INVESTIGATIVE REPORT

Are Treatment Satisfaction, Quality of Life, and Self-assessed Disease Severity Relevant Parameters for Patient Registries? Experiences from Finnish and Swedish Patients with Psoriasis

Catharina HJORTSBERG[1], Annika BERGMAN[1], Anton BJARNASON[2], Hannele HEIKKILÄ[3], Jonas HJELMGREN[4], Åke SVENSSON[5] and Gunnel RAGNARSON TENNVALL[1]

[1]IHE, The Swedish Institute for Health Economics, Lund, Departments of Dermatology, [2]Sahlgrenska University Hospital, Gothenburg, Sweden, [3]University Hospital of Helsinki, Helsinki, Finland, [5]University Hospital of Malmö, Malmö, and [4]Janssen-Cilag, Stockholm, Sweden

Patient registries often lack indicators of the disease as experienced by patients, e.g. treatment satisfaction and self-assessed disease severity. There is scarce information about the relationship between these assessments and currently existing instruments used in treatment evaluation. Our objective was to explore the importance of these indicators among patients with psoriasis in Finland and Sweden, in relation to treatment patterns and current measures of health-related quality of life. Data were collected from a patient survey and a retrospective chart review for 273 patients over 12 months. To assess psoriasis treatment completely, it is necessary to consider the impact of the disease on the patient in terms of treatment satisfaction, disease severity and health-related quality of life. The individual disease burden on patients should play a central role in formulating treatment goals. Clinician- and patient-based perspectives of the overall impact of psoriasis can assist clinical decision-making and evaluations of treatments. *Key words: psoriasis; disease severity; patient satisfaction; HRQoL; patient registries.*

Psoriasis is a chronic, immune system-related dermatological disease that causes inflammation and damages the involved tissues, including primarily the skin. In Sweden, an estimated 250,000 persons have psoriasis (1) and the corresponding figure for Finland is 150,000 (nearly 3% of the populations in both countries) (2). Men and women are equally affected. Plaque psoriasis is the most common form and accounts for more than 80% of all cases (1). Approximately 5–20% of people with psoriasis also have joint inflammation called psoriatic arthritis, which causes pain, stiffness and restricted motion (1). In addition to these physical effects, psoriasis also has a significant impact on a patient's health-related quality of life (HRQoL) (3, 4). Studies have shown that patients with psoriasis experience difficulties such as

maladaptive coping responses, problems in body image, self-esteem, and self-concept and often have feelings of stigma, shame and embarrassment regarding their appearance (5). Moreover, quality of life of partners and relatives of people with psoriasis can also be affected (6). A recent study reports that productivity loss in patients with psoriasis is related primarily to HRQoL and less to disease severity (7).

Several new therapeutic options for psoriasis have been tested in clinical trials in recent years (8). New biological response modulators (BRMs) have been introduced. These new agents are relatively costly (9), but have been shown to have a great impact on symptom relief and HRQoL of a large share of patients who have received biologic treatment (10–12).

Currently, such patient registries as the database The Swedish Registry for Systemic Psoriasis Treatment (PsoReg), which was created in 2007 in order to "analyse safety and effectiveness of different systemic psoriasis treatments" (13), lack information on self-assessed disease severity and patients' satisfaction with treatment. This is a problem for overall evaluation because patient perception of disease status, satisfaction with treatment, and disease burden are key indicators. We know from population-based studies that even patients with limited skin involvement are often dissatisfied with their treatment and find the disease highly problematic in everyday life (14, 15).

The aims of this study were to explore the correlation between patient's treatment satisfaction, quality of life, and self-assessed disease severity based on experience from Finnish and Swedish patients, and to determine whether these parameters should be included broadly in patient registries for patients with psoriasis.

