e-ISSN: 0976-822X, p-ISSN:2861-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2023; 15(6); 379-384

Original Research Article

# A Descriptive Observational Study Determining the Effect of Various Topical Agents in Chronic Plaque Type Psoriasis

**Adil Inam**

**Senior Consultant, Department of Skin and VD, Jai Prakash Narayan Hospital, Gaya, Bihar, India**

**Received: 17-3-2023 Revised: 24-03-2023 / Accepted: 29-04-2023**
**Corresponding author: Dr. Adil Inam**
**Conflict of interest: Nil**

**Abstract**

**Aim:** The aim of this study was to determine the effect of various topical agents in chronic plaque type psoriasis.

**Methods:** The present study was carried out on patients having chronic plaque type psoriasis vulgaris attending dermatology OPD of Department of Skin and VD Jai Prakash Narayan Hospital, Gaya, Bihar, India. After obtaining, written, informed and signed consent 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 enrolled. Total 150 patients were enrolled and were divided in three groups comprising of 50 patients in each group.

**Results:** No significant difference was noted between study groups. 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=0.032), group A and group C (p=0.024) but between group B and group C (p=0.942) difference was not significant. It was found that 14 (48%) out of 50 subjects attained PASI 50 in group A, 31 (62%) out of 50 patients in group B and 32 (64%) out of 50 patients in group C. Physician global assessment scale shows that in Group A, 13 (26%) patients had excellent response, 10 (20%) patients had good response, and 11 (22%) patients had fair response whereas 16 (32%) patients had poor response. In group B, 17 (34%) patients had excellent response, 19 (38%) patients had good response, and 6 (12%) patients had fair response whereas 8 (16%) patients had poor response. In group C, 20 (40%) patients had excellent response, 17 (34%) patients had good response, and 3 (6%) patients had fair response whereas 10 (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

In India, the prevalence of psoriasis varies from 0.44%–2.8%. [1] The majority of these patients have mild‐to‐moderate disease and can be treated with topical agents which provide potential therapeutic efficacy and limit the adverse effects of the systemic treatment to the target tissue. Topical therapy is the treatment of choice in patients with psoriasis affecting <10% body surface area (BSA) (mild psoriasis). [2] Occlusive therapy, in which the skin is covered, often with a plastic membrane,

enhances the penetration of topical agents such as corticosteroids. The occlusive dressings trap heat and moisture, hydrating and macerating the skin and forcing the medication through the plaques. [3-5]

Combination therapy may be indicated when monotherapy fails, for example, the combination of super potent steroids and calcipotriene. [6,7] However, when using multiple topical agents, it is important to be aware of possible compatibility issues, for example, salicylic acid inactivates calcipotriene. [8] On the other hand, anthralin requires salicylic acid for its chemical stability. [9] When it is desirable to use multiple topical agents, patients may be instructed to apply the various medications at separate times throughout the day. Topical agents can be used intermittently or continuously. More potent agents must be used on a short‐term basis to allow for response, and then patients should be instructed to use these agents intermittently for long‐term management. This strategy may reduce the risk of side effects. Adherence to topical treatment is a major issue, being generally poor in the majority of the patients. In compliance studies, 39% of the patients admitted to nonadherence with topical therapy. [10] Adherence has been seen to improve with simple regimens and once a day therapy. Moreover, realistic treatment outcomes should be discussed with patients, and they should be encouraged to participate in decision making.

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. [11,12] Topical treatment is best used to treat psoriasis affecting less than 10% of total body surface area. [13] 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 this study was to determine the effect of various topical agents in chronic plaque type psoriasis.

## Materials and Methods

The present study was carried out on patients having chronic plaque type psoriasis vulgaris attending dermatology OPD of Department of Skin and VD Jai Prakash Narayan Hospital, Gaya, Bihar, India. After obtaining written, informed and signed consent 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 enrolled. Total 150 patients were enrolled and were divided in three groups comprising of 50 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 was 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. [14]

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**

**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 | 1.32 | 1.17 | .032 | -1.65 | 3.58 |
| | Group A | Group C | .840 | 1.13 | .024 | -1.84 | 3.48 |
| | Group B | Group C | -.152 | 1.19 | .942 | -2.84 | 2.42 |

No significant difference was noted between study groups. 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=0.032), group A and group C (p=0.024) but between group B and group C (p=0.942) difference was not significant.

