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INVESTIGATIVE REPORT

The Effect of Treatment on Quality of Life in Psoriasis Patients

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Psoriasis is a chronic skin disease with substantial impact on patients' social and relational ways of living and subsequently on their quality of life. The aim of this study was to evaluate the health-related quality of life (HRQoL) of patients with moderate to severe psoriasis treated with short contact dithranol treatment, UVB phototherapy or inpatient dithranol treatment. HRQoL was evaluated in an open randomized multicentre study by appliance of the Dutch short form of the Sickness Impact Profile and the Psoriasis Disability Index; 250 patients were included. Successful short contact dithranol treatment and UVB phototherapy both led to a comparable improvement in HRQoL immediately after treatment until the end of the follow-up (maximum 1 year). Inpatients experienced a more impaired HRQoL and showed no significant improvement in HRQoL directly following treatment. At the end of the study HRQoL became comparable for all treatment groups. All three treatments led to substantial improvement in HRQoL; however, patients treated by short contact treatment or UVB showed a better HRQoL than inpatients. ***Key words: psoriasis; health-related quality of life; short contact dithranol treatment; inpatient treatment; UVB phototherapy.***

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Psoriasis can be treated by various topical treatments, systemic drugs or photo(chemo)therapy. Because no curative treatment is available yet, all interventions are merely focused on the temporary relief of the burden of psoriasis and improvement in health status or quality of life (i.e. health-related quality of life, HRQoL). To evaluate HRQoL, generally two different variants of HRQoL instruments are available. Generic HRQoL instruments are designed for all kinds of diseases and medical treatments, whereas disease-specific HRQoL instruments are designed to assess HRQoL in specific diagnostic groups of patient populations (1).

The subjective appraisal of psoriasis seems to be highly affected by factors such as the location of the plaques, age, marital status and employment status (2). Psoriasis patients report a lower HRQoL than the general population. A prominent factor in the evaluation of psoriasis is the patients' concern about how they are perceived and evaluated by others. To a large extent this determines the experienced social and emotional consequences of psoriasis (2–4). Common reactions to psoriasis are social discomfort, embarrassment, impaired daily activities, anxiety, anger, depression and social isolation (5). All these reactions may be reflected in higher scores on HRQoL instruments, especially on the domains: social lives, family relationships, leisure time and emotional well-being (3, 6, 7).

To evaluate the effect on HRQoL of three currently available treatment modalities for moderate to severe psoriasis (8) we performed an open randomized multicentre study. The study was performed alongside a cost-effectiveness analysis concerning the same three treatments (9, 10). The treatments under study were: short contact dithranol treatment in a care instruction programme (short contact treatment) at a day-care centre, UVB phototherapy and inpatient dithranol treatment (inpatient treatment). The main goal was to evaluate if HRQoL was influenced in different ways by different treatments, and to evaluate if HRQoL measurements are suitable to use as an alternative outcome measure besides clinical signs. Two HRQoL instruments were applied, one generic and one disease-specific (11, 12).

MATERIALS AND METHODS

Design

An open randomized multicentre study was designed with the following treatments: short contact dithranol treatment in a care instruction programme at a day-care centre, UVB phototherapy and inpatient dithranol treatment. Two extramural day-care centres and four university centres with day-care facilities participated.

Randomization was concealed (envelopes); patients were randomized within three parallel randomization strata over the three treatments under study. Stratum I comprised all three treatments. Stratum II comprised short contact treatment and inpatient treatment, so patients with a contra-indication for UVB phototherapy or who did not want this therapy were randomized within this group. Patients who rejected inpatient treatment were randomized in stratum III, containing short contact treatment and UVB.

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Short contact dithranol treatment was performed in a care instruction programme at a day-care centre. This care instruction programme aims to instruct the patient to recognize the different aspects of his/her disease and to react adequately to it by treatment. Patients were treated and instructed at the day-care centre twice a week, and treated themselves at home on the other 5 days of the week. Dithranol (0.1–5.0%) was applied in a cream and washed off after 15–45 min. UVB phototherapy was performed three times a week. Treatment was started with 50% of the minimal erythemal dose (MED), and increased according to a scheme just below erythema. During inpatient treatment dithranol (0.05–5.0%) in petrolatum was applied diffusely for 24 h.