MATERIALS AND METHODS

The data material was based on a retrospective study of patients with psoriasis from two dermatology clinics in different parts of Sweden, and one clinic in Finland. The inclusion criteria were diagnosis of plaque psoriasis or both plaque psoriasis and psoriasis arthritis. The exclusion criterion was participation in a clinical trial at the time of the study. Because this was a non-interventional study, no sample size calculation was performed and the planned number of subjects (150 patients from each

centre in Sweden and 150–200 patients in Finland) was chosen to represent a reasonable workload for the clinical investigators. Since data collection was retrospective and covered a treatment period of 12 months (from 1 September 2007 to 31 August 2008 in Sweden, and from 15 January 2008 to 14 January 2009 in Finland), each patient had necessarily been diagnosed with psoriasis 12 months or more before inclusion in the study. Each participating centre investigated their local patient registers and included patients who met the inclusion criteria. Patients at the Swedish sites were consecutively included from 31 August 2007 and backwards until the planned number of patients had been reached. The corresponding date in Finland was 31 December 2007. In Sweden, 310 patients were included and in Finland 193 patients.

In Sweden, data were collected from three sources: a patient survey, a review of patient records during one year, and data from the drug register at the Centre for Epidemiology (EpC) at the National Board of Health and Welfare (NBHW, Socialstyrelsen). Data for Finland were collected from two sources: a patient survey and a review of patient records. A code register containing a patient serial number, name and person identification number of patients included was generated at each clinic. The register was kept at the clinic, but the serial number was used to link data from the different sources. Permission to perform the study was obtained from ethics committees in Finland and Sweden and informed consent was received from patients to collect data from the different sources.

Patient survey

A questionnaire including predefined response alternatives was posted to the patients. The questions concerned psoriasis treatment, present health state, disease severity, level of satisfaction with current treatment, reasons for any dissatisfaction, and work status including absences from work and work impairment due to psoriasis. Specifically, patients were asked about number of absence days from work due to psoriasis during the last year (absenteeism) and to estimate how many days they had had psoriasis problems while still working and their working capacity as a percentage during these days (presenteeism).

Treatment satisfaction was measured on a scale from zero, representing very dissatisfied, to ten, representing very satisfied. The patients were also asked to judge their current disease severity on five levels ranging from no problems to very severe problems. Present life quality was captured with the generic EuroQol instrument (EQ-5D), the EQ-5D Visual Analogue Scale (VAS), and the disease-specific instrument the Dermatology Life Quality Index (DLQI).

The EQ-5D is a widely used, validated preference-based instrument designed to measure general health status. EQ-5D could preferably be used together with a disease-specific questionnaire. The instrument is suggested for Quality Adjusted Life Years (QALY) weightings in health-economic evaluations by, for example, the Swedish reimbursement authority (16). It consists of five items to assess degree of physical functioning (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression). Each question is divided into three levels: no problems, some problems, and severe problems. This allows 243 (3^5) possible health states. A single numeric index (weight) of health status can then be generated from the five dimensions. The EQ-5D QALY weight associated with each individual health state was based on weights developed by Dolan et al. (17).

The DLQI instrument contains ten items and the score ranges from 0 to 30. It was developed as a simple, compact, and practical questionnaire for use in dermatology clinical settings to assess limitations related to the impact of skin disease (18). The DLQI has well-established properties of reliability and validity in the dermatology setting (19, 20). It has been proposed that

the score reflects the degree of impairment imposed by the skin disease on HRQoL (21).

Review of patient records and access to drug register data

A review of patient records was conducted by a dermatologist from each centre for those patients who had responded to the survey. Information about drug prescriptions was collected in both countries. In Sweden, detailed data about prescriptions and dispatched drugs from pharmacies of a specified number of drugs used in psoriasis treatment were also collected from the national drug register at the Centre for Epidemiology for the 12-month period. We were unfortunately denied access to similar data from the Social Insurance Institution of Finland (KELA) drug register for Finland.

