ORIGINAL ARTICLES

Assessment of Patient Satisfaction and Preferences With Inhalers in Asthma With the FSI-10 Questionnaire

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BACKGROUND AND OBJECTIVE: Lack of adherence to inhaled corticosteroid therapy is common in patients with asthma, and it has been suggested that allowing patients to choose their own inhalers would resolve this problem. The FSI-10 (Feeling of Satisfaction with Inhaler) is a self-completed questionnaire to assess patient opinions regarding ease or difficulty of use, portability, and usability of devices for delivery of inhaled corticosteroids. The aim of this study was to define the measurement properties of the FSI-10 questionnaire and to use this inventory to compare satisfaction and preferences of patients with asthma regarding 3 different devices for delivery of inhaled corticosteroids: Turbuhaler, Accuhaler, and Novolizer.

PATIENTS AND METHODS: We performed a multicenter, prospective, observational study in 112 stable asthmatic patients (64 women; mean [SD] age, 37 [22] years) treated on a regular basis with inhaled corticosteroids. The use of the devices was explained to the patients and the order in which they should be used in each case was randomly assigned. The devices were used for 7-day periods and at the end of each the FSI-10 questionnaire was completed for the device used. Once the protocol was completed, patients stated their preference for the different devices used.

RESULTS: The FSI-10 was easily understood and rapidly completed, and it exhibited acceptable measurement properties. Factor analysis showed that the measure was unidimensional. Although acceptance of all 3 devices assessed was reasonable, the FSI-10 questionnaire detected significant differences between them: Turbuhaler and Novolizer scored higher than Accuhaler on a number of questions. This preference is partly explained by Turbuhaler having been the device that was commonly used by the patients prior to the study. However, the highest scoring and most often preferred inhaler in patients under 16 years of age was the Novolizer, even though the Turbuhaler had also usually been used by those patients prior to the study.

CONCLUSIONS: The FSI-10 is a useful instrument for assessing the degree of satisfaction of asthmatic patients regarding available inhalation devices. It is easy to understand and complete, and able to identify differences in patient satisfaction with the different inhalers.

Key words: *Preference. Inhalation devices. Corticosteroids. Asthma.*

Satisfacción y preferencia del paciente asmático por los dispositivos de inhalación. Aplicación del FSI-10

ANTECEDENTES Y OBJETIVO: El incumplimiento terapéutico con los corticoides inhalados (CI) es frecuente en los pacientes con asma. Se ha señalado que la elección del dispensador por el paciente facilitaría la solución del problema. El FSI-10 (Evaluación de la Satisfacción con el Inhalador) es un cuestionario autorrellenable que valora las opiniones sobre comodidad, dificultad, transportabilidad y manejabilidad de los dispositivos para CI. El objetivo de este trabajo ha sido definir las propiedades métricas del FSI-10 y comparar, mediante este inventario, la satisfacción y las preferencias de los pacientes con asma respecto a 3 dispositivos para CI: Turbuhaler® (T), Accuhaler® (A) y Novolizer® (N).

PACIENTES Y MÉTODOS: Hemos realizado un estudio observacional, prospectivo y multicéntrico en 112 asmáticos (64 mujeres; edad media ± desviación estándar: 37 ± 22 años) estables y tratados regularmente con CI. Se les explicó la técnica de utilización de los dispositivos a evaluar y, aleatoriamente, se asignó el orden en que debían emplearlos. Usaron los dispositivos durante períodos de 7 días, tras los cuales cumplimentaron el FSI-10. Completado el protocolo, todos ellos expresaron el grado de preferencia por los dispositivos empleados.

RESULTADOS: El FSI-10 resultó fácil de comprender y rápido de cumplimentar, y mostró propiedades métricas acepta-

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bles. El análisis factorial exploratorio muestra la unidimensionalidad de la medida. La aceptación de los 3 dispositivos evaluados fue razonable, pero el FSI-10 detectó diferencias significativas entre ellos: los sistemas T y N se valoraron mejor que A en bastantes preguntas del cuestionario. Esta preferencia responde en parte al hecho de que T era el dispositivo comúnmente utilizado con anterioridad por los pacientes. Sin embargo, para los menores de 16 años el inhalador preferido y mejor puntuado fue N, a pesar de que en este subgrupo también era el T el habitualmente manejado.

