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Efficacy of Oral Vitamin D3 in Addition to Topical Clobetasol Propionate 0.05% Cream in Patient of Chronic Plaque Psoriasis

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A B S T R A C T

***Introduction*:** Psoriasis is chronic immune-mediated disease with a focus on the skin. This condition, which relapses and remitsovera patient's lifetime, affects about 1%-6% of the Indian population. Topical corticosteroids, vitamin D analogues, and retinoids are recommended by the American Academy of Dermatology and the National Psoriasis Foundation as first-line treatments for people with mild to moderate localized plaque psoriasis. Recent studies show role of vitamin D in many immune mediated skin diseases like psoriasis and oral vitamin D remain safe, widely available and inexpensive treatment. Vitamin D3 have also some effects in metabolic syndrome. ***Aim*:** Aim of the study is to see the efficacy and safety of oral vitamin D3 in addition to topical clobetasol propionate 0.05% cream in patients of chronic plaque psoriasis. ***Methodology*:** 64 patients from Department of Dermatology, Venereology and Leprosy, sir T hospital Bhavnagar of chronic plaque psoriasis were randomly divided in two groups. Both the groups were followed up for 10 weeks and evaluated with gross photographs, PASI score and global improvement score. ***Results*:** After 10 weeks improvement in PASI in Group A was 5.17±3.14 and in Group B 6.88±4.06. But while comparing both means using Mann Whitney test, P value was 0.029 which was considered significant. While GIS between group A and Group B was not significant with p value =0.264. ***Conclusion*:** Oral vitamin D can be safe, effective, and cheap therapeutic modality as supplement with topical steroids to psoriasis patients. Unlike most systemic drugs currently used in psoriasis, the adverse effects of which are significant, and many of them are costly.

Keywords: Psoriasis, Psoriasis Area and Severity Index, Global improvement scale, Topical clobetasol propionate.

INTRODUCTION

Psoriasis is a common, immunologically mediated inflammatory dermatosis with genetic predisposition, characterized by erythematous scaly plaques involving the scalp and extensors of limbs affecting 0.5 to 1.5% individuals worldwide. This condition, which relapses and remitsovera patient's lifetime, affects more than 7 million Americans, or roughly 2% of the population [1-3]. The three characteristics of plaque psoriasis, the most common variety, are erythema (redness), scaling (production of white flakes because of excessive keratinocyte shedding), and induration (thicknes soft heplaques) [1]. The National Psoriasis Foundation defines mild to severe psoriasis as lesions covering less than 10% of the body surface area, which describes the majority of patients with this illness [2, 4]. Psoriasis is defined histologically by increased vascularity in the dermis, inadequate keratinocyte differentiation, and epidermal hyper proliferation [5]. Cytokines generated by inflammatory T cells appear to have a significant part in the pathophysiologic process that results in psoriasis. These immune regulatory proteins enhance the migration of inflammatory cells in to the skin as well as the differentiation and proliferation of keratinocytes [6]. Outcome is epidermal proliferation and clinically visible inflammation at the lesion site [6]. Therefore, therapies target both the biological functions associated to keratinocytes and the immune system may be more effective than therapies that focus on just one of the two functions. The choice of a course of treatment might be challenging due to the widely diverse clinical structures and causes of psoriasis [1, 3].

Numerous therapeutic choices, including over-the-counter (OTC) topical medications (such as salicylic acid and coal tar) and prescription topical medications [1, 3], further complicate matters (eg, vitamin D analogues, corticosteroids, topical retinoid) [1, 2, 7]. It is crucial to remember that although current treatments do not provide a cure, they do decrease disease severity and prolong remissions [3]. Topical therapy may decrease symptoms like itching, burning, and soreness that frequently develop at the lesion site [1, 8]. Topical vitamin D analogues, corticosteroids, and retinoids are recommended by the American Academy of Dermatology and the National Psoriasis Foundation as first-line treatments for people with mild to moderate localized plaque psoriasis [2, 3]. The use of topical corticosteroids, topical vitamin D analogues, and their combination for initial symptom control are supported by reliable, high-quality data that is patient-focused. Recent studies show role of vitamin Din many immune mediated skin diseases like psoriasis and oral vitamin D remain safe, widely available and in expensive treatment. Vitamin D3 have also some effects in metabolic syndrome. In this study we will compare efficacy of topical clobetasol propionate and oral vitamin D3 sachet. Our research seeks to examine the study data available on the combination therapy of oral vitamin D3 and topical clobetasol propionate 0.05%for the treatment of persistent plaque psoriasis.