The Psoriasis Area and Severity Index (PASI) and the total percentage of involved body surface (area) were used to evaluate clinical effectiveness (13, 14). The area at the start of treatment (baseline area) was chosen as most prominent reference value to evaluate the treatments. This area was defined by the 'rule of hand' that is also used in the PASI score. The area of the hand of the patient stands for 1% of his/her total body surface (13). Following successful treatment (90% clearance of the baseline area) patients were seen monthly until a relapse occurred (recurrence of 50% of the baseline area), with a maximum follow-up period of 1 year. This cut-off point for a relapse was chosen because the clinical effect of our study treatment had largely disappeared when 50% of the baseline area had recurred. At this point patients had to be able to get another treatment besides the local treatments that were allowed during follow-up. This follow-up treatment was defined in a protocol and consisted of topical treatments only (descaling ointment, coaltar shampoo, betamethasone or desoximetasone lotion or emulsion, clobetasone, fluticasone, betamethasone or clobetasol cream or ointment, calcipotriol ointment, and petrolatum 50% in cr. Lanette I). Therapy failure was defined as $<90\%$ clearance of the baseline area after the maximal treatment period of 12 weeks for short contact treatment or UVB, or after 8 weeks of inpatient treatment. When there was no improvement of the psoriasis during treatment, stop criteria were defined to determine if a treatment could be classified as a therapy failure. These criteria were $<25\%$ improvement in PASI after 2 (inpatient treatment) or 3 (short contact treatment/UVB) weeks of treatment, $<50\%$ improvement in PASI after 4 (inpatient treatment) or 6 (short contact treatment/UVB) weeks of treatment. After therapy failure the study ended.

Evaluation of HRQoL was performed at four time points: the start of treatment, the end of treatment, 3 months' follow-up and the end of the study. A generic and a disease-specific instrument were applied.

Sickness Impact Profile

The Dutch short form of the Sickness Impact Profile (SIP68) was used as the generic HRQoL instrument. The SIP68 was developed in the Netherlands in 1994. It contains 68 items that form 6 subscales covering aspects of health and functional status (Table I) (15–17). Patients are asked to report on their condition as it is on the day of collection. It takes 10 min to answer the questions, which are in a yes-no mode (no=0, yes=1). Scores range from 0 to 68, with higher scores implying higher impairment. The SIP68 correlates well with the original 136-item version of the SIP (15), which was proven to be appropriate in other psoriasis studies (11, 16).

Psoriasis Disability Index

The Dutch translation of the Psoriasis Disability Index (PDI) was used as the disease-specific HRQoL instrument; the score expresses an accumulation of psoriasis-related disability in daily activities, at work, in personal relationships, in leisure activities and in treatment. The PDI was the first disease-specific HRQoL instrument developed for psoriasis patients (18–20). The instrument was designed to measure treatment-induced changes in disability caused by moderate to severe psoriasis (21, 22). Unlike the Emotional Stability subscale of the SIP-68, the PDI does not measure the emotional impact of psoriasis. The clinical severity of psoriasis is described to be no indication of the severity as experienced by the patient. Consequently clinical severity hardly ever correlates with the experienced quality of life as measured by the PDI (11, 23). The instrument was used to reveal the relative benefit of treatment from the patient's view. Respondents consider the past 4 weeks, rating questions on a 7-point linear analogue scale (0 = no disability, 6 = maximum disability). An overall index of disability is derived, representing the sum of all answers, with scores ranging from 0 to 90. The patient's disability increases with the score (24).

