Objective Assessment of Compliance With Psoriasis Treatment

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Objective: To assess patient compliance with psoriasis treatment.

Design: Open prospective study. Patients with psoriasis were examined and completed a brief medical and social history, a compliance assessment sheet, and the Dermatology Life Quality Index (DLQI). Patients were reexamined at 3 months, and their actual treatment use was assessed and compared with the expected use. Medication adherence was assessed by direct questioning.

Setting: Dermatology outpatient clinic.

Patients: Two hundred ninety-four patients fulfilled the inclusion criteria, and 201 completed the study.

Main Outcome Measure: Adherence with topical and oral therapies, using objective and self-reporting methods and description of factors affecting compliance.

Results: The overall mean±SD medication adherence was 60.6%±33.0% (range, 0%-169%). The mean±SD DLQI in the study was 17.4±8.9 (range, 0-30). There was a highly significant negative correlation (r = −0.92) between these variables. Being female, married, employed, and not paying for prescriptions were characteristics associated with increased medication adherence and a lower DLQI. Medication adherence was greater for topical or combined therapy, for once-daily treatment, and for first-time use of treatment. Adverse effects reduced compliance. The major reasons for missing treatment were drinking alcohol, being fed up, forgetfulness, and being too busy. Patients with facial disease and with more extensive disease had lower medication adherence.

Conclusions: A range of disease-related and social factors may affect compliance with psoriasis treatment. The inversely proportional relationship between DLQI and medication adherence reflects the interaction of physical and psychological factors, as well as perceived treatment failure.

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Psoriasis is one of the most important diseases in dermatological practice because it is so common, produces significant morbidity, and has profound effects on patient quality of life. It is a chronic but dynamic skin disease, the extent and location of which change over time. There are many treatment options for patients with psoriasis, varying from simple topical medication to oral therapy with potentially toxic drugs, but there is no cure. In most patients, the need for some form of treatment is lifelong.

Psoriasis, like many other similar dermatitides, tends to be more emotionally than physically debilitating for patients. The effect of psoriasis on a patient is multidimensional, including the physical, social, and psychological health of the person, and is based largely on the patient’s view of his or her condition. Indeed, overall clinical severity of psoriasis, as assessed by the Psoriasis Area and Severity Index, and duration of psoriasis are unrelated to impairment in any areas of health-related quality-of-life measures.1-7

It has been recognized for many years that psoriasis affects patients’ lives. Patients with psoriasis often ascribe a substantial negative effect on their quality of life to this disease and its treatment.1 The psychosocial effects of psoriasis on patients may be profound and may result in considerable stigmatization, social isolation, and discrimination. Finlay and Coles1 found that 84% of patients with psoriasis expressed difficulties in establishing social contacts and relationships and stated that this was the worst aspect of their psoriasis, although soreness and irritation were also important. Ninety-eight percent of patients indicated that they would prefer a cure over a gift of £1000. Seventy-one per-

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In this study, we used the most advanced practical tools to investigate compliance, assessing all of its measurable components according to their definition in health care. These included medication adherence by the pill count or medication weight and interview methods, the outcome-of-care process by the Dermatology Life Quality Index (DLQI), and clinic attendance. We then investigated the relationships between them.

Several strategies have been used to analyze patient compliance. Many investigators divide patient populations on the basis of the median compliance level of the population studied: those above this level are compliers and those below are noncompliers. Although this approach assures the maximum size subgroups for statistical analysis, the median cutoff level used may not have biological or behavioral significance.

Another approach is to select a compliance cutoff level arbitrarily, using levels used or suggested by earlier investigations. In most situations, however, a biological basis for this is not available. Moreover, in descriptive compliance studies in which the investigator wishes to identify specific psychosocial, clinical, or demographic characteristics that may discriminate between compliers and noncompliers, the cutoff points for these determinants may not coincide with those established on the basis of clinical effectiveness.

Therefore, a third approach, used in this study, avoids characterizing individuals as compliers or noncompliers, but instead examines compliance as a continuous variable. This approach can be helpful in investigating the relationship of specific characteristics that affect compliance. The use of continuous variables also determines the statistical approach to the analysis.

Medication adherence is defined as the ratio of the number of prescribed “doses” of therapy taken by the patient to the number of “doses” prescribed for the patient, expressed as a percentage. Expressed in this form, medication adherence would ordinarily be between 0% and 100%. Although this measure of medication adherence is useful, it does not allow distinguishing between the different patterns in which medication is used.

