ORIGINAL ARTICLES

Development of a Questionnaire to Measure Asthmatic Patients’ Knowledge of Their Disease

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OBJECTIVE: To develop a valid, reliable, and sensitive self-administered questionnaire in Spanish to measure the knowledge asthmatic patients have of their disease.

PATIENTS AND METHODS: The face and content validity of the questions was established by consensus among expert pulmonologists. To determine the importance of the questions, they were put to 100 participating asthmatic patients. A further 25 patients participated in the assessment of reliability and sensitivity. The questionnaire was administered 5 times: twice before and 3 times after an educational intervention. The direct and indirect test-retest consistency (κ statistic) and the overall κ value were determined. Sensitivity was assessed from the number of correct answers before and after the intervention (Wilcoxon test; P < 0.05) and from the percentage change (> 40%, clinically significant).

RESULTS: Fifty-nine questions were drawn up and the final version included 20. The direct consistency was between 0.81 and 1 in 76% of the cases before the intervention and in 92% after it. The κ statistic before the intervention was between 0.41 and 1 in 96% of the cases, and between 0.81 and 1 in 88% afterwards. The overall κ values before and after the intervention were 0.12 and 0.43, respectively. The median sensitivity, measured as percentage change, was 67% and 10 patients showed an improvement between 81% and 233%.

CONCLUSIONS: The questionnaire is reliable, has face and content validity, and is very sensitive to change. In view of these results, this instrument is useful for measuring the knowledge asthmatic patients have of their disease in clinical practice and investigation.

Key words: Knowledge questionnaire. Asthmatic patient. Validity. Reliability. Sensitivity.
correctly interpreting measurements of peak expiratory flow rate, and controlling environmental factors that trigger crises. The patient should therefore acquire the appropriate knowledge, skill, expertise, and motivation to apply the treatment in all its aspects. In view of this, patient education forms an essential part of the international guidelines for the treatment of asthma and the objectives of these guidelines include increasing understanding and developing skills. The benefits and importance of educating asthmatic patients have been well documented but further investigation in this area is still necessary.

To date, many studies have assessed the effectiveness of education and self-management programs. Most of the studies in the adult population find that incorporating an educational intervention into medical treatment has effects on a number of variables; for example, it improves the quality of self-management, reduces symptoms, promotes family involvement, improves performance at school and work, favors therapeutic compliance, and reduces the number of hospitalizations and visits to the emergency room. However, other studies in adults do not support those findings, and some studies in children do not reflect any difference between traditional medical care and care that includes education as part of treatment. Use questionnaires on the patients' asthma knowledge to measure the impact of institutional educational programs on knowledge itself and the association between increased disease knowledge and a variety of measures such as therapeutic compliance, the quality of self-management, the frequency and severity of respiratory symptoms, the use of medications, and spirometry. These asthma knowledge questionnaires are available in languages other than Spanish, and recently, a Spanish version was developed and validated especially for parents and guardians of asthmatic children.

Clinicians and investigators are increasingly aware of how important it is to incorporate assessment of patient knowledge into the management and follow-up of diseases, particularly chronic ones, which require strong patient participation for successful treatment. The objective of the present study was to develop a valid, reliable and sensitive self-administered questionnaire in Spanish to measure the knowledge acquired by asthmatic patients in the Asthma Educational Program of the National Institute of Respiratory Diseases (INER) in Mexico City.

Patients and Methods

The study population comprised patients who attended the INER with a diagnosis of persistent asthma in accordance with international guidelines. Thus, diagnosis was based on a medical history indicative of asthma, and spirometry with an obstructive pattern and at least 12% reversibility in the forced expiratory volume in 1 second. We decided to include 150 patients with no age or socioeconomic restrictions. All were able to read and write and had signed an informed consent to participate in the study. When children were included in the study, the family member directly responsible for the minor was also invited to participate. This was a nonrandom convenience sample. Patients with highly uncontrolled asthma or cognitive disorders were excluded. In addition, patients were withdrawn from the study if they did not complete all its stages.