CONCLUSIONES: El FSI-10 es un instrumento útil para evaluar el grado de satisfacción del paciente asmático con los dispositivos de inhalación disponibles. Es comprensible, de fácil manejo y capaz de identificar diferencias de satisfacción entre distintos inhaladores.

Palabras clave: *Preferencias. Dispositivos de inhalación. Corticoides. Asma.*

Introduction

The use of inhaled corticosteroids for the treatment of asthma has increased notably in the last 30 years, during which time ongoing efforts have been made to design and improve the necessary inhaler devices. None of the currently available devices meet all of the criteria for an ideal inhaler.[1] Nevertheless, experience suggests that while those most used in day-to-day practice offer excellent therapeutic results it is not possible to clearly distinguish between the effectiveness of the currently available models.[2] This situation has led expert panels as prestigious as the one responsible for the guidelines of the British Thoracic Society to base choice of the device on patient preference, so long as dosage and administration are evaluated on the basis of careful assessment of clinical response.[3] This recommendation rests essentially on the principle that patient preferences and treatment satisfaction can favor adherence to corticosteroid therapy and, therefore, improve the efficacy of the treatment.[4,5]

To date, little has been published on the preference of patients for different inhalers.[4] In addition, the few standardized instruments specifically designed to analyze this particular element have been developed in cultural contexts that differ from those of Spain,[6-8] perhaps explaining the very limited Spanish contribution to the literature in this area.[9,10] In an effort to address these limitations, one of the authors of the present study (X. B.) recently developed a Spanish inventory, the FSI-10 (Feeling of Satisfaction with Inhaler) questionnaire, designed to determine the ease of use and patient satisfaction in relation to different inhalers, irrespective of the drug used. The FSI-10 is a freely available questionnaire.

The present study was a prospective, observational, multicenter study involving randomized distribution of the tested devices. It was designed to compare patient satisfaction with and preference for 3 commercially available inhalers for administration of corticosteroids—Turbuhaler (Astra-Zeneca, Lund, Sweden), Accuhaler (GSK, Brentford, Middlesex, UK), and Novolizer (Meda Pharma, Brussels, Belgium)—using the FSI-10. In parallel, the peculiarities and measurement properties of the questionnaire were assessed.

Patients and Methods

Patients and Study Design

The study was carried out between April and June 2006 in patients with stable, persistent, mild or moderate asthma who were recruited from the outpatient clinics of 9 Spanish hospitals. All received regular treatment with inhaled corticosteroids at different doses and none had received any other inhaled medication, except for rescue medication with bronchodilators, in the last 6 months. Patients were informed of the aims of the study and provided voluntary consent to their involvement. In children, consent was provided by parents or guardians. Prior to completion of the questionnaire, enrolled patients were interviewed by a member of the research team, who explained how to answer the questions and asked that they do so on their own and honestly.

Each participant received one of the inhalers to be used for a period of 7 days; the order in which they received the different inhalers was randomly assigned. Once that period was finished, each patient was given one of the other inhalers. Thus, the total study period for each patient was 3 weeks.

Randomization of the order in which patients received the different inhalers was done with a Latin square and when changes were made the corticosteroid dose was adjusted on an individual basis to ensure that the dose received by each patient was as similar as possible (budesonide: fluticasone equivalent, 2:1). Before each device was given to the patient, verbal instructions were provided regarding its use and possible errors were corrected using an identical inhaler containing a placebo. At the end of each period of use, patients were asked to complete the FSI-10 questionnaire to assess satisfaction with the inhaler used and they were also asked to provide a practical demonstration of its use with a placebo device. In an effort to minimize between-patient and between-hospital differences, each participating hospital designated a single investigator responsible for instruction of patients, and it was emphasized to those patients that the study inhaler was the one to be used for maintenance treatment. Finally, after completion of the 3 weeks of the protocol, all patients expressed their preference for the tested inhalers according to the following scoring system: 1, first choice; 2, second choice; and 3, last choice. To avoid bias as a result of temporal proximity to the last inhaler tested, when indicating overall preference, patients had access to their previous responses on the FSI-10 questionnaires they had completed for each individual inhaler.

