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ORIGINAL ARTICLE

Design and Validation of a Questionnaire to Measure Treatment Satisfaction in Patients With Moderate-to-Severe Psoriasis: the NEODERMA Study

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Satisfaction questionnaire;
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Spanish Satisfaction With Treatment of Psoriasis Questionnaire (SSTPQ)

Abstract

Background and objectives: The aim of this study was to design and assess the validity, reliability, and sensitivity to change of the Spanish Satisfaction With Treatment of Psoriasis Questionnaire (SSTPQ) for use in patients with moderate-to-severe psoriasis.

Patients and methods: A prospective, multicenter, observational, naturalistic study was designed. The instrument consisted of 12 items scored on a 5-point Likert scale with scores from 0 (very satisfied) to 5 (very unsatisfied), generating a total score of 0 to 48. Patients completed the questionnaire at baseline and then at 3-, 6-, 9-, and 12-month follow-up. At each visit, data were also collected on the Psoriasis Area and Severity Index (PASI), treatment adherence (Morisky-Green questionnaire), and overall treatment satisfaction on a Visual Analogue Scale (VAS) from 0 to 100.

Results: A total of 423 patients were included in the study and 68% completed 12 months of follow-up. Responses were provided to all items in 98.8% of cases. There was a weak correlation between changes in treatment satisfaction on the SSTPQ and changes in PASI score (r=0.38 to 0.33); in contrast, there were strong correlations with changes in the VAS score for overall treatment satisfaction (r=–0.75 to –0.81). Good internal consistency was

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[◊]See Appendix 1 for a list of the members of the NEODERMA Study Group.

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observed (Cronbach α=0.92). The intraclass correlation coefficient was 0.89, with a mean difference in score at 3- and 6-month follow-up of 0.07.
Conclusions: The results obtained suggest that the SSTPQ is a feasible, valid, and reliable tool for the assessment of treatment satisfaction in patients with moderate-to-severe psoriasis.
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PALABRAS CLAVE
Cuestionario de satisfacción;
Tratamiento;
Psoriasis;
Validez;
Fiabilidad;
CESTEP

Diseño y validación de un cuestionario para medir la satisfacción con el tratamiento del paciente con psoriasis moderada y grave: estudio NEODERMA

Resumen
Introducción y objetivos: El objetivo del estudio fue diseñar y evaluar la validez, fiabilidad y sensibilidad al cambio de un cuestionario de satisfacción del tratamiento para el paciente con psoriasis moderada y grave, denominado CESTEP (Cuestionario Español de Satisfacción de Tratamiento en Psoriasis).
Pacientes y métodos: Se diseñó un estudio observacional, prospectivo, naturalístico y multicéntrico. El cuestionario estaba formado por 12 ítems, cada uno de los cuales se valoraba con una escala de tipo Likert con respuestas puntuables de 0 (muy satisfecho) a 5 (muy insatisfecho) (puntuación total de 0 a 48). Los pacientes cumplimentaron el cuestionario de satisfacción en la visita basal y a los 3, 6, 9 y 12 meses de seguimiento. En cada visita se recogieron también las variables clínicas (índice PASI), la adherencia con el tratamiento (cuestionario Morisky-Green) y la valoración global de la satisfacción con el tratamiento mediante una escala analógica visual (EAV) de 0 a 100.
Resultados: Se incluyeron un total de 423 pacientes, de los cuales el 68% finalizaron los 12 meses de seguimiento. El 98,8% de los pacientes completaron todas las preguntas del cuestionario. Los cambios en el cuestionario de satisfacción y en el índice PASI durante el estudio se correlacionaron de manera baja (r de 0,38 a 0,33), pero se observaron, en cambio, correlaciones altas con los cambios en la EAV de satisfacción (*r* de −0,75 a −0,81). Se obtuvo una buena consistencia interna (α de Cronbach de 0,92). El coeficiente de correlación intraclase era de 0,89, con una diferencia media en las puntuaciones, entre la visita a los 3 meses y a los 6 meses de 0,07 puntos.
Conclusiones: Los resultados obtenidos indican que el cuestionario CESTEP para la evaluación de la satisfacción del tratamiento en pacientes con psoriasis moderada y grave puede ser utilizado para tal finalidad, ya que se ha mostrado factible, válido y fiable.
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Introduction

Many patients with moderate or severe psoriasis consider that their quality of life is seriously compromised by the physical, emotional, and social impacts of their condition. Furthermore, in patients with severe psoriasis, there is a general feeling that the treatment they are receiving is ineffective and does not offer them the results they expect.[1,2] Health-related quality of life in patients with psoriasis has been evaluated in numerous studies and systematic reviews.[3,4] A range of previously validated evaluation tools have been used in these studies, including generic multidimensional quality-of-life instruments as well as instruments specifically targeting patients with skin disorders[5-8] and psoriasis in particular.[9,10] Patient-centered measurements are becoming increasingly important in the evaluation of treatment effectiveness, and a growing number of clinical trials are including quality of life as an outcome measure for the assessment of treatments for psoriasis.[11,12]