Statistical analysis

Included in the analysis was the 'intention to treat' population, consisting of all patients randomized who, after baseline measurements, appeared at least once during treatment. At 3 months' follow-up only patients still in remission were analysed. Only completed HRQoL instruments were included; no imputation methods were employed to replace missing data. Due to the design of the study and the patients' flow, different numbers of patients were included at the four possible time points of measurement. Prior to the analysis we checked

Table I. *Short form of the Sickness Impact Profile, SIP68*

Subscales	Items	Questions concerning
Somatic Autonomy (SA)	17	Someone's basal somatic functions like dressing, eating, walking or the need for help concerning these matters
Motor Control (MC)	12	Motor functioning concerning walking, and hand and arm control
Psychological Autonomy and Communication (PAC)	11	If someone functions independently psychically, including verbal communication, with questions on e.g. concentration, being confused, stuttering, and making decisions
Social Behaviour (SB)	12	Possible consequences of a disease concerning interpersonal contacts such as sexual activity, visiting friends, and joining group activities
Emotional Stability (ES)	6	The emotional consequences of a disease with questions on irritability and irritation concerning oneself and others
Mobility Range (MR)	10	Usual daily activities like shopping, cleaning the house and handling financial matters, and to what extent the patients participate in these

whether there was a statistically significant difference between the different centres.

The PDI and SIP68 scores were transformed to a 0–100 point score to facilitate interpretation. Paired t-tests were performed for each treatment separately, to detect statistically significant differences in HRQoL between the four time points of measurement. Testing for differences between the three treatment groups was performed by ANOVA (post hoc test for unequal variances, Dunnett's C). Association measures (Pearson correlation, two-tailed) were applied to determine the relationship between the clinical severity scores (PASI, area score) and the HRQoL measures (SIP68, PDI).

RESULTS

Overall, 250 patients were included in the study. Twelve patients were excluded because they did not return after the baseline assessment (short contact treatment, 7; UVB, 4; inpatient treatment, 1). The 'intention to treat' group consisted of 238 patients. The patient demographics are outlined in Table II. The number of patients and patient flow are depicted in Fig. 1. The mean treatment duration until successful treatment was 75 days (SD 16) for short contact treatment, 72 days (SD 17) for UVB and 37 days (SD 14) for inpatient treatment. The relapse rate after 1 year for short contact treatment, UVB and inpatient treatment was 38%, 58%, and 70%, respectively. Patients successfully treated by short contact treatment had a significantly longer remission time than those receiving inpatient treatment.

Table II. *Demographics of patients in the 'intention to treat' population – mean (SD) of Psoriasis Area and Severity Index (PASI), area of involved skin (Area%) and age, and male/female ratio*

Treatment	*n*	Mean baseline PASI	Mean baseline Area%	Mean age	M/F ratio
Short contact dithranol	100	14.1 (5.5)	19.3 (13.1)	46.1 (13.6)	67/33
UVB	78	14.6 (6.8)	20.1 (13.7)	47.1 (15.3)	53/25
Inpatient dithranol	60	18.2 (8.4)	24.9 (14.6)	47.3 (14.4)	40/20
Overall	238	15.3 (6.9)	21.0 (13.8)	46.7 (14.3)	160/78

M, male; F, female.

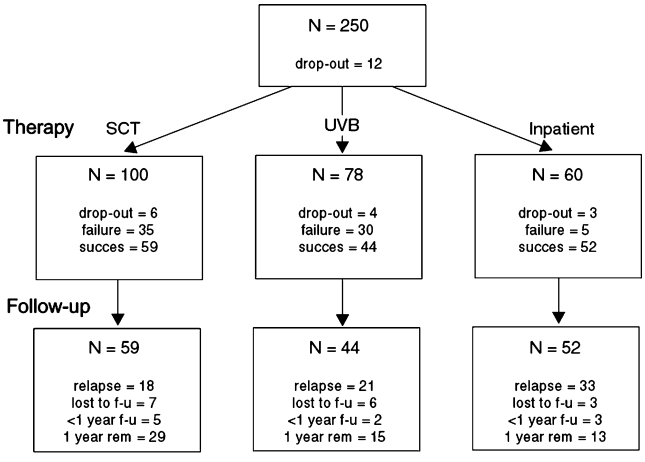

Fig. 1. Flow chart for patients under study. f-u=follow-up; rem=remission; SCT=short contact treatment with dithranol.