The study protocol was approved by the ethics committee of Hospital General Yagüe in Burgos, Spain.

Questionnaire

The FSI-10 is a self-report instrument containing 10 questions, each with 5 possible responses on a 5-point Likert scale (very, fairly, somewhat, not very, hardly at all) scored from 5 to 1, respectively (maximum total score, 50). It assesses the level of satisfaction of patients with the inhaler and includes items on ease or difficulty of use, portability, and usability (Appendix).

Statistical Analysis

The measurement properties of the FSI-10 questionnaire were analyzed by assessing possible item reduction and determining the domain structure. Loss of value was defined as any question left blank by the patient, and it was accepted that those with more than 5% lost responses and those that had more than 75% of the responses at either end of the scale (ceiling and floor

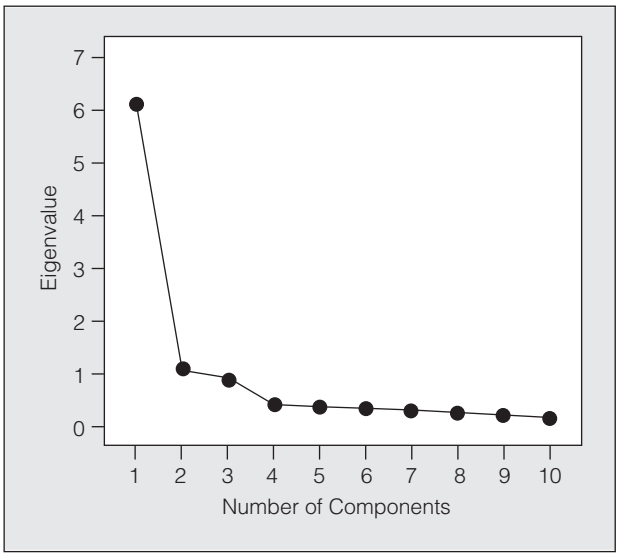

Figure 1. Scree plot for the FSI-10 questionnaire.

effect) could be eliminated. To establish the homogeneity index, the Pearson correlation coefficient between the scores on each question and the total score was calculated; it was estimated that correlation coefficients below 0.4 reflected the absence of a relationship between that question and the other questions in the instrument. Finally, for the correlation between questions, the Pearson correlation coefficient was calculated, assuming that values greater than 0.8 indicated redundancy that would contribute to unnecessary length of the questionnaire. The domain structure of the FSI-10 questionnaire was assessed by factor analysis—principal component analysis with varimax rotation and extraction of factors according to the scree test[11]—and reliability was assessed in terms of internal consistency according to the Cronbach α,[12] considering that values above 0.8 reflected good internal consistency and, consequently, that the different questions measured a single construct or dimension.

The sample size was calculated to allow multiple comparisons between the 3 inhalers, with an individual significance of *P*=.005 and an overall significance of *P*=.016. With a statistical power of 0.80 and a potential loss to follow-up of 10%, the number of patients required was 110.

The values obtained were expressed as mean (SD) or median, and we used repeated measures analysis of variance and the post hoc Bonferroni test, or the *t* test, as appropriate, to compare the inhalers Comparison of frequencies was done by χ^2 test and correlations were analyzed with the Pearson correlation coefficient. Data were analyzed with SPSS version 12.0 (SPSS Inc, Chicago, Illinois, USA).

Results

Patient Characteristics

The final patient group comprised 112 participants (64 female and 48 male) with a mean (SD) age of 37 (22) years. In 78 cases (69.6%), budesonide was the corticosteroid normally used and in 34 (30.4%) it was fluticasone delivered with the Accuhaler. Of those treated with budesonide, the majority (n=67) used the Turbuhaler and the rest (n=11) used the Novolizer. The median dose of budesonide and fluticasone they received was 800 and 400 µg, respectively, distributed in 2 daily doses. During the study period, none of the patients showed changes in their clinical situation and all performed the inhalation maneuver correctly with the different devices at the beginning and end of the study.