Furthermore, patient satisfaction and expectations are gaining importance and relevance as indicators of health care and service quality and of the outcomes of specific treatments; indeed there has been a proliferation of conceptual frameworks, targeted surveys, and studies in this area.[13-15] Patient satisfaction relates to a patient's appraisal of the main features of the health care process, the physician-patient relationship, and general experiences with treatment.[16] Assessing patient satisfaction is a valuable component of studies designed to identify differences between treatments and monitor results, and can also make a useful contribution to decision-making processes and organization of health care services. One of the greatest difficulties associated with measuring patient satisfaction is that it is not a single construct but rather a blend of perceptions and values that are all influenced by many factors such as age, sex, education, socioeconomic status, disease severity, treatment adherence, functional status, outcomes, level of trust, and individual experiences and expectations. Accordingly, measuring patient satisfaction

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using appropriate, reproducible methods poses serious challenges.[17,18]

Few studies have analyzed patient satisfaction with psoriasis treatments and none have used validated instruments specifically designed for this purpose.[19-22] Because patient preferences and satisfaction are important aspects that need to be further explored, we decided to design and validate a Spanish-language questionnaire to measure treatment satisfaction in patients with psoriasis. The aim thus of this study was to design and validate a treatment satisfaction questionnaire for patients with moderate or severe psoriasis.

Patients and Methods

Design and Objectives

We designed a prospective, naturalistic, observational, multicenter study in Spain. The primary objective of the study was to evaluate the validity, reliability, and sensitivity to change of a treatment questionnaire specifically designed for patients with moderate to severe psoriasis. The questionnaire is called the SSTPQ (Spanish Satisfaction With Treatment of Psoriasis Questionnaire). The secondary objectives were to analyze patient satisfaction in relation to treatment effectiveness and tolerability and to evaluate possible differences in satisfaction depending on the treatment received.

Questionnaire Design

Following a review of the literature to examine the current state of knowledge and an analysis of treatment satisfaction questionnaires designed for other diseases[23-25] and existing quality-of-life questionnaires in the area of dermatology,[26,27] it was decided to include the following domains in the SSTPQ: symptoms, benefits and convenience of treatment, knowledge of psoriasis, fulfilment of expectations, and overall satisfaction. The first version of the questionnaire contained 20 items and was reviewed by dermatologists with experience in the treatment of psoriasis. We also contacted Acción Psoriasis, a Spanish association of patients with psoriasis, to request their help with evaluating the suitability of the questions. All the collaborators were told that the aim of the questionnaire was to evaluate treatment satisfaction in patients with psoriasis, and were asked to suggest, where appropriate, new questions or modifications to existing questions. After this initial semantic and content validity analysis, 8 items were deleted, leaving a total of 12 items. Each item was rated on a 5-point Likert-type scale (0, very satisfied; 1, satisfied; 2, neither satisfied nor unsatisfied; 3, unsatisfied; and 4, very unsatisfied). The total score was calculated by adding the individual scores for each item. The total possible score thus ranged from 0 (greatest possible satisfaction) to 48 (least possible satisfaction). A visual analog scale (VAS) for assessing overall satisfaction with treatment was added at the end of the questionnaire. This scale ranged from 0 (worst possible score) to 100 (best possible score). An English translation of the original Spanish questionnaire is provided in Appendix 2.

Patients and Administration of Questionnaire

Between September 2003 and December 2004, 96 dermatologists, all members of the NEODERMA study group and located in different parts of Spain, voluntarily agreed to recruit male and female patients with a diagnosis of moderate psoriasis (psoriasis area and severity index [PASI] score of 10-15) or severe psoriasis (PASI score of >15)[6] seen in routine clinical practice; the patients had to be over 18 years old and receiving treatment for their psoriasis. Recruitment was consecutive and nonrandomized, and signed informed consent was a requirement. Patients with medical or psychological conditions which, in the investigators' opinion, might have prevented them from participating adequately in the study or giving their consent were excluded.

The study lasted for 12 months. After recruitment at the baseline visit (visit 1), the patients were followed up at 3, 6, 9, and 12 months, although the investigators were able to schedule additional visits if they considered this necessary. The treatment prescribed in each case was left to the discretion of the investigator. During the baseline visit, a history was taken and a detailed physical examination performed, with the recording of the following data in an electronic case report form: sociodemographic variables; concomitant diseases; PASI score; psoriasis treatment in the previous 3 months; current psoriasis treatment; adverse treatment effects; variables used to monitor systemic treatments (serum creatinine levels and blood pressure in patients on oral ciclosporin, complete blood count and liver function tests in patients on methotrexate, and liver function and lipid profile in patients on acitretin); and treatment adherence based on the 4-item self-reported adherence measure described by Morisky and Green[28] (4 adequate answers indicated high treatment adherence, 2 or 3 adequate answers indicated moderate adherence, and 3 or 4 inadequate answers indicated nonadherence). With the exception of sociodemographic variables and information on concomitant diseases and previous psoriasis treatment, the above data were recorded at each follow-up visit.

