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STUDY OF DRUG PRESCRIBING PATTERNS IN PSORIASIS AND ASSESSMENT OF RATIONALITY USING SIGN AND NICE GUIDELINES AT A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT: Introduction: Psoriasis is a chronic inflammatory disease of high prevalence. In India the prevalence of psoriasis varies from 0.44 to 2.8%. The main aim of drug utilization research is to facilitate the rational drug use. Without a precise knowledge of how drugs are being prescribed and used, it is difficult to suggest measures to improve the prescribing habits. The economic burden of psoriasis is also a matter of concern to patients due to the permanent cost of treatment and the possibility of lower productivity and absenteeism in the workplace. **Aims and objectives:** To study drug utilization pattern of psoriasis, to estimate direct cost of therapy and to assess rationality using SIGN and NICE guidelines. **Methodology:** Patients attending the Dermatology outpatient department at a tertiary care teaching hospital newly diagnosed with psoriasis by the Dermatologist were enrolled in the study after obtaining written informed consent. **Results:** Total 120 patients received 606 drugs, number of drugs prescribed per patient being 5.05 ± 1.52 (Mean \pm SD). Most frequently prescribed drug was liquid paraffin 120 (100%) followed by pheniramine maleate 80 (66.67%), betamethasone dipropionate + salicylic acid 70 (58.33%), halobetasol dipropionate + salicylic acid 58 (48.33%) and methotrexate 48(40%). The mean cost of treatment per patient for 15 days was INR 693.7 ± 12 . **Conclusion:** To conclude, majority of the patients were prescribed topical agents for treatment of psoriasis, the disease incurred greater financial burden to the patients.

INTRODUCTION: Psoriasis is a chronic inflammatory disease of high prevalence. Psoriasis affects about 0.1 to 3% of the world's population.¹ In the USA, the prevalence of psoriasis was estimated to be around 4.6%, while in Canada it was 4.7%.

Data from Europe show little variation in countries with a range from 1.4% (Norway), 1.55% (Croatia) and 1.6% (UK). In East Africa the prevalence was 0.7% and in the Henan district of China 0.7%.² In India the prevalence of psoriasis varies from 0.44 to 2.8%.³

Psoriasis is characterized by mild to severe involvement of the skin and sometimes of the joints. Psoriasis causes functional impairment, distress and embarrassment to patients. The impact of the disease can result in restrictions to social and recreational activities and productive life, in addition to possible harm to these patients' affective

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and sexual relationships.^{4, 5, 6} The economic burden of psoriasis is also a matter of concern to patients due to the permanent cost of treatment and the possibility of lower productivity and absenteeism in the workplace.⁷

The main aim of drug utilization research is to facilitate rational drug use. Without a precise knowledge of how drugs are being prescribed and used, it is difficult to suggest measures to improve the prescribing habits.⁸ Hence, by undertaking the present study, we sought to study the various parameters related to the drug use pattern of psoriasis, estimation of direct cost to measure the financial burden to the patient and assessment of rationality using Scottish Intercollegiate Guidelines Network (SIGN) and National Institute for health and Clinical Excellence (NICE) guidelines.^{9, 10}

Aims and objectives:

1. To study drug utilization pattern of psoriasis
2. To estimate direct cost of therapy
3. To assess rationality using SIGN and NICE guidelines

Methodology:

A prospective, observational, cross sectional, single centre study was carried out over a period of one year in the dermatology outpatient department after obtaining written approval by an Institutional Review Board and from Head of Dermatology Department. Patients attending the Dermatology outpatient department newly diagnosed with

psoriasis by the Dermatologist were enrolled in the study after obtaining written informed consent from the patient. All patients were screened and enrolled in the study based on the inclusion criteria. The data were collected in the case record form. Case record form included patient's demographic details, clinical diagnosis, history of present illness, past history, family history and treatment prescribed. The complete prescription given to the patient was noted on the case record form. Data were entered in Microsoft Word 2007®. Data were analyzed for the socio-demographic details, drug use pattern, estimation of direct cost and assessment of rationality using SIGN and NICE guidelines.^{9, 10}

Analysis of direct cost:

Direct cost includes estimation of hospital cost, investigation cost and drug therapy cost which was done using patient's bill and Indian drug review 2013¹¹.

RESULTS: In this study prescriptions of 120 newly diagnosed patients of psoriasis attending Dermatology outpatient department were collected and analysed over a period of one year in a tertiary care teaching hospital.

Demographic details:

Mean age of patients was 38.4 ± 10.6 years (10-69yrs). Out of 120 patients 38 (31.67%) were 30-39 years of age group followed by 26 (21.67%) patients belonging to 20-29 years of age group (Fig. 1).