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

| Characteristics | | Group | | |
|---|---|---|---|---|
| | | Group A | Group B | Group C |
| PASI 50 | No | 26(52%) | 19(38%) | 18(36%) |
| | Yes | 24(48%) | 31(62%) | 32(64%) |
| Total | | 50 | 50 | 50 |

It was found that 14 (48%) out of 50 subjects attained PASI 50 in group A, 31 (62%) out of 50 patients in group B and 32 (64%) out of 50 patients in group C.

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

| PGAS | | Group | | |
|---|---|---|---|---|
| | | Group A | Group B | Group C |
| Poor | 0-24% | 16(32%) | 8(16%) | 10(20%) |
| Fair | 25-49% | 11(22%) | 6(12%) | 3(6%) |
| Good | 50-74% | 10(20%) | 19(38%) | 17(34%) |
| Excellent | 75-99% | 13(26%) | 17(34%) | 20 (40%) |
| Total | | 50 | 50 | 50 |

Physician global assessment scale shows that in Group A, 13 (26%) patients had excellent response, 10 (20%) patients had good response, and 11 (22%) patients had fair response whereas 16 (32%) patients had poor response. In group B, 17 (34%) patients had excellent response, 19 (38%) patients had good response, and 6 (12%)

patients had fair response whereas 8 (16%) patients had poor response. In group C, 20 (40%) patients had excellent response, 17 (34%) patients had good response, and 3 (6%) patients had fair response whereas 10 (20%) patients had poor response.

## Discussion

Psoriasis is a chronic inflammatory immune-mediated proliferative skin disorder that predominantly involves the skin, nails, and joints. Robert Willan, the father of modern dermatology, is credited with the first detailed clinical description of psoriasis, and hence, it is also termed as Willan'slepra. [15] 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. Chronic generalised pruritus can be manifested due to systemic disease like chronic renal insufficiency, hepatic disorders, haematological diseases, iron deficiency and malignancies. [16]

No significant difference was noted between study groups. 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=0.032), group A and group C (p=0.024) but between group B and group C (p=0.942) difference was not significant. It was found that 14 (48%) out of 50 subjects attained PASI 50 in group A, 31 (62%) out of 50 patients in group B and 32 (64%) out of 50 patients in group C. Physician global assessment scale shows that in Group A, 13 (26%) patients had excellent response, 10 (20%) patients had good response, and 11 (22%) patients had fair response whereas 16 (32%) patients had poor response. In group B, 17 (34%) patients had excellent response, 19 (38%) patients had good response, and 6 (12%) patients had fair response whereas 8 (16%) patients had poor response. In group C, 20 (40%) patients had excellent response, 17 (34%) patients had good response, and 3 (6%) patients had fair response whereas 10 (20%) patients had poor response. 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%. [17,18] 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 [19,20] the clinical response showed only a slight symptomatic improvement of psoriasis. [19] 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. [21] Regular and appropriate use of emollients improves comfort and reduces scaling, fissuring, and itching in patients with plaque or scalp psoriasis. [22,23]

## 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.

## References

1. Dogra S, Yadav S. Psoriasis in India: Prevalence and pattern. Indian journal of dermatology, venereology and leprology. 2010 Nov 1; 76:595.