During the visits, patients rated their satisfaction with the treatment they were receiving by completing the 12-item SSTPQ. At the baseline visit, only patients who had received treatment in the 3 previous months completed the questionnaire.

The study was approved by the clinical research ethics committee at Hospital Vall d'Hebron in Barcelona and all the participants signed an informed consent form.

Statistical Analysis

For the test-retest reliability analysis, it was estimated that a sample of 63 patients would be sufficient to obtain an intraclass correlation coefficient (ICC) of 0.70 or higher (assuming a minimum coefficient of 0.6) for an α level of .05 and a power of 0.80. Assuming a loss to

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Table 1 Distribution of Patients With Moderate and Severe Psoriasis Throughout the Study Period

	Reasons for Study Noncompletion				
	Loss to Follow-up	Patient's Decision	Physician's Decision	Other	Death
Visit 1 (baseline) (n=423)					
Between visits 1 and 2	41	9	1	1	1
Visit 2 (3 months) (n=370)					
Between visits 2 and 3[a]	33	1	1	1	
Visit 3 (6 months) (n=333)					
Between visits 3 and 4[b]	14	3	2	2	
Visit 4 (9 months) (n=311)					
Between visits 4 and 5	22	1		1	
Visit 5 (12 months) (n=288)					

[a]One patient did not come to the third visit but continued in the study.
[b]One patient did not come to the fourth visit but continued in the study.

follow-up of 10%, it was decided to include 70 patients in this analysis. For the sensitivity-to-change test, it was calculated that 197 patients would be sufficient to detect small differences (0.2 SDs) in scores between questionnaires completed at 2 different time points (baseline and 3 months) with an α level of .05 and a power of 0.80. Assuming a loss to follow-up of 15% in this case, it was decided that 232 patients should be included in the sensitivity-to-change analysis. As this sample size was higher than that required for the test-retest reliability analysis, it was decided to evaluate the 2 properties in the larger group (232 patients).

The feasibility of completing the questionnaire was evaluated by analyzing the percentage of questions left unanswered for each item and for the questionnaire as a whole. To evaluate the adequacy of the 12 items, we performed exploratory principal component analysis and varimax rotation, with the Kaiser-Meyer-Olkin measure of sampling adequacy and the Bartlett test of sphericity, using the scores for the 12 items given at the baseline visit. Construct validity was assessed using Pearson correlation coefficients between questionnaire scores, PASI scores, and VAS scores from the baseline visit. The longitudinal validity of the questionnaire (the ability to detect changes) was tested with Pearson correlation coefficients between changes in questionnaire scores and PASI scores at 3, 6, 9, and 12 months compared to baseline; we also calculated the magnitude of the effect size (small, 0.2-0.5; moderate, >0.5-0.8; and large, >0.8). Internal consistency was analyzed by calculating Cronbach α. Test-retest reliability was evaluated by calculating the ICC between the scores from the 3-month and 6-month follow-up visits in patients in whom there were no changes in either treatment or treatment satisfaction scores. The remaining variables were analyzed using the Mann-Whitney test, the Friedman test, or the Fisher exact test, as appropriate. All calculations were performed using the SPSS statistical package (version 10.3) for Windows. Statistical significance was set at a value of P less than .05.

Results

Description of Population and Overall Results

A total of 499 patients were recruited but 76 were excluded for the following reasons: age of less than 18 years (n=1), PASI score of less than 10 (n=62), and missing satisfaction questionnaire (n=13). Of the remaining 423 patients, 288 completed the study. Loss to follow-up was the main reason for noncompletion of the study (81.5% of all such cases) (Table 1).

There were 262 men and 161 women. The mean (SD) age was 45.9 (13.9) years (range, 18-83 years) and the mean body mass index was 26.7 (4.8) kg/m^2. Concomitant diseases were recorded in 196 patients (46.3%). The most common were endocrine metabolic disorders (102 patients), hypertension (n=76), and depression (n=17). Almost a third (31.4%) of these patients were being medicated for their condition. The mean PASI score was 21.4 (9.2); 112 patients (26.5%) had moderate psoriasis and 311 (73.5%) had severe psoriasis.

In the 3 months prior to inclusion, 419 patients (99.1%) had received treatment for psoriasis. The most common treatments were topical corticosteroids (60.6%), calcipotriol (37.9%), and moisturizing agents/emollients (27.9%). Topical treatments had been prescribed to 57% of the patients and a combination of systemic and topical treatment to 20.3%. Only 6 of these 419 patients, however, had achieved complete clinical remission. Table 2 shows the treatments the patients were receiving at baseline and at the 4 follow-up visits. The most common systemic treatment was ciclosporin alone or in combination; this was being taken by 72.6% of the patients at baseline, 65.4% at 3 months, 49.8% at 6 months, 34.3% at 9 months, and 34.3% at 12 months. Under 10% of patients were on no treatment at some point during the study period. Nonetheless, at the 12-month visit, 42% of patients were on topical treatment only. The proportion of patients in whom treatment was changed ranged from 40% to 48% over the course of the study (Figure 1).

