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Development and Validation of the "Treatment Satisfaction with Medicines Questionnaire" (SATMED-Q)©

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ABSTRACT

Objective: To develop and validate a multidimensional generic questionnaire measuring satisfaction with treatment with medicines. The questionnaire was designed to be used in chronic patients undergoing pharmacological treatment for any disease.

Methods: After a literature review and cognitive debriefing process with an expert panel of six members and 21 chronic patients in four focus groups, a preliminary instrument with 36 items grouped into six dimensions was developed. Three samples of patients were enrolled during the whole process: 1) 12 patients to assess feasibility and pertinence of items; 2) 150 patients for item reduction; and 3) 455 patients for psychometric properties assessment of the instrument. The latter two were stratified by gender, age, and main disease (type 2 diabetes, hypertension, osteoarthritis, benign prostate hyperplasia, chronic obstructive pulmonary disease/asthma, depression, and migraine). Additional measures were gathered for concept validity: clinical and treatment information, patient and clinician assessment of treatment tolerability and effectiveness, treatment satisfaction (Treatment Satisfaction Questionnaire for Medication [TSQM]), and therapeutic compliance (Morisky-Green). Feasibility, reliability, and validity (content, discriminant, construct, and concurrent) were assessed.

Results: Factor analysis item reduction resulted in a 17-item questionnaire with six dimensions: treatment effectiveness, convenience of use, impact on daily activities, medical care, global satisfaction, and undesirable side effects. Unidimensional scales (Cronbach's alpha ranging 0.813–0.912) were correlated, and allowed computation of a summary composite score (alpha = 0.890). SATMED-Q dimensions showed moderate but significant correlations with TSQM dimensions (0.577–0.680). Differences between tolerability and effectiveness groups were found, depending on dimension and whether the clinician or the patient were informing. Therapeutic compliance groups showed differences in some treatment satisfaction dimensions.

Conclusions: The SATMED-Q is a reliable and valid measure of treatment satisfaction, structured in six dimensions, and a summary composite score. Additional work is needed to assess sensitivity to change.

Keywords: daily medical care, development, medicines, patient, psychometric properties, SATMED-Q, treatment satisfaction, validation.

Introduction

In recent years, there has been a series of health changes in the industrialized countries, directly resulting in the introduction of new concepts or elements to be considered in the evaluation and appraisal of health care. Among these changes, mention must be made of the spectacular increase in life expectancy, with the consequent aging of the population. This phenomenon is largely attributable to advances in medicine, and has resulted in changes in mortality and morbidity.

In the treatment of chronic illnesses, the traditional measures of morbidity and mortality, together with other biomedical parameters, only partially evaluate the effectiveness of drugs and other medical interventions which, while prolonging patient life, do not offer a cure. When the administered treatments do not modify the survival rates, when the differences among them are not dramatic, and when the treatments and other medical interventions produce serious side effects for months or even years, the need arises to evaluate effectiveness in other terms [1]. The investigation of health outcomes—a relatively recent discipline—focuses on the measurement of disease and treatment impact upon patient perceived health, among other things, and provides an answer to these new requirements of modern medicine [2,3].

Patient satisfaction is related to all aspects of health care that are of relevance to health. The concept includes satisfaction with both the medical care

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received, and with the specific treatments prescribed [4,5]. Patient satisfaction can be conceived as a pyramid where satisfaction with health care is located at the base. This element is related to all aspects of the care received, and includes patient satisfaction with access to medical care, physician behavior and technical competence, the services provided, the costs, and the treatment selected. At an intermediate level lies global treatment satisfaction, which includes all aspects relating to the latter: effectiveness, convenience, undesirable effects, follow-up, etc. Lastly, at the tip of the pyramid we find satisfaction with the medication received—this being the evaluation made by the patient of the process of administering the medication, and the results associated with it [5].

Satisfaction with medication and with medical treatment appears to be related to patient adherence or compliance with treatment, and constitutes a quality indicator that can be used to improve health care, and which affects patient preferences [4,6–11]. In addition, knowledge of the degree of satisfaction with treatment can contribute to predict treatment compliance and help clinicians take decisions. Consequently, measurement of this parameter is one of the health outcomes which must be complied with in both daily clinical practice and in biomedical research [12]. Until relatively recently, most instruments designed to measure patient satisfaction with medical treatment were specific to a given disease or clinical situation. This obviously not only limited their use, but also precluded comparisons of patient satisfaction with medical treatment between different diseases or medical situations. Recently, Atkinson et al. [13] have developed a generic instrument designed to measure satisfaction with pharmacological treatment for any disease: the Treatment Satisfaction Questionnaire for Medication (TSQM), of which an abridged version is available [14]. The initial version included four dimensions: side effects, effectiveness of the medication, convenience of use (CU), and global satisfaction. Nevertheless, it did not contemplate other dimensions such as satisfaction with medical care or the impact of medication on daily living activities—these being relevant aspects within the satisfaction with treatment construct (particularly as they might refer to the capacity to predict adherence to therapy), because they are viewed by patients as attributes of medical treatment [15–18].

Because of the possible limitations of the TSQM in capturing all patient perceptions and in evaluating all the dimensions necessary to adequately measure the level of satisfaction with drug treatment, the present study was designed with the aim of developing a generic instrument for measuring patient satisfaction with chronic drug-based treatment: The SATMED-Q questionnaire. The idea is to offer a multidimensional generic questionnaire, of limited extent, feasible and easy to self-administer, and with good metric properties (reliability and validity). Likewise, the questionnaire is designed for use with patients presenting any illness and subjected to any type of prolonged pharmacological treatment, although only a limited range of pathologies have been considered. As a result, we hope to develop a measurement instrument that can help clinicians to better orient the management of chronic illnesses toward decisions that in accordance with patient satisfaction will favor treatment compliance and effectiveness. The questionnaire has been developed assuming the Classical Test Theory framework.

Method

Panel of Experts

The questionnaire development process began with the selection of a panel of experts composed of two experts in psychometrics, a clinical pharmacologist, an expert in health outcomes research, two clinical physicians, and an interviewer. In the patient recruitment and assessment phase, four additional clinical physicians were incorporated. The panel of experts supervised all phases of the development and validation of the questionnaire.

A literature review and compilation of the articles published on satisfaction, treatment satisfaction, service satisfaction, and health-related quality of life in both the health-care science and social science settings (Medline, Embase, Current Contents, Cochrane Library) were first carried out. A review and compilation were also made of the existing questionnaires on satisfaction with treatment, and the TSQM [13] was selected as a reference instrument.

Taking these reviews as a starting point, the panel of experts generated an initial series of questions relating to the following aspects of treatment with drugs: global satisfaction, effectiveness, convenience of application, undesirable side effects (UE), expectations, available clinical options, recommendation disposition, short-term consequences, long-term consequences, adherence, satisfaction with medical care, and impact on daily life.