Aim & Objectives

Aim of the study is to see the efficacy and safety of oral vitamin D3in addition to topical clobetasol propionate 0.05% cream in patients of chronic plaque psoriasis. To compare efficacy of topical clobetasol propionate vs Oral vitamin D3 sachets + clobetasol propionate 0.05% in pt. of chronic plaque psoriasis, to assess the improvement of mean PASI score in clobetasol propionate and Vitamin D3 + clobetasol propionate 0.05% treatment from baseline, to assess Global improvement scale in the end of 10 week.

Material & Methods

This was a randomized, double blind, Placebo controlled, parallel group trial conducted at Bhavnagar, Gujarat visiting our OPD of dermatology department. Study prospectively registered under Clinical trial registry of India. 64 patients fulfilling inclusion and exclusion criteria from January 2021 to December 2021. Among 64 participants were randomly allocated into group A (N = 34) and group B (N=30) with the help of closed envelopes prepared through computer based “Random number generator” software.

Inclusion Criteria

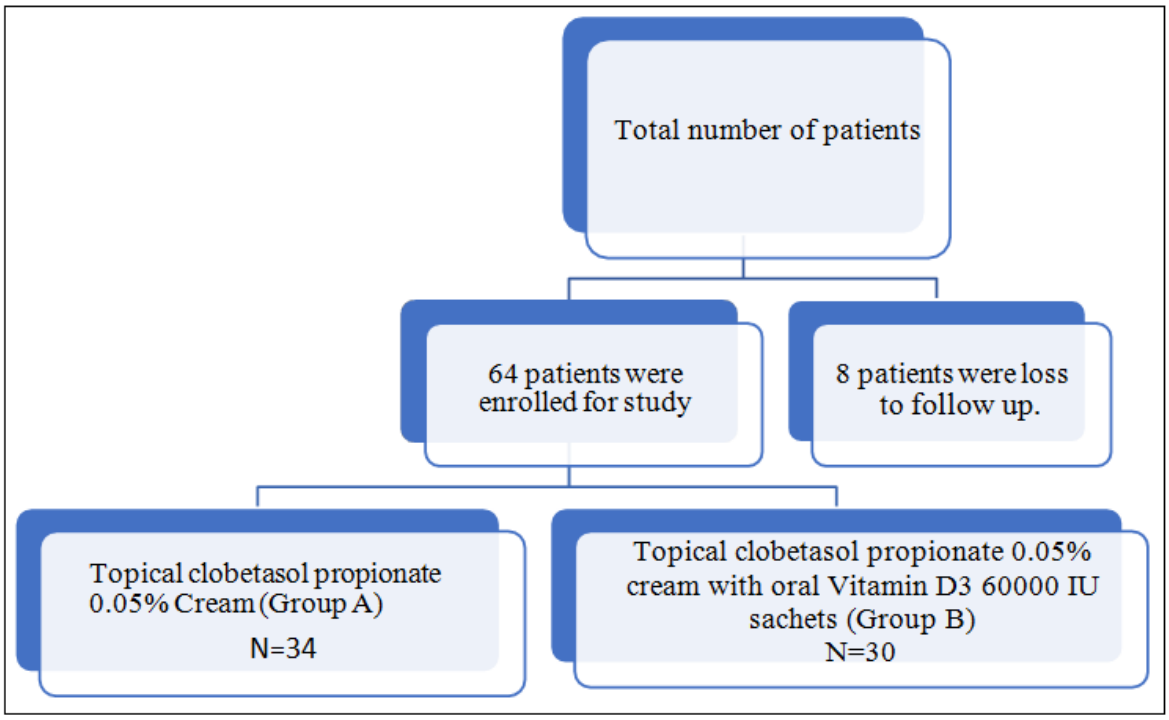
Patient with age group of 18–60, Mild to moderate chronic plaque psoriasis (BSA<20%), Patients suffering from chronic plaque psoriasis who were newly diagnosed or off the treatment for at least 1 month.

Exclusion Criteria

Pregnant and lactating women, other types of psoriasis like guttate psoriasis, pustular, erythrodermicpsoriasis, Patients having psoriatic lesions on face and groin, those who are on treatment inlast4weeks, suffering from any other life- threatening systemic illness like stroke, Myocardial infraction, psychiatric illness, chronic liver disease, chronic kidney disease, Not giving consent for study.

