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Original Research Article

To Determine the Effect of Ammonium Lactate 12% Lotion as Monotherapy and in Combination with Clobetasol Propionate (0.05%) and Calcipotriol (0.005%) in the Management of Chronic Plaque type Psoriasis

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Abstract

Aim: To determine the effect of various topical agents in chronic plaque type psoriasis.

Methods: This was a prospective, randomized study was done in the Department of Skin & VD, Shri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India for 1 year. Total 90 patients were include and were divided in three groups comprising of 30 patients in each group. Group A patients were asked to apply ammonium lactate twice a day, Group B patients were asked to apply ammonium lactate in morning and clobetasol propionate in evening, Group C patients were asked to apply topical ammonium lactate in morning and calcipotriol in evening. PASI scoring of each patient was done at baseline, at the end of 4 weeks and at the end of 8 weeks.

Results: No significant difference was noted between study groups (p=0.54). Further on comparison of individual groups it was found that significant difference was present between PASI at 8 weeks between group A and group B (p=0.041), group A and group C (p=0.031) but between group B and group C (p=0.88) difference was not significant. it was found that 14(46.67%) out of 30 subjects attained PASI 50 in group A, 19(63.33%) out of 30 patients in group B and 19(63.33%) out of 30 patients in group C. Physician global assessment scale shows that in Group A, 7(23.33%) patients had excellent response, 6(20%) patients had good response, and 7(23.33%) patients had fair response whereas 10(33.33%) patients had poor response. In group B, 10(33.33%) patients had excellent response, 11(36.67%) patients had good response, and 4(13.33%) patients had fair response whereas 5(16.67%) patients had poor response. In group C, 10(33.33%) patients had excellent response, 11(36.67%) patients had good response, and 2(6.67%) patients had fair response whereas 6(20%) patients had poor response.

Conclusion: We concluded that the combination therapy is effective, well tolerated with minimal side effects and better compliance was seen. Ammonium lactate can also be considered as one of the topical option as a monotherapy and also as a maintenance therapy.

Keywords: Psoriasis, Ammonium lactate, Topical, Calcipotriol.

Introduction

Psoriasis is a common, chronic, inflammatory, hyper- proliferative disease of the skin and joints. The natural course of the disease is characterized by relapses and remission and thus has a highly unpredictable course. The estimated global prevalence of Psoriasis is 1% - 11.8% of the

general population depending on the ethnicity served and the approximate estimate of psoriatic patients in India accounts for 2.3%.[1-3] The characteristic lesion is a sharply demarcated erythematous plaque with micaceous scale, and the plaques may be localized or widespread in distribution. Psoriasis is a systemic disease process in which up to 20–30% of the patients have or will develop psoriatic arthritis. In addition, in patients with moderate to severe psoriasis, there is an increased relative risk for metabolic syndrome and atherosclerotic cardiovascular disease. Psoriasis also has a significant impact on patients' quality of life, and in surveys, patients feel that the current treatments, although often effective, do not provide a satisfactory long-term solution. Its prevalence and pattern are influenced by diverse genetic, ethnic and environmental factors.[4] The prevalence of pruritus in general population ranges from 8-38% worldwide. But an obvious systemic disease was identified in 14-50% of pruritus patients.[5-7] Chronic generalised pruritus can be manifested due to systemic disease like chronic renal insufficiency, hepatic disorders, haematological diseases, iron deficiency and malignancies.[5] There are several clinical varieties of psoriasis, which differ in their presenting features, severity, natural course and response to the treatment, and hence the choice of therapy may also vary accordingly. The chronic and recurrent nature of psoriasis has resulted in a number of different strategies to maximize treatment efficacy and minimize toxicity. As there is no cure for psoriasis, treatment is only palliative and symptomatic, mainly aimed at inducing prolonged remission and suppressing the disease to a tolerable level, and the therapy is nonspecific and empirical.[8,9] Psoriasis is characterized by well circumscribed, erythematous plaques with silvery white scales that represent a response to an infiltration of inflammatory T cells producing disease-stimulating cytokines in skin lesions. Although no cure is available, the disease can be effectively controlled by various therapeutic options, used alone or in combination.[10,11] Topical treatment is best used to treat psoriasis affecting less than 10% of total body surface area.[12] Topical treatments including emollients, topical corticosteroids, vitamin D analogues, tar based preparations, dithranol, salicyclic acid and topical retinoids can be used as monotherapy or in combination with other agents. To the best of our knowledge, ammonium lactate has been studied for atopic dermatitis but only few studies are available for its usage in psoriasis vulgaris. The aim of our study was to determine the effect of various topical agents in chronic plaque type psoriasis and to study the effect of ammonium lactate 12% lotion as monotherapy and in combination with clobetasol propionate (0.05%) and calcipotriol (0.005%) in patients of chronic plaque type psoriasis and to study the side effects of ammonium lactate, clobetasol propionate and calcipotriol in patients of chronic plaque type psoriasis.

