

Pattern of drug use in the management of psoriasis in a tertiary care hospital: a prospective study

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ABSTRACT

Background: Psoriasis is a chronic skin disease, characterized by chronic and recurrent scaly plaques with itching. The treatment modalities for psoriasis include topical, systemic, and phototherapy (PT). The pattern of therapy may vary depending upon the type, severity, and duration of the disease. As there are few reports in the Indian literature regarding the pattern of drug use in psoriasis and evaluating the efficacy and patient compliance to treatment, the present study was conducted.

Methods: This was a prospective, observational study conducted on 121 newly diagnosed and untreated patients with psoriasis, who attended Dermatology outpatient department of a tertiary care hospital. The severity of the disease was assessed by baseline psoriasis area severity index (PASI) score. Most of the patients were treated with topical therapy consisting of glucocorticoids (GC) monotherapy or combination with, salicylic acid, calcitriol and coal tar. Systemic therapy and PT were considered only for severe cases of psoriasis with baseline PASI score >4. The patients were monitored every 2 weeks for 3 months.

Results: The topical medications induced effective resolution of lesions in most of the patients, along with adequate symptomatic relief. The response to GC monotherapy was found significant (90.47%; $p < 0.001$) and there was 76.13% decrease in PASI score in chronic plaque psoriasis, indicating significant improvement ($p < 0.001$) after 12 weeks of therapy. More than 94% of study patients showed good compliance to medications and only 0.27% showed poor compliance, whereas the other patients showed a moderate compliance of 80-95%.

Conclusions: Most of the patients with psoriasis can be effectively treated with topical medications, and additional systemic and/or PT may be required only for severe cases of chronic plaque psoriasis with baseline score >4. Regular follow-up is required not only to monitor the treatment response, but also to ensure good patient compliance by proper counseling.

Keywords: Psoriasis, Topical therapy, Systemic therapy, Phototherapy

INTRODUCTION

Psoriasis is a chronic and recurrent disease of the skin affecting 0.1-3% of the population worldwide. The overall prevalence estimated in Indian population varies from 0.44% to 2.8%, respectively. Psoriasis is characterized by chronic and recurrent scaly plaques with itching and often associated with physical and psychological morbidity.¹⁻³

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.¹⁻³

The management of psoriasis involves topical medications, systemic drug therapy and also phototherapy (PT). The topical medications include emollients, dithranol, coal tar, calcipotriol, retinoids and glucocorticoids (GC). Systemic therapy includes immunosuppressants such as methotrexate (Mtx) and cyclosporin, retinoids like acitretin and etritinate,

and biological response modifiers such as etanercept, efalizumab, adalimumab, infliximab and alefacept. PT involves ultraviolet B irradiation of the skin and also photochemotherapy. In recent times, laser therapy is also approved for treating localized plaques of psoriasis.^{1,2,4,5}

As there are few reports in the Indian context regarding the overall pattern of drug use, the present prospective observational study was conducted to assess the pattern of drug use in the management of psoriasis, the efficacy and patient compliance in a tertiary care teaching hospital.

METHODS

Study design

This was a prospective study conducted in the Dermatology outpatient department (OPD) of Kerala Institute of Medical Sciences (KIMS) Hospital and Research Center, Bangalore, India for a period of 18 months (from January 1, 2011 to June 30, 2012). Approval and clearance from the Institutional Ethics Committee was obtained before beginning of the study. Written informed consent was taken from all the study patients after fully explaining the study procedure to their satisfaction, in both English and vernacular language. Anonymity, confidentiality, and professional secrecy was maintained for all the study patients.

Inclusion criteria

- a. Patients newly diagnosed as having psoriasis between the age group of 18 and 60 years.
- b. Patients willing to give written informed consent and regular follow-up visits.

Exclusion criteria

- a. Patients already on treatment for psoriasis.

Study procedure

Patients were subjected to a detailed history taking including demographics, family history, present and past medical history and drug history. Pre-disposing or precipitating factors, if any, were also recorded. The available case records were scrutinized to collect any other valid data. A thorough clinical evaluation was carried out to:

- a. Assess the pattern, severity, duration, and natural course of the disease.
- b. Detect any underlying disease, systemic involvement or complications-related to psoriasis.

