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Original Article

The efficacy of several topical medications in the treatment of persistent plaque type psoriasis

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ABSTRACT:
Aim: The purpose of this research was to see how different topical treatments affected chronic plaque type psoriasis. **Material and methods:** The research was carried out in the dermatology division and was prospective and randomised. We included a total of 100 patients and randomly assigned them to one of three groups, each of which consisted of 30 individuals. Patients in Group A were instructed to apply ammonium lactate topically twice daily; patients in Group B were given ammonium lactate in the morning and clobetasol propionate in the evening; and patients in Group C were given topical ammonium lactate in the morning and calcipotriol in the evening. At the beginning, after 4 weeks, and after 8 weeks, patients were given PASI scores to see how they were progressing. **Results:** There was no significant difference between research groups (p=0.649). When individual groups were compared, it was shown that there was a significant difference in PASI at 8 weeks between group A and group B (p=0.039), group A and group C (p=0.027), but not between group B and group C (p=0.967). PASI 50 was achieved by 14 (46.67%) of 30 individuals in group A, 19 (63.33%) of 30 patients in group B, and 19 (63.33%) of 30 patients in group C. According to the physician global evaluation scale, 7(23.33%) patients in Group A had excellent responses, 6(20%) patients had good responses, 7(23.33%) patients had mediocre responses, and 10(33.33%) patients had poor responses. In group B, 10 patients (33.33%) had an outstanding reaction, 11 patients (36.67%) had a good response, 4 patients (13.33%) had a medium response, and 5 patients (16.67%) had a poor response. In group C, 10 patients (33.33%) had an exceptional reaction, 11 patients (36.67%) had a good response, 2 patients (6.67%) had a medium response, and 6 patients (20%) had a poor response. **Conclusion:** There were fewer reported adverse events and improvements in adherence with the combination medication, leading us to the conclusion that it is efficacious. Monotherapy or maintenance treatment with ammonium lactate applied topically is an option to investigate.
Keywords: Psoriasis, Ammonium lactate, Topical, Calcipotriol.

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INTRODUCTION

A chronic inflammatory immune-mediated proliferative skin illness, psoriasis mostly affects the skin, nails, and joints. Psoriasis was initially described in great detail by Robert Willan, the "father of modern dermatology," and is sometimes known as Willan'slepra because of his contribution. [1] The hallmark lesion is an erythematous plaque with micaceous scale, and it may be either locally or systemically distributed. Twenty to thirty percent of those with psoriasis now have or will develop psoriatic arthritis. Patients with moderate to severe psoriasis are also at a higher risk for metabolic syndrome and atherosclerotic cardiovascular disease. Patients' perceptions that present medications, although frequently helpful, do not give an acceptable long-term solution to psoriasis are supported by surveys. A variety of genetic, ethnic, and environmental variables contribute to its overall incidence and pattern. [2-4] There is a vast variation in the prevalence of pruritus throughout different regions of the globe, from 8% to 38%. However, between 14 and 50% of those with pruritus were found to have an apparent systemic illness. [5-7] Systemic illnesses such as chronic renal insufficiency, hepatic problems, haematological diseases, iron deficiencies, and malignancies may cause persistent generalised pruritus. [5] Psoriasis comes in a number of different clinical forms, each with its own set of symptoms and potential treatment plan. Because psoriasis is persistent and may flare up at any time, several approaches have been developed to improve therapy while reducing side effects. Since a cure for psoriasis has yet to be discovered, the primary options for treatment are palliative and symptomatic measures that try to bring about remission and keep the illness at a manageable level by generic and empirical means. [8,9] Psoriasis manifests itself in skin lesions as well-defined, erythematous plaques covered in silvery white scales, which are caused by the invasion of inflammatory T cells that produce disease-stimulating cytokines. There is currently no known cure for the

condition, however it can be managed using a number of treatment approaches. [10,11] Psoriasis affecting less than 10% of total body surface area is best treated with topical therapy. [12] Emollients, topical corticosteroids, vitamin D analogues, tar-based preparations, dithranol, salicyclic acid, and topical retinoids are just a few of the topical therapies that may be used alone or in combination. Ammonium lactate has been examined for atopic dermatitis, although its use in psoriasis vulgaris is less well-documented. Studying the effects 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, as well as the side effects of ammonium lactate, clobetasol propionate, and calcipotriol, was the primary objective of our research.

MATERIAL AND METHODS

After receiving clearance from a protocol review committee and an institutional ethics council, the dermatology department conducted a randomised, controlled trial. With the patient's agreement and approval, we took a thorough medical history.

