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Validation Study of the Spanish Adaptation of the Satisfaction With Asthma Treatment Questionnaire for Inhaled Medication

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OBJECTIVE: Although satisfaction with asthma treatment is an important variable, it has received little attention and few validated measurement instruments are available. The aim of this study was to assess the psychometric properties and the feasibility of the Spanish adaptation of the Satisfaction With Asthma Treatment Questionnaire (SATQ) for inhaled medication.

PATIENTS AND METHODS: This cross-sectional study to validate the adapted SATQ included 239 patients (67.8% women) with stable asthma (mean age, 43.3 years; forced expiratory volume in 1 second, 89% of predicted) and a median time since diagnosis of 10 years. Intermittent asthma was reported in 23.0% of the patients and severe persistent disease in 15.9%. Patients filled out the questionnaire twice.

RESULTS: A 4-dimensional factorial structure could be discerned. These dimensions were similar to the validation of the original questionnaire and explained 55.1% of the variance. Internal consistency was acceptable (Cronbach α, 0.880 for the overall score and 0.600-0.866 for subscales), as was reliability (intraclass correlation coefficient, 0.912 for the overall score and 0.841-0.916 for subscales). A significant moderate correlation was observed between the overall score and physician—and patient—reported satisfaction (ρ=0.295 and 0.507, respectively). Three of the 4 subscales were able to discriminate between categories of the Global Initiative for Asthma. The questionnaire was completed in less than 10 minutes by 92.5% of the patients, and 93.7% left no field blank.

CONCLUSIONS: The Spanish adaptation of the SATQ is a useful, user-friendly instrument for measuring satisfaction with inhaled treatment.

Key words: *Asthma. Patient satisfaction. Questionnaire. Validation study.*

Estudio de validación de la versión adaptada al castellano del cuestionario de satisfacción con la medicación inhalada en pacientes asmáticos (SATQ)

OBJETIVO: La satisfacción con el tratamiento en el asma es un aspecto trascendente, pero escasamente estudiado y con pocos instrumentos de medida validados. Se pretende evaluar las propiedades psicométricas y la factibilidad de la versión adaptada al castellano del cuestionario Satisfaction with inhaled Asthma Treatment Questionnaire (SATQ).

PACIENTES Y MÉTODOS: Se ha diseñado un estudio transversal analítico para la validación de un cuestionario. Se incluyó a 239 pacientes con asma estable (edad media: 43,3 años; un 67,8% mujeres; volumen espiratorio forzado en el primer segundo, un 89% del teórico,), con una mediana de tiempo de diagnóstico de 10 años. El 23,0% presentaba asma intermitente y el 15,9%, persistente grave. Cumplimentaron el cuestionario en 2 ocasiones.

RESULTADOS: Se encontró una estructura factorial con 4 dimensiones, similares a la validación original que explicaban el 55,1% de la variancia. La consistencia interna fue adecuada (alfa de Cronbach de 0,880 para la puntuación total y de 0,600-0,866 para las subescalas), así como la fiabilidad (coeficiente de correlación intraclase de 0,912 para la puntuación total y de 0,841-0,916 para las subescalas). Se observó una correlación significativa, de intensidad moderada, entre la puntuación total y la satisfacción referida por médico y paciente (rho = 0,295 y 0,507, respectivamente). Tres de las 4 subescalas fueron capaces de discriminar entre las categorías de la Global Initiative for Asthma (GINA). El 92,5% de los pacientes completaron el cuestionario en menos de 10 min y el 93,7% no dejaron ninguna pregunta en blanco.

CONCLUSIONES: La versión adaptada del SATQ es una herramienta útil y fácil de usar para medir la satisfacción con el tratamiento inhalado.