The pattern of drug therapy topical or systemic, the drugs or drug combinations used, the type of formulations, method of administration/application, frequency and duration of use, and patient compliance was assessed, evaluated, and monitored.

The severity of psoriatic lesions was assessed by psoriasis area severity index (PASI) score. The response to the treatment was assessed by percentage decrease in PASI score. Patient compliance was assessed by maintaining daily drug reminder chart. Follow-up was done regularly at fortnightly intervals for 3 months to assess treatment response and compliance using PASI scale.

Statistical methods

The collected data were analyzed by using descriptive statistics, namely mean, standard deviation, standard error of mean and RM-ANOVA for quantitative variables. The results were also depicted in the form of tables and graphs. Statistical software namely SPSS v20 (SPSS Inc., Chicago, IL) was used for the analysis of data and Microsoft Word and Excel to generate graphs and tables.

RESULTS

Patient characteristics

During the study period, we assessed 121 newly diagnosed psoriasis patients, who attended the dermatology OPD of KIMS hospital and Research Center, Bangalore. Table 1 summarizes the patient characteristics. Among the study patients, 70 (57.85%) were males and 51 (42.15%) were females. Most of the patients were from urban background (84.3%) and were from upper and lower middle class (85.95%).

Clinical data

The presenting complaints and symptoms in the study patients are presented in Figure 1. Only 16.12% of the patients (n=20) had positive family history suggestive of psoriasis. Twenty-seven patients (22.31%) had a history of hypertension, of which 18 patients were in the age group of 51-60 years. Two patients (1.65%) had bipolar

Table 1: Patient characteristics.

Patient characteristics	Total n (%)
Mean age (SD)	42.2±13.9
Sex	
Male	70 (57.85)
Female	51 (42.15)
Smoking and alcohol consumption	
Smoking	37 (30.57)
Alcohol consumption	9 (7.43)
Non-smoker/non-alcoholics	75 (61.98)
Living status	
Urban	102 (84.30)
Rural	19 (15.70)

SD: Standard deviation

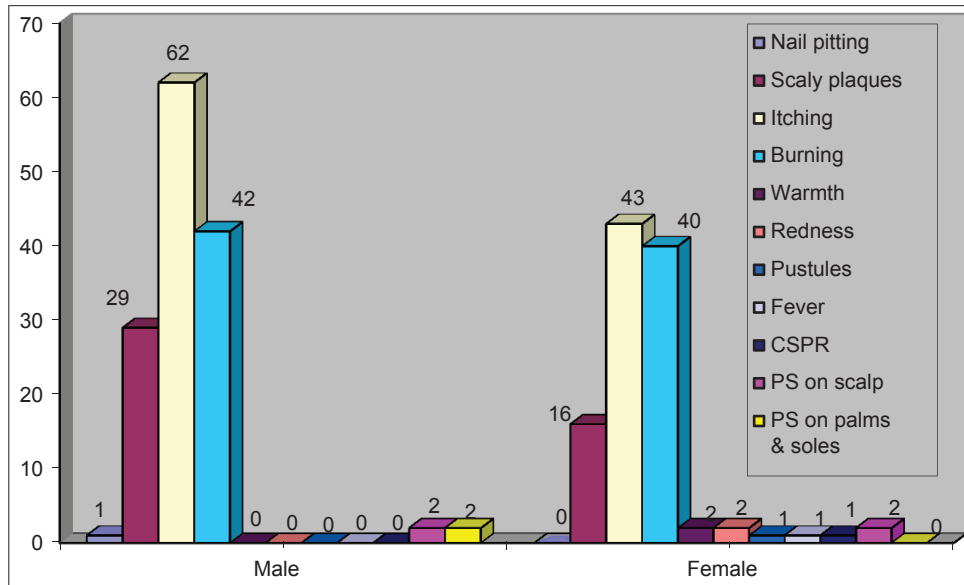


Figure 1: Presenting complaints/symptoms in the study patients.

affective disorder and five patients (4.13%) had a history of rheumatoid arthritis. Thirty-four patients (28.09%) were receiving various medications for chronic illnesses such as hypertension, mood disorders, and rheumatoid arthritis, which were continued throughout the study period.