Participants had to have been diagnosed with persistent chronic plaque type psoriasis affecting less than 10% of body surface area, and they couldn't have used any topical treatments in the last two weeks or taken any systemic psoriasis medicines in the past three months. We included a total of 100 patients and randomly assigned them to one of three groups, each of which consisted of 30 individuals. Patients in Group A were instructed to apply ammonium lactate topically twice daily; patients in Group B were given ammonium lactate in the morning and clobetasol propionate in the evening; and patients in Group C were given topical ammonium lactate in the morning and calcipotriol in the evening. Subjective and objective assessments of therapy response were made at four and eight week intervals, respectively, for each patient. At the beginning, after 4 weeks, and after 8 weeks, patients were given PASI scores to see how they were progressing. In order to evaluate the psoriasis, its severity, and the clinical response 8 weeks later, we will use the Physicians' Global Assessment Scale and the Psoriasis Area and Severity Index. At the beginning of the trial, at the end of 4 weeks, and again at the end of 8 weeks, patients were asked to complete a PASI (Psoriasis Area Severity Index) score. The proportion of patients who achieved PASI 50 (i.e. 50% decrease in disease) at 8 weeks was used to evaluate the treatment's success. The research indicates that a PASI 50 is a meaningful and satisfying answer. [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

ANOVA was used to compare mean PASI at 8 weeks across study groups in Table 1. There was no significant difference between research groups (p=0.649). When individual groups were compared, it was shown that there was a significant difference in PASI at 8 weeks between group A and group B (p=0.039), group A and group C (p=0.027), but not between group B and group C (p=0.967).

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	1.27	1.14	.039	-1.72	3.68
	Group A	Group C	.877	1.11	.027	-1.89	3.49
	Group B	Group C	-.147	1.17	.967	-2.94	2.47

In Table 2, PASI 50 was computed for all three groups, and it was discovered that 14 (46.67%) of 30 subjects in group A, 19 (63.33%) of 30 patients in group B, and 19 (63.33%) of 30 patients in group C achieved PASI 50.

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

Table 3 demonstrates that in Group A, 7(23.33%) patients had great responses, 6(20%) patients had good responses, 7(23.33%) patients had mediocre responses, and 10(33.33%) patients had poor responses. In group B, 10 patients (33.33%) had an outstanding reaction, 11 patients (36.67%) had a good response, 4 patients (13.33%) had a medium response, and 5 patients (16.67%) had a poor response. In group C, 10 (33.33%) patients had an outstanding reaction, 11 (36.67%) had a good response, 2 (6.67%) had a fair response, and 6 (20%) had a bad 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 skin disease. The current study was conducted on patients with psoriasis vulgaris that covered less than 10% of their body surface area and were treated with various topical agents. All baseline parameters were compared in this study and found to be compatible with one another. Mean PASI was calculated at 4 and 8 weeks in all three groups. When efficacy was compared between groups at 4 and 8 weeks, a significant difference was found between group A and group B (p value =0.017 and 0.039 at 4 and 8 weeks respectively) and between group A and group C (p value=0.014 and 0.027 at 4 and 8 weeks respectively), but no significant difference was found between group B and group C (p value=0.614 and 0.967 at 4 and 8 weeks respectively), indicating that group B and group C are equally effective.

PASI 50 was achieved by 46.67% of patients in group A and 63.33% of patients in groups B and C. Using the Physician Global Assessment Scale, 46.67% of patients in Group A, 63.33% in Group B, and 63.33% in Group C had 50% clearance of lesions. Two patients in each group had erythema, and one had skin irritation (burning sensation). During the course of the study, 5 patients in group A, 2 patients in group B, and 3 patients in group C dropped out. On the phone, they stated that they would be unable to arrive on the scheduled date due to personal reasons such as duties, financial issues for travel, and not receiving a satisfactory response after topical discussions. In patients with plaque or scalp psoriasis, regular and appropriate use of emollients improves comfort and reduces scaling, fissuring, and itching. Non-medicated topical moisturisers revealed a response rate ranging from 15 to 47% when employed as a control in topical steroid studies, according to [14,15] guidelines of care for the therapy of psoriasis and psoriatic arthritis. [16,17] Their composition varies greatly throughout this large range. Emollients administered as a monotherapy may enhance skin moisture, barrier function, as well as proliferation and differentiation indicators in individuals with psoriasis, according to two small clinical studies involving 111 patients. [18,19] The clinical response demonstrated only a small reduction in psoriasis symptoms. [18] Emer et al discovered that two weeks of twice-daily ammonium lactate lotion and halobetasol ointment combination therapy 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 to placebo. [20] Adding a second drug (keratolytic, emollient, vitamin D analogue) may also aid sustain clearance and provide a corticosteroid-free alternative. A meta-analysis of 22 trials found that clearing rates after monotherapy varied from 2 to 85 percent, compared to 39 to 100 percent for combination therapies. As a result, emollient (ammonium lactate 12% lotion) is also beneficial as a monotherapy. According to the study, combined medication is more effective than monotherapy.

CONCLUSION

There were fewer reported adverse events and improvements in adherence with the combination medication, leading us to the conclusion that it is efficacious. Monotherapy or maintenance treatment with ammonium lactate applied topically is an option to investigate.

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