Methodology

All Patients having chronic plaque psoriasis who fulfilling inclusion and exclusion criteria, after taking informed consent detailed history will be taken using predesigned case record form. Gross photographs will be taken using mobile camera. Patients will be randomized in 2 groups using random US software.1 group will be given topical clobetasol propionate 0.05% cream daily night application whereas 2nd group will be given oral vitamin D3 sachets once weekly at night after meal with topical clobetasol propionate 0.05% cream daily night application after then patients will be counseled to apply white petroleum jelly in day time and clobetasol cream at night every day. Patients will be asked if they miss to apply topical drug, and for how many days. In both case patients will be followed up after 6 weeks and 10 weeks. PASI score will be recorded at 1st visit and 10 weeks. We were measured outcome based on Improvement in PASI score after treatment and Global improvement scale.



RESULTS

Out of 64 patients, 19 subjects were within 40-49 years (29.7%),16 patients were within 50-59 years (25%),13 subjects were within 30-39 years (20.3%), 9 subjects were within 20-29 years (14.1%) and 7 patients were 60 years (10.9%). 17 patients (26.6%) were females and 47 patients (73.4%) were Males.

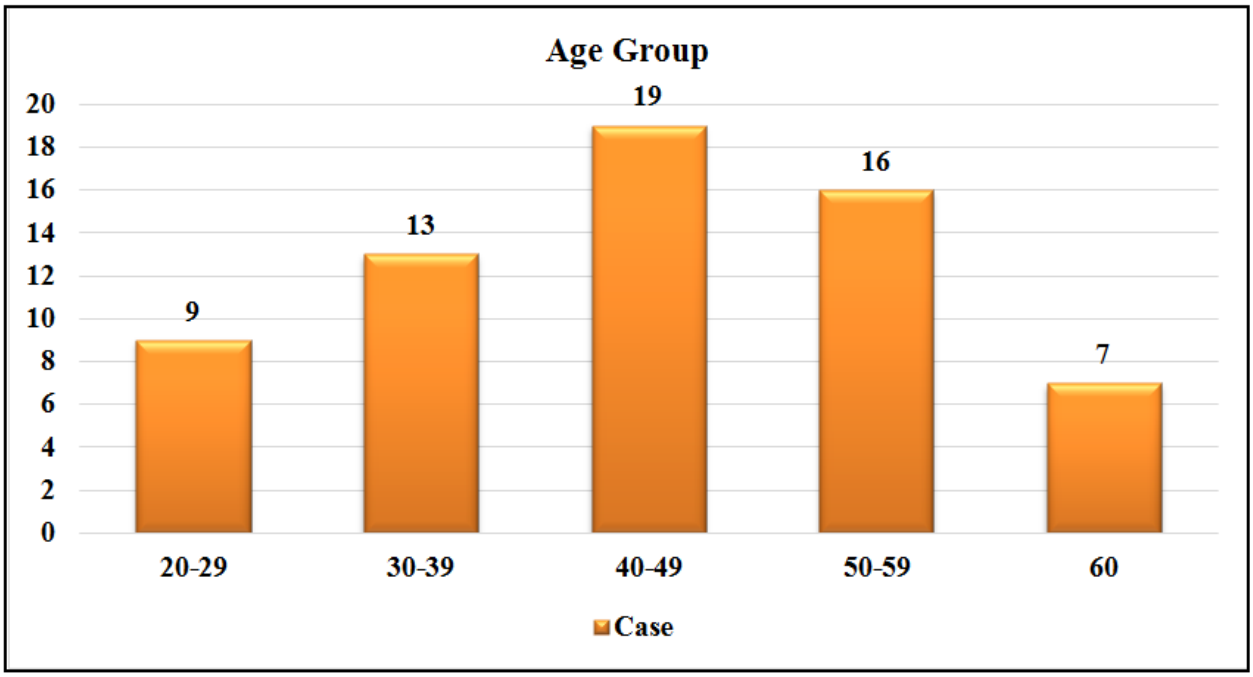


Figure 1: Distribution based on Age groups

Table 1: Mean age in Group A and B with p value

	Group-A (34)	Group-B (30)	p-value
Age	**41.83±12.25**	**45.4±10.1**	**0.211**

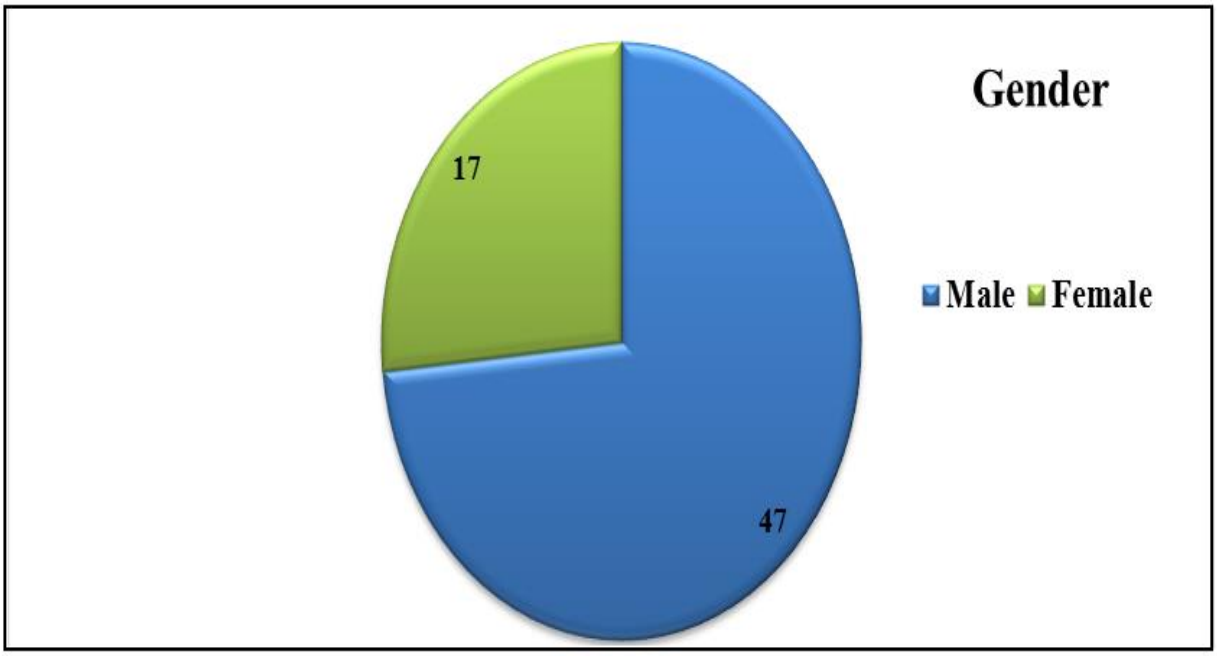


Figure 2: Distribution based on Gender