Palabras clave: *Asma. Satisfacción del paciente. Cuestionario. Estudios de validación.*

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Introduction

Asthma is a considerable problem for public health services. The prevalence of the disease, which is increasing over a wide age range, is between 1% and 5% in Spain.[1] Although effective treatments are currently available for disease management, prognosis depends not

only on correct diagnosis but also on appropriate therapeutic management, which includes education and specific training in treatment usage and which will usually last for the patient's entire lifetime.[2,3] As in many other chronic diseases, the effectiveness of asthma therapy is determined by the patient's circumstances, the treatment, and the level of communication the clinician and patient are able to establish.[4] It is essential that patients trust the medication prescribed, that they feel they can control their symptoms, and that adverse effects are limited and readily tolerated[5]; that is, the patients should feel that the treatment meets their needs. Satisfaction has recently come to be considered as one of the aims of management of asthma patients. In addition to their function of raising awareness of the disease and refining skills for its management, international guidelines should aim to improve the asthma patient's satisfaction so as to build trust and improve therapeutic adherence and self-management of the disease.[2]

Knowledge of patient preferences is essential to improve treatment adherence and outcome. It seems that patients with asthma prefer that their physician play the main role in management of the disease but they do want to be consulted about any changes that affect their treatment.[6] In any case, the expectations, beliefs, and needs of the patients vary greatly from one setting to another, and the view of physicians often differs from the perceptions and needs of patients.[7]

Measurement of the preferences of asthma patients has often assessed the type of device used for drug administration,[8-10] certain nonpharmacologic interventions,[11] desire for information or participation in decision making,[12] the manner in which health care professionals relate to their patients,[13] and the organization of health care.[14] Asthma patients are known to prefer treatments that require lower doses and that do not require blood testing, whereas the route of administration is not decisive in determining treatment satisfaction or dissatisfaction.[15] The ease of use of a treatment in an asthma exacerbation also seems to be important.[16]

Only recently have validated instruments become available in some countries for measuring the satisfaction felt by asthma patients with their treatment,[17-19] but such instruments are not available in Spain. We therefore designed the present study in order to analyze the psychometric properties of the Spanish version of the Satisfaction With Asthma Treatment Questionnaire (SATQ), one of the instruments that has been validated in English-speaking populations for specifically measuring the satisfaction of asthma patients with inhaled treatment.

Patients and Methods

Patients

This study of the psychometric properties of the SATQ included both male and female patients with a clinical diagnosis of asthma. Patients were selected between November 2003 and April 2004 in outpatient clinics of 4 hospital pulmonology services and 4 hospital allergy services, and 11 primary health care clinics. Patients were included consecutively, and each center selected at least 15% of the patients from each of the asthma severity levels according to the Global Initiative for Asthma (GINA) classification[2]: intermittent, mild persistent, moderate persistent, and severe persistent. We included patients aged 18 years or older, who had been stable during the preceding month, that is, those with no changes in asthma treatment, and who had been prescribed inhaled pharmacologic treatment, whether as maintenance or rescue therapy. Patients with terminal disease, those with psychological or psychiatric disorders that might interfere with the study, those who were using parenteral or oral corticosteroids, and those who had problems understanding spoken or written Spanish were excluded from the study. Patients likely to be admitted to hospital during the study were also excluded.

The study was approved by the ethics committee of the Hospital Universitario Clínico San Carlos de Madrid (October 2003) and all patients signed an informed consent form before entering the study.

Study Design

This was an observational study to validate a questionnaire on satisfaction with inhaled treatment.

The validation process required the Spanish version of 2 questionnaires, the SATQ and the Asthma Control Questionnaire (ACQ), to be administered at the same time. In addition, 4 "criterion questions" were added to study the validity of each of the 4 theoretical dimensions of the questionnaire. Likert-type scales were used for the responses to these criterion questions, using the same scales as for the SATQ (ranging from 1, strongly agree, to 7, strongly disagree). The questions were formulated as follows: "My medication is effective for my asthma," "My asthma medication is easy to use," "My asthma medication does not interfere with my everyday life," and "With normal use, my asthma medication does not usually have side effects." Likewise, a question that summarized satisfaction with the same response scale was put to the patients and the health care professionals.