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Table 2 Main Treatments Received by Patients at Baseline and During the Study[a]

Treatment	Baseline (n=423)	Follow-up Period			
		3 mo (n=361)	6 mo (n=361)	9 mo (n=361)	12 mo (n=288)
No treatment	0	14 (3.9)	16 (4.8)	21 (6.8)	27 (9.4)
Topical treatment	35 (8.3)	41 (11.4)	81 (24.3)	95 (30.5)	121 (42.0)
Combined systemic treatment	2 (0.5)	5 (1.4)	8 (2.4)	4 (1.3)	5 (1.7)
Combined systemic treatment+ topical treatment	2 (0.5)	6 (1.7)	7 (2.1)	7 (2.3)	1 (0.3)
Ciclosporin	131 (31.0)	92 (25.5)	54 (16.2)	40 (12.9)	42 (14.6)
Ciclosporin+topical treatment[b]	176 (41.6)	144 (39.9)	102 (30.6)	67 (21.5)	34 (11.8)
Acitretin	10 (2.4)	11 (3.0)	6 (1.8)	5 (1.6)	10 (3.5)
Acitretin+topical treatment	14 (3.3)	12 (3.3)	15 (4.5)	16 (5.1)	9 (3.1)
Methotrexate	14 (3.3)	6 (1.7)	8 (2.4)	9 (2.9)	5 (1.7)
Methotrexate+topical treatment	15 (3.5)	15 (4.2)	17 (5.1)	23 (7.4)	13 (4.5)
Etanercept	4 (0.9)	3 (0.8)	0	0	0
Etanercept+topical treatment	0	0	1 (0.3)	4 (1.3)	3 (1.0)
Phototherapy	20 (4.7)	11 (3.0)	18 (5.4)	19 (6.1)	15 (5.2)
Fumaric acid	1 (0.3)	0	1 (0.3)	0	0
Efalizumab+topical treatment	0	0	0	0	2 (0.7)
Infliximab+topical treatment	0	0	0	0	1 (0.3)

[a]Data are shown as numbers (percentages) of patients.

[b]Main topical treatments combined with oral ciclosporin: corticosteroids, calcipotriol, coal tar, moisturizing agents/emollients, acetylsalicylic acid (dual, triple, or quadruple combination).

Thirty-eight patients (9%) experienced adverse effects and in 21 of these the effects were drug related. The offending drug was ciclosporin in 71.4% of cases, methotrexate in 19% of cases, and acitretin in 4.8% of cases. The most common adverse effects were gastrointestinal disorders (21.1%), sensorimotor disorders (tremors, cramps, paresthesias) (21.1%), hypertension (13.2%), and endocrine metabolic disorders (13.2%). The symptoms were mild in 3 cases, moderate in 33 cases, and serious (pulmonary tuberculosis and hypertension) in 2 cases. Treatment was discontinued permanently in the 2 patients with serious adverse effects, and 1 of them required hospitalization. Treatment was also discontinued permanently in 9 other patients; temporary interruption or dose adjustments were considered necessary in 13 patients.

Of the patients who received ciclosporin at some point during the study period, 4.8% developed elevated serum creatinine levels and 51.5% experienced an increase in

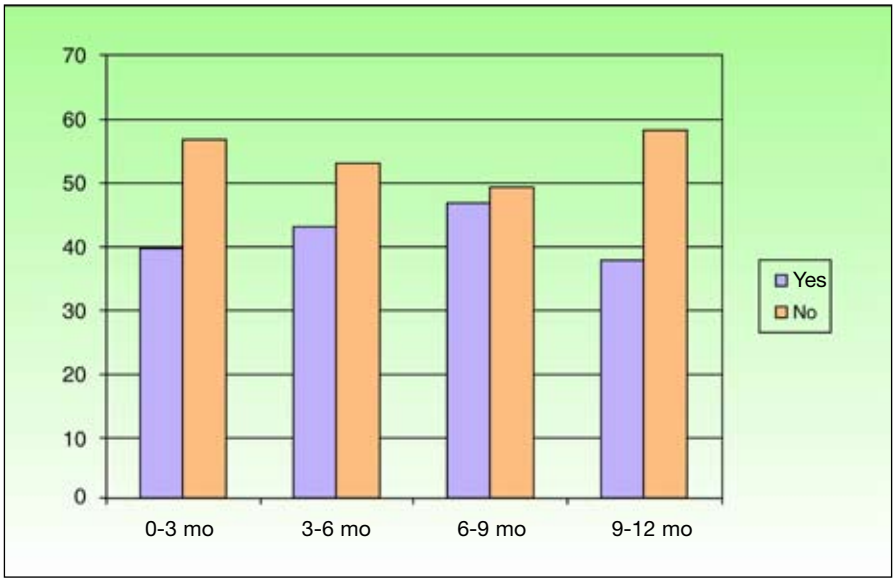

Figure 1 Percentage of patients in whom treatment was changed during the study.