We observed following nail findings in psoriasis observed as respectively: subungual hyperkeratosis (37.5%), nail pitting (32.8%), Onycholysis (25%), oil Drop (17.5%) and Increased longitudinal ridging (20.3%). Out of 64 patients, 11 (17.2%) was having metabolic syndrome in our setting. Out of 64 patients, 34 patients (53.1%) given topical clobetasol propionate e0.05% cream alone and 30 patients (46.9%) were given topical clobetasol propionate 0.05% cream with oral vitamin D3 60000 IU sachets. In our study, we were not observed any side effects of vit. D3 Sachetssuc has Nausea/Vomiting, Constipation, Abdominal Pain, Loss of Appetite, Increased Urination, Mood Change and Unusual Tiredness. We were observed following cutaneous side effect of clobetasol observed as respectively: Atrophy skin (15.6%), Burning (12.5%), Itching (9.4%), Telangiectasia (4.7%) and Infection (1.6%).

Table 2: Frequency of patient in group A and B

Treatment	Frequency	Percent
Without Vitamin D3 **(Group A)**	34	53.1
With Vitamin D3 **(Group B)**	30	46.9
Total	64	100.0

Overall Mean PASI score at 0 week was 8.98±7.50 after then Overall Mean PASI score at 10 week was 2.708± 5.086. So, we could say as overall improvement in PASI score was 6.252± 3.943 after treatment. Group-A had given topical clobetasol propionate 0.05% cream alone whereas Group-B had given topical clobetasolpropionate 0.05% cream with oral vitamin D3 60000 IU sachets. PASI score in topical clobetasol propionate 0.05% cream with oral vitamin D3 60000 IU sachets (Group B) is considered very significant compared to topical clobetasol propionate 0.05% cream (Group A) (p=0.005). Topical clobetasol propionate 0.05% cream with oral vitamin D3 60000 IU sachets (Group B) given treatment was also significant compared to topical clobetasol propionate 0.05% cream (Group A) alone given at 10 week in PASI score observed in our study (p=0.042). According to improvement in PASI score, topical clobetasol propionate 0.05% cream with oral vitamin D3 60000 IU sachets given treatment was considered significant compared to topical clobetasol propionate 0.05% cream given in PASI score observed in our study (p=0.013).