The results (mean and SD) of the SIP68 and the PDI are listed in Tables III and IV, respectively. At the end of inpatient treatment the PDI showed a major hospitalization effect. Therefore at the end of inpatient treatment the PDI was left out of analysis, because it did not reflect psoriasis disability, but merely disability caused by hospitalization. Hence, as patients were unable to carry out leisure time or social activities during their hospital stay, they scored high on disability regarding these items. Statistical analysis showed that there was no influence of centre on the HRQoL scores. The SIP68 and the PDI scores correlated well on all four measurements ($p<0.01$). A correlation between the area score and the PASI on one hand and the PDI or SIP68 scores on the other hand, was found for inpatient treatment at 3 months' follow-up (area/SIP68, $p<0.05$; area/PDI, $p<0.01$; PASI/PDI, $p<0.01$).

Overall, patients with a therapy failure tended to score worse than patients with a successful treatment; a significantly deteriorated score was found for the PDI (UVB, $p<0.05$; short contact treatment, $p<0.001$). Fig. 2 shows the results of the scores of the SIP68 and the PDI with the numbers of completed instruments underneath each time point of measurement. At 3 months' follow-up only patients still in remission were analysed. Only completed HRQoL instruments were included. Due to the design of the study and the patients' flow, different numbers of patients were included at the four possible time points of measurement. At the start of therapy all completed HRQoL questionnaires were included, at the end of therapy only those with a successful therapy were included, because this was the group that was followed-up. This explains the fall in number of patients underneath the figures. At the end of treatment in the inpatient group the PDI scores were left out of analysis. In general, an improvement in the HRQoL score can be observed for the three treatments, for the SIP68 as well as the PDI.

Short contact treatment led to a statistically significant improvement in HRQoL (SIP68, $p<0.05$; PDI, $p<0.001$) directly following treatment, which further improved during the first 3 months of follow-up and remained at an equivalent level until the end of the study. When comparing the SIP68 subscores at the start of treatment with those at 3 months' follow-up, patients experienced a significant improvement in Mobility Range ($p<0.01$) and Emotional Stability ($p<0.05$).

UVB phototherapy gave a statistically significant improvement in HRQoL (SIP68, $p<0.05$; PDI,

Table III. *Results of the Psoriasis Disability Index (PDI) for each of the treatment modalities at the four time points of measurement*

Treatment	Start of treatment (*n*) mean (SD)	End of treatment (*n*) mean (SD)		3 months follow-up (*n*) mean (SD)	End of study (*n*) mean (SD)
		Therapy-failure	Success		
Short contact	(98) 25.2 (17.6)	(35) 27.7 (18.7)	(58) 15.2 (10.0)	(48) 7.0 (8.9)	(47) 9.5 (12.0)
UVB	(78) 27.7 (18.0)	(30) 21.7 (17.7)	(44) 11.5 (15.6)	(36) 8.5 (13.8)	(30) 14.0 (19.3)
Inpatient	(60) 39.7 (21.7)	(5)[a]	(52)[a]	(49) 12.4 (13.1)	(39) 19.6 (16.5)

[a]The PDI for inpatients at the end of treatment was left out of the analysis as noted in the Results section.

Table IV. *Mean and subscores of the Sickness Impact Profile, SIP68 (SD) for each of the treatment modalities at the four measurements, including somatic autonomy (SA), motor control (MC), psychological autonomy and communication (PAC), social behaviour (SB), emotional stability (ES) and mobility range (MR)*

