

Keywords: Efficacy, seborrheic dermatitis, topical Betamethasone.

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INTRODUCTION

Seborrheic dermatitis occurs in approximately 3 to 5 percent of the general population and is a common relapsing inflammatory skin condition with a worldwide distribution.[1] Its incidence most commonly occurs during three age periods – the first three months of life, puberty, and adulthood, with the peak occurring in 40-60 years of age.[2] Diaper rash and cradle cap are usually related to seborrheic dermatitis. Host immune response, genetic bases, oxidative stress, and nutritional and emotional factors have all been shown to play a role in the aetiology and pathogenesis of seborrheic dermatitis.[3] Scalp, face, retro auricular area, and the upper chest are the usual sites of seborrheic dermatitis, which results in flaking, scaling, inflammation, pruritus and erythema.[4] Seborrheic dermatitis is usually a multifactorial disease requiring multiple predisposing factors for its progress. The presence of these factors leads to the production of opportunistic yeast Pityrosporum Ovale Malassezia spp.[5] The fungus utilizes lipids from the skin surface to produce saturated and unsaturated fatty acids, which induce an inflammatory response when left in the individual's skin environment. Antifungal medication response in seborrheic dermatitis treatment shows a strong association between Malassezia and seborrheic dermatitis. Even if the yeast is not critical to the disease pathogenesis, it is at least an exacerbating factor.[5,6] The aim of treatment is not just achieving remission of lesions but also to prevent recurrence of the disease.[7] Topical corticosteroids and antifungals are considered the first-line agents among various treatment options.[8] Tacrolimus is also reported as a successful treatment option.[9] Salicylic acid, Zinc pyrithione and Coal tar are included in other therapeutic options, which are topically applied and work by softening thick and hard crusts that can occur in seborrheic dermatitis.[8] Topical antifungal preparations like Ketoconazole, other Imidazole derivatives, and antifungal drugs of other pharmacological classes such as Ciclopirox, all of which can be used in the form of ointments, creams and lotions and are always used in the recurrent seborrheic dermatitis. In one study, the efficacy of topical Betamethasone was 89% compared

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to 62% with topical Ketoconazole in patients with seborrheic dermatitis.[10]

As we come across with patients of seborrheic dermatitis very often in our practice, this prompted us to compare the efficacy of topical Betamethasone 0.1% w/v and topical Ketoconazole 2% w/v in such patients. Therefore, our study results will help select a convenient and more efficacious treatment modality in patients of seborrheic dermatitis in our local population.

METHODOLOGY

This comparative prospective study was conducted at the Department of dermatology, Pak Emirates Military Hospital, Rawalpindi Pakistan, from February 2019 to August 2019. This study included 80 patients of both genders after informed consent and Hospital Ethical Committee approval (No. A/28). We used WHO calculator to calculate the sample size. Sample size was calculated with confidence level = 95% and alpha = 5% (two-sided) with power = 80%. By using expected (efficacy) proportion in population 1 = 89%10 and expected (efficacy) proportion in population 2=62%.[10] Non-probability consecutive sampling was the sampling technique used.

Inclusion Criteria: Patients of age 15 to 60 years, with seborrheic dermatitis and previously treatment naïve were included in the study.

Exclusion Criteria: Patients with the history of using any topical or systemic medications in the form of antifungal, keratolytic or immune-suppressant for the last six weeks or history of diabetes mellitus, chronic kidney disease, HIV/ AIDS were excluded from the study.

Case of seborrheic dermatitis was defined as when Seborrhea Area and Severity Index (SASI) scores of >4 and involvement of three or more anatomic sites on the face/scalp by physical examination. Efficacy was done on 5 points visual analogue scale and graded as 1-worse, 2-no change, 3 ≤30%, 4 = 30–50%, 5 ≥50% improvement. Efficacy was rated on grade 5 after 12 weeks of treatment.[11]

At the start of the study, baseline demographics like age, gender and SASI score were recorded. Then, a block design was used as a tool to perform randomization. Randomization was 1:1 for Group-A, and Group-B. Sample size for each Group-A (topical Betamethasone valerate 0.1% w/v) and Group-B (topical Ketoconazole 2% w/v) was 40. Patients were instructed to apply the study lotions per randomization once daily to the selected target area for 12 weeks. Data regarding efficacy was assessed after 12 weeks per the operational definition described above from both groups and noted on proforma.

Statistical Package for Social Sciences (SPSS) version 22.0 was used for the data analysis. Analysis was done to compare the proportion of Group-A, and Group-B. Frequency and percentage were computed for qualitative variables like gender, marital status (married/unmarried) and efficacy. Mean ± SD were presented for quantitative variables like SASI score and duration of complaint. The Chi-square test was applied to compare efficacy in both groups, with $p \leq 0.05$ as significant.

RESULTS

A total of 80 patients with seborrheic dermatitis fulfilling inclusion and exclusion criteria were included. The age range in this study was from 15 to 60 years, with the mean age of patients in Group-A being 34.45 ± 6.73 years and in the Group-B was 32.18 ± 6.07 years. The majority of the patients (54, 67.50%), were between 15 to 35 years of age, as shown in Table-I. 31 (38.75%) patients were females, and 49 (61.25%) were males. The mean duration of the disease was 9.77 ± 2.13 months.

Table-I: Age distribution for both groups (n=80).