Focus Groups

Four discussion groups were then formed with patients to document their opinion on the pertinence of the dimensions and items initially contemplated by the panel of experts, and to collect additional information on those aspects of treatment which the experts might have missed. In all groups, the patients were questioned about the following: 1) the time during which they had been taking the medication; 2) their concern about having to take medicines on a permanent basis; 3) the possible side effects of the medication; 4) the effectiveness of the medication in treating their illness; 5) their "adjustment" to the medication; 6) convenience-

inconvenience of taking the medication; 7) the aspects of medication proving inconvenient or bothersome; and 8) their degree of satisfaction with the medication received.

The first group comprised three males and three females, all permanent residents in a nursing home for the elderly in the Community of Madrid, and all receiving chronic drug treatment. The second group likewise comprised three males and three females from a second nursing home for the elderly in the Community of Madrid, and receiving chronic drug treatment. The third group consisted of four women receiving hormone replacement therapy started 7 to 10 years earlier. Lastly, the fourth group consisted of five hypertensive patients (four males and one female) subjected to treatment for 1 to 10 years. Thus, a total of 21 subjects receiving chronic drug treatment were involved. The patient comments and answers were transcribed as literally as possible.

Item Generation

Combining the initial considerations of the panel of experts and the information obtained from the discussion groups, we defined the dimensions considered to be relevant for inclusion in the questionnaire with the generation of a comprehensive list of items in affirmation format, reflecting as far as possible the expressions directly recorded from the patients participating in the discussion groups. The items were designed taking care to ensure that they referred to a single concept (predominantly in an affirmative sense), avoiding double negations and ambiguity, and adopting a first-person format. The answers were scored on a Likert-type scale from 0 to 4, as follows: 0 = "No, not at all"; 1 = "A little bit"; 2 = "Neither a lot, nor a little"; 3 = "Quite a lot"; 4 = "Yes, very much."

One or two items were formulated for each of the following aspects: 1) global satisfaction with current treatment; 2) effectiveness of treatment; 3) information on the disease; 4) discomfort with treatment (including side effects); 5) design/appearance of the product; 6) treatment convenience; 7) intent to continue with the treatment; 8) ease/difficulty of treatment administration; 9) information on the treatment; 10) treatment flexibility (when, where); 11) convenience when not used (transport, storage, etc.); 12) patient's self-confidence in ability to use the treatment; 13) comparison with other treatment; 14) ease of drug purchase; 15) satisfaction with treatment planning; 16) promptness of treatment action; 17) safety; 18) duration of treatment; 19) number of doses; 20) degree to which treatment meets patient expectations; 21) proximity to ideal treatment; and 22) recommendation to friends.

The initially formulated items were evaluated by a semantic discussion and screening process, resulting in 36 items grouped into six sections or dimensions: effectiveness of the medication and its capacity to treat the disease and alleviate symptoms (five items), convenience of the medication and ease of administration (six items), impact of the medication on patient daily life (four items), medical care and follow-up of the illness (four items), UE of the medication (eight items), general opinion and beliefs relating to the medication and health condition (nine items).

Subjects

Because the new instrument aims to measure satisfaction with pharmacological treatment in patients with different diseases, its development and validation were based on the selection of patients diagnosed with disorders showing a high prevalence in our setting, such as type 2 diabetes mellitus (DM2), arterial hypertension, arthrosis, benign prostate hyperplasia (BPH), chronic obstructive pulmonary disease (COPD)/asthma, depression, and migraine.

For patient recruitment, the researchers conducted probabilistic sampling in six hospital centers in the city of Madrid and in the Community of Madrid: Centro de Salud Mendiguchía Garriche in Leganés, Centro de Salud Orcasitas in Madrid, Clínica Madrid in Fuenlabrada, Centro de Salud in Ciempozuelos, Hospital Gregorio Marañón in Madrid, and Centro Ambulatorio de Atención Primaria in Parla.

The patients were selected from among those visiting the center and who met the following study inclusion criteria: outpatients of either sex and over 18 years of age, diagnosed with one of the aforementioned diseases, with two or more months of treatment for the disorder at the time of selection, the ability to understand and answer the health questionnaires included in the study, and willing to sign the informed consent form.

The study, of a multicenter, cross-sectional and observational design, was conducted under the conditions of normal clinical practice as refers to disease treatment, and all patients were requested to grant informed consent to utilization of their data and inclusion of the latter in a database. The study protocol was approved by the Clinical Research Ethics Committee of Universidad Autónoma de Madrid.

Three different samples were used: 1) pilot sample: composed of 12 randomly recruited patients; 2) reduction sample: selected taking three segmentation criteria into account: gender (male, female); age (<65 years, >65 years) and pathology (DM2, hypertension, arthrosis, BPH, COPD/asthma, depression, and migraine); and 3) validation sample: selected taking into account the same segmentation criteria as in the reduction sample.

The size of the pilot sample was considered sufficient to evaluate feasibility and pertinence of the questionnaire, and to determine whether the items were clearly understood by the patients.

The size of the reduction sample was determined based on the criterion of Rummel [19], whereby the ratio subjects/variables should be no less than 4/1. Considering the number of items of the first version of the questionnaire, and moreover taking into account that some subjects could give nonevaluable answers, a minimum of 150 patients was considered advisable. Consequently, we decided to select six subjects for each combination of gender (two levels), age (two levels), and pathology (seven levels): this represented a total of 156 individuals, taking into account that women cannot be included in the BPH group. Patient selection was random and sequential, until the indicated subject quotas were covered.

The size of the validation sample was calculated based on the same criteria: because the final questionnaire was to contain no more than three questions per dimension (18 questions maximum), the sample required to apply factor analysis was found to be 72 patients. Nevertheless, the sample size was overdimensioned to allow statistical comparisons between meaningful groups related to the validity study: we decided to select a minimum of 50 patients (25 males and 25 females) corresponding to each of the seven pathologies considered in the study—representing a minimum of 350 patients in total.

The reduction sample finally comprised 150 patients. Although a similar patient quota was assigned to each of the participating centers, recruitment was carried out competitively among the centers to accelerate the patient recruitment process. For this reason, the quotas contemplated in the original design (six subjects per stratum) could not be precisely covered; nevertheless, the deviations were not considered to be relevant to the effects of representativeness. The validation sample comprised 455 patients. Table 1 reports the number of cases sampled per stratum, in addition to the mean age, mean body mass index, and the distributions corresponding to the variables of race and educational level.

Reduction of the Questionnaire

The initial 36-item questionnaire was administered to the pilot sample. Patient comments and information about comprehension and reading problems with the proposed items were collected.

