

Original Research Article

Effectiveness and safety profile of fluticasone propionate 0.05% in paediatric dermatoses

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ABSTRACT

Background: Topical corticosteroids are effective in the treatment of paediatric dermatoses. However, concerns regarding possible side effects of topical steroids have limited the use of moderate-potency corticosteroids in children. Objective of this study was to evaluate the effectiveness and safety profile of fluticasone propionate 0.05% cream in paediatric dermatoses.

Methods: A total 84 children between 6 months to 12 years of age with moderate to severe dermatoses (< or =30% body surface area) were treated with fluticasone propionate 0.05% cream twice daily for 4 to 6 weeks. Adverse effects of topical steroids were analyzed.

Results: Out of total 84 patients, 46 (54.76%) patients completely cured at 4 weeks and 23 (27.38%) patients at 6 weeks, while remaining 11 (13.10%) patients showed moderate improvement, 4 were lost for follow up after 2 weeks. Only in 2 patients we observed hypopigmentation of skin, otherwise in all patients no significant side effect were seen.

Conclusions: Fluticasone propionate 0.05% cream appears to be quite safe for the treatment of moderate to severe dermatoses for up to 4 to 6 weeks in children less than 12 years of age.

Keywords: Fluticasone propionate, Paediatric dermatoses, Safety profile

INTRODUCTION

Paediatric dermatoses are major public health problem which is associated with significant morbidity.¹ Skin diseases constitute 30% of all paediatric population.² The prevalence of childhood dermatoses in various parts of India has ranged from 9% to 35% in various studies.³ Paediatric dermatoses can be acute chronic and recurrent. The chronic dermatoses are associated with significant morbidity and psychological impact. Paediatric dermatoses is special clinical entity which requires a separate view from adult dermatoses as there are important differences in clinical presentation, treatment and prognosis. Paediatric dermatoses are

influenced by socio-economic status, climatic exposure, dietary habits and external environment as compared to adults.⁴

Glucocorticoids are widely used in the treatment of various eczemas due to their wide range of anti-inflammatory properties.⁵ However, their use is restricted in paediatric population as consequences of various adverse effects like hypopigmentation, atrophy, telengectasias, striae etc. Now a days various clinical trials are done to prove the safety and tolerability of topical steroids. Fluticasone propionate has been found efficacious and having low risk of adverse events.⁶

Fluticasone propionate is a moderate potent topical glucocorticoid, and side effect of this depends on the thickness of epithelium, dose, how it is applied, occlusion and along with its potency. The study was carried out to evaluate effectiveness and safety profile of fluticasone propionate in paediatric dermatoses.

METHODS

It was open labelled non comparative study conducted at dermatology department of Shree Balaji Institute of Medical Sciences, Chhattisgarh, from July 2023 to December 2023. Ethical approval from institutional ethical committee was taken. A total 84 children were included in the study of either sex and age less than 12 years with different types of dermatoses. Children with infections and those already having scars and atrophy and on any other medications were excluded. Study includes the patients with dermatosis < or =30% body surface area involvement.

Fluticasone propionate 0.05% cream were given to the parents on the first visit for 2 weeks. Fingertip unit (FTU) method was demonstrated and instructions were given to apply thin layer of cream gently apply twice daily for 2 weeks. Signs and symptoms e.g. pruritus, scaling, erythema, induration, lichenification were recorded on day one and successive follow up visits at 2nd, 4th and 6th weeks using a severity scale from 0 to 3 (none to severe). Each child was assessed during follow up visits by two same dermatologists. Individual’s signs and symptoms, scores, improvement score and overall evaluation were analysed. We were specifically look for any side effects such as hypopigmentation, atrophy, telengectesiae, striae etc. Data were statistically analysed by Epi Info and Microsoft Excel.

RESULTS

A total 84 children with different types of dermatoses (Table 1) were included in the study out of which 53 (63.10%) were boys and 31 (36.90%) were girls, with male to female ratio was 1.7:1. The lowest age of presentation was 6 months and eldest being 12 years with mean age of presentation was 7.21 years, Shown in (Table 2). Atopic dermatitis was most common (25%) while least common was nummular eczema (9.52%).

Table 1: Different types of paediatric dermatoses (n=84).