This study is not the first that measures medication adherence of topical treatments by measuring the used weight. These methods were used in previous studies, facilitated by the rule of hand for calculating treatment use.

**METHODS**

**STUDY DESIGN**

This was an open prospective study of 294 consecutive patients, with varying demographics and different degrees of severity of psoriasis, representing the range of a hospital-based outpatient population. Disease duration was between 2 and 7 years. The study lasted 12 weeks, with all assessments performed at week 0 and week 12 at routine outpatient appointments. Two hundred one patients completed the study at the appropriate time. Those who were unable to attend the 12-week appointment were excluded from the analysis.

**COMPLIANCE ASSESSMENT**

We used several objective methods of assessing compliance.
Pill Count and Medication Weight

Pill count and weight of topical therapy were used to objectively measure medication adherence.

Quality-of-Life Assessment Tool

A validated quality-of-life assessment tool was used to assess the effect of the skin disease (disease severity). Quality of life is defined as a multidimensional construct that reflects the quality of the physical, emotional, social, and role- or function-associated life situation of an individual. The degree of consensus between the desired and the actual life situation is part of quality of life. According to a World Health Organization definition, quality of life consists of the physical, emotional, and social well-being of an individual.

The assessment of quality of life is increasingly being used as a measurement tool in the evaluation of health care outcomes and lifestyle status. There are several systems for evaluating quality of life. These range from the general (Medical Outcomes Study 36-Item Short-Form Health Survey) to the disease-specific (Psoriasis Disability Index). We included a tool specific to skin disease, the DLQI, because it is generalizable (allowing comparison with other skin diseases), simple to administer, reproducible, and validated. The DLQI has been specifically designed to be practical and to be of clinical value when used in a busy clinical setting. It is based on a scoring range from 0 to 30, consisting of 10 questions, each with a score from 0 to 3.

Clinic Attendance

Clinic attendance was used to assess ongoing interaction with the responsible clinicians.

Interview Medication Adherence

Interview medication adherence, in which the patient is asked specifically about his or her treatment compliance, was used for comparison purposes.

SUBJECTS

Two hundred one patients with psoriasis were recruited from the routine dermatology outpatient clinic of The General Infirmary at Leeds. Inclusion criteria were patients of either sex, aged 18 to 65 years, with a firm diagnosis of psoriasis; prescribed oral, topical, or combined treatment; and ability to give informed consent. Pregnant or lactating women and patients with associated disease were excluded.

PROCEDURES

Two hundred ninety-four patients with psoriasis were initially seen in the outpatient department and gave informed consent to be included in the study. These included patients attending a consultant clinic and those attending a nurse-led clinic. The patients were not informed about the aim of the study with regard to compliance assessment. The local research ethics committee granted ethical approval for such an approach, agreeing that such information would itself affect compliance. The patients were clinically examined and interviewed. Patients were given another routine clinic appointment after 3 months and were asked to bring their treatment products with them. Two hundred one patients (68.4%) completed the follow-up questionnaires and were included in the study. Clinic attendance was monitored as a measure of patients’ compliance with ongoing clinical monitoring.

MEDICATION ADHERENCE AND QUALITY OF LIFE

The amount of prescribed treatment that should have been used by the patient was assessed on the basis of disease extent. At the first interview, patients were requested to fill in a questionnaire consisting of a medical history, the DLQI questions, and a patient assessment sheet regarding various social factors, including smoking habits (mild, 1-10 cigarettes per day; moderate, 11-20; and heavy, >20) and alcohol consumption (moderate, 14 U/wk for women and 21 U/wk for men).

Topical Treatment

The amount of topical treatment that should have been used by the patient was assessed by estimating the surface area involved by psoriasis by using the rule of hand. This was then used to calculate the number of fingertip units (FTUs) that should be used by the patient (1 FTU = 0.5 g = 2% of surface area). The patients had been instructed how to use the FTUs to manage treatment application.

Oral Treatment

For oral treatment, the number of tablets that should have been taken by the patient was assessed by calculating the number of tablets prescribed for the patient per day times the number of days. The tablets were prescribed at the first visit and counted at the last interview, and medication adherence was calculated.

Interview Medication Adherence

Interview medication adherence was calculated by asking the patients to assess how much treatment they had used. The interviews took 25 to 65 minutes. The level of medication adherence admitted by the patient at the interview was used for comparison with the objective findings.