Statistical analyses

DLQI scores and EQ-5D weights were related to the treatment of the psoriasis disease and to disease severity. Correlations were performed to test for significant associations between variables. To test for a relationship between variables on an interval scale we have analysed the data using the Pearson's correlation coefficient. Spearman's rank correlation was applied when one or both of the variables being analysed consisted of ranks, i.e. data on an ordinal scale. F-tests and *t*-tests were performed to test significant differences between groups of patients. All statistical tests were performed at the 0.05-level of significance and were two-sided unless otherwise specified.

RESULTS

Patient characteristics

The response rate in Finland was 57%, as 110 of the 193 patients responded. In Sweden, 163 patients responded out of 310, corresponding to a response rate of 53%. Most of the patients were between 50 and 65 years of age and the majority of the respondents were men (66% in Sweden and 59% in Finland). Plaque psoriasis was the most common diagnosis, and 17.6% in Finland and

Table I. *Baseline demographics and social characteristics*

Patient characteristics	Swedish patients ($n=163$)	Finnish patients ($n=110$)
Male, *n* (%)	108 (66)	65 (59)
Mean age, years (min, max)	51 (22, 76)	53 (26, 75)
Median time since diagnosis, years (min, max)	14 (2, 71)	18 (2, 65)
Plaque psoriasis, *n* (%)	145 (89.0)	89 (82.4)
Plaque psoriasis + psoriasis arthritis, *n* (%)	18 (11.0)	19 (17.6)
Other chronic disease, *n* (%)[a]	57 (35.0)	61 (55.5)
Malignant disease	5 (3.1)	4 (3.6)
Cardiovascular disease	22 (13.5)	42 (38.2)
Collagenosis or other joint disease	9 (5.5)	3 (2.7)
Asthma or chronic obstructive lung disease	8 (4.9)	6 (5.4)
Diabetes	9 (5.5)	11 (10.0)
Kidney disease	1 (0.6)	0 (0)
Other chronic disease	30 (18.4)	50 (45.4)
Full-time employed, *n* (%)	82 (50.3)	58 (53.6)
Part-time employed, *n* (%)	12 (7.4)	8 (7.3)

[a]Several of the patients had more than one chronic disease.

Table II. *Definition of treatment groups*

Type of treatment	Swedish patients, *n* (%)	Finnish patients, *n* (%)
Emollients only	38 (23.3)	11 (10.0)
Topical corticosteroids: Patients who have used topical corticosteroids during part of or during the entire examined time period. Patients can also have used emollients.	66 (40.5)	49 (44.5)
Systemic (not biological): Patients who have used systemic treatment but not biological agents during part of or during the entire time period[a].	34 (20.9)	38 (34.5)
Systemic and biological (mix): Patients who have used both systemic treatment and biological treatment at any time during the 12 months. Patients have used biological treatment less than 12 months[a].	6 (3.7)	6 (5.5)
Biological <12 months: Patients who have used biological treatment less than 12 months during the examined time period. None of these patients have used other systemic treatment during the time period[a].	9 (5.5)	2 (1.8)
Biological 12 months: Patients who have used biological treatment during the whole examined time period[a,b].	10 (6.1)	4 (3.6)
Total	163 (100.0)	110 (100.0)

[a]Patients can also have used emollients and/or topical corticosteroids; [b]Patients can also have used other systemic treatment.

11% in Sweden had been diagnosed with both plaque psoriasis and psoriasis arthritis. Moreover, 55.5% of Finnish patients and 35% of Swedish patients were diagnosed with another chronic disease (Table I).

It is common that patients with psoriasis use multiple drug treatments concurrently, i.e. both local, systemic and biological treatment. Therefore, we divided the patients hierarchically into six different treatment groups depending on the most potent medication the patient had used during the last 12 months, as shown in Table II.

Emollients and topical corticosteroids alone were used by 164 of the patients (64% in Sweden and 54% in Finland) during the study period, while 72 patients (21% in Sweden and 34% in Finland) had used systemic treatment (not biological). In total, 37 patients (15% in Sweden and 12% in Finland) had used biological treatment during part of or during the whole 12-month period. Fourteen patients (6% in Sweden and 4% in Finland) had used biological treatment during the whole time-period.