Treatment	Subscore/SIP	Start of treatment	End of treatment		3 months follow-up	End of study
			Therapy failure	Successful		
Short contact	SA	0.3 (1.7)	0.7 (3.1)	0.1 (0.8)	0.1 (0.8)	0.3 (1.2)
	MC	5.6 (13.4)	11.0 (23.6)	3.0 (9.8)	3.1 (10.0)	2.0 (8.0)
	PAC	9.3 (19.7)	7.0 (16.5)	6.6 (15.3)	4.8 (11.6)	3.0 (8.5)
	SB	11.3 (17.7)	16.0 (21.2)	6.4 (12.4)	5.8 (13.8)	5.3 (13.6)
	ES	12.5 (24.0)	8.6 (22.6)	5.1 (12.5)	3.4 (10.2)	2.8 (10.0)
	MR	3.5 (11.9)	5.4 (16.5)	0.7 (2.5)	0.4 (1.2)	0.4 (2.0)
	SIP68	**7.1 (11.4)**	**8.1 (14.3)**	**3.6 (6.1)**	**2.9 (6.0)**	**2.3 (5.2)**
UVB	SA	0.1 (0.7)	0.0 (0.0)	0.3 (1.2)	0.5 (2.2)	0.4 (1.5)
	MC	5.6 (14.5)	6.1 (12.6)	4.4 (14.5)	6.7 (18.6)	8.3 (20.6)
	PAC	9.4 (19.5)	7.0 (16.9)	6.0 (17.4)	7.3 (18.8)	6.7 (18.9)
	SB	13.4 (20.6)	10.6(16.9)	6.8 (17.6)	6.7 (17.0)	12.2 (24.7)
	ES	14.1 (23.6)	9.0 (15.8)	6.8 (17.7)	5.1 (14.8)	7.2 (19.9)
	MR	3.6 (9.3)	2.3 (8.2)	1.8 (6.6)	0.8 (2.8)	1.7 (5.9)
	SIP68	**7.7 (10.9)**	**5.8 (6.7)**	**4.3 (10.3)**	**4.5 (10.1)**	**6.1 (12.0)**
Inpatient	SA	1.4 (4.1)	1.2 (2.6)	0.7 (2.5)	0.8 (2.4)	0.7 (2.8)
	MC	9.7 (14.2)	8.3 (11.8)	7.8 (16.1)	5.8 (14.0)	5.3 (14.1)
	PAC	13.7 (23.3)	12.7 (23.7)	12.3 (25.0)	14.8 (16.9)	6.5 (18.3)
	SB	23.7 (24.3)	25.0 (21.2)	18.6 (26.4)	10.7 (19.5)	9.6 (13.3)
	ES	21.8 (28.1)	23.3 (19.0)	15.4 (29.2)	11.9 (25.5)	6.8 (17.0)
	MR	7.1 (13.9)	32.0 (39.6)	5.5 (12.1)	3.7 (9.9)	2.3 (7.1)
	SIP68	**12.9 (12.4)**	**17.1 (11.3)**	**10.1 (14.7)**	**8.0 (12.3)**	**5.2 (8.6)**

$p<0.001$) directly following treatment, which remained significant after 3 months of follow-up (SIP68, $p<0.01$; PDI, $p<0.001$). At the end of the study the PDI worsened significantly ($p<0.05$) when compared with 3 months' follow-up. Comparing the SIP68 sub-domains at the start of treatment with 3 months' follow-up, a significant improvement was observed in Social Behaviour ($p<0.01$).

Inpatient treatment did not lead to a statistically significant improvement in the SIP68 score directly following treatment. At 3 months' follow-up, the improvement in HRQoL became significant (SIP68, $p<0.05$; PDI, $p<0.001$). From 3 months' follow-up to the end of the study the PDI score showed a significant worsening ($p<0.001$). Comparing the sub-domains of the SIP68 from the start of treatment with 3 months' follow-up, a significant improvement could be observed for Social Behaviour ($p<0.01$).