STATISTICAL ANALYSIS

On completion of the study, the data were tabulated using Microsoft Excel 2000 (Microsoft Corp, Redmond, Wash), and descriptive analysis was carried out. Analyse-it (Analyse-it Software Ltd, Leeds) for Microsoft Excel and Minitab Software (Minitab Inc, State College, Penn) were used to assess the characteristics of the sample. The categorical variable data were used to provide a descriptive summary (mean ± SD), comparing the distribution of each categorical variable, ie, sex (male vs female), marital status (married vs single), and employment (employed vs unemployed). Independent t test was used throughout, with 95% confidence interval. Spearman rank correlation analysis of the pairwise categorical variables was used.

The Department of Epidemiology and Health Services Research, Bio-Statistics Unit, Sub-Unit of Medical Statistics, School of Medicine, University of Leeds, Leeds, reviewed the statistical analysis and the presentation and interpretation of the data in the “Results” and “Comment” sections and approved them.

RESULTS

CLINIC ATTENDANCE

Of 294 patients, 201 (68.4%) attended the second appointment at the correct time, completed both interviews, and were included in the analysis. The 93 exclu-
The mean age of the patients was 45.1 ± 10.1 years (range, 20-65 years). There was no significant correlation between medication adherence and age. The overall mean medication adherence in the study was 60.6% ± 33.0% (range, 0%-169%). The mean DLQI was 17.4 ± 8.9 (range, 0-30). There was a highly significant correlation (r = −0.92) between DLQI score and medication adherence (Figure 1). All the determinants associated with increased medication adherence were also associated with a lower DLQI. The DLQI values were the same at the first and last interviews for all patients.

SOCIAL DETERMINANTS

Women had a significantly higher mean medication adherence rate (77.9% ± 29.0%, n = 112) than men (38.8% ± 24.0%, n = 89) (P < .001) (Table 1). The mean medication adherence for single persons was 44.2% ± 35.0% (n = 104), while for married persons it was 78.2% ± 19.0% (n = 97) (P < .001). The mean medication adherence for the employed group was 68.9% ± 34.0% (n = 134), and for the unemployed group it was 43.9% ± 25.0% (n = 67) (P < .001). The mean medication adherence for those who paid for medication was 45.5% ± 27.8% (n = 102), and for those who did not pay, it was 76.2% ± 30.8% (n = 99) (P < .001).

Table 1. Social Factors Affecting Compliance and Dermatology Life Quality Index (DLQI)

<table>
<thead>
<tr>
<th>Social Variables</th>
<th>Medication Adherence, %</th>
<th>DLQI</th>
<th>r Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male (n = 89)</td>
<td>38.8 ± 24.0</td>
<td>23.8 ± 5.5</td>
<td>−0.87</td>
</tr>
<tr>
<td>Female (n = 112)</td>
<td>77.9 ± 29.0</td>
<td>12.4 ± 7.7</td>
<td>−0.87</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single (n = 104)</td>
<td>44.2 ± 35.0</td>
<td>22.7 ± 7.1</td>
<td>−0.92</td>
</tr>
<tr>
<td>Married (n = 97)</td>
<td>78.2 ± 19.0</td>
<td>11.8 ± 6.9</td>
<td>−0.94</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed (n = 134)</td>
<td>68.9 ± 34.0</td>
<td>14.8 ± 4.2</td>
<td>−0.91</td>
</tr>
<tr>
<td>Unemployed (n = 67)</td>
<td>43.9 ± 25.0</td>
<td>22.8 ± 7.5</td>
<td>−0.90</td>
</tr>
<tr>
<td>Medication payment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paying (n = 102)</td>
<td>45.5 ± 27.8</td>
<td>22.0 ± 7.0</td>
<td>−0.89</td>
</tr>
<tr>
<td>Nonpaying (n = 99)</td>
<td>76.2 ± 30.8</td>
<td>12.7 ± 8.0</td>
<td>−0.90</td>
</tr>
</tbody>
</table>

Data are given as mean ± SD unless otherwise indicated. P < .001 for all comparisons.

DRUG REGIMEN DETERMINANTS

Patients starting treatment for the first time and those continuing treatment had mean medication adherence values of 90.1% ± 26.4% and 46.9% ± 26.1%, respectively (P < .001) (Table 2). The mean medication adherence for the patient group reporting adverse effects was 45.7% ± 26.6% (n = 93) and was 73.3% ± 32.9% (n = 108) for the group who did not (P < .001). Analyzed according to treatment frequency, the mean medication adherence for the once-daily group was 82.3% ± 37.4%, compared with 44.0% ± 23.0% for the twice-daily group (P < .001). The mean medication adherence for oral, topical, and combined treatments was 46.1% ± 30.0%, 71.9% ± 34.0%, and 74.2% ± 19.8%, respectively, with the difference between oral and topical treatments being highly significantly different (P < .001).