Table 3: Mean PASI (Psoriasis Area and Severity Index) in Group A and B with Pvalue

	Group-A (34)	Group-B (30)	p-value
PASI (0 Week)	**6.45± 3.84**	**10.0±7.046**	**0.005**
PASI (10 Week)	**1.28±1.30**	**3.11±5.16**	**0.042**
PASI Difference	**5.17±3.14**	**6.88±4.06**	**0.029**

Among 64 patients, GIS (N=2) was highest percentage (51.6%) observed which suggest much improvement than baseline. whereas GIS (N=6) was least percentage (1.6%) suggest no change observed in our study population. Mean Global improvement scale is not significant at the end of 10 weeks between Group A and Group B in our study (p=0.264).

Table 4: Frequency of GIS (Global improvement scale)

GIS	Frequency	Percent
1.0	21	32.8
2.0	33	51.6
3.0	6	9.4
4.0	3	4.7
6.0	1	1.6
Total	64	100.0

Table 5: Mean GIS in Group A and B with p value

	Group-A (34)	Group-B(30)	p-value
GIS	1.852 ± 1.048	2.0 ± 0.7878	0.264

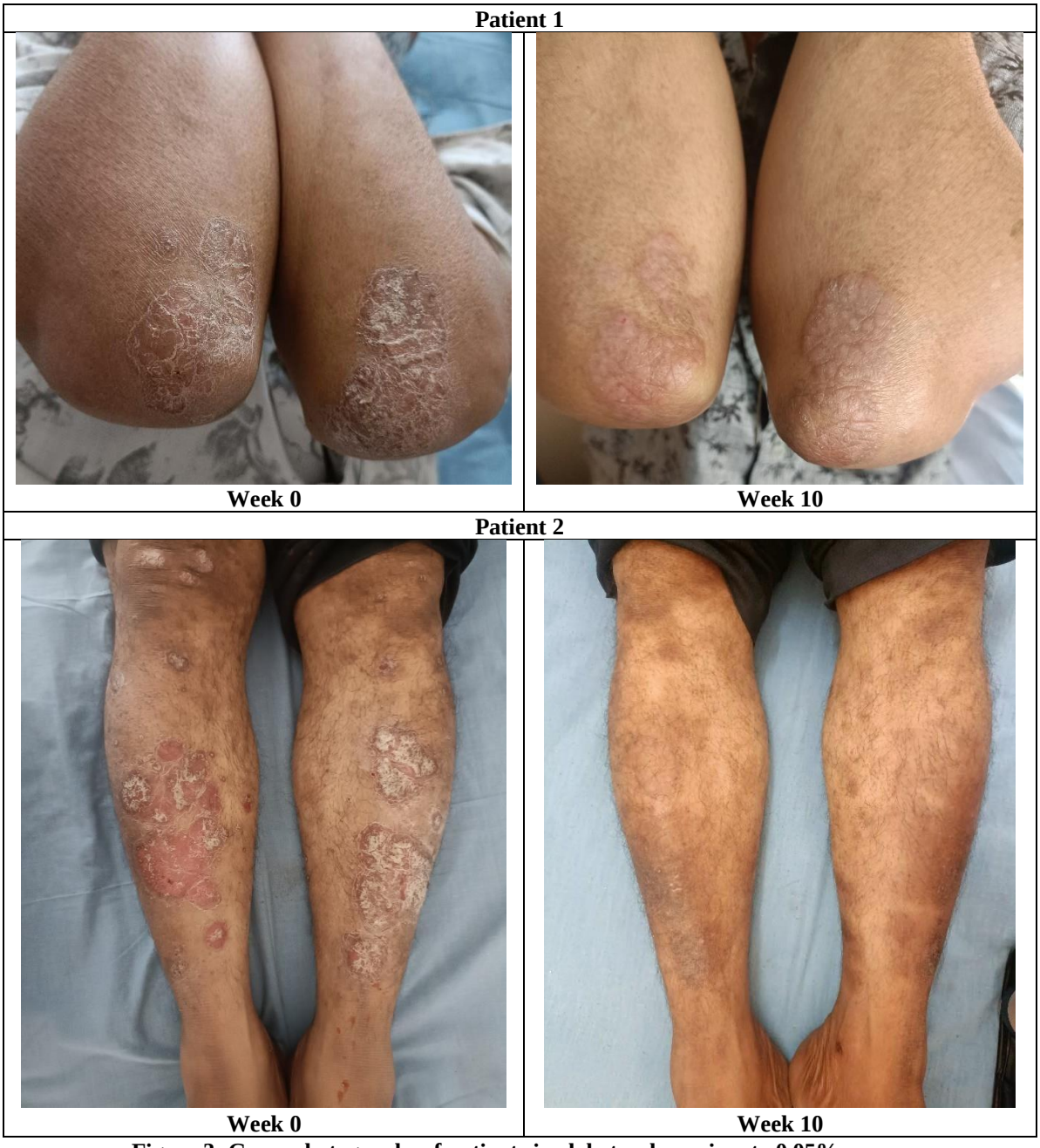


Figure 3: Gross photographs of patients in clobetasol propionate 0.05% cream (Group A)