The revised questionnaire incorporating the contributions of the pilot sample was in turn administered to the reduction sample. The information obtained from this sample was then used for the following: 1) to check adjustment of the patient responses to the structure (dimensions or subscales) proposed by the group of experts; 2) to assess the metric properties of the items; and 3) to reduce the number of questions to a maximum of three per dimension.

Reduction of the questionnaire and determination of the underlying dimensions were carried out via a sequence of exploratory factor analyses, and based on the analysis of internal consistency. The factor analyses made use of two extraction methods: principal components and principal axes; and two rotation methods: varimax (orthogonal) and oblimin (oblique) [20].

Table 1 Demographic characteristics of patients included in the study

	Item reduction sample (n = 150)	Psychometric properties testing sample (n = 455)
Age (years): mean (SD)	58.96 (15.73)	62.07 (13.61)
Sex, male: n (%)	79 (52.7)	229 (50.3)
BMI (kg/m^2): mean (SD)	26.98 (4.13)	27.77 (4.71)
Race: n (%)		
Caucasian	148 (98.7)	443 (97.4)
African	1 (0.6)	6 (1.3)
Other	2 (1.3)	6 (1.3)
Education: n (%)		
No high school diploma	76 (50.3)	247 (54.3)
High school graduate	27 (17.9)	106 (23.2)
Professional training diploma	19 (12.6)	42 (9.2)
College graduate	21 (13.9)	54 (11.8)
Unknown	8 (5.3)	6 (1.3)

	Male		Female		Male		Female	
No. of patients by disease	<65 (%)	≥65 (%)	<65 (%)	≥65 (%)	<65 (%)	≥65 (%)	<65 (%)	≥65 (%)
Diabetes	5 (3.3)	6 (4.0)	5 (3.3)	4 (2.7)	17 (3.7)	16 (3.5)	7 (3.7)	21 (4.6)
Hypertension	9 (6.0)	5 (3.3)	5 (3.3)	7 (4.7)	21 (4.6)	27 (5.9)	27 (5.9)	27 (5.9)
Osteoarthritis	4 (2.7)	6 (4.0)	6 (4.0)	7 (4.7)	17 (3.7)	18 (3.9)	17 (3.7)	18 (3.9)
BPH	6 (4.0)	7 (4.7)	—	—	16 (3.5)	24 (5.3)	—	—
COPD/asthma	5 (3.3)	6 (4.0)	5 (3.3)	5 (3.3)	13 (2.9)	16 (3.5)	15 (3.5)	15 (3.5)
Depression	4 (2.7)	6 (4.0)	6 (4.0)	7 (4.7)	15 (3.3)	14 (3.1)	24 (5.3)	17 (3.7)
Migraine	8 (5.3)	2 (1.3)	13 (8.7)	1 (0.7)	10 (2.2)	5 (1.1)	19 (4.2)	9 (2.0)
Total	41 (27.3)	38 (25.3)	40 (26.7)	31 (20.7)	109 (23.9)	120 (26.4)	119 (26.2)	107 (23.5)

BMI, body mass index; BPH, benign prostate hyperplasia; COPD, chronic obstructive pulmonary disease; 65, 65 years old.

Heuristics for determining the optimum number of factors comprised the Kaiser K1 rule, the percentage of variance accounted for, and the magnitude of the eigenvalues after rotation [21–23]. A number of decision rules were used, because of the tendency of all of them to either underestimate or overestimate the correct number of factors in different contexts [21,24–26]. Internal consistency was evaluated by means of Cronbach's alpha reliability coefficient, and the change in alpha coefficient after deleting each item from the scale [23].

In this reduction of the length of the questionnaire and analysis of dimensionality, we adopted the proposals of Gorusch and Russell [27–29]. First, we discarded those items with a clear floor or ceiling effect (i.e., items with more than 50% of answers concentrated in the first or last answer category). Second, an exploratory factor analysis was made with the 36 items of the scale to determine the number of underlying factors or dimensions (subscales). Lastly, we analyzed the dimensionality (factor analysis) and internal consistency (Cronbach's alpha coefficient) of each subscale, assuming all of them to be unidimensional.

In this latter step, those items with lower loading in the first dimension, or cross-loading in more than one dimension were discarded. Items with lowest contribution to the scale overall alpha coefficient were also proposed for deletion. Items were discarded one by one until leaving three items in each subscale (except the subscale medical care, which was left with two items). After each deletion, the same analyses were repeated until the unidimensional structure of each subscale was found to be stable, without further improvement in the alpha coefficient.

Finally, an exploratory factor analysis was carried out with all the refined subscales to check that the structure remained stable. All statistical analyses were made using the SPSS version 14.0 statistical package.

Psychometric Properties of the Final Version

The abridged or final version of the questionnaire was included in a case report form (CRF), together with clinical information of relevance for the patient, sociodemographic information, a Spanish adaptation of the TSQM [13], the Morisky-Green compliance questionnaire [30], and the clinician and patient evaluations of tolerability and effectiveness.

The CRF was distributed in the validation sample. The data obtained from this sample were then used for the following: 1) to assess the metric properties of the questionnaire; and 2) to elaborate norms for the Spanish population.

The following metric properties of the final questionnaire were studied: 1) feasibility: administration time, floor and ceiling effects, percentage of missing values in each item; 2) reliability: internal consistency, evaluated by means of Cronbach's alpha coefficient and the Pearson correlation coefficient between items and between each item and the total composite score; test–retest (temporal stability), evaluated by correlating two administrations of the questionnaire based on the Pearson correlation coefficient and intraclass correlation coefficient (ICC) [31–33]; 3) content validity: ensured by the panel of experts and by patient consultation in the four discussion groups. In addition, we used the evaluations of six referees, whose degree of consensus in assigning items to dimensions was established by the coefficient of Rovinelli and Hambleton [34]; 4) construct validity: the structure in dimensions of the answers gathered with the final questionnaire was established by exploratory and confirmatory factor analysis. With both types of analysis the aim was to contrast the dimensional structure of the final scale and the allocation of each item to its respective dimension; 5) concurrent validity: correlations were made of the SATMED-Q scores with those of the treatment satisfaction questionnaire (TSQM) [13] and the Morisky-Green compliance questionnaire [30]; and 6) discriminant validity: an analysis was made of the capability of each item to discriminate between the 25% of subjects with the lowest scores and the 25% with the highest scores (established from the total composite scale scores), and of the capability of each subscale and of the composite scale to discriminate between groups of patients formed from evaluations of effectiveness and tolerability conducted by the clinicians and by the patients. These evaluations were carried out on a 4-point ordinal scale (poor, acceptable, good, and excellent), according to patient and clinician perceptions. All analyses were made using the SPSS version 14.0 (SPSS, Chicago, IL) statistical package and Amos 6.0 (SPSS).

