A study of the use of drugs in patients suffering from psoriasis and their impact on quality of life

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Abstract:
Objective: To study the use of drugs in patients suffering from psoriasis and their effect on quality of life (QOL).

Materials and Methods: This was a prospective, observational study carried out in newly diagnosed patient of psoriasis at Department of Pharmacology and Outpatient Department of Skin and Venereal diseases at tertiary care teaching hospital, and patients were divided into three groups: Group A: topical therapy alone, Group B: methotrexate with topical therapy, and Group C: cyclosporine with topical therapy. The efficacy of drug was measured using Psoriasis Area Severity Index (PASI). QOL was measured using Psoriasis Disability Index. Patients were followed up at 1 month and 6 months of treatment. Statistical analysis was done using analysis of variance (ANOVA) test.

Results: A total 126 patients were enrolled, out of which 114 patients completed the study. PASI score was reduced significantly (P < 0.001) in each treatment group and QOL score was significantly (P < 0.001) decrease in Group B and C as compared to baseline at the end of 6 months. A significant (P < 0.001) reduction in PASI score and QOL was observed in patients of Group B and C as compared to Group A. Correlation between efficacy and QOL was not significant in all three treatment groups.

Conclusion: Combination therapy (topical + systemic) is more efficacious and associated with significant improvement of QOL as compared to topical therapy alone. Methotrexate and cyclosporine are equally efficacious in treating and improving the QOL in patients suffering from psoriasis.

Key words: Psoriasis, Psoriasis Area Severity Index, Psoriasis Disability Index, quality of life

Psoriasis is a common chronic inflammatory, immune-mediated disease that predominantly affects the skin and joints.¹ It is genetically determined dermatological disorder which follows a relapsing and remitting course.² The worldwide prevalence of psoriasis is around 2% while studies in developed countries have reported higher prevalence rates of on average about 4.6%.³ The prevalence of psoriasis in India ranges from 0.44% to 2.8%.⁴ Psoriasis may affect patients’ life adversely, for example, emotional status, psychological stress, self-esteem, relationships, work, social activities, financial burden, and even physical function, particularly in patients with psoriasis arthritis.⁵ Emotional stress also influences the development and exacerbation of psoriasis in 37%–78% of patients.⁶ In addition to disease itself, drugs used for the treatment of psoriasis may cause adverse drug reaction(s) (ADRs). These factors affect the quality of life (QOL). Hence, QOL measures can be used to guide and evaluate treatment interventions. The World Health Organization (WHO) defines QOL as “Individual perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.”⁷ Data regarding the efficacy of drugs used for the treatment of psoriasis and its effect on QOL for psoriasis are not available from western part of India. Hence, this study was designed to study the use of drugs in patients suffering from psoriasis and their impact on QOL.

Materials and Methods

After taking permission from the Institutional Ethics Committee (EC/Approval/35/14) and Head of Department of Skin and Venereal diseases, this prospective, observational, single-center study was carried out at Department of Pharmacology and Outpatient Department of Skin and Venereal diseases of a tertiary care
teaching hospital of Ahmedabad for duration of 18 months. After obtaining written informed consent, more than 18 years of age, of either gender, newly diagnosed patient of psoriasis with moderate severity, as well as willing to participate in the study were included in the study. Diagnosis of psoriasis was done by dermatologist. Patients who could not comprehend the questionnaires were excluded from the study. Patients were enrolled according to convenient sampling method.

Based on prescribed treatment, patients were grouped as: Group A: Clobetasol propionate (0.05%) + salicylic acid (3%) lotion for scalp application and betamethasone valerate (0.05%) cream for body surface application. Group B: Tablet methotrexate (7.5 mg/week) along with topical treatment; clobetasol propionate (0.05%) + salicylic acid (3%) lotion for scalp application and betamethasone valerate (0.05%) cream for body surface application. Group C: Capsule cyclosporine (100 mg 2 times a day) along with topical treatment; clobetasol propionate (0.05%) + salicylic acid (3%) lotion for scalp application and betamethasone valerate (0.05%) cream for body surface application. Group B, each patient has given folic acid along with methotrexate. All the drugs (generic or branded generic) were dispensed from hospital pharmacy.

### Parameters Observed

The baseline data including demographic details, clinical history, details of lesions, and details of the drug treatment were recorded in prevalidated case record form. The efficacy of drug was measured using Psoriasis Area Severity Index (PASI). PASI is a validated objective measurement of psoriasis severity which ranges from 0 to 72. Higher the score more will be severity of psoriasis. QOL was measured using Psoriasis Disability Index (PDI). The score in each question ranges from 0 to 3, and total score ranges from 0 to 45. A Higher score indicates greater impairment of QOL. All the recruited patients were followed up at 1 month (1st follow-up) and 6 months (2nd follow-up) of treatment. At each follow-up visit, presenting complaints, any change in drug treatment, PASI score, and QOL were recorded and analyzed at the end of the study. Detail of the ADR was also recorded and analyzed.