The major reasons for missing treatment were drinking alcohol, being fed up, forgetfulness, and being too busy, with mean medication adherences of 36.7% ± 24.6%, 42.9% ± 20.3%, 55.9% ± 29.1%, and 78.4% ± 17.6%, respectively (Figure 2).
SMOKING HABITS AND ALCOHOL CONSUMPTION

The mean medication adherence for the nonsmokers was 86.0% ± 18.0% (n = 75), while it was 45.5% ± 30.0% (n = 126) for the smokers (P<.001) (Table 3). Heavy smoking produced the greatest effect. The mean medication adherence for patients who stated that they did not drink alcohol was 91.5% ± 29.0% (n = 38), while it was 53.4% ± 30.0% (n = 163) for those who consumed alcohol (P<.001).

LESION EXTENT AND PATIENT SENSITIVITY

The mean medication adherence for patients with psoriasis of the body was 69.6% ± 30.8% (n = 145), while it was 37.4% ± 27.0% (n = 56) for patients with facial disease (P<.001) (Table 4). One hundred thirty-one patients (65.2%) found 3 or more sites of disease to be annoying and embarrassing, while 70 (34.8%) found this to be so for fewer than 3 sites. The mean medication adherence for the former group was 44.7% ± 25.0% and 90.3% ± 25.0% for the latter (P<.001).

NUMBER OF PRESCRIBED FTUs VS MEDICATION ADHERENCE AND WELL-BEING

The number of prescribed FTUs per day vs medication adherence showed a significant negative correlation (r = −0.66), indicating that medication adherence decreases with an increase in the number of prescribed FTUs per day (Figure 3). Therefore, increasing disease extent adversely affects compliance.

The number of prescribed FTUs per day vs DLQI showed a significant positive correlation (r = 0.71), indicating that the DLQI increases with an increase in the number of prescribed FTUs per day (Figure 4).

INTERVIEW MEDICATION ADHERENCE

The mean interview medication adherence in the study was 92.0% ± 6.0% (range, 75%-100%).

COMMENT

Because of the instinctive aversion to skin disease and because of the skin's function as a major organ of social and sexual communication, it is understandable that skin disease leads to psychological disturbance, particularly of well-being.29

In this study, patients with psoriasis showed variable effects of their disease on quality of life, which was related in part to the different sites and extent of involvement, with facial disease having a marked effect. It is likely that self-image is one of the bases for the association of skin and psychological disturbance and is reflected in the DLQI. That these factors affect patient compliance seems intuitively correct, but this has rarely been demonstrated.

This study was designed to evaluate compliance with topical and oral therapies in patients with psoriasis by using the most objective methods of assessment. In addition, it assessed factors affecting compliance. These factors may be common to many skin diseases, but this has not been proved.

Table 3. Effect of Smoking and Alcohol Consumption on Dermatology Life Quality Index (DLQI)*

<table>
<thead>
<tr>
<th>Social Variable</th>
<th>Medication Adherence, %</th>
<th>DLQI</th>
<th>r Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking habit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No (n = 75)</td>
<td>86.0 ± 18.0</td>
<td>10.0 ± 6.0</td>
<td>−0.85</td>
</tr>
<tr>
<td>Yes (n = 126)</td>
<td>45.5 ± 30.0</td>
<td>21.9 ± 9.0</td>
<td>−0.82</td>
</tr>
<tr>
<td>Alcohol consumption</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes (n = 38)</td>
<td>91.5 ± 29.0</td>
<td>9.6 ± 3.0</td>
<td>−0.68</td>
</tr>
<tr>
<td>No (n = 163)</td>
<td>53.4 ± 30.0</td>
<td>19.3 ± 8.0</td>
<td>−0.92</td>
</tr>
</tbody>
</table>

*Data are given as mean ± SD unless otherwise indicated. P<.001 for both comparisons.

Table 4. Compliance and Dermatology Life Quality Index (DLQI) vs Disease Distribution and Extent

<table>
<thead>
<tr>
<th>Lesion Variable</th>
<th>Medication Adherence, %</th>
<th>DLQI</th>
<th>r Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion distribution</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Body type (n = 145)</td>
<td>69.6 ± 30.8</td>
<td>14.9 ± 8.0</td>
<td>−0.85</td>
</tr>
<tr>
<td>Face included (n = 56)</td>
<td>37.4 ± 27.0</td>
<td>23.8 ± 3.3</td>
<td>−0.71</td>
</tr>
<tr>
<td>No. of sites</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥3 (n = 131)</td>
<td>44.7 ± 25.0</td>
<td>21.8 ± 5.1</td>
<td>−0.90</td>
</tr>
<tr>
<td>&lt;3 (n = 70)</td>
<td>90.3 ± 25.0</td>
<td>9.3 ± 5.4</td>
<td>−0.60</td>
</tr>
</tbody>
</table>

*Data are given as mean ± SD unless otherwise indicated. P<.001 for both comparisons.