Material and methods

This was a prospective, randomized study was done in the Department of Skin & VD, Shri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India for 1 year, after taking the approval of the protocol review committee and institutional ethics committee.

Patients suffering from stable chronic plaque type psoriasis involving less than 10% of body surface area and those had neither applied topical for last 2 weeks and nor taken systemic drugs for psoriasis for last three months, were include in this study.

Methodology

Total 90 patients were include and were divided in three groups comprising of 30 patients in each group. Group A patients were asked to apply ammonium lactate twice a day, Group B patients were asked to apply ammonium lactate in morning and

clobetasol propionate in evening, Group C patients were asked to apply topical ammonium lactate in morning and calcipotriol in evening. Each patient was asked to do follow up at four weeks and eight weeks interval and response of treatment was evaluated subjectively and objectively. PASI scoring of each patient was done at baseline, at the end of 4 weeks and at the end of 8 weeks. So that after 8 weeks psoriasis, severity and clinical response will be assessed based on PASI scores and subjective assessment by Physician Global Assessment Scale. PASI (Psoriasis Area Severity Index) Score for the selected patients was taken at baseline, at the end of 4 weeks and at the end of 8 weeks during the study period. The efficacy of the treatment regimen was analyzed by how many patients attained PASI 50(i.e. 50% reduction in disease) at the end of the study i.e. 8 weeks. In literature attainment of PASI 50 is considered a satisfactory and a meaningful response.[13]

Assessment of the effect of treatment Physicians Global Assessment Scale (PGAS)

Poor 0–24% clearing
Fair 25–49% clearing
Good 50–74% clearing
Excellent 75–99% clearing
Clear 100% clearing

Results

In Table 1 Comparison of mean PASI at 8 weeks between study groups was performed using ANOVA. No significant difference was noted between study groups (p=0.54). Further on comparison of individual groups it was found that significant difference was present between PASI at 8 weeks between group A and group B (p=0.041), group A and group C (p=0.031) but between group B and group C (p=0.88) difference was not significant.

Table 1: Multiple Comparisons of mean PASI at 8 weeks between groups (Post hoc analysis using Tukey's HSD)

Dependent Variable	(I) Group	(J) Group	Mean Difference (I-J)	Std. Error	P value	95% Confidence Interval	
						Lower Bound	Upper Bound
PASI at 8 weeks	Group A	Group B	1.28	1.15	.041	-1.73	3.69
	Group A	Group C	.878	1.12	.031	-1.88	3.50
	Group B	Group C	-.148	1.18	.88	-2.95	2.48

In Table 2 PASI 50 was calculated in all three groups and it was found that 14(46.67%) out of 30 subjects attained PASI 50 in group A, 19(63.33%) out of 30 patients in group B and 19(63.33%) out of 30 patients in group C.