Preliminary Validation of the FSI-10 Questionnaire

The following analysis took into consideration the responses of all participants on the 3 occasions they completed the questionnaire (n=336).

The mean time to complete the questionnaire was 6.36 (3.9) minutes and no differences were encountered according to level of education, sex, or age. None of the 10 items on the questionnaire were left without response. However, there was some accumulation of responses at the extremes of the response scale, although the distribution was always unimodal. The accumulation of responses in the highest category only exceeded 50% on items 2 and 6 (53% and 51%, respectively). The FSI-10 displayed adequate homogeneity and a correlation of more than 0.8 was only found between questions 1 and 2.

Regarding the domain structure of the questionnaire, the scree plot (Figure 1) showed that, in principle, the number of components to extract should be 2, since the eigenvalue of the third component was less than 1. The first factor (explained variance, 50.6%) grouped 8 of the 10 items on the questionnaire (items 1 to 8) and displayed excellent internal consistency (Cronbach $\alpha = 0.93$), which remained essentially stable when the weight of each item was controlled for (a negligible increase in Cronbach α only with elimination of item 7). The second factor (explained variance, 21%; Cronbach $\alpha = 0.79$) included only items 3, 9, and 10, with the saturation of item 3 lower than that observed in factor 1 (0.74 vs 0.44 in factors 1 and 2, respectively). These results raise questions about the viability of maintaining a bifactorial structure. The limited number of items in the second factor, along with the moderate reliability that it logically presents, support considering a unifactorial structure for this questionnaire. In fact, the unifactorial solution grouping the 10 items together gives values greater than 0.59 in all cases and the Cronbach α for the questionnaire as a whole is more than satisfactory (0.92).

Nevertheless, in an effort to minimize the possible error variance that could occur as a result of considering the responses of the same patients on 3 different occasions, these same analyses were reproduced independently for each of the different situations (Turbuhaler, Accuhaler, and Novolizer). The results of the subsequent factorial analyses were congruent with those described for the 3 devices considered together.

Scores on the FSI-10 Questionnaire

In the whole sample, the total score on the FSI-10 for each of the inhalers was 44.8 (5.7) for the Turbuhaler, 39.5 (6.5) for the Accuhaler, and 43.38 (6.4) for the Novolizer. Statistically significant differences were observed between the scores for the Turbuhaler and Accuhaler devices (*P*=.001) and between those for the

Accuhaler and Novolizer devices (*P*=.001). The total scores on the FSI-10 for the Turbuhaler and Novolizer, however, were comparable (*P*=.17).

The direction of these results did not change when taking into account sex or the length of time since onset of disease, but a significant negative correlation ($r = –0.29$, *P*=.021) was observed between age and total score on FSI-10 for the Novolizer device. Comparison of means for the total scores on the FSI-10 for each of the 3 inhalers, grouping patients according to age—older than 16 years (n=88) and 16 years or younger (n=24)—revealed that the significance of the correlation was due to the total score for the Novolizer inhaler being significantly higher in the younger than in the older group (Table 1).

Table 2 shows the mean scores for each of the items on the questionnaire administered following use of the Turbuhaler, Accuhaler, and Novolizer in the complete patient group. As can be seen, the scores for the Turbuhaler and Novolizer were similar and significantly higher than those obtained for the Accuhaler on 5 of the 10 items, relating to ease of preparation (item 2), ease of use (item 3), ease of performing normal activities when using the inhaler (item 5), comfort of the mouthpiece (item 6), and overall satisfaction with the device (item 10). On items 1 (ease of learning the maneuver) and 4 (ease of cleaning and hygiene), the best-scoring device was the Turbuhaler, although without statistically significant differences compared with the Novolizer, while for items 7 and 8 (portability and convenience in terms of weight and size) the Turbuhaler ranked first and was followed by the Novolizer and finally the Accuhaler. Finally, on question 9 ("When using the inhaler, are you left with the feeling that you used it correctly?"), the highest scores were

TABLE I
Differences in Total Score on the FSI-10 Questionnaire for the Different Inhalers According to the Age of the Patients

	Age, y		*P*
	≤16	>16	
Turbuhaler	44.1 (4.6)	43.4 (5.3)	NS
Accuhaler	38.6 (7.6)	39.6 (8.4)	NS
Novolizer	45.1 (4)	41.9 (8)	.037

[a]Results are expressed as means (SD).
Abbreviation: NS, not significant.