Figure 2 shows the sites affected in various types of psoriasis. In patients with chronic plaque psoriasis, the PASI score ranged from a minimum of 0.3 to the maximum of 12.6, with the mean PASI score of 2.43±2.42, as depicted in Table 2.

Treatment modality and outcome

Therapy for psoriasis mainly involved topical application of various medications along with systemic and PT in selected cases. The topical therapy alone was considered in all patients with the baseline PASI score of <4. Majority of the patients (n=95; 78.51%) were treated with topical medications, which included GC, salicylic acid (SA), calcitriol and coal tar, either as monotherapy or in combination of two or more drugs, in the form of creams or ointments. Systemic therapy with oral Mtx 7.5 mg once weekly, supplemented with folic acid, was used in eight patients (6.61%) with severe chronic plaque psoriasis with base line PASI score >7, in combination with topical therapy. The combination of topical + systemic + PT was used only for very severe cases of chronic plaque psoriasis with baseline PASI score >8. Topical therapy included GCs as monotherapy (n=3), and in combination with calcitriol (n=2), along with emollients. Systemic therapy was given as Mtx 7.5 mg orally once weekly for 12 weeks. The outcome of topical + systemic + PT is shown in Figure 3.

Table 3 shows treatment outcome in different types of psoriasis. In chronic plaque psoriasis (n=109), the mean PASI score, which was 2.43 at baseline, was reduced to 0.58 after 12 weeks of therapy, with 76.13% decrease in

Table 2: Baseline PASI score of study patients.

Type of psoriasis	PASI scores		
	Minimum	Maximum	Mean±SD
Chronic plaque	0.3	12.6	2.43±2.42
Guttate	0.8	0.9	0.85±0.07
Nail*	-	-	0.4
Pustular*	-	-	1.6
Erythrodermic*	-	-	14
Palmoplantar	0.6	2	1.54±0.55
Scalp	0.2	0.3	0.25±0.07

*One patient with each of these lesions. PASI: Psoriasis area severity index, SD: Standard deviation

PASI score indicating significant improvement (p<0.001). Guttate psoriasis (n=2) was treated with topical medications as GC monotherapy (n=1) and GC + SA (n=1). The mean PASI score was reduced from 0.85 at baseline to 0 after 10 weeks (100%) indicating complete resolution, and hence the treatment was discontinued, except the emollients. The treatment response to various forms of psoriasis is summarized in Table 3.

Patient compliance to medications

The patient compliance for various medications at different visits is shown in Table 4. As these medications were prescribed for self-application/administration without supervision, the compliance to medication was assessed by daily drug reminder chart and graded depending upon the number of applications/doses missed over a period of 30 days i.e., >95% ≤3 applications/doses missed in a period of 30 days; 80-95% = 3-12 applications/doses missed over a period of 30 days; <80% ≥12 applications missed in a period of 30 days; compliance of >95% is considered as good, 80-95% as moderate and <80% as poor.

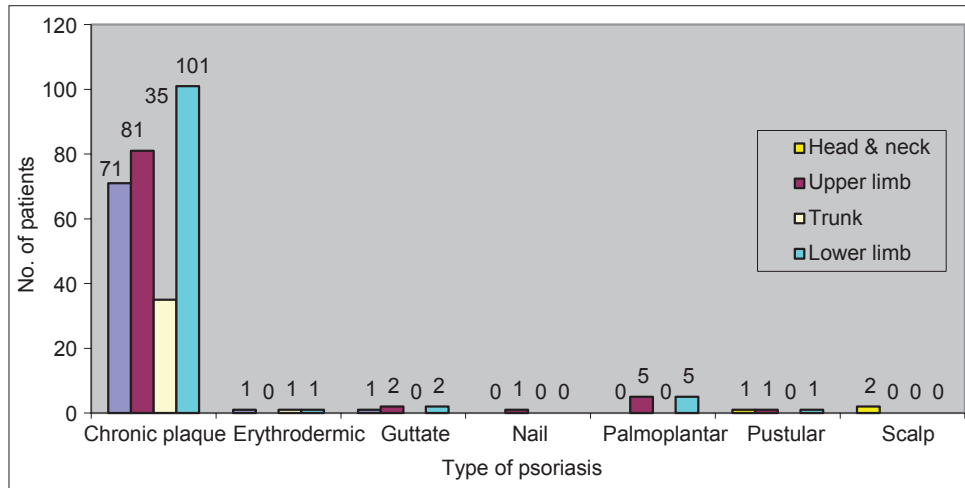


Figure 2: Body sites affected in study patients.