Treatment patterns, treatment satisfaction and quality of life

The question on self-assessed disease severity revealed that the majority of patients on *Systemic and biological (mix)* and *Biological 12 months* treatment experienced their disease as mild at the time of the survey, as illustrated in Fig. 1. None of the patients, on biological treatment, experienced the disease as severe. However, 17% of the patients in the *Systemic and biological* group and 20% of the patients in the *Systemic (not biological)* group reported severe problems.

Fig. 1 also shows the degree of satisfaction with current treatment. We find a significant difference between the treatment groups regarding treatment satisfaction ($p \leq 0.000$). Patients in the *Emollients* group are least satisfied and patients in the *Biological treatment < 12 months* and *Biological 12 months* groups are most satisfied with their current treatment. Patients on *Systemic (not biological)* are less satisfied with their treatment compared with patients who have received biological treatment only for 12 months or less ($p \leq 0.001$). The
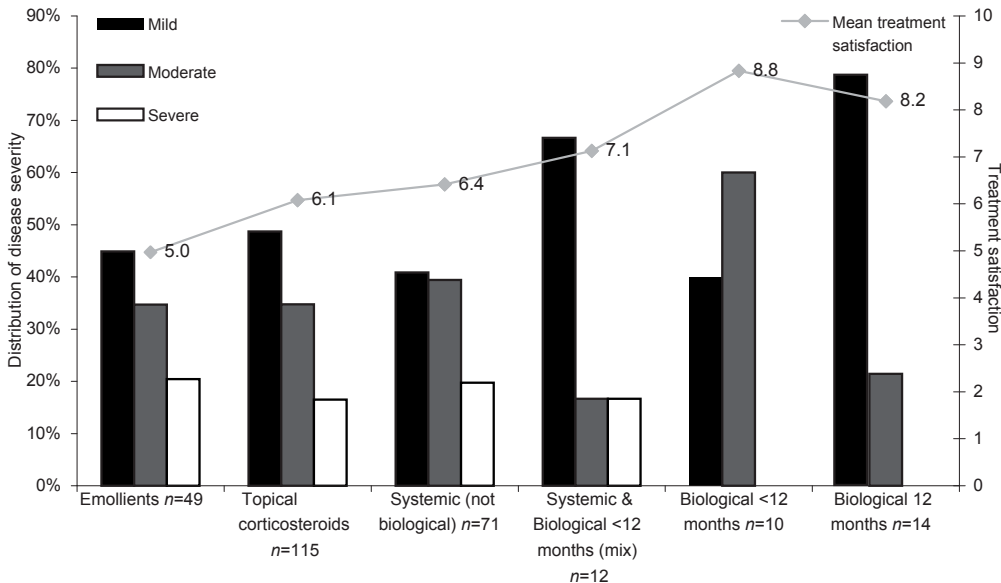

Fig. 1. Distribution of self-assessed disease severity (mild, moderate or severe), and degree of satisfaction with treatment (0 = very dissatisfied, 10 = very satisfied) per treatment group, *n* = 271 (2 missing).
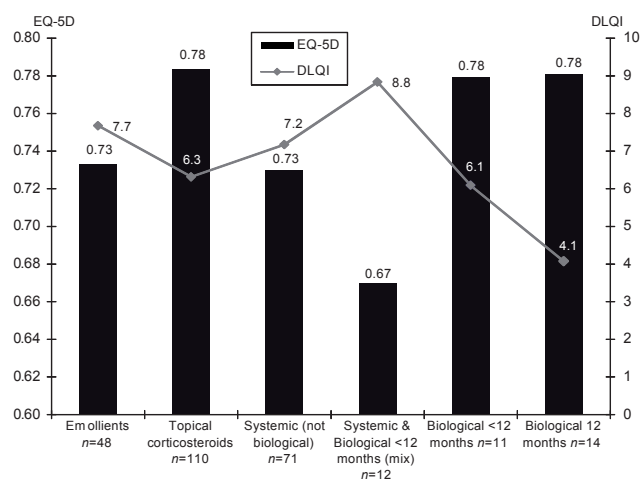
Fig. 2. Quality of life: Mean EuroQol (EQ-5D) and Dermatology Life Quality Index (DLQI) as reported by patients in Finland and Sweden, *n* = 266 (7 missing).