In order to assess the reliability of the instrument, the questionnaires were administered twice to each patient. In the first visit, sociodemographic data (age, sex, socioeconomic level, and profession) were recorded. In addition, the following clinical data were recorded: weight, height, body mass index, asthma severity according to the GINA criteria, smoking habit, spirometric variables (forced expiratory volume in 1 second [FEV_1], forced vital capacity [FVC], and the FEV_1/FVC ratio expressed as a percentage), number of exacerbations and admissions to hospital in the preceding 12 months, and medication taken for asthma in the preceding month.

A second testing session for assessing the reliability of the questionnaire took place between 15 days and 1 month after the first session. Patients who presented clinical

deterioration observed by a physician or reported by the patient were excluded from the analysis of reliability.

The SATQ and ACQ were administered along with the criterion questions at both the first and second visits.

The time taken to fill out the SATQ (<3 min, 3-5 min, 5-10 min, and >10 min) and the number of unanswered items were recorded as a measure of the feasibility of the Spanish version.

Each participating physician was supplied with a Peak Flow Meter (Trimedica, Girona, Spain) for measuring the peak expiratory flow (PEF) in liters per minute at both visits.

Questionnaire

The Spanish version of the SATQ was used, along with the ACQ as an additional instrument.

Cultural adaptation of a questionnaire is divided into 2 phases: linguistic validation and measurement of its psychometric properties. These 2 processes are necessary for validating an instrument in a language and culture other than the one of the initial assessment.[20]

The adapted version of the SATQ was obtained after a process of linguistic validation that comprised translation and back-translation. The comprehensibility was assessed with a small sample of patients who were native Spanish speakers. This process was performed by MAPI Research International.

The SATQ is a self-administered questionnaire with 26 items, in which the patient responds to 26 affirmations with scores between 1 (strongly disagree) and 7 (strongly agree). The 26 items are grouped into 4 conceptual subscales: "effectiveness" (items 5, 7, 12, 13, 22, 24, 25, and 26), "ease of use" (items 1, 2, 4, 8, 10, 16, and 19), "burden of asthma medication" (3, 9, 15, 17, 20, and 23), and "side effects and worries" (items 6, 11, 14, 18, and 21). The scores for items 3, 6, 9, 11, 14, 17, 18, 20, 21, and 23 were reversed to correct the scale. The sum of the scores obtained for the items of a given dimension is divided by the number of items answered (at least 5, 5, 4, and 3 responses in the "effectiveness," "ease of use," "burden of asthma medication," and "side effects and worries" subscales respectively) to obtain a corrected score between 1 and 7. The same procedure is used to obtain a total score for the entire questionnaire.

The ACQ questionnaire was used to assess the patients' subjective perception of how well the symptoms were controlled. This is a self-administered questionnaire containing 6 questions on the symptoms and the medication used in the last week. The responses are on a scale of 0 to 6 points, where 0 corresponds to lack of symptoms or no medication use and 6 to the worst symptoms or greatest use of inhaled medication. This questionnaire, whose Spanish version has been validated,[21] is considered an ideal instrument for evaluating how well asthma symptoms are controlled.

Statistical Analysis

Quantitative variables were presented as means (SD) or medians and interquartile range (first-third quartile) if the distribution was asymmetric. The qualitative variables were presented as absolute frequencies and/or percentages.

The dimensionality of the SATQ was studied by a factorial analysis to extract the main components with varimax (orthogonal) rotation. The solution was constrained to 4 dimensions to determine how well the structure of the Spanish questionnaire coincided with that of the original one.

The concurrent validity was measured by determining the correlation of the SATQ scores with the criterion questions for each subscale and the assessment of overall satisfaction with the medication made by the physician and the patient. For the "effectiveness" subscale, we studied the correlation with PEF rates obtained with the peak flow meter. Given that 1 of the components of satisfaction with treatment is symptoms control, the correlation between the SATQ and ACQ scores was assessed by calculation of the Spearman correlation coefficient (ρ).

The discriminatory validity was assessed by whether the SATQ was able to distinguish between patients with different classifications according to the GINA criteria, between patients with different lung function, PEF, and FEV_1/FVC%, grouped by terciles, between patients with and without exacerbations or admissions to hospital in the past year, and between patients who used 1, 2, or 3 inhalers. Analysis of variance (ANOVA) and the Student *t* test for independent samples were used.

