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Original Research Article

Assessment of safety and effectiveness of desoximetasone emollient cream 0.25% in comparison to mometasone cream 0.1% in Indian patients with eczema

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ABSTRACT

Background: Topical corticosteroids have become indispensable in the treatment of eczema. The current study was conducted to assess the safety and effectiveness of Desoximetasone emollient cream 0.25% (DESO) compared to Mometasone cream 0.1% (MOM) in patients with eczema.
Methods: This was a prospective, observational, open label, multicentre post marketing study at real-life scenario. Newly diagnosed, treatment naïve patients with clinical diagnosis of eczema were enrolled. All patients received either DESO or MOM for 3 weeks. Primary end point was proportion of patients developing adverse events. Secondary endpoints comprised of change in visual analog scale for perception of improvement in intensity of pruritus at day 14 and day 21 from baseline, change in eczema area and severity index (EASI) score at day 0 and day 21.
Results: 45 patients in DESO group and 43 patients in MOM group completed study. DESO and MOM were well tolerated. Severity of pruritus was significantly reduced in 54.59% patients in DESO group compared to 45.60% patients in MOM group on day 14 ($p=0.023$). Severity of pruritus was reduced in 69.16% patients in DESO group as compared to 66.97 % patients in MOM group on day 21 (p=NS). There was a statistically significant reduction ($p<0.001$) in EASI score at day 21 and as compared to baseline within the study groups, but without any difference between the groups.
Conclusions: Desoximetasone 0.25% emollient cream was well tolerated in the treatment of eczema with earlier reduction in pruritus as compared to Mometasone furoate 1% cream.

Keywords: Desoximetasone emollient cream 0.25%, Eczema, Mometasone cream 0.1%, Pruritus

INTRODUCTION

Eczema is a chronic, non-infective, inflammatory dermatological condition with pruritic, erythematous, inflamed and/or asteatotic skin. Different treatments are available to combat this dermatosis, topical corticosteroids (TCs) being the most commonly prescribed ones.[1]

Corticosteroids have many applications in treating inflammation and diseases of immune function based on their noteworthy anti-inflammatory and immunosuppressive effects.[2]

Topical corticosteroids are cornerstone for treatment for many inflammatory skin conditions. Initial success with hydrocortisone spurred the development of new topical corticosteroids by modifying both the ring structure and side chains of the hydrocortisone molecule, leading to compounds with variable anti-inflammatory potency and side-effect profiles.[3]

Desoximetasone (desoximetasone; 9-fluoro-11β,21-dihydroxy-I6α-methyl-pregna-I,4-diene-3. 20-dione) is a fluorinated glucocorticoid agent derived from dexamethasone, differing from that drug only by the absence of a hydroxyl group in the C-17 position, thus increasing its lipophilic properties and topical activity as compared with the parent compound.[4]

Also, double bond at C1–C2 position leads to enhanced glucocorticoid activity and 16 methyl substitution leads to less allergenic potential as compared to compounds as compared to compounds with no C16-methyl substitution and hydrocortisone.[5,6]

Desoximetasone 0.25% cream (DESO) is placed in high potency category of topical corticosteroids.[7]

Mometasone furoate 0.1% (MOM) is a medium potency topical corticosteroid for the treatment of corticosteroid responsive dermatoses.[7]

Various clinical trials have established efficacy and safety of Desoximetasone and Mometasone in the treatment of eczema.[4,8] However, comparative safety and effectiveness comparison of these topical corticosteroids in real-world clinical settings is not reported. Also, there is a huge scope to generate more country-specific data about the effectiveness and safety of DESO and MOM cream in eczema in patients of the Indian subcontinent. Therefore, this prospective, observational, multi-centre, post-marketing surveillance study at real-life scenario was planned to collect comparative data on the effectiveness and safety of desoximetasone emollient cream versus mometasone cream in Indian patients suffering from eczema.

METHODS

This was a prospective, observational, multi-center, post-marketing surveillance study to compare the safety and effectiveness and of desoximetasone emollient cream 0.25% versus mometasone furoate cream 0.1% in Indian patients suffering from eczema conducted in 5 centres in India.

For this comparative study, based on the study by Rajka et al and the proportion used to measure the parameter of adverse events, 0.1% with and alpha error of 5%, the corresponding z value was Z=1.9, with the minimum percentage difference to be deemed significant as 1%, the sample size required was 39 in each group.[9]

Patients

Newly diagnosed, treatment naïve patients with clinical diagnosis of eczema were screened and 91 eligible subjects were enrolled from 5 centres. The study was conducted between April 2018 and October 2019.