Types of dermatoses	N (%)
Atopic dermatitis	21 (25)
Seborrhoeic dermatitis	18 (21.42)
Nummular eczema	8 (9.52)
Pityriasis alba	15 (17.85)
Papular urticaria	19 (22.61)
Contact dermatitis	39 (3.57)

Table 2: Age and sex wise distribution of the patients.

Age group (in years)	Boys	Girls	Total
1 years to 4 years	12	08	20
5 years to 8 years	20	12	32
9 years to 12 years	21	11	32
Total	53	31	84

The most common symptoms was pruritus seen in 79 (94.10%) followed by erythema 44 (52.38%), scaling 24 (28.57%), induration 19 (22.61%) and lichenification was 4(4.75%). The overall effectiveness of fluticasone propionate in relief of signs and symptoms of paediatric dermatoses was shown in (Table 3). Out of total 84 patients, 46 (54.76%) patients completely cured at 4 weeks and 23 (27.38%) patients at 6 weeks, while remaining 11 (13.10%) patients showed moderate improvement, 4 were lost for follow up after 2 weeks. No significant side effect were seen, only in 2 (2.38%) patients we observed hypopigmentation of skin. Overall patients comfort and effectiveness was evaluated which was significant.

Table 3: Overall effectiveness of in relief of signs and symptoms.

Signs and symptoms	N	2 nd week	4 th week	6 th week
Pruritus	79			
Mild	34	18	6	
Moderate	14	12	13	
Severe	6	3	-	
Resolved	20	48	69	
Erythema	44			
Mild	17	7	6	
Moderate	7	-	1	
Severe	-	-	-	
Resolved	15	49	16	
Scaling	24			
Mild	13	4	3	
Moderate	3	-	1	
Severe	-	-	-	
Resolved	10	16	13	
Induration	19			
Mild	11	3	7	
Moderate	3	-	1	
Severe	-	-	-	
Resolved	20	29	25	
Lichenification	4			
Improved	1	1	2	
Resolved	-	-	-	

DISCUSSION

Paediatric dermatoses is a quite common condition and topical corticosteroids are the mainstay of treatment. Numerous studies and clinical trials have been conducted

to obtain excellent results on efficacy and tolerability while minimizing adverse effects of corticosteroids.⁷

The youngest patient in our study was 6 months. The earliest reported age was 2 weeks in study conducted by Kanwar et al.⁸ The mean age of our study population was 7.21 years, which was almost similar to Handa et al study which were reported 7.1 years.⁹ The most common dermatoses found in our study was atopic dermatitis (25%) while least common is an eczema (9.52%) in contrast to infections and infestations were (56.6%) and eczemas were (8.8%) by Podder et al study in paediatric age group.¹⁰ The clinical improvement was seen in 54.76%, whereas 13.10% had moderate improvement over a period of 6 weeks. One large study Lebowhl et al in children showed a clinical response of 28.8% over a period of 14 months.¹¹

Topical steroids constitute the mainstay of the treatment paediatric dermatoses. Literature search shows the use of mid- and superpotent corticosteroids for the treatment of dermatoses in adults. There is a complete lack of published study that describes the use of topical steroids in different formulation and in different strengths in pediatric dermatoses. We found that fluticasone propionate 0.005% ointment used twice daily for 6 weeks was effective for paediatric dermatoses (< or =30% body surface area). Fluticasone propionate 0.05% cream has antipruritic, anti-inflammatory, and vasoconstrictive properties.¹² The mechanism of the anti-inflammatory activity of the topical steroids is unclear. Side effects were few and limited to atrophy and hypopigmentation in few lesions. Only in 2 (2.38%) patients we observed only hypopigmentation of skin, otherwise in all patients no significant side effect were seen. Thus, fluticasone propionate cream 0.05% is a quite safe and effective drug for paediatric dermatoses with a rapid response upto 4 to 6 weeks.

There were few limitations in this study which were small sample size, no long term follow-up, and no well-designed scoring system for evaluation of the severity of paediatric dermatoses.

CONCLUSION

Mid-potency steroid fluticasone propionate cream 0.05% twice daily significantly decreases the signs and symptoms of paediatric dermatoses upto 4 to 6 weeks. The side effects associated with fluticasone propionate are few, limited to hypopigmentation.

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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