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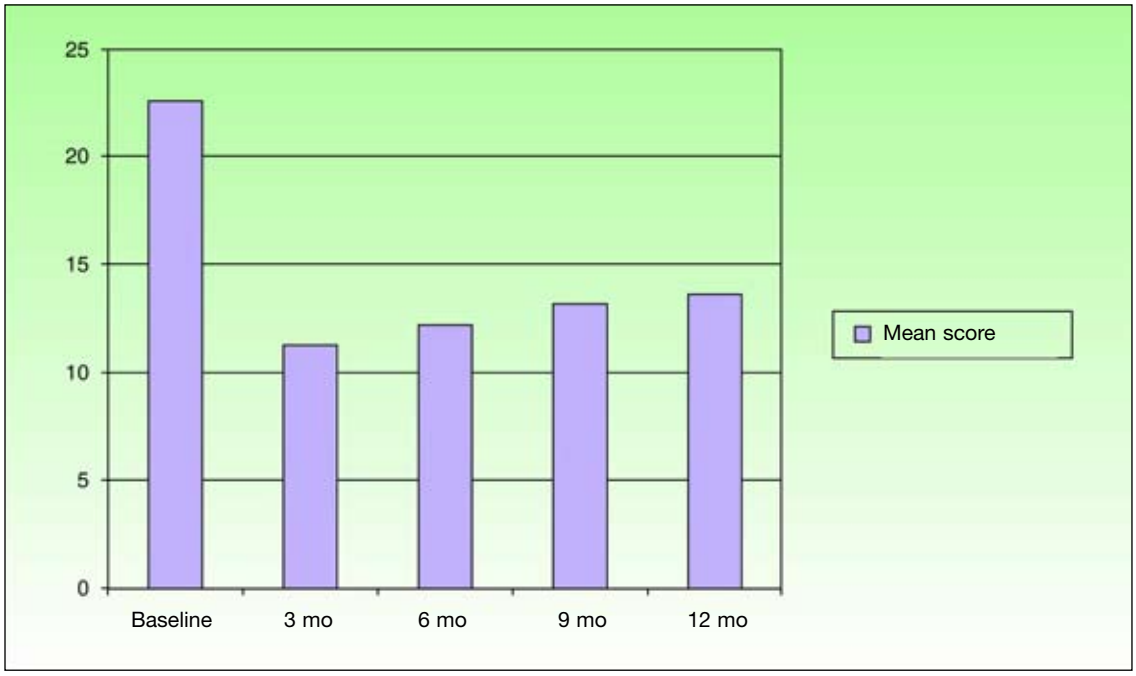

Figure 2 Changes in mean satisfaction scores measured by the questionnaire during the study period (lower scores indicate greater satisfaction).

blood pressure. Hypercholesterolemia was detected in 43.1% of patients treated with acitretin and increased gamma-glutamyl transpeptidase levels in 28.3% of those treated with methotrexate.

Overall treatment adherence improved significantly ($P<.01$) over the course of the study, with the proportion of those giving 4 adequate answers in the Morisky-Green test increasing from 40% at baseline to 60.8% at 3 months, 55.6% at 6 months. 56.1% at 9 months, and 55.6% at 12 months.

Validation of Questionnaire

At the baseline visit, 4 patients reported not having received any treatment in the previous 3 months. The remaining 419 patients completed the satisfaction questionnaire; missing answers were detected in just 5 (1.2%) of the questionnaires, meaning that 98.8% of the patients who completed the questionnaire answered all the items.

The measure of adequacy of the questionnaire items obtained in the factorial analysis was 0.943 (Bartlett test of sphericity, $P<.001$), with a single dimension explaining 54.6% of the original variance.

The mean (SD) questionnaire score was 22.6 (9.5) for patients with moderate psoriasis and 27 (2.6) for those with severe psoriasis ($P=.49$). Baseline scores were weakly, though significantly, correlated with PASI scores ($r=0.145$, $P<.003$) and strongly correlated with VAS scores ($r=-0.806$, $P=.001$). The same tendency was observed during the follow-up visits, with correlation coefficients of between 0.38 and 0.33 for PASI scores and between −0.75 and −0.81 for VAS scores. Satisfaction scores measured by the questionnaire for patients whose disease severity did not change between baseline and follow-up varied by between 0.56 and 2.51 points, with a small effect size (<0.3). In contrast, the scores of patients whose disease improved over the course of the study changed by between 10.66 and 13.65 points, with a large effect size (of between 1.13 and 1.49). The overall effect size was 1.21 at 3 months, 1.07 at 6 months, 0.86 at 9 months, and 0.92 at 12 months.