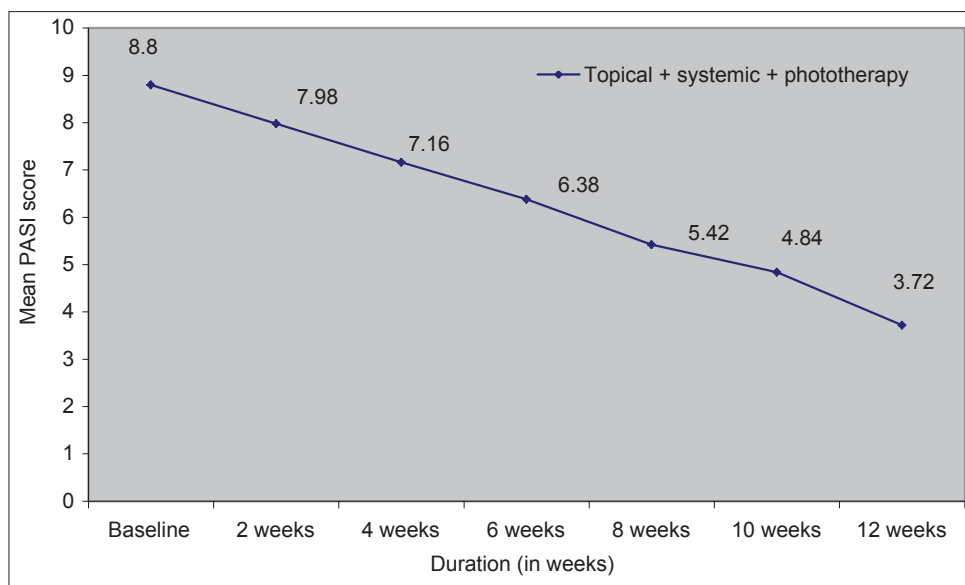


Figure 3: Response to topical + systemic + phototherapy in study patients.

DISCUSSION

In our study, the mean age of the patients was 42.2±13.9 years and majority of the study patients (47.11%) were in the age group of between 18 and 40 years, which was in accordance with other studies, indicating peak incidence in third and fourth decades of life.^{4,6} Among the study patients, 70 (57.85%) were males and 51 (42.15%) were females, indicating higher prevalence in males, as also observed in other studies.^{3,7-12} The commonest symptom complained by majority of the patients (86.77%) was itching. The pattern of symptoms were consistent with the observations in other studies.^{3,7,10-12} We found only 16.12% of the patients (n=20) had positive family history suggestive of psoriasis. Other studies have reported positive family history ranging from 15 to 40%.^{3,8-11,13,14}

Only 30 patients (24.79%) were current smokers and alcohol use was reported in nine patients, habitual in one patient and social drinking in other eight patients. Heavy smoking and heavy alcohol abuse are known to aggravate

psoriasis.^{2,9,14,15} Twenty-seven patients (22.31%) had a history of hypertension, of which, 18 patients were in the age group of 51-60 years. Thirty-four patients (28.09%) were receiving various medications for chronic illnesses like hypertension, mood disorders, and rheumatoid arthritis, which were continued throughout the study period. Chronic plaque psoriasis was the most common type, observed in 90.08% of the patients (n=109). No patient had more than one type of lesions. Similar clinical pattern of psoriasis was observed in other studies.^{3,7,9-11} Lower limb was the most commonly affected body site (90.9%), followed by upper limbs (74.38%), head and neck (62.80%) and trunk (29.75%). Similar pattern was observed in other studies.^{3,10} However, in some of the other studies, scalp and trunk were the most common sites affected.¹¹

In patients with chronic plaque psoriasis, the PASI score ranged from a minimum of 0.3 to the maximum of 12.6, with the mean PASI score of 2.43±2.42. The baseline PASI score recorded was in accordance with other studies, which have