Scoring

Summing up the direct scores of the items yields a total composite score ranging between 0 and 68. The observed total composite score can be transformed to a more intuitive and easier to understand metric with a minimum of 0 and a maximum of 100, using the following expression:

$$Y' = \frac{Y_{obs} - Y_{\min}}{Y_{\max} - Y_{\min}} \times 100 = Y_{obs} \times 1471$$

where $Y_{\max} = 68$ (maximum total score); $Y_{\min} = 0$ (minimum total score); Y_{obs} = total score obtained by the patient; and Y' = transformed score. A similar expression can be used to change the metric of each individual dimension.

Results

Discussion Groups

The four discussion groups yielded coincident results. Good adjustment to medication was observed in all

Table 2 Reduction sample: internal consistency of subscales

Domains	Number of items		Cronbach's alpha		% variance explained*
	Initial	Final	Initial	Final	
Treatment effectiveness	5	3	0.825	0.821	65
Convenience of use	6	3	0.830	0.857	78
Impact on daily living activities	4	3	0.890	0.890	75
Medical care	4	2	0.886	0.844	76
Undesirable side effects	8	3	0.851	0.880	75
Global satisfaction	9	3	0.792	0.847	69

*Percentage of variance accounted for by the first factor in each subscale.

cases: most of the participants claimed medication to have become just another part of daily routine.

The first aspect considered to be fundamental for satisfaction with the medication was effectiveness, which soon evidenced to be one of the principal motivations for taking a drug. A second aspect also considered to be important was confidence in the physician and the capacity of the latter to make himself understood by the patient. Another aspect considered to be relevant was patient expectations in relation to the capacity of the drug to heal or alleviate the disease (this being particularly apparent in the hypertensive subjects, where those patients who had developed hypertension as a consequence of some other disorder trusted that the time would come when they would no longer need the medication).

The information obtained from these groups confirmed that no contents of interest or relevance for chronic patients had been obviated or left out.

Reduction of the Questionnaire

Table 2 reports the internal consistency results before (initial scale, 36 items) and after item reduction (final scale, 17 items). The values recorded for Cronbach's alpha coefficient (above 0.82 in all subscales of the final version) reflect good internal consistency. The percentage of variance accounted for by the first dimension of each subscale suggests that the subscales are one-dimensional.

The results of the factor analysis (Table 3) corroborate the presence of six dimensions (five with eigenvalues above 1, and the sixth with an eigenvalue of

Table 3 Reduction sample: exploratory factor analysis solution (oblimin rotation)

SATMED-Q	Factors					
	CU	MC	UE	GS	TE	ID
Treatment effectiveness						
Relief of symptoms	–0.064	0.155	–0.041	–0.005	**–0.911**	0.164
Time to start working	–0.033	–0.282	–0.051	0.243	**–0.713**	–0.240
Feel better	0.393	0.070	0.083	–0.084	**–0.614**	–0.201
Convenience of use						
Ease of medication use	**0.759**	–0.016	–0.192	0.158	0.077	–0.055
Convenience of medication use	**0.947**	–0.004	0.059	0.026	–0.003	0.070
Frequency of medication use	**0.553**	–0.044	–0.377	0.097	–0.085	–0.135
Impact on daily living/activities						
Leisure activities	0.073	0.181	–0.057	0.056	–0.102	**–0.725**
Personal hygiene	–0.006	–0.031	0.038	–0.034	0.138	**–0.975**
Usual daily activities	–0.042	0.155	–0.041	0.070	–0.148	**–0.795**
Medical care						
Medical disease information	0.003	**0.952**	0.024	0.050	0.021	–0.071
Treatment disease information	–0.025	**0.943**	–0.035	0.039	–0.048	–0.068
Global satisfaction						
Confident in treatment adherence	0.089	0.042	0.112	**0.888**	0.015	0.116
Pleasure of being treated	0.000	0.025	–0.067	**0.867**	–0.008	–0.087
Global satisfaction	0.001	0.022	–0.138	**0.758**	–0.050	–0.107
Undesirable side effects						
Impact on physical activities	–0.028	–0.005	**0.931**	0.112	0.033	0.013
Impact on leisure activities	–0.080	0.017	**0.933**	0.007	–0.002	0.033
Impact on daily living activities	0.051	–0.022	**0.887**	–0.147	–0.036	–0.069
Eigenvalues	6.548	2.670	1.538	1.390	1.169	0.979
Percentage of variance explained (%)	38.517	15.708	9.046	8.178	6.878	5.758
Factor correlation matrix						
Medical care	0.000					
Undesirable side effects	–0.344	–0.002				
Global satisfaction	0.388	0.155	–0.381			
Treatment effectiveness	–0.226	–0.170	0.149	–0.263		
Impact on daily living/activities	–0.280	–0.276	0.247	–0.269	0.295	

CU, convenience of use; GS, global satisfaction; ID, impact on daily living/activities; MC, medical care; TE, treatment effectiveness; UE, undesirable side effects. Bold indicates the highest factor loading for each item (row) in the corresponding dimension (column).

0.979), which account for 84.09% of the total available variance, with communalities ranging between 0.751 and 0.965. In the results of the factor solution (17 items, six dimensions, oblimin rotation), it can be seen that all the items preferentially load in their corresponding theoretical dimension. Only two items load below 0.70 in their dimension ("feel better" = –0.612; "frequency of medication use" = 0.553) and above 0.30 in a dimension other than their own ("feel better" = –0.393 in CU; "frequency of medication use" = –0.377 in UE). Therefore, the analysis of the answers indicates excellent assignment of the items in their corresponding theoretical dimensions.

Although the items of the subscale UE show a clear floor effect (percentage of subjects in the first response category between 75.2% and 80.4%), the subscale has been included in the final questionnaire because in addition to its other good metric properties, the experts decided that the subscale is important for assessing drug safety. Nevertheless, the results of the factor analysis after excluding the three items of the UE subscale prove equally conclusive: the analysis yielded five dimensions (four with eigenvalues above 1, and the fifth with an eigenvalue of 0.995), which account for 82.10% of the total variance, with communalities of between 0.707 and 0.960. In the results of the factor solution (14 items, five dimensions, oblimin rotation), all items are seen to preferentially load in their theoretical dimension. Only one item loads below 0.70 in its dimension ("feel better" = 0.630) and above 0.30 in a dimension other than its own ("feel better" = 0.362 in CU).

Finally, the relationship between dimensions ranges from low to moderate: the correlations among the subscales CU, UE, and global satisfaction range between 0.34 and 0.39; the remaining correlations are bellow 0.30. Satisfaction measured by the subscale medical care appears to be independent to both CU and UE.