A Cronbach α of 0.92 was obtained for the internal consistency analysis. In the test-retest reliability analysis conducted in 111 patients whose treatment did not change between the 3-month and the 6-month visit and who had a VAS score difference of less than 10 points, the ICC was 0.89, with a mean difference in questionnaire scores of 0.07 (6.28) points.

The mean satisfaction scores recorded during follow-up ranged from 11.3 (7.5) at 3-month follow-up to 13.6 (8.5) at 12-month follow-up (Figure 2). As shown in Table 3, the overall satisfaction scores were better in patients receiving systemic treatment (either alone or in combination with topical treatment) than in those receiving topical treatment alone. The difference was particularly remarkable at 3 and 6 months. Similar findings were seen for the VAS scores. The rate of high treatment adherence was also higher in patients receiving systemic treatment.

The mean PASI score was 7.0 (7.8) at 3 months, 6.7 (7.3) at 6 months, 7.2 (7.9) at 9 months, and 6.5 (6.8) at 12 months, with statistically significant differences ($P<.01$) with respect to the mean baseline score of 21.4 (9.2). The changes in PASI scores during follow-up were weakly, though significantly ($P<.01$), correlated with changes

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Table 3 Treatment Satisfaction and Adherence By Type of Treatment

	Systemic Treatment			Phototherapy	Topical Treatment
	Monotherapy	Topical Treatment	Combined		
Satisfaction questionnaire scores, mean (SD)					
Baseline	18.1 (8.2)	19.6 (9.1)	18.2 (8.0)	22.5 (10.1)	24.8 (9.2)
3 mo	9.6 (6.0)	11.6 (7.7)	26.0	10.7 (5.5)	18.6 (10.9)
6 mo	11.8 (8.1)	11.1 (7.1)	14.2 (14.1)	9.5 (2.1)	18.0 (7.0)
9 mo	13.9 (9.7)	12.8 (7.7)	10.0 (5.8)	10.1 (9.3)	14.0 (10.0)
12 mo	12.5 (7.4)	11.9 (7.3)	16.5 (8.4)	15.0 (10.7)	14.9 (9.5)
Visual analog scale scores, mean (SD)					
Baseline	50.5 (29.5)	48.8 (27.4)	50.6 (27.0)	42.7 (31.1)	35.8 (27.3)
3 mo	77.0 (20.7)	67.6 (27.4)	30.0	80.8 (19.3)	45.7 (36.8)
6 mo	70.5 (25.7)	71.1 (23.1)	65.8 (27.0)	87.5 (3.5)	51.5 (26.2)
9 mo	65.2 (27.5)	65.4 (25.0)	77.2 (13.4)	80.7 (17.9)	60.6 (29.6)
12 mo	69.4 (29.0)	65.6 (28.5)	61.7 (28.1)	70.2 (28.5)	61.2 (29.4)
High treatment adherence,[a] no. of patients (%)					
Baseline visit	31 (63.3)	35 (42.2)	7 (70)	15 (40.5)	77 (32.6)
3 mo	54 (74)	70 (55.6)	1 (100)	2 (33.3)	6 (60)
6 mo	35 (70)	55 (53.9)	2 (40)	1 (50)	7 (31.8)
9 mo	22 (75.9)	34 (48.6)	4 (80)	4 (57.1)	20 (45.5)
12 mo	26 (81.3)	31 (60.8)	3 (50)	7 (87.5)	23 (33.3)

[a]Four adequate answers on the Morisky-Green test.[28]

in questionnaire scores (r=0.378 at 3 months, r=0.348 at 6 months, r=0.326 at 9 months, and r=0.354 at 12 months) (Figure 3). At 12 months, the improvement in PASI scores was 64.3% for systemic treatment alone, 75.1% for combined systemic and topical treatment, and 60.8% for topical treatment alone.

At the 3-month visit, patients who did not experience any adverse effects had a significantly better questionnaire