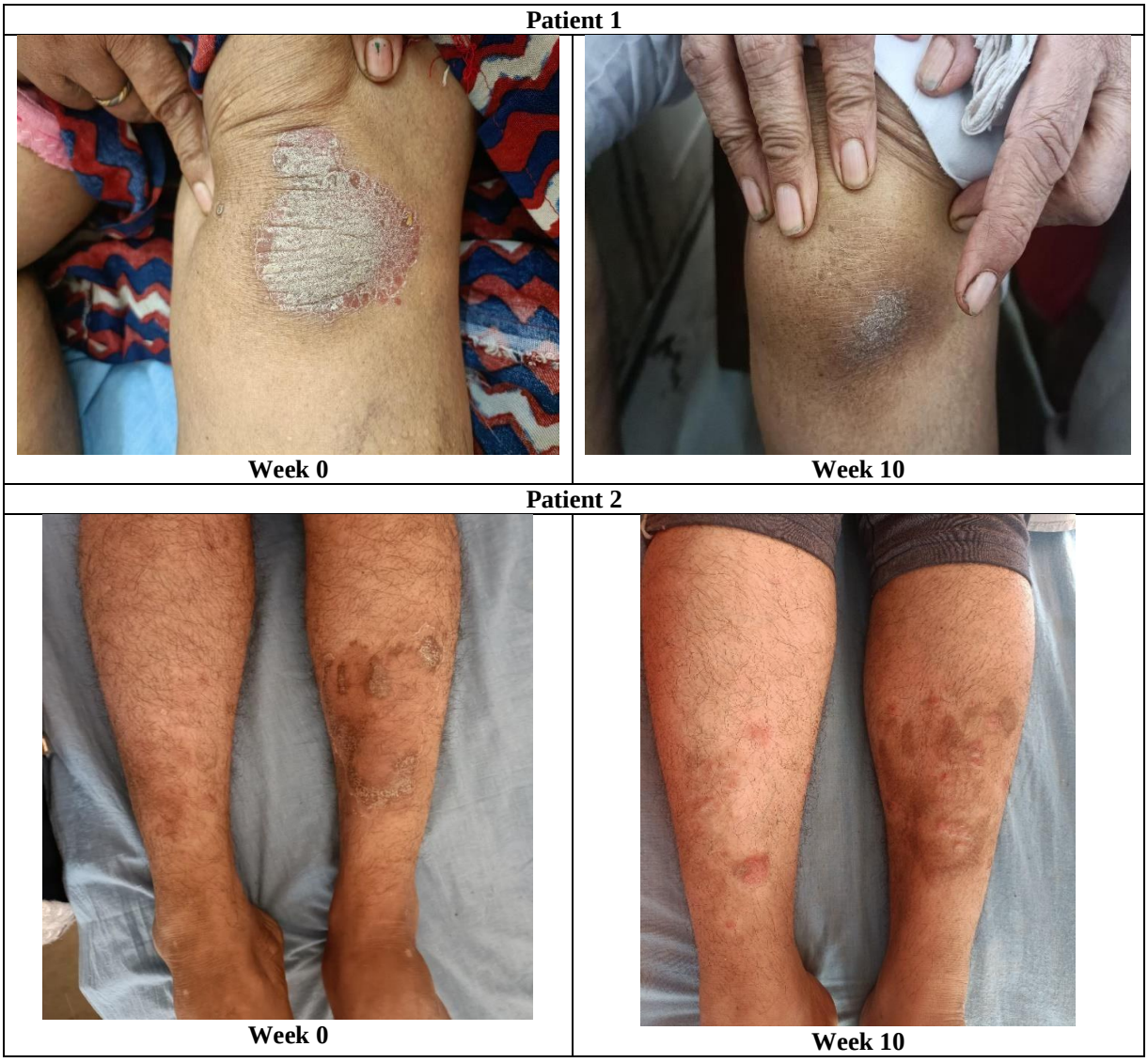


Figure 4: Gross photographs of patients in clobetasol propionate 0.05% cream with oral vit D3 60000 IU sachets (Group B)