Table 2: Assessment of PASI 50 in Groups (A, B, C)

Characteristics		Group		
		Group A	Group B	Group C
PASI 50	No	16(53.33%)	11(36.67%)	11(36.67%)
	Yes	14(46.67%)	19(63.33%)	19(63.33%)
Total		30	30	30

In Table 3 Physician global assessment scale shows that in Group A, 7(23.33%) patients had excellent response, 6(20%) patients had good response, and 7(23.33%) patients had fair response whereas 10(33.33%) patients had poor response. In group B, 10(33.33%) patients had excellent response, 11(36.67%) patients had good response, and 4(13.33%) patients had fair response whereas 5(16.67%) patients had poor response. In group C, 10(33.33%) patients had excellent response,11(36.67%) patients had good response, and 2(6.67%) patients had fair response whereas 6(20%) patients had poor response.

Table 3: Comparison of Physician Global assessment scale between Groups (A, B, C)

PGAS		Group		
		Group A	Group B	Group C
Poor	0-24%	10(33.33%)	5(16.67%)	6(20%)
Fair	25-49%	7(23.33%)	4(13.33%)	2(6.67%)
Good	50-74%	6(20%)	11(36.67%)	11(36.67%)
Excellent	75-99%	7(23.33%)	10(33.33%)	10(33.33%)
Total		30	30	30

Discussion

Psoriasis is a common, chronic, inflammatory disease of the skin. The present study was done on patients having psoriasis vulgaris less than 10% body surface area and they were treated with various topical agents. In present study, all baseline parameters were compared and were found to be compatible with each other. In all three groups mean PASI was calculated at 4 and 8 weeks. When efficacy was compared individually between groups at 4 weeks and 8 weeks, significant difference was found between group A and group B (p value =0.019 and 0.041 at 4 and 8 weeks respectively) and between group A and group C (p value=0.016 and at 0.031 at 4 and 8 weeks respectively) but no significant difference was found between group B and group C (p value= 0.54 and 0.88 at 4 and 8 weeks respectively) showing that group B and group C are equally effective but group A is less effective than group B and group C.

PASI 50 was attained by 46.67% patients in group A, 63.33% patients each in group B and in group C. Physician Global Assessment Scale was used, 46.67% patients in group A, 63.33% patients in group B and 63.33% patients in group C had ≥50% clearing of lesions. In each group 2 patient had erythema and one had skin irritation (burning sensation). During the course of the study, 5 patients dropped out in group A, 2 patients in group B and 3 patients in group C. On telephonic conversation they informed inability to come on scheduled date because of personal reasons such as duties, financial issues for travelling and not getting satisfactory response after topical Regular and appropriate use of emollients improves comfort and reduces scaling, fissuring, and itching in patients with plaque or scalp psoriasis.[14,15] Guidelines of care for the management of psoriasis and psoriatic arthritis state that when used as a control in topical steroid trials, non-medicated topical moisturizers demonstrated a response rate ranging from 15 to 47%.[16,17] This broad range shows great variability of their composition. In 2 small clinical trials which includes 111 patients shows that emollients used as a monotherapy may improve skin hydration, barrier function, as well as proliferation and differentiation markers in patients with psoriasis[18,19] the clinical response showed only a slight symptomatic improvement of psoriasis.[18] In a randomized study done by Emer et al it was found that combination therapy of twice-daily ammonium lactate lotion and halobetasol ointment for two weeks effectively cleared plaque psoriasis in approximately 75% of patients whereas Halobetasol ointment weekend-only maintenance therapy in combination with twice-daily ammonium lactate lotion effectively sustained initial improvement for a significantly longer period of time when compared with placebo.[20] Adding a second agent (keratolytic, emollient, vitamin D analogue) may also help effectively maintain clearance and offer a corticosteroid sparing option. A meta-analysis of 22 studies reported that clearing rates following monotherapy ranged from 2 to 85 percent versus clearance rates of 39 to 100 percent for combination the rapies. Thus emollient (ammonium lactate 12% lotion) as a monotherapy is also effective.

Study explains that the combination therapy is more efficacious as compared to monotherapy.

Conclusion

The present study concluded that the combination therapy is effective, well tolerated with minimal side effects and better compliance was seen. Ammonium lactate can also be considered as one of the topical option as a monotherapy and also as a maintenance therapy.

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