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Original Research Article

Comparative real world clinical assessment of fixed dose combination of mometasone and fusidic acid cream versus fluticasone and mupirocin ointment in the management of atopic dermatitis with secondary bacterial infection

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ABSTRACT

Background: Bacterial skin infections caused by gram positive bacteria are mostly encountered in paediatric age group. These infections are found to commonly complicate atopic dermatitis with prevalence of 80-100%, and are treated with fixed dose combination (FDC) of topical corticosteroids and antibiotics.
Methods: This retrospective study was conducted in patients ≥2 years of age with a diagnosis of atopic dermatitis with secondary bacterial infections and having investigator's global assessment score of 2 or 3. Patient's clinical outcomes were analysed on the basis of skin infection rating scale (SIRS) wherein each of signs/symptom were rated on scale of 0 to 3.
Results: The 206 patients had received FDC of mometasone and fusidic acid (MF) and 159 patients had received fluticasone and mupirocin (FM). Percentage of patients achieving complete clearance of symptoms/signs was higher in MF group as compared to FM. Percentage of patients achieving clinical success were significantly higher with mometasone. Recurrences and percentage of patients with clinical failure were higher in FP group.
Conclusions: Effectiveness of MF FDC was significant as compared to FM, FDC in terms of complete clearance of lesions, increased number of patients achieving clinical success and less number of recurrences.

Keywords: Mometasone, Fluticasone, FDC, Secondary bacterial infections

INTRODUCTION

In developing countries like India, superficial bacterial infections are one of the commonest infections seen in paediatric patients. Gram-positive bacteria like, *Staphylococcus aureus* and group A β-haemolytic *Streptococcus* (GABHS) are the most common causative organisms in such infections[1] along with some gram-negative organisms and anaerobes. Other skin diseases such as scabies, varicella, and atopic dermatitis are also complicated by bacterial skin infections.[2]

Topical antibacterial are preferred over systemic anti-bacterial since they target only infected area and are devoid of adverse effects associated with systemic drugs. In addition, they also accelerate clinical cure, prevent recurrences in affected individuals, and minimize the spread of infection. But in recent years, management of bacterial skin infections has become challenging due to increase in anti-bacterial resistance.[3]

Many patients of atopic dermatitis present with secondary bacterial skin infection. Prevalence of this condition has been documented as 80-100% as per published reports.[4,5]

In such conditions, FDC of topical corticosteroids and topical anti-bacterial like topical MF cream or FM ointment are most commonly prescribed. However, their comparative effectiveness and safety data is very scarce in India. Therefore, the present study was planned to compare the effectiveness and safety of FDCs of mometasone furoate 0.1% and fusidic acid 2% cream and fluticasone propionate 0.005% and mupirocin 2% ointment in Indian patients of atopic dermatitis associated with secondary bacterial infections.

METHODS

After ethics committee approval, the present retrospective study was conducted in patients ≥2 years of age with a diagnosis of atopic dermatitis with secondary bacterial infections during July 21 to October 21. Patients with an investigator's global assessment score of 2 or 3 who were either treated with FDC of mometasone furoate 0.1% and fusidic acid 2% or fluticasone propionate 0.005% with mupirocin 2% and complete treatment details of 1 week along with clinical evaluation data of 2 weeks, available through electronic medical records, were included in the study. Medical records of those patients in whom treatment plan was changed during the treatment period were excluded from the study.

Patient's clinical outcomes were analysed on the basis of SIRS at baseline, day 3, 7 and 14, wherein each of signs/symptom like pus, crust, erythema, itching and pain were rated on scale of 0 to 3; 0 being absent and 3 indicating severe disease. Clinical outcomes were categorised as:[6] Clear/almost clear- investigator's global assessment (score of 0 or 1) at day 3 and 7 in both the groups, clinical success- SIRS score of 0 each for pus, crust and pain and 0/1 for erythema and itching at day 3 and day 7, clinical improvement- SIRS score of 0 for exudates (pus) which does not meet all the criteria for clinical success at day 3 and 7, clinical failure at day 7 in both the groups [SIRS score of ≥1 for pus] and recurrence at day 14.