TABLE 2
Mean Values and Differences in Score on the Different Items of the FSI-10 Questionnaire for Each of the Inhalers Analyzed (Complete Patient Group)

Item	Turbuhaler	Accuhaler	Novolizer	*P*
1	4.6 (0.06)	4.4 (0.1)	4.4 (0.1)	T vs A, *P*=.001 T vs N, NS N vs A, NS
2	4.6 (0.07)	4.2 (0.1)	4.6 (0.08)	T vs A, *P*=.017 T vs N, NS N vs A, *P*=.001
3	4.5 (0.07)	4.1 (0.1)	4.6 (0.08)	T vs A, *P*=.002 T vs N, NS N vs A, *P*=.002
4	4.6 (0.07)	4.2 (0.1)	4.4 (0.1)	T vs A, *P*=.002 T vs N, NS N vs A, NS
5	4.6 (0.07)	4.2 (0.1)	4.3 (0.03)	T vs A, *P*=.011 T vs N, NS N vs A, *P*=.04
6	4.6 (0.06)	4 (0.1)	4.5 (0.1)	T vs A, *P*=.001 T vs N, NS N vs A, *P*=.004
7	4.5 (0.08)	3.4 (0.1)	3.9 (0.1)	T vs A, *P*=.001 T vs N, *P*=.002 N vs A, *P*=.001
8	4.5 (0.08)	3.5 (0.1)	4 (0.1)	T vs A, *P*=.001 T vs N, *P*=.001 N vs A, *P*=.001
9	3.9 (0.1)	3.7 (0.1)	4.5 (0.1)	T vs A, NS T vs N, *P*=.004 N vs A, *P*=.001
10	4.4 (0.1)	3.9 (0.1)	4.3 (0.1)	T vs A, *P*=.001 T vs N, NS N vs A, *P*=.01

Abbreviations: A, Accuhaler; N, Novolizer; NS, not significant; T, Turbuhaler.
[a]Data are expressed as mean (SD).