patients estimated their average output capacity at work/studies (work productivity) during their last psoriasis outbreak to 82.1% (SD 1.6), but no significant difference can be detected by the treatment group. Patients also responded to what type of problem they were experiencing with their current treatment. The most common problems were limited effects from treatment, sticky cream, and that the treatment was time consuming.

On average, the patients' QoL measured by EQ-5D was quite high, mean QALY weight 0.75 (SD 0.23). The mean DLQI score was 6.8 (SD 6.1), which corresponds to a moderate effect on the patient's life. As illustrated in Fig. 2, the groups *Topical corticosteroids*, *Biological <12 months* and *Biological 12 months* all had an EQ-5D score above the mean, while the DLQI score varied between 6.3 (moderate effect on patient's life) and 4.1 (small effect on patient's life) for these patient groups. The lowest EQ-5D score (indicating the lowest QoL) was reported by patients in the group *Systemic and Biological <12 months*, and this group also had the highest DLQI, 8.8 (moderate effect on patient's life). However, no statistically significant differences for QoL measured by EQ-5D and DLQI could be detected between the treatment groups.

Table III shows the correlations between the HRQoL measures, patient treatment satisfaction, self-assessed

disease severity and work productivity. We find that patients having higher discomfort and a larger effect on their lives according to DLQI have lower QoL according to EQ-5D. We note that the DLQI score is more highly correlated with self-assessed disease severity than with the EQ-5D. The correlations with treatment satisfaction show that patients who are less satisfied with their treatment also have more severe disease and a lower HRQoL according to EQ-5D and DLQI. We find that work productivity is more correlated with HRQoL than with self-assessed disease severity.

DISCUSSION

The present study is based on a patient sample of 273 patients with psoriasis being treated in Finland and Sweden. Our results reveal differences in self-assessed disease severity, treatment satisfaction and HRQoL depending on which type of treatment the patient has received. We observe that patients treated with biological agents seem to have higher QoL compared with other patients. Most of the patients in this treatment group also state that they experience "no problem" or "mild problem" with their illness. In addition, these patients are more satisfied with their treatment compared with the other groups.

We lacked information from any patient registry in Finland, but in Sweden there is a database PsoReg, containing information about more than 800 patients on systemic treatment (including biological treatment) from all over Sweden (22). In comparison with the data published from PsoReg, we find several similarities. The age distribution is similar to our study, with most patients between 40 and 65 years of age (22). Furthermore, just as in PsoReg, men were overrepresented in our study population (63% vs. 60% in PsoReg) (22). Similar overrepresentation of male patients in Swedish dermatology centres has been noted in other studies (23, 24). In PsoReg, the mean EQ-5D score for patients at inclusion was 0.75 (SD 0.23) and the DLQI score was 7.44 (SD 7.2) (22). In our study, the mean EQ-5D score for the whole patient population was 0.75 (SD 0.23) and the DLQI score was 6.8 (SD 6.1). However, our patient sample also includes patients that have been treated with

Table III. *Correlations^a among patient-related outcome measures,* n = *273*

Measure	DLQI	EQ-5D	EQ-5D VAS	Patient treatment satisfaction	Self-assessed disease severity	Productivity at work
DLQI	1.0					
EQ-5D	−0.5234	1.0				
EQ-5D VAS	−0.5008	0.5738	1.0			
Patient treatment satisfaction	−0.4175	0.2807	0.3758	1.0		
Self-assessed disease severity	0.7067	−0.4900	−0.4331	−0.5367	1.0	
Productivity at work	−0.4735	0.4126	0.3892	0.0695, ns	−0.1689*	1.0