The reliability of the SATQ was evaluated by estimating internal consistency with the Cronbach α level. The test-retest reliability was measured in patients who did not perceive any changes in their symptoms between the first and second observations. The Student *t* test for paired data and the intraclass correlation coefficient (ICC) were used.

The feasibility was assessed by recording the frequency of each of the established categories for the times taken to fill out the SATQ and the percentage of unanswered questions. The floor and ceiling effects were assessed by calculating the percentage of responses with maximum or minimum scores. An item was considered to have reached a ceiling value when at least 75% of the patients assigned the maximum score to that item, and a floor effect was when at least 75% of the patients assigned the minimum score.

The level of significance was set to .05 for all 2-sided tests, corrected in the case of multiple comparisons. All analyses were done with the SAS statistics package, version 8.2 for Windows. Follow-up and statistical analysis of the study were carried out by Clinical Data Care S.L.

Results

Patient Characteristics

In total, 241 patients were enrolled in the study, although 2 were excluded for the purposes of the present analysis because they did not meet the inclusion criteria

TABLE 1
Characteristics of the Study Population*

Age, y	
Mean (95% CI)	43.3 (41.2-45.4)
Median (Q1-Q3)	42.0 (29.6-52.9)
BMI, kg/m^2	
Mean (95% CI)	26.0 (25.4-26.6)
Median (Q1-Q3)	25.6 (22.6- 29.0)
Time since diagnosis, y	
Median (Q1-Q3)	10 (4- 20)
Sex	
Male	77 (32.2%)
Female	162 (67.8%)
Education	
No schooling	9 (3.9%)
Primary	77 (33.2%)
Secondary	79 (34.1%)
Higher education	67 (28.9%)
Main activity	
Currently working	148 (63.2%)
Homemaking	37 (15.8%)
Unemployed	18 (7.7%)
Extent of disability	2 (0.9%)
Retired	23 (9.8%)
Student	6 (2.6%)
Smoking	
Nonsmoker	151 (63.2%)
Ex-smoker,	45 (18.8%)
Occasional smoker	18 (7.5%)
Regular smoker	25 (10.5%)
GINA categories	
Intermittent	55 (23.0%)
Mild persistent	70 (29.3%)
Moderate persistent	76 (31.8%)
Severe persistent	38 (15.9%)
Number of relapses in the past year	
Unknown	2 (0.8%)
0	100 (41.8%)
1	57 (23.8%)
≥2	80 (33.5%)

*CI indicates confidence interval; BMI, body mass index; Q1, first quartile; Q3, third quartile.

TABLE 2
Scores on the Satisfaction With Inhaled Asthma Treatment Questionnaire (4 Subscales and Overall) and Asthma Control Questionnaire, and Overall Perception of Satisfaction*

	First Visit	Second Visit
SATQ subscales		
Effectiveness	5.8 (5.1-6.3)	5.9 (5.1-6.4)
Ease of use	6.1 (5.6-6.7)	6.1 (5.6-6.6)
Burden of asthma medication	5.2 (4.3-6.0)	5.1 (4.3-6.0)
Side effects and worries	4.8 (3.4-5.8)	4.8 (3.6-5.8)
Total SATQ score	5.5 (5.0-5.9)	5.6 (5.0-6.1)
Overall satisfaction		
Perception of the physician	6.0 (5.0-7.0)	6.0 (6.0-7.0)
Perception of the patient	6.0 (6.0-7.0)	6.0 (6.0-7.0)
ACQ	0.7 (0.3-1.5)	0.7 (0.2-1.3)

*Values are presented as median (first-third quartile). ACQ indicates Asthma Control Questionnaire; SATQ, Satisfaction with Asthma Treatment Questionnaire for inhaled medication.

(they were aged <18 years). The sociodemographic and clinical characteristics of the patients are presented in Table 1.