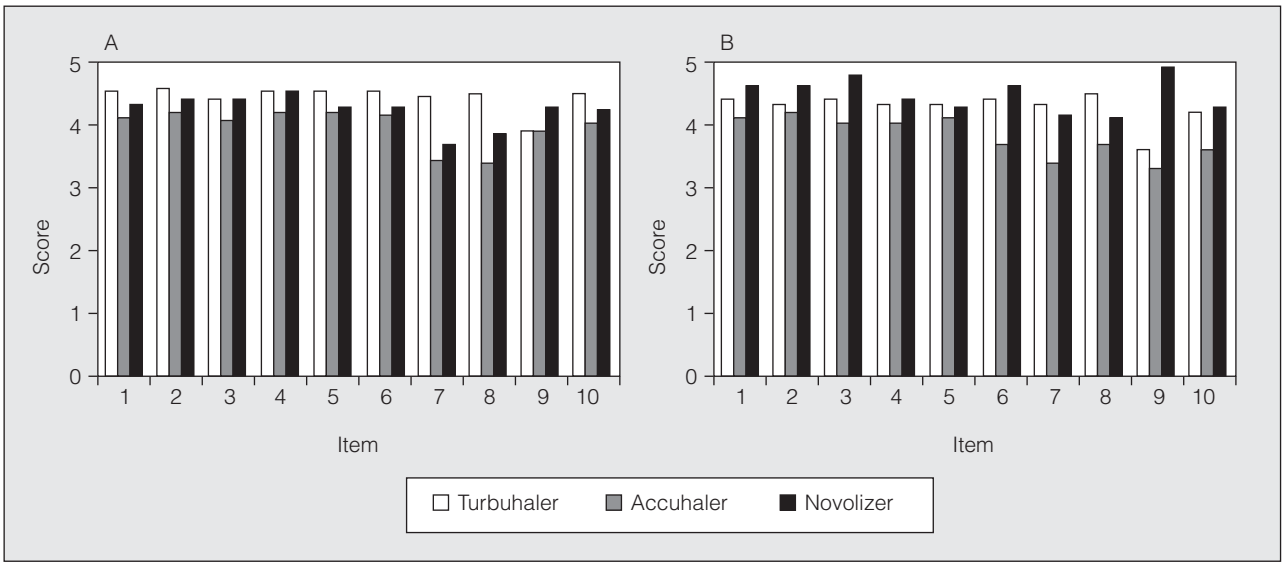

Figure. 2. Mean scores for each of the items on the FSI-10 questionnaire in patients older than 16 years (n=88) (A) and aged 16 years or younger (n=22) (B) with the 3 devices tested.

obtained for the Novolizer, with no significant differences between the Turbuhaler and Accuhaler.

Figure 2 shows the scores for each of the questions on the FSI-10 for patients older than 16 years and patients 16 years or younger. In the older patients, the results showed a fairly similar pattern to that observed for the whole group; in fact, on 7 of the items (2, 3, 4, 5, 8, 9, and 10), the results were completely congruent. However, patients aged 16 years or less responded differently: *a)* the Novolizer scored best on items 1, 2, 3, 6, and 9; *b)* the scores for the Novolizer were similar to those for the Turbuhaler and higher than those for the Accuhaler for items 4, 7, and 10; *c)* there were no differences between the devices on item 5; and *d)* Turbuhaler was only the highest-scoring device on item 8.

Preference for Different Inhalers

When the patients were asked at the end of the study to rank the inhalers according to preference, 41% chose Turbuhaler, 35% Novolizer, and the remainder (24%) Accuhaler. The differences between these frequencies were not statistically significant (χ^2 test). The following preferences were observed for patients older than 16 years when the group was divided according to age: the Turbuhaler was chosen by 50%, the Novolizer by 27%, and the Accuhaler by 23% (*P*=.025). In the younger patients, the order of preference changed, such that the preferred inhaler was now the Novolizer device (60%), while Turbuhaler and Accuhaler were only preferred by 20% of patients in each case (*P*=.04). Since the device normally used could have been a source of bias, we analyzed the order of preference in relation to this variable, leaving out those who used the Novolizer inhaler because there were so few. The most commonly used device in asthmatic patients aged less than 16 years was the Turbuhaler (71%). Patients aged more than 16 years who were treated regularly with the Turbuhaler (n=50) expressed preference for the Turbuhaler in 55% of the cases, the Novolizer in 33%, and the Accuhaler in 12%. For the users of the Accuhaler (n=30), the preferences were the Accuhaler in 57%, the Turbuhaler in 33%, and the Novolizer in 10%.

Discussion

Assessment of patient satisfaction with health care received is an area which was driven forward notably in the United States in the 1970s as a result of the appearance of consumer groups, and it has gradually been incorporated into the analysis of the results of health care along with other measures for which the source of information is essentially the patient (quality of life, utility, and treatment adherence).[13-16] Treatment satisfaction has been defined as a measure of the process of using a treatment and its associated results, or as the attitude of the individual in relation to the various dimensions that make up the treatment, combining expectations with experience.[5] In the case of asthma, we know that lack of patient satisfaction with treatment tends to be associated with a worse disease course and poorer disease control,[17] and it is also accepted that the greater the degree of satisfaction with a treatment, the better the treatment adherence.[3,4]

In the present study, we analyzed the satisfaction of asthmatic patients with different corticosteroid inhalers and their preferences for particular devices through the use of a new specifically designed instrument, the FSI-10. To date, the only standardized instrument with similar characteristics that has been available for use in the Spanish population is the translated version of the Satisfaction with

Inhaled Asthma Treatment Questionnaire (SATQ),[18] initially described by Campbell et al.[6] The SATQ contains 26 items grouped in 4 domains (effectiveness of treatment, ease of use, medication burden, and side effects and worries), and the Spanish version displays a similar, although not identical, domain structure to the original version.[18] According to the authors of the questionnaire, it has acceptable internal consistency and a good test-retest reliability,[6] but they did not specify the minimum clinically significant difference or the sensitivity to change. In fact, the only questionnaire on patient satisfaction and preferences for inhalers in which those 2 parameters are defined is the Patient Satisfaction and Preference Questionnaire (PASPQ).[8,19] To our knowledge, there is no Spanish translation of the PASPQ, and the SATQ has not yet been used to assess differences in preference for inhalers.