Table 3: Treatment outcome in different types of psoriasis.*

Type of psoriasis	PASI score								% decrease from baseline [†]
	Visit #0 (baseline)	Visit #1 (2 weeks)	Visit #2 (4 weeks)	Visit #3 (6 weeks)	Visit #4 (8 weeks)	Visit #5 (10 weeks)	Visit #6 (12 weeks)		
Chronic plaque	Mean±SD	2.43±2.42	2.19±2.27	1.89±2.05	1.59±1.86	1.35±1.65	1.1±1.48	0.58±1.23	76.13 (P<0.001) [@]
	SEM	0.24	0.22	0.20	0.18	0.16	0.14	0.12	
Guttate [‡]	Mean±SD	0.85±0.07	0.6±0	0.4±0.28	0.2±0.28	0.1±0.14	0	0	100
	SEM	0.49	-	0.19	0.19	0.09	-	-	
Nail [‡]	Mean±SD	0.4±0	0.3±0	0.3±0	0.2±0	0.1±0	0	0	100
	SEM	-	-	-	-	-	-	-	
Pustular	Mean±SD	1.6±0	1.5±0	1.4±0	1.1±0	1±0	0.8±0	0.2±0	87.5
	SEM	-	-	-	-	-	-	-	
Erythro-dermic [°]	Mean±SD	14±0	1.1±0	0.9±0	0.7±0	0.4±0	0.3±0	0	100
	SEM	-	-	-	-	-	-	-	
Palmoplantar	Mean±SD	1.54±0.55	1.42±0.51	1.14±0.43	0.96±0.35	0.66±0.43	0.48±0.41	0.1±0.14	93.50
	SEM	0.24	0.22	0.19	0.15	0.19	0.18	0.06	
Scalp [°]	Mean±SD	0.25±0.07	0.2±0	0.15±0.07	0	0	0	0	100
	SEM	0.49	-	0.49	-	-	-	-	

*Overall result with all the modalities of treatment. [@]RM-ANOVA test applied only to groups with sample >10. [†]Outcome of therapy expressed as % change in PASI score from baseline. [‡]With guttate psoriasis (n = 2) and nail psoriasis (n=1), there was complete resolution of lesions at visit #5 (10 weeks). [°]With erythrodermic psoriasis (n = 1), there was complete resolution of lesions at visit #6 (12 weeks). [°]With scalp psoriasis (n=2), there was complete resolution of lesions at visit #3 (6 weeks). PASI: Psoriasis area severity index, SD: Standard deviation, SEM: Standard error of the mean

also observed that majority of the patients had less severe lesions with PASI <10.^{6-9,11,16,17}

Most of the patients (n=95; 78.51%) were treated with topical medications, which included GC, SA, calcitriol and coal tar, either as monotherapy or in combination of two or more drugs, in the form of creams or ointments. Clobetasol and halobetasol are the most potent topical steroids preferred in psoriasis for their anti-inflammatory and antiproliferative action.¹⁸ Other studies also have reported similar pattern of topical therapy, with more than 90% of the cases treated with topical medications, GCs being most widely employed drugs as monotherapy, and only in a few cases combined therapy with other topical agents calcitriol, SA and coal tar. Among the GCs, clobetasol was used in majority of the cases.^{5,6,16,17,19-21}

Systemic therapy with oral Mtx 7.5 mg once weekly, supplemented with folic acid, was used in eight patients (6.61%) with severe chronic plaque psoriasis with base line PASI score >7, in combination with topical therapy. Topical therapy included GCs as monotherapy in five patients, GC + calcitriol + SA in one patient, GC + calcitriol in one patient and GC + SA in one patient. Other studies also have reported systemic therapy with Mtx for severe plaque psoriasis in a similar regimen.^{16,18,21,22}

The combination of topical + systemic + PT was used only for very severe cases of chronic plaque psoriasis with baseline PASI score >8. Topical therapy included GCs as monotherapy (n=3), and in combination with calcitriol (n=2), along with emollients. Systemic therapy was given

as Mtx 7.5 mg orally once weekly for 12 weeks. Similar pattern of triple therapy has been reported in several other studies, but considered only for those cases with baseline PASI score >10.^{6,16-18,21,22}