Inpatients scored significantly worse on both HRQoL instruments at the start of treatment compared with the other two treatment groups; they also remained at a relatively higher level during the study. At the end of treatment inpatients scored significantly worse on the SIP68 ($p<0.01$) compared with patients with short contact treatment; this difference remained significant up to 3 months' follow-up ($p<0.05$). Compared with both other treatment modalities the Social Behaviour sub-domain of the SIP68 for inpatient treatment was impaired more at the start and the end of treatment ($p<0.01$). At the end of treatment, additionally inpatient treatment scored worse in the Mobility Range sub-domain ($p<0.01$) compared with short contact treatment. At the end of the study both HRQoL scores became comparable for the three treatment modalities, except for the PDI score for inpatient treatment. This was significantly worse ($p<0.05$) than the PDI score for

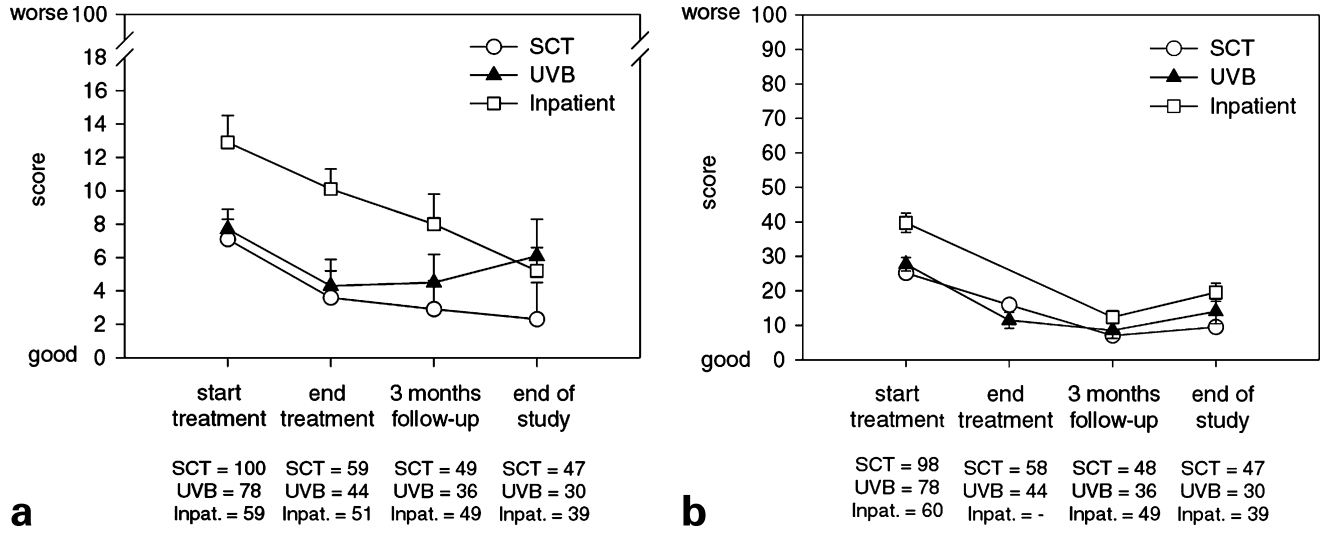

Fig. 2. (a) Mean SIP68 scores (SEM) and (b) mean PDI score (SEM) of short contact treatment (SCT), UVB phototherapy (UVB) and inpatient treatment (Inpat) at the four measurements, with the number of patients who completed the instrument.

short contact treatment. Although HRQoL was impaired more in inpatient treatment, and it did not lead to a significant improvement in HRQoL at the end of treatment, the actual gain in HRQoL was comparable for any of the three treatment modalities at 3 months' follow-up.