Our estimates in the preliminary validation of the FSI-10 indicate that the questionnaire is understandable and easy to use, and that is has quite satisfactory measurement properties. Given its unidimensionality, the FSI-10 offers a score summarizing the various aspects that patients seem to use when expressing their level of satisfaction with a specific device (simplicity of learning and use, ease of use, portability, etc) and the possibility of assessing them independently by considering each item separately. Since we have not yet established the instrument's sensitivity to change or the minimum clinically significant difference, the final interpretation of the findings obtained with the questionnaire should be considered provisional and exploratory, bearing in mind that validation of any inventory is the result of an ongoing process through the continued use of the instrument and cannot be based on the conclusions of a single study.[20] Nevertheless, taking this premise into consideration, the results of the present study indicate that, although all the inhalers that were tested seem to be reasonably well accepted—the mean score was close to or more than 4 ("very") for a large number of items on the FSI-10—there were significant differences between them, at least from a statistical point of view.

In general, the Turbuhaler and Novolizer devices (particularly the Turbuhaler) were associated with the greatest satisfaction, as they had higher scores than Accuhaler for many of the questions on the FSI-10. Nevertheless, in the group of asthmatic patients aged 16 years or younger, the Novolizer was the most often preferred and highest scoring inhaler.

In our opinion, beyond the detailed analysis of the items for which one or another inhaler displayed advantages, there are 2 main conclusions to be drawn from the results of our study. The first is that prior and continued use of a particular inhaler affects the final satisfaction expressed by the patient when asked to choose between different devices. In the design of the study, we were particularly careful to ensure that participants knew how to use the inhalers. Nevertheless, the order of preference was clearly influenced by prior experience with some of the devices. The only way of controlling this effect would be to design a new study in which the participants had never used an inhaler. We also do not know how long an inhaler should be used in order for the patient to become accustomed to the device and consider it the most satisfactory compared with other options.

The second conclusion is that, at least in our study, younger asthmatic patients display a level of satisfaction with the Novolizer that is not explained by familiarity with the device, since the Turbuhaler device was more commonly used in that group. One possible explanation would be that the level of satisfaction and preference in this group are influenced by the positive response to novelty that is common in this age group. Nevertheless, it is noteworthy that the choice was of the Novolizer rather than the Accuhaler device. It may therefore be supposed that, compared with the other 2 devices, some particular features of the Novolizer are more attractive to asthmatic patients in this age group. According to the items on which the Novolizer scored the highest, these aspects would include ease of learning, ease of preparation and use, convenience, fitting of the apparatus to the lips, and feeling of having used the device correctly. Unfortunately, the number of patients aged 16 years or younger included in this study was too small to reach definitive conclusions on this point.

In summary, we believe that the FSI-10 questionnaire is a useful instrument with which to assess the degree of satisfaction of asthmatic patients regarding available inhalation devices, as it is understandable, easy to use, and requires little time to complete. The present preliminary and exploratory study shows that the instrument is able to detect differences between different inhalers, though such differences should be interpreted with caution until the stability of the measure, its sensitivity to change, and the minimum clinically significant difference have been determined.