Psychometric Properties of the Final Version

Feasibility. The nonresponse rate in the validation sample (455 patients) was very low: 96.7% of the patients answered all the questions in the questionnaire. The mean response time was 4.71 minutes (SD = 4.65). The median was 4 minutes. The fastest patient completed the questionnaire in 1 minute, and the slowest in 35 minutes. Only 12.6% of the patients took more than 10 minutes to respond.

The total composite scores exhibited a negative skewed distribution, with a mean of 75.03 and a standard deviation of 14.76. The median was 77.08. The minimum recorded score was 17.36, and the maximum 100. The responses, for all items, were distributed along all the proposed response categories. With the exception of the subscale UE, the distribution of the responses showed a slight negative skewness; the item with the most skewed distribution (willingness to continue treatment) accumulated 44% of the responses in the upper part of the scale. All distributions were unimodal.

The subscale UE accumulated the responses in the lower portion of the scale: between 66% and 75% of the responses were located in the category "No, not at all." This floor effect was also found in the reduction sample and, in our opinion, justifies the possibility of using this subscale independently to the rest as an indicator of situations of lack of tolerability.

Reliability. The estimation of internal consistency (Cronbach's alpha coefficient) with the validation sample exceeds the value of 0.81 for all subscales (Table 4). With the total composite scale, a value of 0.879 has been obtained (0.890 when excluding the subscale UE). The first eigenvalue is markedly bigger than the second on all subscales, and the first dimension of each subscale accounts for a percentage of variance between 73% and 90%—thus indicating that the subscales behave in a one-dimensional manner.

To analyze the discriminative capacity of each item considered individually, two patient groups were created from the scores obtained in the total composite scale. The first group comprised the 25% of patients with the lowest scores, although the second comprised the 25% of patients with the highest scores. Comparison between these two groups with the Student *t*-test yielded significant differences for all items ($t_{127} > 6.4$ and $P < 0.0005$ in all cases).

The scale was administered to 128 patients a second time several days after the first administration

Table 4 Validation sample: internal consistency statistics

	No. of items	Alpha	First eigenvalue	Second eigenvalue	% variance explained*
Treatment effectiveness	3	0.813	2.193	0.440	73
Convenience of use	3	0.861	2.351	0.393	78
Impact on daily living/activities	3	0.851	2.319	0.503	77
Medical care	2	0.885	1.794	0.206	90
Undesirable side effects	3	0.912	2.557	0.284	85
Global satisfaction	3	0.855	2.328	0.476	78
Total composite score	17	0.879			

*Percentage of variance explained by the first factor in each subscale.

(mean = 3; SD = 1.015; minimum = 1; maximum = 9). Cronbach's alpha coefficient on occasion of this second administration was 0.889 for the total composite scale (17 items). The correlation between administrations was 0.945, and the ICC was 0.943, with a 95% confidence interval of (0.928–0.957). The mean total composite score was 50.28 (SD = 9.80) for the first administration, and 50.24 (SD = 9.94) for the second. The difference between these means was not significant ($t_{127} = 0.37$, $P = 0.716$). It can be concluded therefore that the scale remains stable between measurements.

Content validity. Although content validity was warranted by the initial work of the panel of experts, six independent referees were asked to classify each item of the final scale in the dimension where they considered it to belong. Each referee should score items in the six possible dimensions, assigning a value of 1 if the item measures the dimension, –1 if the item does not measure the dimension, and 0 if it is not clear. When all referees agree and items belong to a unique dimension, a given item should attain an average value of 1 in the dimensions it belongs to, and –1 in the alternative dimensions. After applying the coefficient of Rovinelli and Hambleton to the responses of the referees, the highest coefficients for each item were obtained in their corresponding theoretical dimension, with values ranging from 0.63 (item 12) to 0.93 (items 16 and 17). In addition, very low coefficients were obtained for all items in the remaining dimensions, with values ranging between –0.42 and 0.28. These results indicate excellent agreement among the referees, and confirm correct correspondence between referee assessment and the initial allotment of the items in their respective theoretical dimensions.

Construct validity. The dimensionality of the questionnaire has again been analyzed with the data obtained from the validation sample. The results of the exploratory factor analysis corroborate the presence of six dimensions (five with eigenvalues above 1, and the sixth with an eigenvalue of 0.876), which account for 80.83% of the total variance, and communalities between 0.720 and 0.905. In the results of the factorial solution (17 items, six dimensions, oblimin rotation; see Table 5), all items are seen to preferentially load in their theoretical dimension. Only two items load below 0.70 in their dimension ("relief of symptoms" = 0.681; "global satisfaction" = 0.612), and none load above 0.30 in a dimension other than their own. Therefore, the analysis of the answers indicates

Table 5 Validation sample: exploratory factor analysis solution (oblimin rotation)

	Factors					
SATMED-Q	ID	UE	CU	MC	GS	TE
Treatment effectiveness						
Relief of symptoms	0.117	0.031	–0.051	0.072	0.168	**0.681**
Time to start working	–0.123	0.003	0.095	–0.005	–0.018	**0.947**
Feel better	0.189	0.014	–0.035	0.023	–0.003	**0.725**
Convenience of use						
Ease of medication use	0.021	0.000	**0.891**	0.048	–0.062	0.043
Convenience of medication use	–0.037	–0.035	**0.889**	–0.011	0.127	–0.074
Frequency of medication use	0.072	–0.032	**0.794**	–0.038	0.025	0.075
Impact on daily living/activities						
Leisure activities	**0.844**	–0.046	–0.048	–0.024	0.167	–0.025
Personal hygiene	**0.753**	0.106	0.221	0.051	–0.095	0.020
Usual daily activities	**0.909**	–0.060	–0.062	0.021	0.005	0.073
Medical care						
Medical disease information	–0.012	–0.001	–0.059	**0.963**	–0.006	–0.010
Treatment disease information	0.003	–0.019	0.055	**0.926**	0.018	0.013
Global Satisfaction						
Confident in treatment adherence	–0.006	0.110	0.052	0.049	**0.916**	–0.075
Pleasure of being treated	0.061	–0.102	0.080	0.016	**0.793**	0.099
Global satisfaction	0.087	–0.140	–0.023	–0.003	**0.612**	0.290
Undesirable side effects						
Impact on physical activities	0.018	**0.912**	–0.017	–0.006	0.016	–0.015
Impact on leisure activities	–0.020	**0.948**	0.000	–0.009	0.016	0.002
Impact on daily living activities	0.001	**0.900**	–0.028	–0.008	–0.005	0.051
Eigenvalues	6.050	2.611	1.776	1.383	1.044	0.876
Percentage of variance explained (%)	35.591	15.361	10.449	8.135	6.144	5.153
Factor correlation matrix						
Undesirable side effects	–0.047					
Convenience of use	0.314	–0.197				
Medical care	0.264	–0.095	0.120			
Global satisfaction	0.421	–0.164	0.285	0.274		
Treatment effectiveness	0.506	–0.082	0.245	0.269	0.447	

CU, convenience of use; GS, global satisfaction; ID, impact on daily living/activities; MC, medical care; TE, treatment effectiveness; UE, undesirable side effects. Bold indicates the highest factor loading for each item (row) in the corresponding dimension (column).

excellent assignment of the items in their corresponding theoretical dimensions.