In the month prior to study enrollment, 51 patients (21.3%) had been treated with short-acting or long-acting β-agonists, 179 (74.9%) had received inhaled corticosteroids in combination with other drugs, and 9 (3.8%) had received other treatments. A single inhaler was used by 18.0% of the population (n=43); most of these had intermittent asthma (34 patients). In contrast, 51.9% (n=124) used 2 inhalers and 26.4% (n=63) used 3; most of the users of 2 and 3 inhalers had persistent asthma (n=179).

SATQ Scores

The scores on each of the subscales of the SATQ and the overall score at the first and second visits are presented in Table 2.

Dimensionality

The factorial solution had 6 factors with eigenvalues greater than 1. However, the scree plot indicated that a 4-factor solution might be more appropriate given that extracting more factors hardly increased the percentage of the variance explained. The 4-factor solution explained 55.1% of the variance (31.3%, 10.2%, 7.8%, and 5.8% for factors 1, 2, 3, and 4, respectively). Table 3 shows the matrix of the rotated components. Factors 1, 2, 3, and 4 generally corresponded to "effectiveness," "ease of use," "burden," and "side effects" described for the English version.

The loading factor for item 1 was high for the "effectiveness" and "ease of use" dimensions, and item 19 loaded on components 1 and 2. In the English version, the loading factor for items 15 and 17 was higher for the "burden" component, whereas in the Spanish version, it corresponded to "ease of use." Items 6 and 21, which refer to "side effects and worries," loaded more strongly on "burden of asthma medication" in the present analysis. The loading factor for question 22 was low for all of the 4 predefined domains.

Given that the resulting factorial structure was essentially in line with that published for the English version of the questionnaire, the remaining analyses are based on the structure of 4 subscales proposed in the original validation study.[18]

Validity

The concurrent validity was assessed by determining the Spearman correlation coefficients for SATQ scores (overall and for each subscale) with the score on the corresponding criterion question. The correlation coefficients are shown in Table 4. The coefficients ρ for correlation with the criterion question were statistically significant for all subscales. Additionally, for all subscales, the coefficient for correlation with the overall satisfaction as perceived by the patient was higher than with the satisfaction perceived by the physician.

TABLE 3
Matrix of Rotated Components (Varimax Rotation) for the Spanish Version of the English Questionnaire From Campbell and Colleagues[18]

Items	Statement	Component			
		1	2	3	4
1	Es fácil saber cómo y cuándo debo tomar mi medicación para el asma (F)	0.589	0.421	–0.009	0.054
2	Siempre tengo el inhalador apropiado para el asma cuando lo necesito (F)	0.343	0.701	0.013	–0.017
3	Llevar encima mi inhalador para el asma puede resultar incómodo (I)	–0.083	0.321	0.506	–0.066
4	Es fácil encontrar el inhalador adecuado cuando lo necesito (F)	0.406	0.625	0.015	0.093
5	Mi inhalador me ayuda a sentir que puedo controlar los síntomas del asma (E)	0.845	0.235	0.075	–0.002
6	Me preocupa no estar tomando adecuadamente la medicación para mis síntomas (S)	0.096	–0.073	0.696	0.123
7	Siento que controlo mi enfermedad (E)	0.811	0.131	0.109	0.066
8	Me resulta fácil incorporar mi medicación para el asma en mi vida diaria (F)	0.471	0.582	0.114	0.018
9	Me da vergüenza utilizar mi inhalador para el asma en público (I)	–0.063	0.335	0.377	0.129
10	Rara vez salgo de casa sin llevar encima mi inhalador (F)	0.078	0.501	–0.060	–0.228
11	Mi medicación para el asma me deja la boca y la garganta secas (S)	–0.030	–0.051	0.087	0.840
12	Me gustaría seguir tomando mi medicación actual para el asma (E)	0.527	0.279	0.061	0.086
13	Cuando tomo mi medicación, estoy seguro de que los síntomas del asma estarán controlados (E)	0.817	0.164	0.151	–0.037
14	Mi medicación para el asma me deja mal sabor de boca (S)	–0.044	–0.038	0.136	0.840
15	Mi inhalador para el asma me cabe bien en el bolso o en el bolsillo (I)	0.253	0.527	0.160	–0.104
16	Me resulta fácil acordarme de tomar mi medicación para el asma (F)	0.397	0.628	0.074	–0.017
17	A veces salgo de casa con el inhalador equivocado (I)	0.043	0.504	0.291	0.236
18	Mi medicación para el asma me afecta a la voz (S)	0.113	0.043	0.174	0.696
19	Me siento seguro cuando uso mi inhalador (F)	0.825	0.335	0.085	–0.007
20	Usar más de un inhalador puede ser un lío o un problema (I)	0.080	0.370	0.540	0.041
21	Me preocupa que mi inhalador no me proporcione suficiente medicación (S)	0.193	–0.18	0.769	0.068
22	Recomendaría mi inhalador a otra persona con asma (E)	0.15	–0.008	–0.123	0.262
23	Me gustaría que mi medicación para el asma fuera más fácil de tomar (I)	0.237	0.114	0.682	0.041
24	Mi medicación para el asma me proporciona un alivio duradero (E)	0.829	0.054	0.026	0.131
25	Mi medicación para el asma es muy eficaz (E)	0.849	0.106	0.113	0.078
26	Mi medicación para el asma me da la confianza que necesito para afrontar el día (E)	0.827	0.160	0.049	0.001