### Statistical Analysis

The data were entered in Microsoft Excel Worksheet version 2007 and analyzed using GraphPad demo version 3.06, (GraphPad Software, Inc., La Jolla, CA, USA 32 bit for Windows). $P < 0.05$ was considered statistically significant. Intragroup comparison was done between baseline and at each follow-up visits by repeated measure analysis of variance (ANOVA) test, followed by post hoc analysis using Tukey–Kramer multiple comparison test. Intergroup comparison was done between Group A, B, and C by one-way ANOVA test, followed by post hoc analysis using Tukey–Kramer multiple comparison test. Correlation between PASI score and QOL was made using Pearson parametric correlation test.

### Results

A total of 126 patients were enrolled during the study period of 18 months, out of which 114 patients completed the study while 12 patients were lost to follow-up. The mean age of the total patients was 41.07 ± 1.05 (Group A, B, and C was 41.01 ± 1.87, 41.31 ± 1.76, and 40.93 ± 1.47 years, respectively). There was no significant difference in mean age between all three groups. Male to female ratio in Group A, B, and C was 1.89:1, 2.2:1, and 2.3:1, respectively.

The most common presenting complaint of the patients was scaling of skin in all the three groups [Table 1]. It was reported that most common exacerbating factors for psoriasis were seasonal weather changes, especially in winter (71 [62.2%]), followed by stress (49 [42.9%]) and irregular sleep habit (24 [21%]). Past history of hypertension and diabetes was reported in 15 (13.1%) and 6 (5.2%) patients, respectively. Concomitant diabetes and hypertension were present in 13 (11.4%) patients. Two (1.75%) patients had a history of bronchial asthma. It was observed that 50 (43.86%) patients had disturbed sleep, history of alcohol intake - 18 (15.79%) patients, and smoking - 23 (20.17%) patients. Twenty-five (22%) patients reported a family history of psoriasis.

The baseline mean PASI score in Group A, B, and C was 11.59 ± 0.14, 12.35 ± 0.34, and 12.72 ± 0.20, respectively. PASI score between treatment groups which shows that all the three groups were comparable at baseline. As shown in Figure 1, there was a significant reduction in PASI score at 1st and 2nd follow-up visit in all the treatment groups. Improvement in severity of symptoms in a patient of Group A, B, and C is shown in Figure 2. To compare the efficacy of Group A, B, and C, the mean difference of the baseline and 2nd follow-up data was calculated and measured for each group. The mean difference of PASI scores for Group A was 4.60 ± 0.33, for Group B was 7.18 ± 0.37, and for Group C was 7.37 ± 0.28. Mean difference of PASI score was significantly ($P < 0.001$) higher in Group B and C as compared to Group A. It was also observed that mean difference was not significant between Group B and C.

The baseline mean QOL score was comparable between all the three groups. As shown in Table 2, there was no significant reduction in QOL score in patients treated with Group A, whereas in Group B and C, there was a reduction in QOL score at each follow-up visit. To compare the change in QOL score between Group A, B, and C, the difference of QOL between baseline and 2nd follow-up data was calculated. The mean value of the difference was measured for each treatment group. The mean difference of total QOL scores in Group A was 0.56 ± 0.18; for Group B, mean difference was 6.53 ± 0.46; and

### Table 1: Analysis of presenting symptoms in patients of psoriasis (n=114)

| Symptoms                        | Group A (n=52), n (%) | Group B (n=32), n (%) | Group C (n=30), n (%) |
|---------------------------------|-----------------------|-----------------------|-----------------------|
| Scaling                         | 41 (78.84)            | 24 (75.00)            | 23 (76.66)            |
| Red lesion over body            | 18 (34.61)            | 11 (34.38)            | 10 (33.33)            |
| Burning pain over lesion        | 5 (9.61)              | 3 (9.38)              | 3 (10)                |
| Thick lesion over body          | 7 (13.46)             | 4 (12.50)             | 5 (16.66)             |
| Itching                         | 34 (65.38)            | 22 (68.75)            | 20 (66.66)            |
| Joint pain                      | 3 (5.77)              | 2 (6.25)              | 2 (6.67)              |

Group A (n=52): Topical treatment (betamethasone valerate and clobetasol propionate + salicylic acid), Group B (n=32): Methotrexate + topical treatment (betamethasone valerate and clobetasol propionate + salicylic acid), Group C (n=30): Cyclosporine + topical treatment (betamethasone valerate and clobetasol propionate + salicylic acid)
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**Table 2: Quality of life score using Psoriasis Disability Index in patients suffering from psoriasis (mean±standard error of mean)**

| Group   | Baseline   | 1st follow-up | 2nd follow-up |
|---------|------------|---------------|---------------|
| Group A | 13.65±0.69 | 13.41±0.48    | 13.09±0.52    |
| Group B | 14.19±0.83 | 12.16±0.76*   | 7.66±0.45**   |
| Group C | 14.46±0.59 | 12.94±0.67*   | 7.23±0.55**   |

*P<0.001 at 1st follow-up as compared to baseline in Group B and C. **P<0.001 at 2nd follow-up as compared to baseline in Group A, B, and C. *P<0.001 at 2nd follow-up as compared to 1st follow-up in Group B and C. *P<0.01 at 1st follow-up as compared to baseline in Group B and C.*

for Group C, mean difference was 7.18±0.47. Mean difference of QOL score was significantly (P<0.001) higher in Group B and C as compared to Group A. It was also observed that mean difference in QOL score was not significant between Group B and C.