2. Van de Kerkhof PC, Barker J, Griffiths CE, Kragballe K, Mason J, Menter A, Papp K. Psoriasis: consensus on topical therapies. Journal of the European Academy of Dermatology and Venereology. 2008 Jul;22(7):859-70.
3. Bourke JF, Berth-Jones J, Hutchinson PE. Occlusion enhances the efficacy of topical calcipotriol in the treatment of psoriasis vulgaris. Clinical and experimental dermatology. 1993 Nov 1;18(6):504-6.
4. Patel T, Bhutani T, Busse KL, Koo J. Evaluating the efficacy and safety of calcipotriene/betamethasone ointment occluded with a hydrogel patch: a 6-week bilaterally controlled, investigator-blinded trial. Cutis. 2011 Sep 1;88(3):149-54.
5. Volden, K Kragballe, PCM van de Kerkhof, K Åberg, RJ White G. Remission and relapse of chronic plaque psoriasis treated once a week with clobetasol propionate occluded with a hydrocolloid dressing versus twice daily treatment with clobetasol propionate alone. Journal of dermatological treatment. 2001 Jan 1; 12(3):141-4.
6. Kaufmann R, Bibby AJ, Bissonnette R, Cambazard F, Chu AC, Decroix J, Douglas WS, Lowson D, Mascaro JM, Murphy GM, Stymne B. A new calcipotriol/betamethasone dipropionate formulation (Daivobet TM) is an effective once-daily treatment for psoriasis vulgaris. Dermatology. 2002;205(4):389-93.
7. Vakirlis E, Kastanis A, Ioannides D. Calcipotriol/betamethasone dipropionate in the treatment of psoriasis vulgaris. Therapeutics and Clinical Risk Management. 2008 Feb 29;4(1):141-8.
8. Del Rosso J. Pharmacotherapy update: current therapies and research for common dermatologic conditions. The many roles of salicyclic acid. Skin Aging. 2005; 13:38-42.
9. Green PG, Forbes DR, Kennedy CT. The stability of dithranol in various bases. British Journal of Dermatology. 1985 Jul; 113:26-.
10. Van de Kerkhof PC, De Hoop D, De Korte J, Cobelens SA, Kuipers MV. Patient compliance and disease management in the treatment of psoriasis in the Netherlands. Dermatology. 2000;200(4):292-8.
11. Kumar B, Kumar R, Kaur I. Coal tar therapy in palmoplantar psoriasis: old wine in an old bottle? Int J Dermatol 1997;36(4):309–12.
12. Ademola J, Frazier C, Kim SJ, Theaux C, Saudez X. Clinical Evaluation of 40% Urea and 12% Ammonium Lactate in the Treatment of Xerosis. Am J Clin Dermatol 2002;1;3(3):217–22.
13. Das RP, Jain AK, Ramesh V. Current concepts in the pathogenesis of psoriasis. Indian J Dermatol 2009;54 (1):7–12.
14. Fluhr JW, Cavallotti C, Berardesca E. Emollients, moisturizers, and keratolytic agents in psoriasis. Clin Dermatol 2008;26(4):380–6.
15. Glickman FS. Lepra, psora, psoriasis. Journal of the American Academy of Dermatology. 1986 May 1;14(5 Pt 1): 863-6.
16. Okhandiar RP, Banerjee BN. Psoriasis in the tropics: an epidemiological survey. J Indian Med Assoc. 1963.
17. Childhood psoriasis: often favorable outcome. Prescrire Int 2009;18(104): 275
18. Van Duijnhoven MWFM, Hagenberg R, Pasch MC, van Erp PEJ, van de Kerkhof PCM. Novel quantitative immunofluorescent technique reveals improvements in epidermal cell populations after mild treatment of psoriasis. Acta Derm Venereol 2005; 85(4):311–7.
19. Rim JH, Jo SJ, Park JY, Park BD, Youn JI. Electrical measurement of moisturizing effect on skin hydration and barrier function in psoriasis

patients. Clin Exp Dermatol 2005;30 (4):409–13.
20. Jaroslav Chladek, JiØ1 Grim, JiØina Martinkova, Marie Simakova, Jaroslava Vaniekova, Vira Koudelkova, Marie Noiekova. Pharmacokinetics and pharmacodynamics of low- dose methotrexate in the treatment of psoriasis. Br J Clin Pharmacol 2002; 54(2):147-156.
21. Lebwohl M, Kathryn M. New roles for systemic retinoids. J Drugs Dermatol 2006;5(5):406–9.
22. Dawn A, Yosipovitch G. Treating itch in psoriasis. Dermatol Nurs 2006;18 (3):227–33.
23. Raut AS, Prabhu RH, Patravale VB. Psoriasis clinical implications and treatment: a review. Crit Rev Ther Drug Carrier Syst 2013;30(3):183–216.