Safety was assessed by no. of adverse events (AE) reported. Results were presented as mean scores, and groups were compared using unpaired t test and fisher exact test with level of significance as $p<0.005$. Difference in proportion of patients with change in mean scores (based on improvement criteria) were analyzed using Chi square test. Data was analyzed using the IBM SPSS (Statistical package for social sciences) statistics version 20.

RESULTS

Total of 365 patients' data was collected from 69 centres across India, out of which 206 patients had received MF and 159 patients had received fluticasone + mupirocin. The baseline characteristics in both the treatment groups were comparable (Table 1).

Table 1: Baseline demographics.

Variables	MF (n=206)	FM (n=159)	P value
Gender, N (%)			
Male	110 (53)	89 (56)	
Female	96 (47)	70 (44)	
Age (years) (SD)	34.27±13.62	33.19±14	0.385
Duration of therapy (weeks) N (%)			
1	46 (22)	40 (25)	0.421
2	160 (78)	119 (75)	0.447

Percentage of patients achieving clear/almost clear status of investigator's global assessment in both treatment groups were comparable and the difference was not statistically significant except at day 7, wherein percentage of patients achieving complete clearance of symptoms/signs was higher in MF group as compared to FM group (p=0.02) (Figure 1).

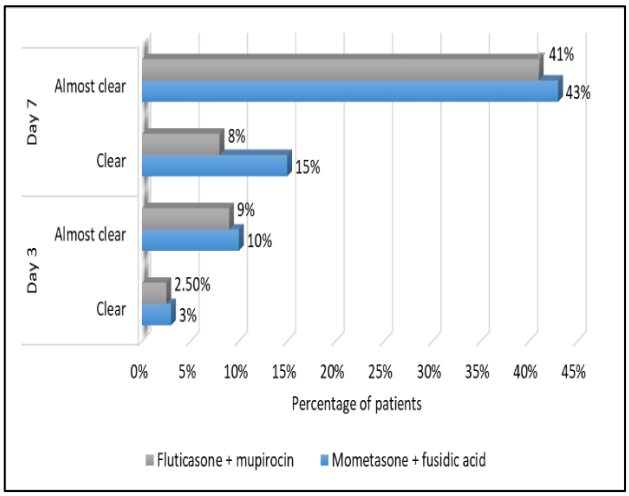

Figure 1: Percentage of patients achieving clear/almost clear category of investigator's global assessment (score of 0 or 1) at day 3 and 7.

Percentage of patients achieving clinical success was more in MF group as compared to FM group. Difference in effect between both groups was statistically significant at day 3 (p=0.05) and day 7 (p=0.03) (Table 2).

Table 2: Percentage of patients achieving clinical success category of SIRS at day 3 and 7 in both groups.

Day of therapy	MF, N (%)	FM, N (%)	P value
Day 3	13 (7)	5 (3)	0.05
Day 7	109 (53)	65 (36)	0.03

Percentage of patients achieving clinical improvement was comparable in both the groups at day 3 and day 7 and the difference was not statistically significant (Table 3).

Table 3: Percentage of patients achieving clinical improvement at day 3 and 7 in both the groups.

Day of therapy	MF, N (%)	FM, N (%)	P value
Day 3	5 (2)	2 (1.2)	0.472
Day 7	2 (1)	1 (0.6)	0.751

Percentage of patients showing clinical failure (SIRS score of ≥1 for pus) at day 7 were less in MF group as compared to FM group. The difference was not statistically significant (Table 4).

Table 4: Percentage of patients showing clinical failure in both the groups.

Day of therapy	MF, N (%)	FM, N (%)	P value
Day 7	69 (33)	60 (37)	0.575

Recurrences were maximum in patients who received fluticasone with mupirocin (11%) as compared to MF (4%) and this difference was statistically significant (p=0.01) (Figure 2).