Of the affirmations, the factor that loads on the item in the original questionnaire is indicated in parenthesis. E indicates effectiveness; U, ease of use; B, burden of asthma medication; S, side effects and worries.

The coefficients for correlation between the overall SATQ and ACQ scores were –0.209 (P=.001) and –0.263 (P<.0001) in the first and second visits, respectively. The coefficients for correlation between the "effectiveness" subscale and the ACQ score were –0.214 (P<.001) and –0.286 (P<.001), respectively.

The "effectiveness" domain score did not correlate with PEF measured with the peak flow meter (ρ=–0.069 and 0.059 in the first and second visits, respectively).

Three of the 4 subscales of the SATQ could distinguish between patient classifications according to the GINA criteria. The "effectiveness" subscale provided the greatest discrimination (P<.050). "Ease of use" distinguished between patients with intermittent and moderate or severe persistent asthma (P<.050). The "side effects and worries" subscale distinguished between patients with intermittent asthma and those with severe persistent asthma (P<.050), and the "burden of asthma medication" domain did not discriminate between categories of the GINA classification. The overall score did not differ statistically according to GINA category.

For lung function (FEV_1/FVC% and PEF), no differences were found between different terciles for scores on any of the subscales or for the overall score.

The "side effects and worries" subscale distinguished between patients with and without exacerbations in the year prior to study entry (mean [SD], 4.35 [1.57] and 4.87 [1.37], respectively; P=.009), although it did not discriminate between those with severe and nonsevere exacerbations (P=.214). Finally, no differences were found on any of the subscales according to whether patients had been

TABLE 4
Spearman Coefficients for Correlation Between Each Dimension and the Criterion Questions and Overall Perception Question Put to the Physician and the Patient

Satistaction with Asthma Treatment Question	First Visit		
	Criterion Question	Overall Satisfaction	
		Physician	Patient
Dimensions			
Effectiveness	0.600*	0.353*	0.598*
Ease of use	0.434*	0.300*	0.481*
Burden of asthma medication	0.165†	0.098	0.203*
Side effects and worries	0.246*	0.126	0.220*
Overall score	0.295*	0.507*	

*P<.01.
†P<.05.

TABLE 5
Mean (SD) Scores in the First and Second Visits for Patients in a Stable Clinical Condition: Intraclass Correlation Coefficients*

SATQ	Visit		*P*	ICC (95% CI)
	First†	Second†		
Dimensions				
Effectiveness	5.6 (1.1)	5.7 (1.0)	.009	0.916 (0.891-0.935)
Ease of use	6.0 (0.9)	6.0 (0.9)	.108	0.899 (0.868-0.922)
Burden of use	5.1 (1.2)	5.0 (1.2)	.408	0.860 (0.819-0.892)
Side effects	4.6 (1.5)	4.7 (1.4)	.117	0.841 (0.794-0.878)
Overall score	5.4 (0.8)	5.4 (0.8)	.057	0.912 (0.886-0.932)

*ICC indicates intraclass correlation coefficient; CI, confidence interval; SATQ, Satisfaction with Asthma Treatment Questionnaire.
†Data presented as mean (SD).

admitted to hospital at some point during the previous year.