**Correlation between Psoriasis Area Severity Index Score and Quality of Life**

Correlation between PASI score and QOL was carried out using Pearson parametric correlation test. In Group A, correlation coefficient (r) value was 0.07 which shows little or no relationship between PASI score and QOL. In Group B and C, correlation coefficient (r) value was 0.29 and 0.13, respectively, which shows a weak positive correlation between PASI score and QOL. The correlation was not significant in any of the treatment group (P>0.05). Figure 3a-c shows the correlation in Group A, B, and C.

**Adverse Drug Reactions**

A total of 22 ADRs were reported during the study period. In Group A, a total of seven ADRs were reported including itching (2), dryness of skin (2), and redness of skin (3). In Group B, a total of eight ADRs were reported including itching (3), nausea (4), and abdominal discomfort (1). In Group C, a total of seven ADRs were reported including headache (1), tiredness (2), nausea (3), and itching (1). According to the WHO Uppsala Monitoring Centre scale, it was found that 22% of patients have a family history of psoriasis. A higher number of male patients (67.5%) was observed in our study which is similar to a study conducted in Northern Taiwan which may be because patients who could comprehend with the questionnaire were enrolled in our study, whereas illiterate patients were excluded, many of whom might be female. It was observed that most common exacerbating factors were weather changes, especially in winter (62.2%) which could be due to covered up skin, dry air, or lack of sun in winter. We found that 22% of patients have a family history of psoriasis. It is significant to study the impact of various factors on quality of life in patients suffering from psoriasis.

**Discussion**

In the present study, we have correlated efficacy and QOL in a newly diagnosed patient suffering from psoriasis on different treatments.
which is similar to study carried out by Ejaz et al.\[13\]. However, Raychaudhuri and Farber found that 54% of the adults had a positive prevalence of family history which is higher than our study.\[14\] This difference is due to patients may unaware about their parent’s disease status or may be due to different genetic basis.\[13\]

Reduction of PASI score in each treatment group indicates that there was a decrease in severity of the disease at each follow-up visit. This finding is similar to a study carried out at Punjab, India.\[15\] which shows that topical and combination therapies are efficacious. However, when intergroup comparison was done, it was observed that combination of topical therapy with methotrexate and cyclosporine is more efficacious than topical therapy alone. We also observed that reduction of PASI score was not significant between Group B and C which is similar to study carried out at Dhulikhel Hospital, in which it was reported that methotrexate and cyclosporine are equally efficacious.\[16\]

In our study, there was no significant reduction in QOL score in patients treated with Group A, whereas in Group B and C, there was a significant reduction in QOL score at each follow-up visit. In a multicenter observational study carried out in Spain, it was found that after 4 months of treatment (topical, systemic, biological, and phototherapy); there was a significant reduction in total PDI, but comparison was not carried out between specific treatment groups, and multiple tools were used to measure QOL (e.g., Dermatology Life Quality Index, short form-36 [SF-36], PDI, and EQ-5D).\[17\]

In intergroup comparison, we observed that mean difference of QOL score was significantly higher in Group B and C as compared to Group A which suggest that there was a significant reduction of QOL score in Group B and Group C as compared to Group A. We also observed that there was no significant difference in reduction of QOL score between Group B (methotrexate with topical therapy) and Group C (cyclosporine with topical therapy) which is similar to a study carried out in the Netherlands where SF-36 QOL questionnaire was used to compare QOL between treatment groups, and topical treatment was not used along with systemic drug.\[18\]

A correlation between PASI score and QOL was studied to determine the relationship between the efficacy of drug treatment and QOL. Correlation coefficient (r) in Group A, B, and C was 0.07, 0.29, and 0.13, respectively. We observed that there was no significant correlation between PASI score and QOL in any of the treatment group which is similar to study carried out by Yang et al.\[19\]. Correlation of efficacy and QOL was not observed in our study which may be because QOL is a subjective parameter, and apart from the disease severity, QOL also depends on the other factors including age, day-to-day activities, cosmetic effect, and relationships with family members and friends.\[20\]. In addition, the chronic nature, irritation due to lesion, and disease affecting visible parts of the body are associated with psychological stress.\[21\]. Hence, emotional burden of disease itself has a negative impact on QOL.\[22\]. This study highlights that there was a reduction in severity score (PASI) in each treatment group, but QOL was improved only up to some extent.

Limitation of the study includes the fact that this in an observational study in a small sample of patients. Furthermore, a longer duration of evaluation may give a better idea of the impact of drug therapy on QOL.

**Conclusion**

Combination therapy (topical + systemic) is more efficacious than topical therapy alone. Patients treated with combined...
topical and systemic therapy (methotrexate and cyclosporine) demonstrate a better improvement in QOL as compared to those receiving topical therapy alone. Methotrexate and cyclosporine are equally efficacious in treating and improving QOL in patients of psoriasis.

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Conflicts of Interest
There are no conflicts of interest.

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