In GC monotherapy used as clobetasol, halobetasol and betamethsone (n=66), the decrease in the mean baseline score was 91.03%, which was highly significant (p<0.001). In patients treated with GC + SA (n=15), the decrease after 12 weeks of therapy was 82.73%. Though it was highly significant (p<0.001), the decrease in PASI score was slightly lesser than GC monotherapy. However, considering the higher baseline PASI score in these patients and also possible biological variation, the response may be considered similar, but it appears that addition of SA may not have a significant additional advantage over GC monotherapy. The response to calcitriol monotherapy, which was used in only two patients with the mean PASI score of 0.55, the decrease in the mean PASI score was 63.63%. However, in patients treated with calcitriol + GC (n=7; baseline PASI score 1.39), there was 93.5% improvement probably indicating that this combination was more effective than calcitriol monotherapy. In four patients with baseline PASI score of 2.13 treated with calcitriol +SA + GC (n=4), the response was similar to calcitriol + GC. In one patient treated with GC + coal tar + SA, the baseline PASI score of one was reduced to 0 by 8 weeks. Other studies have reported the overall efficacy of topical therapy ranging from 70 to 90% decrease in baseline PASI score, the GC monotherapy being most effective and the addition of other drugs such as calcitriol did not have any additional advantage.^{5,19,21,23-28}

Table 4: Patient compliance to medications at different visits*.

Compliance ^f	GC	GC+SA	GC+ Calcitriol	GC+CT+ SA	Calcitriol	GC+ Calcitriol+SA	Systemic+ Topical therapy	PT+Topical therapy ^g	PT+Topical+ Systemic ^h	Total
Visit #1 (week 2) %										
>95	63 (52.07)	14 (11.57)	7 (5.79)	-	2 (1.65)	4 (3.31)	7 (5.79)	12 (9.92)	5 (4.13)	114 (94.21)
80-95	2 (1.65)	1 (0.83)	-	1 (0.83)	-	-	1 (0.83)	1 (0.83)	-	6 (4.96)
<80	1 (0.83)	-	-	-	-	-	-	-	-	1 (0.83)
Total	66 (54.55)	15 (12.4)	7 (5.79)	1 (0.83)	2 (1.65)	4 (3.31)	8 (6.61)	13 (10.74)	5 (4.13)	121 (100)
Visit #2 (week 4) %										
>95	64 (52.89)	14 (11.57)	7 (5.79)	-	2 (1.65)	4 (3.31)	7 (5.79)	11 (9.09)	5 (4.13)	114 (94.21)
80-95	2 (1.65)	1 (0.83)	-	1 (0.83)	-	-	1 (0.83)	2 (1.65)	-	7 (5.79)
<80	-	-	-	-	-	-	-	-	-	-
Total	66 (54.55)	15 (12.4)	7 (5.79)	1 (0.83)	2 (1.65)	4 (3.31)	8 (6.61)	13 (10.74)	5 (4.13)	121 (100)
Visit #3 (week 6) %										
>95	63 (52.07)	15 (12.4)	5 (4.13)	-	2 (1.65)	4 (3.31)	6 (4.96)	13 (10.74)	5 (4.13)	113 (93.39)
80-95	2 (1.65)	-	2 (1.65)	1 (0.83)	-	-	2 (1.65)	-	-	7 (5.79)
<80	1 (0.83)	-	-	-	-	-	-	-	-	1 (0.83)
Total	66 (54.55)	15 (12.4)	7 (5.79)	1 (0.83)	2 (1.65)	4 (3.31)	8 (6.61)	13 (10.74)	5 (4.13)	121 (100)
Visit #4 (week 8) %										
>95	65 (53.72)	15 (12.4)	4 (3.31)	1 (0.83)	1 (0.83)	3 (2.48)	7 (5.79)	12 (9.92)	5 (4.13)	113 (93.39)
80-95	1 (0.83)	-	3 (2.48)	-	1 (0.83)	1 (0.83)	1 (0.83)	1 (0.83)	-	8 (6.61)
<80	-	-	-	-	-	-	-	-	-	-
Total	66 (54.55)	15 (12.4)	7 (5.79)	1 (0.83)	2 (1.65)	4 (3.31)	8 (6.61)	13 (10.74)	5 (4.13)	121 (100)
Visit #5 (week 10) %										
>95	63 (52.07)	14 (11.57)	5 (4.13)	1 (0.83)	2 (1.65)	4 (3.31)	8 (6.61)	13 (10.74)	5 (4.13)	115 (95.04)
80-95	3 (2.48)	1 (0.83)	2 (1.65)	-	-	-	-	-	-	6 (4.96)
<80	-	-	-	-	-	-	-	-	-	-
Total	66 (54.55)	15 (12.4)	7 (5.79)	1 (0.83)	2 (1.65)	4 (3.31)	8 (6.61)	13 (10.74)	5 (4.13)	121 (100)
Visit #6 (week 12) %										
>95	66 (54.55)	15 (12.4)	7 (5.79)	1 (0.83)	2 (1.65)	3 (2.48)	7 (5.79)	13 (10.74)	3 (2.48)	117 (96.69)
80-95	-	-	-	-	-	1 (0.83)	1 (0.83)	-	2 (1.65)	4 (3.31)
<80	-	-	-	-	-	-	-	-	-	-
Total	66 (54.55)	15 (12.4)	7 (5.79)	1 (0.83)	2 (1.65)	4 (3.31)	8 (6.61)	13 (10.74)	5 (4.13)	121 (100)