The SATQ distinguished between patients who used a single inhaler and those who used 2 for the "effectiveness" (*P*=.030) and "ease of use" (*P*=.043) subscales but not for the "burden" or "side effects and worries" subscales or for the overall score.

Reliability

In the assessment of internal consistency of the SATQ, the α levels obtained were high for the "effectiveness" and "ease of use" subscales, with values of 0.866 and 0.811, respectively, and acceptable for the "burden of asthma medication" and "side effects and worries" subscales, with values of 0.600 and 0.708, respectively. For the overall evaluation of the questionnaire, the α level was 0.880. The clinical status of 15 patients worsened between the test and the retest. These patients were excluded from the test-retest reliability assessment. The ICCs for overall score and the 4 subscales are presented in Table 5. The comparison of the mean scores obtained in the test and retest did not reveal any significant differences, except for the "effectiveness" dimension. Nevertheless, the ICCs were high for the 4 subscales and for the overall score.

Feasibility

In the first visit, 32 patients (13.5%) took less than 3 minutes to fill out the SATQ, 94 (39.5%) took between 3 minutes and 5 minutes, 94 (39.5%) between 5 minutes and 10 minutes, and 18 (7.6%) took more than 10 minutes. Overall, 93.7% (n=224) answered all 26 questions of the SATQ, whereas 3.8%, 0.8%, and 1.7% of the population left blank questions 1, 2, and 9, respectively. The times taken to fill out the questionnaire and the percentages of unanswered questions were similar in the second visit. No item received the maximum score from more than 75% of the population (that is, there was no ceiling effect), although more than 50% of the participants gave the maximum score for 6 items (1, 2, 4, 8, 17, and 18). No significant grouping was seen for low scores (lack of floor effect).

Discussion

The main aim of this study was to describe the psychometric properties of the Spanish version of the SATQ for evaluating the satisfaction of patients with their inhaled asthma medication, as well as the applicability of the questionnaire in routine clinical practice.

The SATQ is a instrument whose validity and reliability were acceptable after adaptation. It was also easy to fill out in the clinics where asthma patients are assessed and monitored. The dimensionality of the adapted version of the SATQ was similar but not identical to the English version. The percentage of the variance explained by each of the factors was fairly similar in the Spanish version and in the original version (55.1% and 48.3%, respectively), but there were some differences. The 2 items (6 and 21) related to problems with the medication loaded on the same factor, burden of treatment, whereas in the original version, these items loaded on side effects.[18]

Questions 15 and 17 are formulated such that, according to the face validity, they are closer to the concept of "ease of use" than to "burden of asthma medication." Item 19 was moderately correlated with its original domain ("ease of use"), but it also showed a strong correlation with the "effectiveness" domain. This may be because patients associate the safety of a medication with its efficacy.

Question 1, translated as if it were "It's easy to know how and when I should take my asthma medication," also loads on 2 domains, possibly because of the double *how and when* (*cómo y cuándo*) formulation in Spanish. The *how* (*cómo*) could be associated with ease of use and the *when* (*cuándo*) with effectiveness.

Question 22, translated as if it were "I would recommend my inhaler to another person with asthma" deserves a separate mention. In a health care system such as the Spanish one, where patients are encouraged not to follow advice from outside the health care setting through government-sponsored publicity campaigns, this item could perhaps be eliminated. In our case, we repeated the factorial analysis without item 22 and found no substantial change in the dimensionality of the questionnaire.