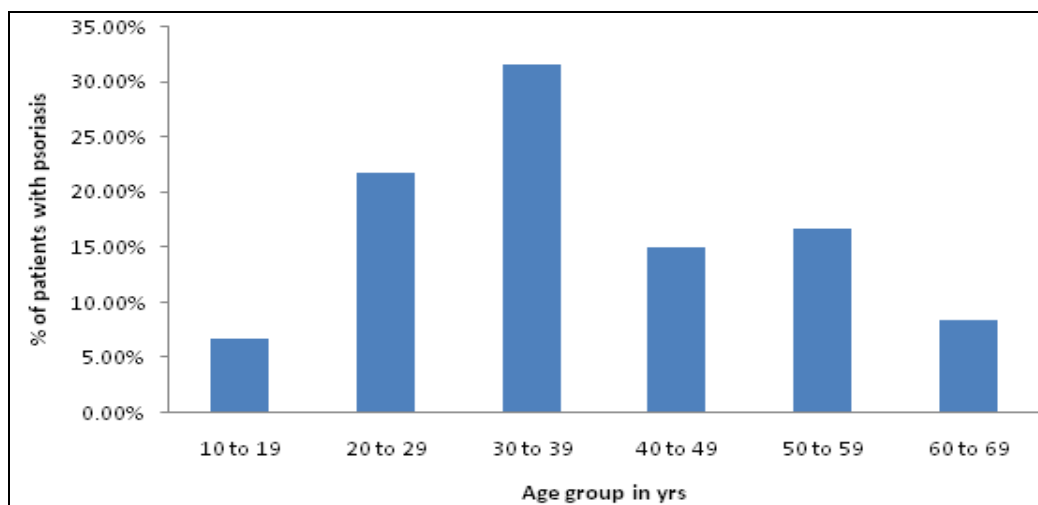


FIG 1: AGE DISTRIBUTION OF PATIENTS WITH PSORIASIS

Male: female ratio was 2.3:1. About 20 (23%) male patients belonged to 20-29 and 30-39 yrs of age

group. About 18 (50%) female patients belonged to 30-39 yrs of age group (**Table 1**).

TABLE 1: GENDER DISTRIBUTION OF PATIENTS WITH PSORIASIS

Age group	Male 84 (70%)	Female 36 (30%)	Total 120 (100%)
10-19	8 (9.52%)	-	8 (6.67%)
20-29	20 (23.81%)	6 (16.67%)	26 (21.67%)
30-39	20 (23.81%)	18 (50%)	38 (31.66%)
40-49	8 (9.52%)	10 (27.78%)	18 (15%)
50-59	20 (23.81%)	-	20 (16.67%)
60-69	8 (9.52%)	2 (5.55%)	10 (8.33%)

Common complaints:

Most common complaints were dryness 112 (93.33%), itching 80 (66.67%), redness 38 (31.67%) and skin lesion 18 (15%).

About 86 (70%) patients were prescribed 3-5 drugs and 28 (23%) patients were prescribed 6-8 drugs (**Fig 2**).

Common Site:

TABLE 2: SITES INVOLVED IN PSORIASIS (n=120)

Site involved	No. of patients (%)
Upper limb	70 (58.33)
Lower limb	66 (48.33)
Abdomen	56 (46.67)
Scalp	42 (35)
Back	38 (31.66)
Chest	4 (3.33)

The most common sites involved were upper limb 70 (58.33%), followed by lower limb 66 (48.33%), abdomen 56 (46.67%), scalp 42 (35%) of patients **Table 2**.

Family history:

About 10 (8.3%) patients had a positive family history for psoriasis.

Drug use pattern:

Total 120 patients received 606 drugs, the number of drugs prescribed per patient being 5.05 ± 1.52 (Mean \pm SD).