Methodology

This study was conducted in accordance with principles of the Declaration of Helsinki, International Conference on Harmonization- Good Clinical Practice (ICH-GCP) guidelines, and Indian regulatory guidelines (Indian Council of Medical Research (ICMR) and Indian GCP guidelines). Ethical clearance was obtained from Independent Ethics Committee. (Dhanashree Hospital, Pune, IECDH/2018/02, Dated: 19.02.2018) CTRI registration was obtained. Written informed consent was obtained with vide registration number, CTRI/2018/03/012300 from each patient prior to screening. Patients >10 years of age of either gender who were capable of complying with protocol requirements and who were clinically diagnosed with eczema and attending outpatient settings in dermatology clinics or hospital were included in the study. The patients were newly diagnosed, treatment-naïve with clinical diagnosis of eczema. The type of eczema, duration of disease was noted in the case report form (CRF). The patients were treated with desoximetasone emollient cream 0.25% or mometasone cream 0.1% as per dermatologist's discretion and approved Prescribing Information. Patients with history of hypersensitivity to any of the of study medication, pregnant and nursing women were excluded.

Patients with documented comorbid systemic disorders of the cardiovascular, central nervous, gastrointestinal, respiratory systems, hormonal disorders, and chronic inflammatory conditions, which, in the opinion of the investigator may have a potential health risk to the patient were excluded based on study investigator's description. Also, patients receiving oral immunosuppressive medications prior to 3 weeks of study were excluded.

Details of the study for adults was explained in local language to the patient/Legally acceptable representative (LAR) through a Patient Information Sheet (PIS). For children between the 10 to 18 years, the study information was explained in local simple language through a Child Information Sheet, and their parents were explained through a Parent Information Sheet. The patients were evaluated at baseline (1st visit), Day 14 (2nd visit) and Day 21 (3rd visit). The severity of disease and extent of the body involvement components was noted by the investigators. The severity of disease was assessed clinically by grading (0 - None, 1 Mild, 2-

Moderate, 3 -Severe) for each signs viz. erythema, edema/papulation, excoriation and lichenification in 4 different regions of head/neck, trunk, upper and lower extremities. For each region, the average of severity was considered. For assessing the extent of the disease, percentage involvement of each of the 4 regions was noted. From this data, Eczema Area and Severity Index (EASI) score was calculated on day 0 and day 21.[10] Patient's intensity of pruritus was noted using visual analogue scale (VAS) score (0 to 100) and evaluated on day 0, day 14 and day 21.

Patients were observed for any local adverse events throughout the study. The primary end point of the study was proportion of patients developing adverse events with Desoximetasone 0.25% emollient cream during 21 day's treatment period in comparison to Mometasone 0.1% cream and nature of adverse events. The secondary endpoint was change in Visual Analog scale (VAS) for perception of improvement in intensity of pruritus at day 14 and day 21 from baseline.

Statistical analysis

Data was analysed by using Statistical package for social sciences (SPSS) 20.0 software. Data was analysed as per modified intent to treat and as per protocol analysis. Values were compared with their baseline records and data was expressed as mean± standard deviation (SD). Change from baseline in various parameters and treatment groups differences were assessed by student t test. For statistical tests, $p \leq 0.05$ was considered as significant.

RESULTS

Total of 91 patients with eczema were enrolled in the study, out of which, 45 patients in DESO group and 43 patients in MOM group completed the study and three patients lost to follow-up.

Thus, data of 88 patients as analysed. 46 were female patients while 42 were male patients. (Table 1).

26 (29.54%) of patients had atopic dermatitis, 16 (18.18 %) patients had contact dermatitis followed by other types of eczema like nummular eczema 11 (12.50%), dyshidrotic eczema 10 (11.36%), hand eczema 9 (10.22%), neurodermatitis 11 (12.50%), stasis dermatitis 5 (5.68%), (Figure 1).

Adverse events

Both topical preparations were well tolerated by the study population. In DESO group, one patient showed mild hypopigmentation while in MOM group, one patient showed mild burning.

Change in VAS for perception of improvement in intensity of pruritus

There was decrease in VAS score for perception of intensity of pruritus in both the groups on day 14 and day 21 as compared to baseline. (Table 2)

Table 1: Patient demographic profile.

Number of Patients	**88 (DESO group: 45, MOM group: 43)**
Age (years), Mean ±SD	36.45 ± 15.68
Gender	
Male (number)	42
Female (number)	46

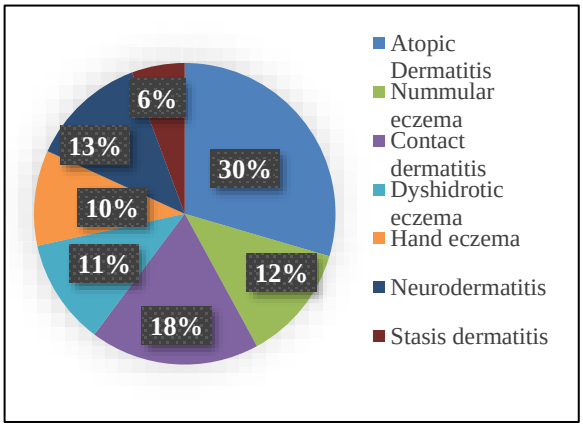

Figure 1: Patients (%) with different types of eczema.