Given that the differences obtained between the English and Spanish version were small, it was

appropriate to adopt a single structure for the purpose of comparing the results with the different versions. Thus, the originally proposed structure was adopted for the subsequent analyses. The validity of the domains was assessed by comparing them with the corresponding criterion questions. All subscales had a significant relationship with their criterion question, although the strength of this correlation was only moderate to high for the "effectiveness" and "ease of use" subscales. Moreover, these subscales correlated better with satisfaction expressed by the patient than with the physician's assessment. This is a valuable aspect because it makes the instrument sensitive to differences in perception between health care professionals and patients.[7,22]

Both the overall score and the "effectiveness" subscale score correlated negatively with symptom control as measured with the ACQ (a higher SATQ score and lower ACQ score correspond to better symptom control), although this correlation was weak (absolute values <0.3). In the classification according to the GINA criteria, higher scores were obtained for the "side effects" subscale (greater satisfaction) in patients with milder signs and symptoms. However, lower scores were obtained on the "effectiveness" and "ease of use" subscales (less satisfaction) in patients with intermittent asthma than in patients with persistent asthma. None of the dimensions distinguished between patients with different lung function, regardless of whether measured by spirometry (FEV_1/FVC%) or a peak flow meter (PEF).

This failure points to a discrepancy between the objective clinical situation (GINA state, PEF, FEV_1, etc) and satisfaction. A single measurement of lung function might provide a poor reflection of the day-to-day experience of the patient, as has already been shown in other studies.[23,24] In fact, some asthma patients do not actually perceive the improved lung capacity resulting from bronchodilator use.[25] Furthermore, some studies found a link between the preferences of asthma patients and their lung function characteristics as measured, for example, by FEV_1, but that link was only weak or moderate.[26,27] In other respiratory diseases such as chronic obstructive pulmonary disease, studies have shown that patients in the early stages of the disease score lower on quality-of-life scales than those at intermediate stages of the disease.[28] Quality of life and treatment satisfaction are not the same thing, but there is a certain overlap. It is believed that patients have greater expectations in the initial stages of the disease, and that satisfaction might be defined as a balance between expectations and the extent to which these are met.[29] Therefore, even though the clinical situation of such patients is better, they also report greater satisfaction with any intervention, including treatment.

The internal consistency, a measure of reliability, was acceptable according to standard criteria,[30] given that the α values were greater than 0.7 for all dimensions except "side effect and worries" (0.60) and were somewhat lower than those found in the validation of the original scale (between 0.71 and 0.88).[18] The test-retest reliability yielded an acceptable ICC. Comparison of the means confirmed this reliability, even for the effectiveness domain, despite a difference of a tenth of a point in the second measure, which, although significant, was not, in our opinion, clinically relevant because the lower limit of sensitivity in questionnaires that use the same scales is 0.5.[23]

The SATQ is easy to fill out in the real-life setting of the clinics in the Spanish health system. The questionnaire was completed in less then 5 minutes by 53% of the patients and in less than 10 minutes by 92.5%, a finding that is in line with the findings for the English version, which was completed in less than 7 minutes by 60% of the patients.[18] The percentage of missing responses was low, given that 93.7% of the patients answered the questionnaire in full.

The only subscale with a hint of a ceiling effect was "ease of use," suggesting that, in general, the questionnaire was sufficiently sensitive to different stages of the disease.

The strong points of the this study include the careful design and implementation of the different constructs of the instrument in its initial format, a factorial grouping in the adapted version similar to the original version, particularly for the "effectiveness" and "ease of use" domains, acceptable consistency for measurement of satisfaction, and good acceptance on the part of the patient and the health care professional, as confirmed in real-life clinical settings. Validation of the adapted instrument was also done with a sufficiently large sample size (more than twice the number of subjects included in the validation process for the original format), with sufficient representation for all disease severities, regions of Spain, and socioeconomic categories.

Aspects still to be addressed include sensitivity to change (responsiveness) and assessment of the "minimum clinically relevant difference" with this questionnaire. Furthermore, some changes to the composition of the domains may arise with use of the questionnaire, because validation is an ongoing process that will not stop once the results of the study are published.[31]

In conclusion, we believe that assessment of the satisfaction of asthma patients with their inhaled treatment is of utmost importance. The SATQ represents a valid and reliable instrument for evaluating this satisfaction.

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