In the same way as in the reduction sample, validation of the items of the subscale UE reveals a marked floor effect. On excluding the three items corresponding to that subscale from the analysis, the results reveal the presence of five dimensions (four with eigenvalues above 1, and the fifth with an eigenvalue of 0.875), which account for 79.56% of the total variance, and communalities between 0.688 and 0.905. In the results of the factor solution (14 items, five dimensions, oblimin rotation), all items were seen to preferentially load in their theoretical dimension. Only two items load below 0.70 in their dimension ("relief of symptoms" = 0.675; "global satisfaction" = 0.661), and none load above 0.30 in a dimension other than their own.

The relationship between dimensions ranges from low to moderate: the strongest correlations are found between the subscale impact on daily living activities and the subscales global satisfaction (0.42) and treatment effectiveness (0.51). Surprisingly, satisfaction associated to impact on daily living activities does not appear to be associated to UE.

Lastly, Figure 1 shows the result of the confirmatory estimation of the proposed theoretical structure of the questionnaire, using the generalized minimum squares method. All loadings are significant ($P < 0.001$), as are all the correlations among factors ($P < 0.05$), except the correlation between UE and impact on daily living activities ($P = 0.051$). The goodness of fit statistics indicate a good or very good fit: GFI = 0.938; AGFI = 0.909; CFI = 0.860; RMR = 0.069 and $\chi^2/df = 2.225$. Only the RMSEA statistic = 0.053 shows a moderate value. It was needed to fix the variance error of the second indicator of the dimension medical care, to avoid estimation taking a value outside range (Heywood case); a value of 0.01 was imposed, taking as reference the uniqueness estimations of the exploratory factor analysis. This result was to be expected: because the dimension only includes two indicators, the estimation of the error variance may be locally underidentified.

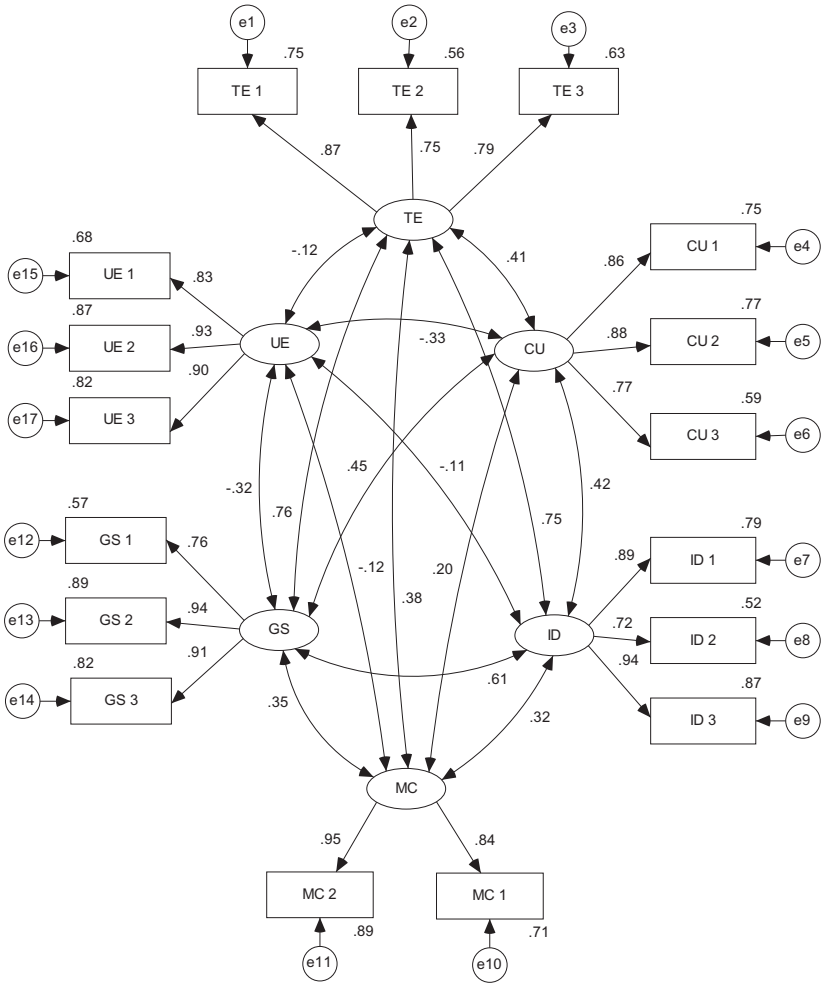

Figure 1 Confirmatory factor analysis estimates. CU, convenience of use; GS, general satisfaction; ID, impact on daily activities; MC, medical care; TE, treatment effectiveness; UE, undesirable side effects.

Table 6 Correlations between SATMED-Q dimensions and TSQM and Morisky-Green compliance

	TSQM					
SATMED-Q	Effectiveness	Side effects	Convenience of use	Global satisfaction	Total score	Morisky-Green
Treatment effectiveness	**0.68**	0.19	0.32	0.67	0.61	0.20
Convenience of use	0.32	0.34	**0.68**	0.37	0.56	0.13**
Impact on daily living/activities	0.44	0.19	0.28	0.55	0.50	0.15***
Medical care	0.19	0.02 NS	0.11**	0.28	0.19	0.09*
Undesirable side effects	0.18	**0.58**	0.24	0.25	0.43	0.22
Global satisfaction	0.60	0.27	0.41	**0.68**	0.66	0.09*
Total composite score	0.61	0.39	0.51	0.70	**0.74**	0.22

$P < 0.0001$ in all cases, except: *$P < 0.05$, **$P < 0.01$, ***$P < 0.001$.
NS, non-significant. Bold indicates the correlation of each SATMED-Q dimension with the congruent TSQM dimension, which should be the highest in the column.

Concurrent validity. The SATMED-Q scores significantly correlate with the scores of the Spanish version of the TSQM (Table 6): a correlation of 0.74 was obtained between the total composite scores of both scales, with correlations ranging from 0.58 to 0.68 between dimensions of similar contents ($P < 0.0005$ in all cases).

A significant relationship was also found between the scores of the SATMED-Q and those of the Morisky-Green compliance test. The correlations proved significant for both the total composite score and for all the subscales except medical follow-up and UE—which only reached marginal significance.