DISCUSSION

In our study short contact dithranol treatment, UVB phototherapy and inpatient dithranol treatment all led to an improvement in HRQoL, although at different time intervals following therapy. Improvement in HRQoL following different local, systemic, combined or inpatient treatments has been reported in many other studies (7, 25, 26). Inpatients are known to score worse on HRQoL instruments, reporting more anxiety and depression, an impaired ability to express anger, and having worse scores for irritability and aggression (27, 28). Inpatient treatment in this study also led to worse HRQoL scores than the other two treatment modalities; although inpatient treatment resulted in a higher clinical response rate (Fig. 1) and the treatment time was shorter, there was no improvement in HRQoL at the end of treatment. Only after 3 months of follow-up the HRQoL of inpatients showed significant improvement. The worse HRQoL score at the end of treatment is thought to be partly due to clinical treatment itself, as this substantially impairs a person's social and leisure time activities. The fact that inpatients showed higher impairment in the sub-domains Social Behaviour and Motor Range supports the assumption that inpatients are substantially disabled because of hospitalization. This assumption may also explain why the HRQoL scores improved during the follow-up. It reflects the improved appraisal of HRQoL due to the return of the patient to their normal social surroundings. A significant improvement in Emotional Stability following treatment was only observed after short contact treatment. Probably this is a direct consequence of the care instruction programme used, which gives the patient a feeling of control over the disease and consequently might positively affect their emotional stability.

The individual perception of living with psoriasis varies considerably. A correlation between the PDI and the SIP on one hand and the clinical severity of the psoriasis on the other hand was hardly ever found in other studies (28). We observed such a correlation only once, at 3 months' follow-up in the inpatient group. A possible explanation might be that following inpatient treatment, the remission period was shorter compared with the other two treatment modalities. The (rather rapidly) recurring psoriatic lesions might negatively influence a patient's emotional and behavioural reaction to these recurring lesions, and consequently yield worse HRQoL scores.

Developed as a general measure of health and focused primarily on performance- and activity-based dimensions, the SIP68 was not expected to score high in patients with psoriasis, who in general are healthy and active (7). Although the original SIP has been used successfully in psoriasis studies (7, 11), the SIP68 was never used in this field before. Studies using the SIP68 in other patient populations can be used as an indicative point of reference. Our patients with psoriasis experienced impairment comparable to patients suffering from Crohn's disease (SIP68 = 8.7), ankolysing spondylitis (SIP68 = 13.7) or patients with back and neck complaints (SIP68 = 7.6). They experienced far less impairment in general HRQoL compared with patients with a spinal lesion (SIP68 = 29.6) or with cancer (SIP68 = 16.9) (29). The PDI scores we found are

consistent with PDI scores reported in other studies on HRQoL in psoriasis patients (11, 12, 23, 30, 31).

The fact that at the start of treatment inpatients already scored higher on both HRQoL instruments compared with patients treated with short contact treatment or UVB might be interpreted as a drawback of this study. A possible cause could have been the randomization procedure that might have partially led to a selection bias. This is possibly also mirrored in the (not significant) higher PASI and area% scores of inpatients at the baseline measurement. The three parallel randomization strata were chosen because of the clinical set-up of this study (e.g. treatments were too different to offer them to everybody). If we had not conducted the study in this way, we would never have been able to include a substantial number of patients.

The higher scores in the inpatient group might also be attributed to a difference in patients' perceptions of their disease. Patients who experience their psoriasis as very severe and disabling, will probably have less problems with inpatient treatment than patients who are less disabled by their psoriasis. Consequently, the knowledge that treatment was going to be provided clinically might have meant that these patients went on to experience their psoriasis as more impairing. Psoriasis can be rather therapy-resistant. We did not incorporate previously given therapies and therapy results in the analysis of this study. It might be useful in following studies to do so.

Although the gain in HRQoL at 3 months' follow-up in any of the three treatment modalities was equal, inpatient treatment induced a smaller improvement of HRQoL scores than short contact treatment or UVB up to 3 months' follow-up. However, the clinical scores were best for inpatient treatment, with only 5 of 60 patients (8.3%) with a therapy failure compared with 35 of 100 patients (35%) treated with short contact treatment and 30 of 78 (38.5%) patients treated with UVB. Still, when comparing HRQoL following short contact treatment with HRQoL following inpatient treatment, short contact treatment deserves preference.

In conclusion, HRQoL measurements in psoriasis patients show differences between treatments but do not seem to be suitable to replace clinical outcome measures. They certainly are an advantageous additive measure besides clinical outcome measures, as they show what a treatment comprises for the patient. When choosing a suitable psoriasis treatment that matches with the individual needs of the patient, HRQoL data can help the clinician in making a choice.

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