DISCUSSION

About 2% of the world's population suffers from the chronic, inflammatory condition psoriasis [9, 10]. Although there are many different alternatives for treatment, many mild to moderate instances of plaque psoriasis will necessitate the usage of many medications over the course of the disease. In some cases, a combination of topical, systemic, and/or phototherapy may be necessary. To best treat psoriasis, particularly in patients with stubborn or severe disease, it's critical to employ and understand combination, rotational, or sequential therapy more frequently. Numerous medications are available and used in clinical settings to treat psoriasis. Unfortunately, there is still a dearth of trustworthy information on the various possible combinations of therapy. There are several case reports and series on this subject, but there aren't many sizable, randomized, controlled clinical trials as of yet. The combinations that have the highest support from the literature include topical vitamin D derivatives combined with topical corticosteroids, topical vitamin D derivatives combined with phototherapy, and phototherapy combined with oral retinoids. Recent studies show role of vitamin D in many immune mediated skin diseases like psorias is and oral vitamin D remain safe, widely available and inexpensive treatment. Vitamin D3 have also some effects in metabolic syndrome. In this study we will compare efficacy of topical clobetasol propionate and topical clobetasol propionate with oral vitamin D3 sachet. In the present study, 64 patients with chronic plaque psoriasis were divided into two groups: Group-A (Topical clobetasol propionate 0.05% cream) and Group-B (Topical clobetasol propionate 0.05% cream with oral vitamin D3 60000IU sachets). Group-A had not given vitamin D3 whereas Group-B had given to vitamin D3 60000IU sachets once a week for 10 weeks treatment. Overall mean age of Group-A was 41.83±12.25 years whereas overall mean age of Group-B was 45.4±10.1. There was no statistical difference observed between the of mean age of patients who received or not received vitamin D3 treatment. Our study was compatible with the study of Al-Sultany H.A. *et al*., [11] He was also enrolled patients between their groups of overall mean age had not statistical difference. In our study, 47 (73.44%) were males whereas 17(26.56%) were

females. Among group-A patients, 26 (76.47%) were males whereas 8(23.53%) were females. In our study, group- A was male to female ratio was 3.25:1. Among group-B patients, 21 (70%) were males whereas 9(30%) were females. In our study, group-B was male to female ratio was 2.33:1. We were not observed significant association between gender and given vitamin D3 treatment. (p=0.7632) Our study was compatible with the study of Al-Sultany H. A *et al*., [11]He was also enrolled patients between their groups of gender was not statistical difference observed in our study. Overall mean age of Group-A was 41.83±12.25. Among this group was having highest percentage observed in the age group of 40-49 years (23.53%) and 50-59 years (23.53%) age group. In this group, male to female ratio was 3.25:1.Among group-A, mean PASI score was 6.45± 3.84 observed at 0 week. Whereas mean PASI score was 1.28±1.30 observed at 10th week. Overall improvement in mean PASI score was 5.17±3.14 which is statistically significant. Which suggest topical clobetasol is efficacious for treatment of chronic plaque psoriasis. Al-Sultany*et al*., observed baseline PASI 15.1+3.72- and 3-month PASI 10.4+2.32 with % of improvement 31.12 + 56.44(p= 0.033) which is statistically significant. Overall mean age of Group-B was 45.4±10.1. Among this group was having highest percentage observed in the age group of 40-49 years. (36.67%) In this group, male to female ratio was 2.33:1. Among group-B, mean PASI score was 10.0±7.046 observed at 0 week. Whereas mean PASI score was 3.11±5.16 observed at 10th week. Overall improvement in mean PASI score was 6.88±4.06 which is statistically significant. Which suggest topical clobetasol with oral Vitamin D3 sachets is also efficacious for treatment of chronic plaque psoriasis. Al-Sultany*et al*., Observed baseline PASI 15.3+1.14- and 3-month PASI 5.2+4.43 with 66.01 +30.13% of improvement (p=0.014) which is statistically significant. In Our study, we observed significant improvement in PASI at the end of 10 week in Group B compare to Group A. (p=0.013). Al-Sultany H. A. *et al*., observed significant improvement in PASI score among patients who took in addition to the topical steroid oral vitamin D (p=0.033) which is similar to our study. Ingram M. A. *et al*., [12]had given GroupA-100,000 International Units (IU) vitamin D3/month for 12 months (200,000 IU at baseline; n = 67) and Group B - identical placebo (n = 34). They observed PASI did not differ between groups at any time. AlkaDogra*et al*.,[13]observed Vitamin D, analogues 1α hydroxy vitamins D3 and 1,25 (OH)2 D3 were found to be effective in psoriasis compared to placebo. Mean Global improvement scale is not significant between Group A and Group B in our study (p=0.264).