REFERENCES

1. Sanchis J. New trends in aerosol therapy: the clinicians view. Eur Respir Rev. 1994;18:106-7.
2. Dolovich MB, Ahrens RC, Hess DR, Anderson P, Dhand R, Rau JL, et al. Device selection and outcomes of aerosol therapy: evidence-based guidelines: American College of Chest Physicians/American College of Asthma, Allergy, and Immunology. Chest. 2005; 127: 335-71.
3. British Thoracic Society, Scottish Intercollegiate Guideline Network. British guideline on the management of asthma. Thorax. 2003;58 Suppl 1:1-94.
4. Anderson P. Patient preference for and satisfaction with inhaler devices. Eur Respir Rev. 2005;96:109-16.
5. Badia X. La satisfacción con el tratamiento. Med Clin (Barc). 2005;125:98-9.
6. Campbell JL, Kiebert GM, Partridge MR. Development of the Satisfaction with Inhaled Asthma Treatment Questionnaire. Eur Respir J. 2003;22:127-34.
7. Welch MJ, Nelson HS, Shapiro G, Bensch JW, Sokol WN, Smith JA, et al. Comparison of patient preference and ease of teaching inhaler technique for Pulmicort Turbuhaler versus pressurized metered-dose inhalers. J Aerosol Med. 2004;17:129-39.
8. Schurmann W, Schmidtmann S, Moroni P, Massey D, Qidan M. Respimat Soft Mist inhaler versus hydrofluoroalkane metered dose inhaler: patient preference and satisfaction. Treat Respir Med. 2005;4:53-61.

9. Serra Batlles J, Plaza V, Vadiola C, Morejón E. Patient perception and acceptability of multidose dry powder inhalers: a randomized crossover comparison of Diskus/Accuhaler with Turbuhaler. J Aerosol Med. 2002;15:59-64.
10. Giner J, Torrejón M, Ramos A, Casán P, Granel C, Plaza V, et al. Preferencias de los pacientes en la elección de dispositivos de inhalación en polvo. Arch Bronconeumol. 2004;40:106-9.
11. Cattell RB. The scree test for the number of factors. Multivar Behav Res. 1966;1:140-61.
12. Crombach LJ. Coefficient alpha and the internal structure test. Psychometrika. 1951;16:297-334.
13. Clancy CM, Eisenberg JM. Outcomes research: measuring the end results of health care. Science. 1988;282:245-6.
14. Fitzpatrick R. Surveys of patient satisfaction: I. Important general considerations. BMJ. 1991;302:887-9.
15. Donabedian A. Evaluating the quality of medical care. Milbank Mem Fund Q. 1996;44:166-203.
16. Patrick DL, Chiang YP. Measurement of health outcomes in treatment effectiveness evaluations: conceptual and methodological challenges. Med Care. 2000;38 9 Suppl:14-25.
17. Markson LE, Vollmer WM, Fitterman L, O´Connor E, Narayanan S, Berger M, et al. Insight into patient dissatisfaction with asthma treatment. Arch Intern Med. 2001;161:379-84.
18. Martín Fernández J, Barcina Sánchez C, Jiménez Jiménez FJ, Marazuela Bermejo R. Estudio de validación de la versión adaptada al castellano del cuestionario de satisfacción con la medicación inhalada en pacientes asmáticos. Arch Bronconeumol. 2006;42: 575-82.
19. Kozma CM, Slaton TL, Monz BU, Hoddr R, Reese PR. Development and validation of a patient satisfaction and preference questionnaire for inhalation devices. Treat Respir Med. 2005;4: 41-52.
20. Guyatt GH, Feeny DH, Patrick DL. Measuring health-related quality of life. Ann Intern Med. 1993;118;622-9.

APPENDIX

FSI-10 (Feeling of Satisfaction With Inhaler) Questionnaire

How would you score the inhalation device you have used in the last week on the following points? Choose only 1 response, the one that best reflects your opinion. There are no right or wrong answers. We simply want to know your opinion on certain features of the inhaler.

Please answer honestly and do not leave any questions unanswered.

1. Has it been easy to learn how to use the inhaler?
   ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all
2. Was it easy to prepare the inhaler for use?
   ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all
3. Was it easy to use the inhaler?
   ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all
4. Was it easy to keep the inhaler clean and in good working condition?
   ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all
5. Was it easy to continue normal activities with the use of the inhaler?
   ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all
6. Did the inhaler fit your lips comfortably?
   ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all
7. Was using the inhaler easy in terms of size and weight?
   ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all
8. Was it easy to carry the inhaler with you?
   ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all
9. After you've used the inhaler, do you have the feeling that you used it correctly?
   ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all
10. Overall, considering your responses to the previous questions, were you satisfied with the inhaler?
    ☐ Very ☐ Fairly ☐ Somewhat ☐ Not very ☐ Hardly at all