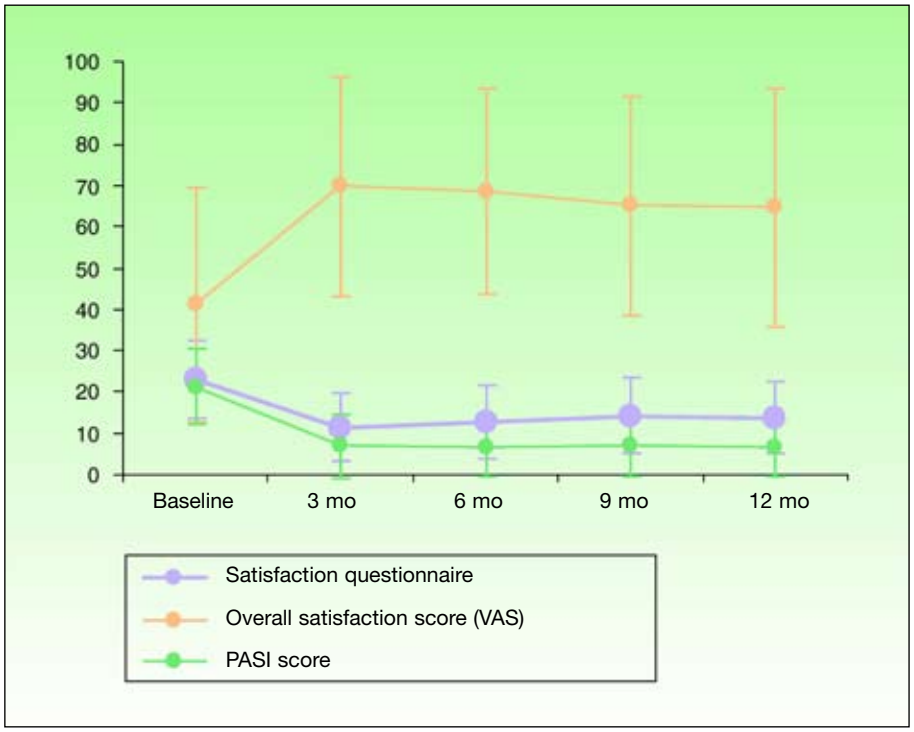

Figure 3 Changes in satisfaction questionnaire scores, visual analog scale (VAS) scores, and psoriasis area and severity index (PASI) scores during the 12-month follow-up period.

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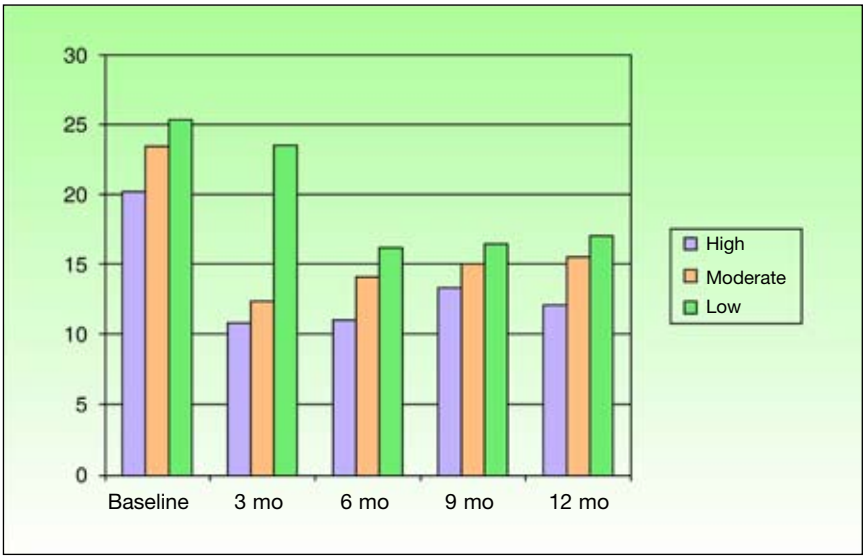

Figure 4 Association between mean satisfaction questionnaire scores (lower scores indicate greater satisfaction) and treatment adherence classified according to the Morisky-Green test[28] as low, moderate, or high.

score than those who did (11.0 [7.5] vs 16.2 [11.5], *P*<.01). Those who adhered well to treatment also expressed a greater sensation of satisfaction (Figure 4).

Discussion

The findings of the present study indicate that the SSTPQ, a 12-item questionnaire designed to evaluate treatment satisfaction in patients with moderate or severe psoriasis, can indeed be used for the purpose with which it was designed as it not only proved feasible to complete but also satisfied the established validity and reliability criteria. The questionnaire, thus, represents an important step towards meeting the increasing need for the use of patient-centered measurement tools to contribute to the evaluation of the effectiveness of treatment and perceived quality-of life in patients with psoriasis.

Knowing how satisfied or unsatisfied a patient is with a particular treatment in terms of the improvement or worsening of symptoms is an important part of evaluating dermatology treatments, particularly in chronic diseases or within the framework of clinical trials. Nevertheless, several studies have shown that this aspect of treatment evaluation is generally overlooked. A systematic review of 125 randomized clinical trials published between 1994 and 2001 in 5 international dermatology journals showed that just 32 (25.6%) of these trials analyzed efficacy variables related to patient opinions and just 17 (13.6%) mentioned these variables in the introduction or methods sections.[11] Even though patient-centered variables are often reported in dermatological studies, including those of psoriasis, the information provided is often incomplete or deficient, probably because of the scarce attention paid to these variables. In the case of patient satisfaction with treatment, the lack of specific, validated instruments is an additional problem.