*Assessed by daily drug remainder chart. ^b>95% compliance means <3 doses/applications missed in a period of 30 days; 80-95% compliance means 3-12 doses/applications missed in a period of 30 days; and <80% compliance means >12 doses/applications missed in a period of 30 days. ^cCompliance assessed for topical and systemic therapy only. ^dReported reasons for poor-compliance were patients "not finding time," forgetfulness, lack of clarity about instructions, adverse effects and cost of the treatment. GC: Glucocorticoids, SA: Salicylic acid, PT: Phototherapy

In chronic plaque psoriasis (n=109), the mean PASI score which was 2.43 at baseline, was reduced to 0.58 after 12 weeks of therapy, with 76.13% decrease in PASI score indicating significant improvement ($p < 0.001$). Other studies have also reported a similar range of improvement (70-90%) with different modalities of treatment for more than 6 months.^{21,22} The response to GC monotherapy (n=58) as assessed at visit 6 (12 weeks) was 90.47%, which was highly significant ($p < 0.001$), whereas therapy with GC + SA (n=13) showed a relatively lower rate of response (82.16%) though it was statistically significant ($p < 0.001$). The response to calcitriol + GCs (n=5) at the end of 12 weeks appeared to be highly significant with 95.94% decrease in mean baseline PASI score, but could not be subjected to statistical evaluation because of smaller sample size. The response to the combination of calcitriol + GC + SA which was used in four patients (mean baseline PASI score 2.13), the decrease in PASI score was 92.95% after 12 weeks. Considering the higher mean baseline score compared to other subgroups the combination of calcitriol + GC + SA appears to be highly effective. In other studies, the treatment response in chronic plaque psoriasis did not differ significantly between GC monotherapy and GCs combined with other topical agents when continued up to 6 months.^{5,19,21,23-28} Hence, it appears that GC monotherapy alone may be sufficient in most of the patients with chronic plaque psoriasis when it is not very severe (PASI score < 4), and addition of other topical agents may only produce a marginal improvement in response.

More than 94% of study patients showed good compliance to medications and only 0.27% showed poor compliance, whereas the other patients showed a moderate compliance of 80-95%. The reported reasons for moderate and poor compliance were not finding time, forgetfulness, lack of clarity of instructions, adverse effects and cost of the treatment. However, the compliance was improved by proper counseling and reassurance. In other studies, poor compliance was as high as 39% and the obvious reasons were adverse effects, cost of the therapy and forgetfulness.^{21,23}

Topical therapy is effective in most of the patients with psoriasis to induce and maintain resolution of lesions, and considered for all the cases with baseline PASI score < 4 . Systemic and PT may be required only for severe cases of chronic plaque psoriasis with baseline PASI score > 4 , along with topical medications. The medications generally chosen for topical therapy included GCs, either as monotherapy or in combination with other topical agents like SA, calcitriol and coal tar, along with various emollients. Regular follow-up is required not only to monitor the treatment response, but also to ensure good patient compliance by proper counseling.

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Conflict of interest: None declared

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

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