Age (Years)	Group A (n=40)		Group B (n=40)		Total (n=80)	
	No. of Patients	Age%	No. of Patients	Age%	No. of Patients	Age%
15-35	26	65.0	28	70.0	54	67.50
36-60	14	35.0	12	30.0	26	32.50
Mean ± SD	34.45 ± 6.73		32.18 ± 6.07		32.88 ± 6.23	

The mean disease duration was 9.77 ± 2.13 months, and the mean SASI score was 23.71 ± 5.55. Efficacy of Group-A (topical Betamethasone valerate 0.1%) was seen in 35 (87.50%) patients, while in Group-B (topical Ketoconazole 2%) was seen in 25 (62.50%) patients (p-value = 0.010) as shown in the Table-II.

Table-II: Comparison of efficacy of topical Betamethasone valerate0.1% w/v and topical Ketoconazole 2% w/v in patients of seborrheic dermatitis.

Efficacy	Group-A, (n=40)	Group-B, (n=40)	p-value
Yes	35 (87.50%)	25 (62.50%)	0.010
No	5 (12.50%)	15 (37.50%)	

DISCUSSION

Topical Betamethasone valerate 0.1% and topical Ketoconazole 2% are used widely to treat seborrheic dermatitis. Different studies showed the varied response of these topical preparations. In our study, topical

Betamethasone valerate 0.1% proved more efficacious. Reduction of bothersome symptoms like pruritus and clearance of visible signs of disease are the two primary therapy goals for seborrheic dermatitis. Face and scalp are usually the most commonly affected anatomical areas, redness and itching on the scalp in a patient who is having facial seborrheic dermatitis indicate that both sites need to be treated. Scaly and reddened skin in exposed areas like ears and face, dandruff, and pruritus, along with the chronic and relapsing nature of seborrheic dermatitis, leads to decreased quality of life and self-esteem.[11] FDA-approved systemic treatment options for seborrheic dermatitis are lacking. Long-term management requiring multiple medications further contributes to the burden of disease.[12]

Various other low- to mid-potency corticosteroids and Hydrocortisone has been used successfully in treating seborrheic dermatitis. In a double-blind study in which Hydrocortisone 1% cream and Ketoconazole 2% cream were compared in 72 patients having mild-to-moderate seborrheic dermatitis, it was found that these two agents had a similar response and led to reductions in redness, itching, papules and scaling.[13] In a 4-week randomized, double-blind control trial, topical Atorvastatin has a comparable effect to topical Betamethasone 0.1% lotion.[14] Another study showed that the efficacy of topical Betamethasone was 89% compared to 62% with topical Ketoconazole in patients with seborrheic dermatitis.[10] In another open-label, randomized trial, Betamethasone 0.1% cream was compared with Pimecrolimus 1% cream in 20 patients having seborrheic dermatitis.[15] It was found that these two drugs were equally effective in reducing scaling, erythema, and pruritus. A single-blinded study by Ortonne *et al*, observed 62 patients having seborrheic dermatitis over the face, chest and scalp, which were treated with topical 2% Ketoconazole foaming gel or with a 0.05% Betamethasone dipropionate lotion for four months. They observed a significantly higher response rate of Ketoconazole 2% foaming gel than Betamethasone dipropionate 0.05% lotion.[16] The efficacy of ketoconazole 2% cream was compared with hydrocortisone 1% cream in another study in the treat-ment of a pediatric population with infantile seborr-heic dermatitis having aged between two months to two years. The authors concluded that the efficacy of both the drugs was not significantly different in the treatment of infantile seborrheic dermatitis and recommended that Ketoconazole can be another option in the infantile seborrheic dermatitis treatment, leading to avoidance of the topical corticosteroids' side effects especially following long-term use and when applied over large surface area.[17] A comparative study conduc-ted by Rigopoulos D showed that topical steroid (Beta-methasone 17-valerate 0.1% cream) was more effective than calcineurin inhibitor for treating seborrheic dermatitis, but it was not statistically significant.[18] Thus as potent steroids have better anti-inflammatory properties for which it is used in the management of seborrheic dermatitis, they should be used cautiously to decrease their adverse effect, or these can be replaced with other treatment modalities with better safety profile. In a study, in comparison with baseline, Beta-methasone significantly improved seborrheic dermatitis lesions.[19] In addition, no statistically significant differences between azoles and steroids in their effects on producing total clearance of seborrheic dermatitis lesions.[20] In our study, the efficacy of Group-A (topical Betamethasone valerate 0.1%) was seen in 35 (87.50%) patients, while in Group-B (topical Ketoconazole 2%) was seen in 25 (62.50%) patients (p-value=0.010), which strengthen other studies conducted elsewhere in which topical Betamethasone valerate 0.1% was more efficacious then topical Ketoconazole 2% and is also cost-effective.

LIMITATIONS OF STUDY

Our study had limitations, like we did not investigate risk factors, and the control group was not included.

CONCLUSION

Efficacy of topical Betamethasone valerate 0.1%w/v is higher than topical Ketoconazole 2% w/v in patients of seborrheic dermatitis. Therefore, we recommend that topical Betamethasone valerate 0.1% may be used as first-line therapy in the treatment of seborrheic dermatitis in order to improve the social life, emotional well being and leisure activities of these particular patients.

Conflict of Interest: None.

Author's Contribution

AA: Main author, NA:, MR: Conception,design, acquisition of data, analysis and interpretation of data, MT: Drafting the article or revising it critically.

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