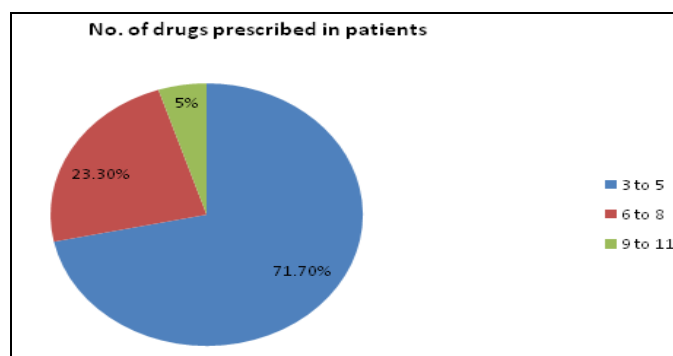


FIG 2: NO. OF DRUGS PRESCRIBED IN PATIENTS OF PSORIASIS

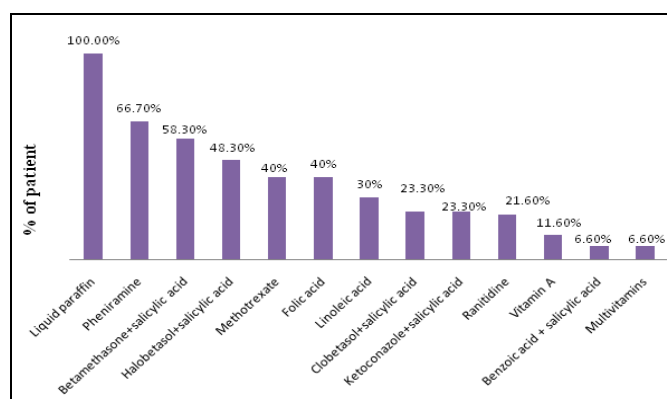


FIG 3: COMMONLY PRESCRIBED DRUGS IN PSORIASIS

Most common drugs prescribed were liquid paraffin 120 (100%) followed by pheniramine maleate 80 (66.67%), betamethasone dipropionate + salicylic acid 70 (58.33%), halobetasol dipropionate +salicylic acid 58 (48.33%), methotrexate 48 (40%) and folic acid 48 (40%) (**Fig 3**). Most frequently prescribed topical drug was liquid paraffin 120 (100%) followed by betamethasone dipropionate + salicylic acid 70 (58.33%), halobetasol dipropionate + salicylic acid 58 (48.33%) and clobetasol propionate + salicylic acid 28 (23.33%) (**Table 3**).

TABLE 3: TOPICALLY PRESCRIBED DRUGS IN PSORIASIS (n=120)

Drug Name	No. (%)
Liquid paraffin	120 (100%)
Betamethasone dipropionate + salicylic acid	70 (58.33%)
Halobetasol dipropionate + salicylic acid	58 (48.33%)
Clobetasol propionate + salicylic acid	28 (23.33%)
Ketoconazole + salicylic acid	28(23.33%)
Benzoic acid + salicylic acid	8 (6.67%)
Fusidic acid	4 (3.33%)
Fluocinolone acetonide	2 (1.67%)
Salicylic acid	2 (1.67%)

TABLE 4: SYSTEMICALLY PRESCRIBED DRUGS IN PSORIASIS (n=120)

Drug Name	No. (%)
Pheniramine maleate	80(66.67%)
Methotrexate	48(40%)
Folic acid	48(40%)
Linoleic acid	36 (30%)
Ranitidine	26 (21.66%)
Vitamin A	14 (11.67%)
Multivitamin	8 (6.67%)
Azithromycin	4 (3.33%)
Etanercept	2 (1.67%)

Most frequently prescribed drugs by systemic administration were pheniramine maleate 80 (66.67%) followed by methotrexate and folic acid 48 (40%), linoleic acid 36 (30%) (**Table 4**).

Photo chemotherapy:

Photo chemotherapy (NBUVB) was administered in 6 (5%) patients. Methoxsalen lotion and tablet was administered to 6 (5%) patients prior to NBUVB therapy.

Route of administration:

Majority of the drugs prescribed were administered by topical route 304 (50.1%) followed by oral route 242 (39.9%) and subcutaneous route 2 (0.33%). About 92% of drugs were prescribed by brand name. Drugs supplied from hospital were 26.73%. About 77.2% drugs belonged to National list of Essential Medicines India¹². About 36.6% drugs belonged to WHO model list of Essential medicines.¹³ About 350 (50.33%) of prescribed drugs are mentioned in the NICE guideline for psoriasis⁹ and about 364 (60.06%) of prescribed drugs are mentioned in the SIGN guideline for psoriasis.¹⁰

Estimation of direct cost:

Estimation of direct cost of patient was calculated for 15 days. Some drugs are supplied by hospital free of cost. The mean cost of drug therapy per patient includes cost of all the prescribed drugs based on their market price. The mean cost of treatment per patient for 15 days was INR 693.7 ± 12. The mean cost of drug therapy per patient for 15 days was INR 485.4 ± 12. The mean cost of investigation per patient was INR 198.3. The mean cost of hospital fees per patient was INR 10.

DISCUSSION: In India, few studies have been done on drug use pattern of psoriasis.¹⁴ There is a scarcity of data concerning drug utilization pattern of psoriasis amongst the general population of India. In the present study prescriptions of 120 newly diagnosed patients of psoriasis attending Dermatology outpatient department at a tertiary care teaching hospital were collected and analysed.