Figure 3. The effect of the amount of prescribed topical treatment on medication adherence. y = −0.04x + 0.93. r = 0.44.

Figure 4. The effect of the amount of prescribed topical treatment on Dermatology Life Quality Index (DLQI). y = 0.45x − 0.79. r = 0.51.
The mean medication adherence (60.6%) in this study is consistent with previously published work regarding several chronic disorders. However, some studies have shown that adverse effects were a factor in reducing compliance with oral therapy. In this study, and it may be that fear of adverse effects occurrence of adverse events also reduced compliance. Treatment should be less time-consuming and easier. The methods give much lower figures for compliance overall than are achieved by the more subjective method of asking the patient directly about his or her treatment use (interview medication adherence). This demonstrates the unreliability of subjective methods, affected by the desire of patients to appear to have complied with prescribed treatment.

Overall, there was a highly significant negative correlation ($r = -0.92$) between DLQI score and medication adherence. This was an unexpected finding, as we anticipated that patients reporting a greater extent of disease would comply better. The inversely proportional relationship between DLQI and medication adherence likely reflects the fact that psoriasis compromises well-being, and this, along with previous experience of treatment effects, leads to a lack of faith in disease treatment. Deterioration in quality of life, often associated with adverse social factors and treatment failure, is related to treatment compliance.

Our results confirm that, in patients with psoriasis, the area of skin disease involvement is often not a reliable guide to disability. Rather, psoriasis affects the psychological well-being of patients in different ways according to their social circumstances and backgrounds.

Overall, there are 3 main groups of factors affecting compliance. These are social factors, treatment-related factors, and disease distribution factors.

**SOCIAL FACTORS**

Our method of analysis does not allow us to detect which social factors are independent variables, but it seems likely that smoking behavior and alcohol consumption are related. Patients identified some social factors as being important issues for their compliance. Drinking alcohol, apparently unrelated to age, was the major reason reported for missing doses of treatment. While forgetfulness was also a factor, this was not the primary reason in this study, in contrast to data previously reported. There is a well-known association between cigarette smoking, alcohol consumption, and psoriasis. It appears that these behavioral characteristics also affect the patients’ response to their disease and its treatment.

**TREATMENT-RELATED FACTORS**

Compliance with oral treatment was much lower than that associated with topical treatment. Compliance with combined treatment was equivalent to that of topical treatment. These findings were unexpected, as the use of oral treatment should be less time-consuming and easier. The occurrence of adverse events also reduced compliance in this study, and it may be that fear of adverse effects was a factor in reducing compliance with oral therapy. However, some studies have shown that adverse effects did not significantly affect adherence, with others disagreeing. Interestingly, combined oral and topical treatment was associated with a higher medication adherence. This higher adherence remains unexplained but likely indicates increased patient confidence in such a therapeutic regimen. Other important factors were frequency of treatment and whether treatment had been used in previous disease episodes.

**DISEASE DISTRIBUTION FACTORS**

The main disease-related factor affecting compliance was disease distribution. Facial disease produced greater effects on the DLQI and lower medication adherence. These results are consistent with previously reported work.

**STUDY LIMITATIONS**

Our methods do not detect patterns of treatment use, although we assessed the predictable effects of adverse events. We avoided bias by not disclosing the true nature of the study and by maintaining limited selection criteria for entry. We did not seek to identify the effect of single patient characteristics with regard to other individual characteristics. The assessment of compliance as a continuous variable in this study allows comparison of the distribution of each categorical variable, ie, sex, marital status, and employment. These methods did not set out to establish any one factor as most highly correlated; rather, overall patterns of individual characteristics correlated with compliance.

In summary, we identified several important factors affecting medication adherence in patients with this common skin disease. Many of these factors may be related to each other and form overall patterns of patient behavior, which may be amenable to intervention. It is important to go beyond collection of data about treatment use to application of data to positively affect compliance. Better measures of medication compliance permit evaluation of secondary resistance to therapy (as opposed to primary treatment failure) that may be associated with suboptimal treatment use.

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