CONCLUSION

In clinical practice, combination treatment of psoriasis is generally used. For patients with relatively mild to moderate psoriasis, fast-acting, topical corticosteroid agents may be used initially, while slower acting, safer vitamin D analogs may be used in combination to speed healing and minimize long-term exposure and side effects of topical corticosteroids. Vitamin D has role in regulate keratinocyte proliferation and differentiation, and modulate the immune response, and analogs of topical vitamin D area well-established treatment for mild- to moderate psoriasis. Oral vitamin D supplementation can be safe, effective, and cheap therapeutic modality to psoriasis patients. Unlike most systemic drugs currently used like methotrexate, cyclosporine, TNF alpha inhibitors, biologics in psoriasis, the adverse effects of which are significant, and many of them are costly. Topical vitamin D3 analogs are also costly compare to oral vitamin D3. We were not observed any adverse symptoms such as nausea, vomiting, loss of appetite and abdominal pain in group B after given oral Vitamin D3. We also observed rising trend of metabolic syndrome in psoriasis patients in our study and role of Vitamin D in metabolic syndrome is observed in literature. According to improvement in PASI score, topical clobetasol propionate 0.05% cream with oral vitamin D3 60000 IU sachets given treatment was considered significant compared to topical clobetasol propionate 0.05% cream given in PASI score observed in our study. So, our concluding remark is addition of oral vitamin D3 with topical clobetasol propionate 0.05% cream can be safe, effective and cheap therapeutic modality in mild to moderate chronic plaque psoriasis.

REFERENCE

1. Menter, A., Gottlieb, A., Feldman, S. R., Van Voorhees, A. S., Leonardi, C. L., Gordon, K. B., ... &Bhushan, R. (2008). Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *Journal of the American Academy of Dermatology*, *58*(5), 826-850.
2. National Psoriasis Foundation. Topical treatments. National Psoriasis Foundation website. www.psoriasis.org/about-psoriasis/treatments/topicals. Accessed January 7, 2015.
3. Menter, A., Korman, N. J., Elmets, C. A., Feldman, S. R., Gelfand, J. M., & Gordon, K. B. (2009). American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. *J Am AcadDermatol*, *60*(4), 643-659.
4. Kurd, S. K., &Gelfand, J. M. (2009). The prevalence of previously diagnosed and undiagnosed psoriasis in US adults: results from NHANES 2003-2004. *Journal of the American Academy of Dermatology*, *60*(2), 218-224.
5. Nestle, F. O., Kaplan, D. H., & Barker, J. (2009). Psoriasis. *N Engl J Med*, 361, 496-509.
6. Monteleone, G., Pallone, F., MacDonald, T. T., Chimenti, S., & Costanzo, A. (2011). Psoriasis: from pathogenesis to novel therapeutic approaches. *Clinical science*, *120*(1), 1-11.
7. Uva, L., Miguel, D., Pinheiro, C., Antunes, J., Cruz, D., Ferreira, J., & Filipe, P. (2012). Mechanisms of action of topical corticosteroids in psoriasis. *International journal of endocrinology*, *2012*(1), 561018.

8. Van de Kerkhof, P. C. M., De Hoop, D., De Korte, J., Cobelens, S. A., &Kuipers, M. V. (2000). Patient compliance and disease management in the treatment of psoriasis in the Netherlands. *Dermatology*, *200*(4), 292-298.
9. Christophers, E. (2001). Psoriasis−epidemiology and clinical spectrum. *Clinical and experimental dermatology*, *26*(4), 314-320.
10. Kurd, S. K., &Gelfand, J. M. (2009). The prevalence of previously diagnosed and undiagnosed psoriasis in US adults: results from NHANES 2003-2004. *Journal of the American Academy of Dermatology*, *60*(2), 218-224.
11. Al-Sultany, H. A. Oral Vitamin D Therapy for Chronic Plaque-Psoriasis among Iraqi Patients, Efficacy, and Safety.
12. Ingram, M. A., Jones, M. B., Stonehouse, W., Jarrett, P., Scragg, R., Mugridge, O., & von Hurst, P. R. (2018). Oral vitamin D3 supplementation for chronic plaque psoriasis: a randomized, double-blind, placebo-controlled trial. *Journal of Dermatological Treatment*, *29*(7), 648-657.
13. Dogra, A., &Arora, A. K. (2014). Nail psoriasis: the journey so far. *Indian journal of dermatology*, *59*(4), 319-333.