Gender distribution:

In the present study ratio of male to female (2.3:1) was very high. An Indian study by Bedi et al reported male female ratio 2.4:1 which was comparable to our study.¹⁵ In another study from North India male to female ratio being 2.03:1.¹⁶ The disease psoriasis shows a mere preponderance in the male gender.

Age distribution:

In our study out of 120 patients 38 (31.67%) were belonging to 30-39 years of age group followed by 26 (21.67%) patients belonging to 20-29 years of age group. Thus, the highest numbers of patients were seen in the age group of 20-39 years 64 (53.34%). An Indian study by Meenu Vijayan et al reported that the majority of the patients (39%) had onset of disease between 21-40 years¹⁴. Mehta et al observed the onset of disease was highest between 21-30 years (36%)¹⁷. So, the results of above studies are in concordance with our study.

Age of onset:

In our study, the mean age of onset of disease was 38.4±10.6 years. In an Indian study by Meenu Vijayan et al the mean age of onset of the disease was a 38.34±16.05 year, which was comparable to our study.¹⁴ In our study, the mean age of onset of the disease in females was lower (36.9 years) than male (39.2 years). In a study of Northern India women had a lower mean age of onset (27.6 years) compared to men (30.9 years).¹⁶

Common complaints

In our study most common complaint were dryness 112 (93.33%) along with itching 80 (66.67%). However, Bedi et al noted itching to be a significant complaint in 81% of the patients¹⁵. Okhandiar *et al.* found pruritus to be present in 95% of their cases¹⁸. Kaur *et al.* found that pruritus was complained by 65% patients.¹⁶

Site of psoriatic lesion:

In our study most common site involved was upper limb 70 (58.33%), followed by lower limb 66 (48.33%), abdomen 56 (46.67%), scalp 42 (35%) of patients. Okhandiar *et al* found that the extensors (93%) were the most common site of involvement, followed by the scalp (88%)¹⁸. In contrast, to our study result a study by Meenu et al where scalp was the most common initial site affected accounting for 28% of patients followed by elbow 22%, leg 14%, feet 13%, palm & soles 10%, arms 7%, trunk 4% and axilla in 2% of patients.¹⁴ Kaur *et al* also reported scalp (25%) as the most common first site of involvement followed by legs (20.6%) and arms (11.7%).¹⁶

Family history

In the present study 10 (8.3%) patients had a positive family history of psoriasis. Bedi et al reported a positive family history of psoriasis in 14% of their patients.¹⁵ In a study by Meenu et al, 7% of the patients had a positive family history of psoriasis.¹⁴ Zrnic et al reported a family history in 8.5% patients.¹⁹ Thus, family history in the present study is within the range observed in the above studies. This indicates the possible role of genetic factors in the etiology. In contrast, to our study Farber *et al.* reported familial occurrence in 36% of their patients.²⁰ So, Indian studies report a lower familial incidence of the disease as compared to study done abroad.

Drug use pattern:

In our study total 120 patients received 606 drugs. Average number of drugs is an important index of prescription analysis and in the present study it was 5.05 ± 1.52 (Mean \pm SD). It is preferable to keep the average number of drugs per prescription as low as possible since higher number of drugs can lead to increased risk of drug interactions, adverse drug reactions, poor medication compliance and eventually financial burden to the patient.²¹ However, considering the progressive chronic nature of this disease, polypharmacy was necessary.

Most commonly prescribed drug were liquid paraffin 120 (100%) followed by pheniramine maleate 80 (66.67%) which corresponds to the patient complains of dryness and itching

respectively. According to the NICE and SIGN guidelines regular emollient use may be considered to reduce fall of scales and help with other symptoms, including itch for psoriasis.^{9, 10} So, prescribing emollients is a rational therapy and as per the standard guidelines.

Topical steroids like betamethasone dipropionate + salicylic acid were prescribed in 70 (58.33%) and halobetasol dipropionate + salicylic acid in 58 (48.33%) patients. A previous study reported in the UK population that topical corticosteroids have been most frequently prescribed medications and were received by (61.4%) of patients.²² According to SIGN guidelines potent topical corticosteroids (alone and in combined preparations with salicylic acid or with calcipotriol) are in short term use more effective than placebo and similarly effective as calcipotriol and other vitamin D analogues.⁹ So in our study prescription of topical steroid + salicylic acid in the majority of patients was justified.