Table 2: Dispersion of VAS for perception in intensity of pruritus at baseline (Day 0), Day 14 and Day 21 in study population at different visits.

Day	DESO		MOM		P value*
	Mean	SD	Mean	SD	
0	63.60	20.819	68.44	22.485	0.297
14	28.88	13.939	37.23	13.319	0.023
21	19.61	23.095	22.60	18.228	0.538

* by unpaired t-test

Table 3: Dispersion of EASI in study population on day 0 and day 21 (comparison between study groups).

Day	DESO		MOM		P value*
	Mean	SD	Mean	SD	
0	4.904	9.1514	3.388	3.4377	0.311
21	1.714	5.2640	0.642	1.4278	0.240

* by unpaired t-test

Severity of pruritus was reduced in 54.59% patients in DESO group as compared to 45.60 % patients in MOM group on day 14 (p=0.023). Severity of pruritus was reduced in 69.16% patients in DESO group as compared to 66.97 % patients in MOM group on day 21 (p=NS).

Table 4: Dispersion of EASI score in study population on day 0 and day 21 (comparison within study groups).

EASI score (on day 0 and day 21)	DESO		CI	MOM		CI	P value*
	Mean	SD		Mean	SD		
	3.4548	6.5573	1.4114 - 5.4981	3.2167	3.2187	2.1276 - 4.3057	0.001

*by paired t-test, CI: confidence interval

Change in eczema area and severity index score

There was a statistically significant reduction (p<0.001) in EASI at day 21 compared to baseline within the study groups, with no difference between the groups. (Table 3 and Table 4)

DISCUSSION

The major therapeutic goals for management of eczema are symptomatic relief, control of acute flares and restricting recurrences. For treatment of moderate-to-severe cases of eczema, the standard regimen involves intermittent use of topical corticosteroids. Topical corticosteroids have become essential in the treatment of various dermatoses.[11]

Desoximetasone is a high potent fluorinated corticosteroid for topical use which has often been judged superior overall in patients with inflammatory dermatoses to several other steroid preparations of intermediate potency (e.g. betamethasone valerate 0.1%, triamcinolone acetonide 0.1 %, fluocinolone acetonide 0.025%).[12]

The effect of topical mometasone furoate 0.1% in various topical preparations has been well studied over many years.[13]

We performed this clinical study to assess real-world clinical comparative data on the safety and effectiveness of desoximetasone emollient cream 0.25% versus mometasone cream 0.1% in Indian patients with eczema.

The primary end point was proportion of patients developing adverse events. Both the study drugs were well tolerated. DESO was well tolerated with only one patient showing mild hypopigmentation while in MOM group, 1 patient showed mild burning.

In our study, significant reduction in itching was seen on day 14 with DESO cream with decrease in intensity of pruritus being 54.59% as compared to 45.60 % in the MOM cream group. (p=0.023)

The decrease in pruritus was numerically greater with DESO (69.16%) on day 21 as compared to MOM (66.97%) but was not statistically significant. (p=0.538)

Mitra et al evaluated the efficacy and safety of 0.25% Desoximetasone compared to 0.12% betamethasone valerate which also belongs to medium potency steroid. Percentage reduction in itching was significantly greater with desoximetasone at the end of week 1 and week 3 of treatment.[14] Our findings are also similar with greater reduction in pruritus with desoximetasone at day 14 as compared to Mometasone cream which was significant. This was because of higher potency of desoximetasone versus mometasone.

There was a statistically significant reduction (p<0.001) in EASI on day 21 compared to baseline within the study groups, but without any difference between the groups.

Ashton et al compared 0.25% desoximetasone with betamethasone valerate 1% in treatment of eczema where each treatment produced significant reduction in score at week 1. The reduction was maintained from week 1 to week 2 and reduced further from week 2 to week 3 for 0.25% desoximetasone treatment.

Desoximetasone also produced reduction in body area affected with eczema.[15] Similar results were obtained in this study where there was significant reduction in EASI score within the groups as compared to baseline.

Desoximetasone was well tolerated in most patients in most published clinical trials.[4] Our study confirms this in Indian population.

The strength of this study is that it documents the safety and efficacy of desoximetasone and mometasone in a real world setting as it provides information about potential efficacy and safety associated with treatment in routine practice.

The limitations of this study is that we could not conduct the study in a double blind fashion. A study in larger number of patients is needed in the future.

CONCLUSION

Desoximetasone 0.25% emollient cream was well tolerated in the treatment of eczema with earlier reduction in pruritus as compared to Mometasone furoate 1% cream.

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Conflict of interest: None declared
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