^aAll correlations were significant at $p \leq 0.000$, unless otherwise noted.
*$p \leq 0.05$.
ns: non-significant; DLQI: Dermatology Life Quality Index, EQ-5D: EuroQol; VAS: visual analogue scale.

only topical therapy during the observational period, while PsoReg is limited to patients treated with systemic drugs. A substantial number of patients had both psoriasis and other chronic diseases. This could, of course, also have had an influence on the patient's well-being.

A German study concluded that patients who cannot adequately be managed with standard treatments have high disease activity and a lower HRQoL (25). We find that patients on systemic treatment (not biological) are less satisfied with their treatment compared with patients who have received biological treatment. It is therefore possible that these patients are treated sub-optimally. The results from the present study indicate that there are still potential health gains to be made through initiation of new more effective treatments for some patients treated with systemic drugs.

One limitation of the present study is the small number of patients and especially the small number of patients on systemic treatment. A second limitation of the study is that the patients were collected from specialized clinics at university hospitals; as such, the study population may be unrepresentative. Typically, patients with moderate and severe psoriasis problems are treated in dermatological clinics in Finland and Sweden. The number of patients with severe psoriasis who were treated with systemic agents, and especially biologic drugs, was relatively low, perhaps because of the exclusion of patients participating in a clinical trial at the time of the present study. There might therefore be a selection bias due to the exclusion criteria causing fewer patients with severe psoriasis and thus less patients on systemic drugs.

Our study reveals the importance of considering self-assessed disease severity, treatment satisfaction, and HRQoL. It is evident from this survey that patients with psoriasis, who experience limitations in their HRQoL, experience their disease as severe and are dissatisfied with their treatment. Moreover, we can conclude that treatment satisfaction varies between treatment groups. Patients on biological treatment during the whole study period seem to be most satisfied with their treatment. Some of the patients treated with systemic agents other than biological might benefit from a more optimal psoriasis treatment, as some are dissatisfied with their treatment. One possible explanation can be that the conventional traditional and new treatment options are not being used consistently (26). Patients can easily be followed up in a patient register and with more information available about their disease a more optimal treatment can be chosen. Moreover, patient registers should include all patients with psoriasis and not only those on systemic treatment. Patients with self-assessed severe disease would particularly benefit from patient registers adding more information, as a more optimal treatment for these patients would mean large positive effects on their overall QoL.

The findings of the present study imply that it may be insufficient to ask patients about treatment satisfaction. It is also important to ask about work productivity. As shown in a previous German study, the correlation between HRQoL and work productivity in the present study is higher than between work productivity and disease severity (7).

The relatively high correlation between DLQI and self-assessed disease severity in the present study indicates that this way of assessing the patient's condition could be used to evaluate symptoms and effects of treatments. Currently, treatment satisfaction is often used as a treatment goal in the Nordic countries, but our study shows a relatively low correlation between treatment satisfaction and HRQoL measures and between treatment satisfaction and self-assessed disease severity. This could mean that those pursuing this traditional treatment goal may be over-treating some patients, and under-treating others. The individual disease burden on the patient should play a central role in formulating treatment goals.

For a complete assessment of psoriasis treatment, it is necessary to provide evidence of the impact of the disease on the patient in terms of treatment satisfaction, disease severity, and HRQoL. A large European study on 18,000 patients with psoriasis also concluded the importance of these measures (15). Users of patient registers will benefit if the registers include this information, since the patients' views are of great value to anyone interested in improving the treatment and management of psoriasis. Clinician- and patient-based perspectives of the overall impact of psoriasis can assist clinical decision-making and evaluations of appropriate treatments.

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