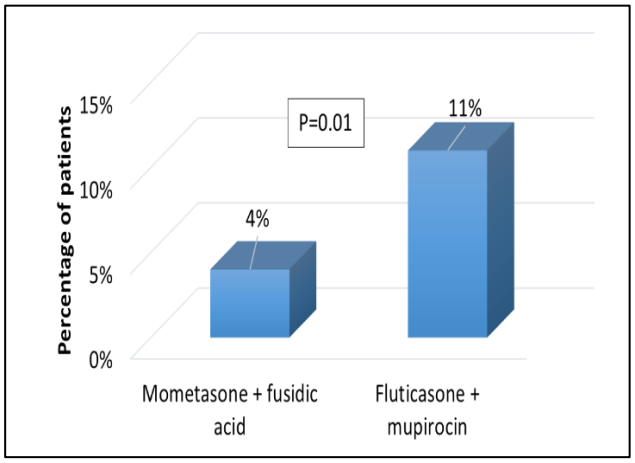

Figure 2: Percentage of patients showing recurrence at day 14 in both the groups.

Both the drugs were found to be safe and well tolerable with no adverse events reported.

DISCUSSION

Fusidic acid is a topical bacteriostatic drug whose efficacy is well established and is active against major bacteria like *Staphylococcus*, *Streptococcus*, etc. which are known to cause superficial skin infections. Mupirocin is topical bactericidal drug. Both these drugs have good percutaneous absorption.[7]

In terms of efficacy, mupirocin and fusidic acid have been analysed in various comparative clinical trials.[8,9] In these clinical trials the efficacy of both the topical antibacterial was comparable. In a clinical study done by Vasani et al effectiveness of both the topical antibacterial were compared in patients of pyoderma. It was found that there was greater reduction in mean clinical severity score at the end of therapy in fusidic acid group as compared to mupirocin group (5.40 as compared to 5.11).[10] In a clinical trial done by Velappan et al the efficacy of both the antibacterial were compared in patients of impetigo on the basis of percentage of patients achieving clinical success (SIRS score) at day 4 and day 7. It was reported that efficacy of both the drugs was same and there was no statistical difference.[7] This was in contrast to the findings of present study wherein there was greater number of patients achieving complete clearance of lesions at day 7 and percentage of patients achieving clinical success at day 3 and 7 in MF group and the difference was statistically significant.

Some of the factors that might account for such difference might be increasing resistant bacterial strains against mupirocin, reduced efficacy of mupirocin in presence of exudative, weeping lesions and presence of blood as it had high protein binding property.[2] Moreover, it was reported to be 80% more cost effective as compared to mupirocin.[2] These factors might also contribute to higher percentage of recurrence in fluticasone with mupirocin group in the present study.

In the present study, clinical failure in both the groups was comparable and there was no statistically significant difference. Probable reasons for clinical failure might be poor patient compliance, failure to remove crust by soaking it in saline wrap before application of drug, excess pus formation.[11]

Wachs et al in their double-blind clinical study compared topical antibiotic/corticosteroid combination with topical antibiotic and corticosteroid monotherapy in patients of infected atopic dermatitis. Authors concluded that combination therapy reduced the mean scores of infection, inflammation and overall severity to a greater extent than the antibiotic or corticosteroid monotherapy.[6] This might be the reason for increasing use of antibiotic corticosteroid combination in patients of bacterial skin infections.[4,6] In a clinical study done by Kharkar et al the effectiveness of mometasone was found to significantly more in patients of eczema and dermatitis as compared to fluticasone.[12] Thus, the anti-inflammatory effect of mometasone can be considered to be better as compared to fluticasone.

The only major shortcoming is its retrospective nature.

CONCLUSION

To the best of our knowledge, the present study is the first real world comparison between mometasone and fluticasone in AD. The only major shortcoming is its retrospective nature. Based on the findings of the present study, effectiveness of FDC of mometasone furoate 0.1% with fusidic acid 2% cream was significant as compared

to fluticasone propionate 0.005% with mupirocin 2% ointment in terms of complete clearance of lesions, increased number of patients achieving clinical success and less number of recurrences.

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Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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