The internal consistency of the SSTPQ (α=0.2) can be considered optimum. A noteworthy feature of the questionnaire was the low percentage of questions left blank; this ranged from 0.2% to 0.7% for individual items, and was just 1.2% for the questionnaire as a whole. The fact that 98.8% of the respondents answered all the questions demonstrates not only that they were interested in having their opinion heard, but also that the questionnaire was attractive to them. It can thus be considered that the SSTPQ can be administered to the vast majority of Spanish-speaking patients with moderate or severe psoriasis and aged over 18 years. While based on psychometric methodologies, the questionnaire was also designed with input from groups of experts in the treatment of psoriasis as well as from patients (represented by the Spanish psoriasis association, Acción Psoriasis). Measurement instruments which take into account the opinions and preferences of target populations offer considerable added value. We also compared VAS and PASI scores to test the longitudinal validity and sensitivity to change of the questionnaire. The test-retest reliability analysis in patients whose treatment remained unchanged between the 3-month and the 6-month visit revealed an ICC of 0.89 (mean difference in questionnaire scores of 0.07 points).

The mean satisfaction score measured by the questionnaire during follow-up (13.3) was lower than the baseline score of 22.6 (corresponding to previous treatments), indicating a substantial improvement in the perceived effectiveness of treatment over the course of the study.

Questionnaire scores were weakly, though significantly, correlated with PASI scores, and strongly correlated with VAS scores both at baseline and during the follow-up visits. In patients whose disease severity remained unchanged during the study, the questionnaire proved to be sensitive

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to treatment-related changes, with an effect size ranging from under 0.3 at baseline to over 0.8 during follow-up (0.92 at 12 months). As expected, treatment satisfaction was higher in patients who had no adverse effects and in patients with high adherence. On analyzing satisfaction according to the type of treatment received, it was seen that systemic treatment were associated with greater satisfaction (measured by both the questionnaire and the VAS), particularly at the 3-month and the 6-month visit. The mean improvement in PASI scores at the end of the study was also better in patients who had received systemic treatment (alone or in combination) than in those who had received topical treatment only.

In conclusion, the SSTPQ may contribute to meeting the need for a simple, valid, and reliable tool for evaluating the impact of psoriasis treatment on patient satisfaction in routine clinical practice.

Conflict of Interest

The study was conducted with the support of Novartis Farmacéutica, S.A.

Dr Miquel Ribera Pibernat has participated in clinical trials, presentations, and consultancy work sponsored by Novartis, Wyeth, Schering-Plough, and Merck-Serono.

Dr Esteban Daudén Tello has served on an advisory board, acted as a consultant, received research grants and support, participated in clinical trials, and received honoraria as a speaker for the following pharmaceutical companies: Abbott, Astellas, Biogen, Centocor Ortho Biotech Inc., Galderma, Glaxo, Janssen-Cilag, Leo Pharma, Merck-Serono, Pfizer, Novartis, Schering-Plough, Stiefel, Wyeth Pharmaceuticals, and 3M.

Dr Luis Puig is a consultant for Novartis International.

Dr Vicente García-Patos Briones has participated in clinical trials, presentations, and/or consultancy work sponsored by Novartis, Wyeth, and Schering-Plough.

Dr José Manuel Herranz Hermosa has participated in clinical trials, presentations, and consultancy work sponsored by Novartis, Wyeth, Schering-Plough, Merck-Serono, Abbott, and Janssen-Cilag.

Dr Xavier Bordas Orpinell has participated in clinical trials, presentations, and consultancy work sponsored by Novartis, Wyeth, Schering-Plough, Merck-Serono, and Abbott.

Dr Francisco Vanaclocha Sebastián is a researcher or consultant for Abbott and Janssen-Cilag and has worked as a researcher or consultant for Merck-Serono, Novartis, Schering-Plough, and Wyeth.

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Appendix 1.

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Appendix 2. Spanish Satisfaction With Treatment of Psoriasis Questionnaire for Use in Patients With Moderate or Severe Psoriasis[a]

	Questions	Response				
		Very satisfied	Satisfied	Neither satisfied nor unsatisfied	Unsatisfied	Very unsatisfied
1	Are you satisfied with the way in which your treatment expectations were met?					
2	How satisfied are you with how the treatment relieved the discomfort of your skin disease (color, pain, stinging)?					
3	How satisfied are you with how the treatment reduced the extension of your psoriasis?					
4	How satisfied are you with how the treatment reduced the intensity (redness, scaling, bumps) of your psoriasis?					
5	Do you feel satisfied with the speed with which your psoriasis has improved?					
6	To what extent are you satisfied enough with the treatment to recommend it to someone with similar psoriasis to yours?					
7	Do you feel satisfied with how your treatment has agreed with you in the last 3 months?					
8	Are you satisfied with how practical/ convenient your treatment has been for you?					
9	Considering your psoriasis and the treatment you are receiving, do you feel satisfied with the frequency of visits to your doctor?					
10	Do you consider that the benefit of the treatment of your psoriasis outweighs the possible undesirable effects?					
11	How satisfied are you with your level of knowledge about available psoriasis treatments?					
12	How satisfied are you with your current treatment?					

Overall rating of satisfaction with treatment

Rate your overall satisfaction with the treatment from 0 to 100, where 0 is the worst possible score and 100 is the best possible score

0_____100

[a]This English version is an unvalidated translation of the questionnaire, provided only for purposes of understanding the present study.

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