Discriminant validity. To evaluate the degree to which the dimensions of the SATMED-Q discriminate between groups which are expected to differentiate, we used the effectiveness and tolerability assessments made by both the clinicians and the patients, on a 4-point ordinal scale: poor, acceptable, good, excellent. The observed relationship between clinician and patient assessment is important: tau-b = 0.59 ($P < 0.0005$) in the case of effectiveness, and tau-b = 0.66 ($P < 0.005$) in the case of tolerability (in both instances with N = 453).

The assessments of the clinicians were used to establish four groups of effectiveness and four groups of tolerability (poor, acceptable, good, excellent). The same procedure was applied in the case of patient assessment. Table 7 reports the results of each of these groups in the SATMED-Q. The comparisons made reveal significant differences that depend on the dimension evaluated and on the evaluator (clinician or patient).

The groups of effectiveness formed with the assessments of the clinicians differ in the total composite score and for all the subscales ($P < 0.0005$ in all cases) except convenience ($P = 0.315$) and UE ($P = 0.220$). The groups of effectiveness conformed with the assessments of the patients yield similar results: very significant differences are found in the total composite score and for all the subscales ($P < 0.0005$) except medical follow-up ($P = 0.051$) and UE ($P = 0.034$). The tendency of the observed differences is always the same: as perceived effectiveness increases, so do the satisfaction scores (the linear component being the only one to reach significance in all cases where differences are observed). The Kendall tau-b correlation coefficients between the satisfaction scores and the effectiveness assessments show relationship patterns almost identical to those obtained with the analysis of variance: the evaluations made by the clinicians correlate with the level of satisfaction in all dimensions ($P < 0.0005$) except convenience ($P = 0.969$) and UE ($P = 0.366$). In turn, the evaluations made by the patients correlate with their level of satisfaction in all dimensions ($P < 0.0005$ in all cases except medical follow-up, where $P = 0.008$).

The groups of tolerability formed with the assessments of the clinicians differ in the total composite score and for all the subscales ($P < 0.001$ in all cases) except convenience ($P = 0.088$), impact of the medication ($P = 0.168$) and medical follow-up ($P = 0.036$). The groups of tolerability formed with the assessments of the patients differ in the total composite score and for all the subscales ($P < 0.0005$) except medical follow-up ($P = 0.330$). The tendency of the differences found in the most relevant dimension in this context (UE) is linear: as perceived tolerability increases, so does satisfaction in relation to UE. The Kendall tau-b correlation coefficients between the satisfaction scores and the tolerability assessments show relationship patterns almost identical to those obtained with the analysis of variance: the evaluations made by the clinicians correlate with the level of satisfaction in all dimensions ($P < 0.0005$) except convenience ($P = 0.257$), impact of medication ($P = 0.207$), and medical follow-up ($P = 0.110$). In turn, the evaluations made by the patients correlate with their level of satisfaction in all dimensions ($P < 0.0005$) except medical follow-up ($P = 0.127$).

Lastly, the dimension convenience allows discrimination of the level of satisfaction associated to the different forms of drug administration. In the global validation sample, 83.4% of the patients were receiving medication via the oral route, although 12.4% received inhaled treatment, and 4.2% received medication via the parentheral route. The mean scores

Table 7 SATMED-Q dimension summaries (N, mean, and standard deviation) by groups defined on effectiveness and tolerability (clinician and patient)

		Effectiveness						Tolerability					
		Clinician assessment			Patient assessment			Clinician assessment			Patient assessment		
Groups	Dimensions	N	Mean	SD	N	Mean	SD	N	Mean	SD	N	Mean	SD
Treatment effectiveness	Bad	14	39.29	30.56	22	33.71	26.29	7	70.24	29.99	17	61.76	25.69
	Fair	89	62.73	25.25	92	58.33	23.15	44	60.98	21.55	66	60.48	23.54
	Good	215	68.99	19.11	247	72.98	16.06	206	68.49	21.57	246	70.09	19.80
	Excellent	131	81.49	16.09	87	85.44	16.82	192	74.78	21.26	119	78.01	22.17
Convenience of use	Bad	14	75.60	17.74	22	68.94	23.74	7	84.52	17.63	17	63.24	32.55
	Fair	90	77.59	21.15	94	69.15	26.38	44	74.05	16.98	67	71.02	23.32
	Good	216	72.57	23.72	248	74.13	22.20	207	71.94	24.05	248	71.87	22.76
	Excellent	132	75.82	23.97	87	83.33	19.77	194	77.23	23.34	119	83.96	19.74
Impact on daily living/activities	Bad	14	45.24	30.26	22	40.15	28.60	7	76.19	30.21	17	62.25	25.36
	Fair	90	59.72	27.20	94	58.33	26.15	44	60.98	23.83	67	59.08	26.89
	Good	217	64.06	23.87	249	65.83	22.34	208	63.98	25.28	249	64.59	23.97
	Excellent	132	73.67	19.48	87	78.16	18.99	194	67.57	23.14	119	71.08	22.75
Medical care	Bad	14	71.79	18.90	22	63.64	27.52	7	71.43	36.60	17	66.91	32.16
	Fair	90	72.83	28.29	94	72.21	24.33	44	65.06	27.57	67	74.07	24.07
	Good	217	74.06	24.04	249	74.30	23.37	208	73.92	24.55	249	73.34	23.82
	Excellent	132	79.55	19.31	87	78.45	22.77	194	76.55	21.01	119	76.89	22.17
Global satisfaction	Bad	14	52.98	36.92	22	44.32	33.86	7	76.19	17.63	17	68.63	16.54
	Fair	90	72.78	23.93	93	68.46	21.94	44	71.02	20.53	67	69.28	23.49
	Good	214	75.97	20.06	247	79.89	16.77	205	75.20	21.78	246	76.73	19.80
	Excellent	130	85.58	14.78	85	88.53	15.75	192	81.25	20.41	117	84.76	21.37
Undesirable side effects	Bad	14	89.88	13.15	22	82.20	26.51	7	73.81	26.10	17	61.76	27.33
	Fair	90	88.89	21.85	94	87.15	22.15	44	78.03	25.17	66	85.10	18.23
	Good	216	86.77	21.45	248	88.24	19.42	206	87.62	20.36	248	87.53	20.97
	Excellent	132	91.35	16.10	87	93.68	14.60	195	92.61	16.58	120	97.15	9.63
Total composite score	Bad	14	63.29	19.30	22	55.49	17.29	7	75.40	14.56	17	64.09	17.55
	Fair	89	71.99	16.66	91	68.60	16.62	44	68.36	13.28	65	69.43	16.11
	Good	210	73.44	14.01	243	76.01	11.84	200	73.45	15.34	241	74.05	13.71
	Excellent	127	80.90	11.88	83	84.21	11.71	189	78.11	13.80	116	81.66	13.06

obtained on the convenience subscale by these three subject groups were 75.6, 78.87, and 44.7, respectively. Patient satisfaction relating to convenience with the medication administered via the parentheral route was significantly lower than for oral dosing ($P = 0.003$) and inhaled treatment ($P < 0.001$).