According to NICE guideline first-line therapy describes traditional topical therapies (such as corticosteroids, Vitamin D and Vitamin D analogues, dithranol and tar preparations). Second-line therapy includes the phototherapies (broad- or narrow-band ultraviolet B light and psoralen plus UVA light [PUVA]) and systemic non-biological agents such as ciclosporin, methotrexate and acitretin. Third-line therapy refers to systemic biological therapies such as the tumour necrosis factor antagonists adalimumab, etanercept and infliximab, and the monoclonal antibody ustekinumab that targets interleukin-12 (IL-12) and IL-23.¹⁰ Systemic agents like methotrexate along with folic acid were prescribed in 48 (40%) patients. Folic acid was administered to prevent methotrexate induced folic acid deficiency. A UK study also showed that methotrexate and ciclosporin have been the most frequently prescribed systemic treatments (prescribed to 36.2% & 8.1% of patients respectively).²³

Photo chemotherapy (NBUVB) was administered in 6 (5%) patients. According to SIGN guideline the review concluded that PUVA using oral psoralen, PUVA using topical psoralen ('bath PUVA'), narrow band UVB phototherapy (NBUVB), and broad band UVB phototherapy

(BBUVB) were effective in clearing psoriasis. UVA alone does not clear psoriasis. In our study methoxsalen lotion and tablet was administered to 6 (5%) patients prior to NBUVB therapy, which was according to NICE and SIGN guideline. PUVA was not prescribed to patients as it is known to be associated with high risk of skin cancer (squamous cell carcinoma), basal cell carcinoma (BCC) and malignant melanoma.⁹ This also explains lower number of patients on photochemotherapy at our setup. The short wavelengths found in BBUVB are more likely to cause burning than NBUVB. According to SIGN guideline a systematic review and meta-analysis addressed the question of efficacy of NBUVB versus BBUVB for the treatment of psoriasis. Ten of eleven studies demonstrated a clear advantage of NBUVB compared to BBUVB. The study concluded that the use of BBUVB for psoriasis is no longer appropriate.⁹

Biological agents like Etanercept was prescribed in 2 (1.67%) of patients. As majority of patients coming to our hospital belonged to the lower economic class, affordability was a major factor concerning the use of biological agents. In our study, most patients (60%) were managed with topical psoriasis agents only and (40%) were prescribed systemic psoriasis agents, as compared to the UK based study where majority of patients with psoriasis (94%) were managed on topical psoriasis agents, and only 4% were prescribed systemic psoriasis agents.²³ Though corticosteroids are the most commonly prescribed drugs topically for psoriasis their use is associated with a number of adverse effects like striae, hypopigmentation, atrophy and telangiectasias when used topically. The systemic effects such as suppression of hypothalamic pituitary adrenal axis can be associated with long-term topical application of potent steroids especially, in younger patients.²⁴

About 350 (50.33%) of drugs used are mentioned in the NICE guideline for psoriasis and 364 (60.06%) of drugs used are mentioned in the SIGN guideline for psoriasis^{9, 10}. About 50% of drugs prescribed were administered topically followed by orally (39.9%) and subcutaneously (0.33%). About 8% of drugs were prescribed by generic name. Only 26.7% of drugs prescribed were from the

hospital supply. Many patients attending the outpatient department belonged to the lower socioeconomic strata and would have to buy proprietary drugs from other relevant pharmacy outlets. About 77.2% drugs belonged to the National list of Essential medicines India.¹² About 36.6% drugs belonged to the WHO model list of Essential medicines.¹³

Cost of therapy:

The mean cost of treatment per patient for 15 days was INR 693.7 ± 12. This adds to the greater financial burden to the patient. Patients with psoriasis incur greater health care resource utilization and costs compared with the general population.²⁵

CONCLUSION: In our study majority of patients were prescribed topical agents for treatment of psoriasis and the disease incurred greater financial burden to the patients. About 50% of drugs used are mentioned in the NICE guideline for psoriasis and 60% of drugs used are mentioned in the SIGN guideline for psoriasis.

Strengths of the study:

The present study was prospective in nature carried out at a tertiary care teaching hospital. To our knowledge this study is first of its kind in India, which covered demographic pattern, drug use pattern and estimation of direct cost to the patient. The treatment administered was checked for their rationality using the SIGN/NICE guidelines for psoriasis.

Limitations of the study:

1. The present study was cross sectional and single centered carried out at a tertiary care teaching hospital; therefore the results of this study cannot be applied to the general population.
2. As majority of patients belonged to lower socioeconomic class biological agents like etanercept were not prescribed to the majority of patients, which if prescribed would have given a more realistic picture regarding use of it.

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CONFLICT OF INTEREST: Nil.

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