Norms. The correction norms are shown in Table 8. These norms allow us to transfer the observed metric 0 to 100 scores to the corresponding deciles in the normative sample. For example, a woman with a total composite score of 73 would be located in decile 4—meaning that 40% of the women in the population report similar or lower global satisfaction as she does.

Table 8 SATMED-Q total composite deciles by gender

	Male		Female		Total	
Deciles	Min.	Max.	Min.	Max.	Min.	Max.
1	31.94	52.78	17.36	52.78	17.36	52.78
2	54.17	62.50	54.17	62.50	54.17	62.50
3	63.89	68.75	63.89	68.75	63.89	68.75
4	69.44	73.61	69.44	73.61	69.44	73.61
5	75.00	76.39	74.31	76.39	74.31	76.39
6	77.08	79.17	77.08	79.17	77.08	79.17
7	79.86	84.03	80.56	84.03	79.86	84.03
8	84.72	88.19	84.72	88.19	84.72	88.19
9	88.89	91.67	88.19	91.67	88.19	91.67
10	93.06	100.00	92.36	100.00	92.36	100.00

Discussion

It has become increasingly recognized that the viewpoint of the patient should be taken into account when evaluating a medical treatment. One domanin of such a patient-oriented evaluation is patient satisfaction with treatment or treatment satisfaction.

Treatment satisfaction is a relatively recent area of interest within health outcomes research, and appears to be increasingly used as a patient-reported outcome when testing new or existing treatments [35]. Patient satisfaction with the medication received is of growing concern in clinical practice. On one hand, this is because satisfaction helps evaluate the goodness and convenience of the medication provided. On the other hand, the fact that treatment satisfaction is associated to increased patient adherence to therapy and to a greater patient desire to continue using the drug [36,37] may help predict treatment compliance and improve effectiveness of the administered therapy—with closer follow-up of those patients expected to adhere less to treatment.

In fact, in recent years, evaluations have been made of satisfaction with treatment for different pathologies and involving different drugs based on the use of specific measurement instruments [38–42], in an attempt to obtain complementary data to facilitate improved decision-making in correctly treating patients. Mea-

surements have even been made of satisfaction among patients included in clinical trials in the early stages of development of a new drug, as an additional source of information to be used in selecting the best dose of the new drug in subsequent clinical trials [43].

The aim of this study was to develop and explore the metric properties of a new generic instrument to measure treatment satisfaction for use in clinical practice involving any disease and any medication. Our findings show that the SATMED-Q questionnaire is valid, reliable, and feasible for routine use in normal clinical practice, both as a unidimensional instrument (using the total composite score) and for exploring patient satisfaction with different aspects of treatment (for which the subscales of the instrument have also been shown to be valid and reliable).

The results reveal that the SATMED-Q has very good metric properties. From the feasibility perspective, the response rate is highly satisfactory (almost all patients answered all questions), and the administration time was very brief: 4 minutes on average—thus making it very feasible for use at any level of health care, and particularly in primary care, where the time available for attending patients is usually limited.

As to the reliability of the questionnaire, internal consistency and test–retest reliability show values above the accepted minimum standards [44], both as relates to the total composite score and in terms of the individually considered subscales. In addition, the individual analysis of the items indicates that all of them offer good discriminative capacity.

The different aspects analyzed in relation to the validity of the questionnaire have also yielded satisfactory results. Content validity (originally established by the panel of experts) has been confirmed by the presence of substantial interreferee agreement. In turn, the study of the responses based on exploratory and confirmatory factor analysis corroborated the initially proposed theoretical structure; specifically, the study corroborated the presence of six subscales or dimensions: CU, impact on daily activities, treatment effectiveness, global satisfaction, UE, and medical care. The observed relationship among the different dimensions suggests that the scores of the different subscales can be combined in a meaningful total composite score. As refers to concurrent validity, the scores of the SATMED-Q show a moderately strong correlation (between 0.58 and 0.74) with the scores of the TSQM (a questionnaire used as a reference). In comparison, the observed correlations between the SATMED-Q and the Morisky-Green treatment compliance questionnaire were appreciably weaker. Lastly, in relation to discriminant validity, we likewise recorded satisfactory results on comparing the SATMED-Q scores with the assessment of effectiveness and tolerability made by the clinicians and patients; as perceived effectiveness increases, so does satisfaction, although increased perceived tolerability is in turn associated with an increase in satisfaction in terms of UE.

The SATMED-Q offers certain advantages over the TSQM, particularly as refers to the presence of two additional dimensions: one for assessing medication impact upon daily living activities, and the other for evaluating patient satisfaction with medical care. These two aspects are highly appreciated by patients and can be of help for clinicians in taking treatment decisions [5].

Another salient aspect of the SATMED-Q, also found in the TSQM, is its generic nature. The instrument can be used to compare patient satisfaction with drug treatment irrespective of the type of medication or disease involved. Because of the few questionnaires that offer this profile, this particular feature makes the instrument all the more useful.

One limitation of this study is that it involves a cross-sectional design and is not capable of examining casual influences of low treatment satisfaction on clinically relevant outcomes. In addition, responsiveness to change of this questionnaire was not examined in this cross-sectional study. Prospective studies are planned to address this issue. Another limitation of the present study is that it only included patients with seven chronic disorders, and extrapolation of the results to other diseases therefore must be performed with due caution. Drug interactions and comorbidities have not been studied, and the present design does not allow such inquiries. Further studies involving other diseases and different drugs are needed to confirm the findings. A final limitation of the SATMED-Q is that the primary validation enrolled patient samples obtained in Spain; consequently, validation of this instrument in international settings is unknown and must be tested.

Conclusions

The SATMED-Q questionnaire is a recently developed patient-reported outcomes generic measure to assess treatment satisfaction. The findings of the present study suggest that the instrument has good acceptability as well as satisfactory psychometric properties, including validity of the subscales and reliability of the subscales and composite scales. The findings support the use of the SATMED-Q as a treatment satisfaction with medication measure both in daily medical practice and in clinical research. Moreover, the SATMED-Q instrument may contribute to our understanding of patient medication-related decisions and behaviors, thus proving SATMED-Q to be both an important determinant and outcome of effective clinical care.

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Supplementary material for this article can be found at: http://www.ispor.org/publications/value/ViHsupplementary.asp

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