The self-administered questionnaire was designed to explore aspects of asthma knowledge that are most relevant to the patient's condition. The questionnaire was based on the overall content of the educational program run by the INER and, in general terms, included the following topics: symptoms, crisis trigger factors, diagnosis, flow measurements, treatment, use of inhalers and spacers, and prevention. The content of this program covered the topics proposed in several references in the literature.

The questionnaire was developed in order to measure a construct, in this case, the knowledge acquired by the patients after taking an asthma educational course at the INER. It was to be based on multiple-choice questions with no internal homogeneity, given that they indicate or express different attributes of a complex phenomenon. It was to be sensitive to change, valid, and reliable. The questionnaire was developed according to the method described below. We also wanted the questionnaire to assess multiple attributes with different questions (Figure).

Drafting, Selection, and Validity of the Questions

Three pulmonologists with expertise in asthma drew up questions necessary to determine the disease knowledge of the patients who attended a check-up at the INER. The pulmonologists used international guidelines on diagnosis and treatment to orient the questions. Each question was written on a card and coded with a number. Multiple-choice type questions were designed with 3 possible responses, including the option “I don’t know.” The face and content validity of the instrument was determined. We had no external reference against which to validate the questions so we consulted 3 expert pulmonologists specialized in asthma at the INER. These experts reviewed the questions and determined their validity by consensus, according to a modified form of the Delphi method.

Classification of Questions in Decreasing Order of Importance

One hundred patients with persistent asthma of all degrees of severity participated in determining the importance of the questions. They were asked to place the questions in decreasing order of importance and rate the importance attributed to each question with a number from 1 to 5 (1, not important; 2, not very important; 3, fairly important; 4, important; 5, very important).

Reduction in the Number of Questions and Application of the Preliminary Version of the Questionnaire

The questions were selected for the definitive version of the questionnaire using 2 methods: a) by consensus, according to the decision made by the panel of asthma experts on the content of the questionnaire, and b) by taking into account the average importance calculated from the individual ratings of importance attributed to the questions by the patients. The average importance for a given question was obtained from the sum of the products of each level of importance multiplied by the frequency with which that particular rating was assigned. After applying this process, 20 questions remained in the draft version of the questionnaire with the highest importance rating. A further 25 asthmatic patients who had not participated in the asthma educational program of the INER then answered the draft questionnaire to screen for incomprehensible questions.
The 20 selected questions were administered in five administrations of the questionnaire: the first and second administration and between the third and fourth administration. The fifth administration, in decreasing order are shown in Tables 1 and 2. Twenty questions were selected to form the definitive version of the questionnaire according to how often the initial questions were rated as important by the patients and the consensus of the expert panel. The questions covered the following topics: 1 question on the causes of asthma; 1 on pathophysiology; 2 on treatment goals; 1 on activities that asthmatic patients can carry out; 13 on everything do to with medication; 7 on flow measurement, spacers, and inhalation techniques for aerosol medication; and 13 on self-management (see Appendix for an English translation).

The characteristics of the 100 patients who participated by rating the importance of the 59 initial questions in decreasing order are shown in Tables 1 and 2. Twenty questions were selected to form the definitive version of the questionnaire according to how often the initial questions were rated as important by the patients and the consensus of the expert panel. The questions covered the following topics: 1 question on the causes of asthma; 1 on pathophysiology; 2 on treatment goals; 1 on activities that asthmatic patients can carry out; 13 on everything do to with medication; 3 on flow measurement, spacers, and inhalation techniques for aerosol medication; and 13 on self-management (see Appendix for an English translation).

The 20 selected questions were administered in preliminary form to a further 25 patients with asthma who had participated in the educational course. These patients were also asked to comment on the content of the questionnaire. No doubts or questions arose about the content of the questionnaire, and so this version was made the definitive one. With the 20 questions selected, 5 versions of the questionnaire were made retaining the content and wording but changing their order.
Evaluation of Reliability of the Questionnaire

The number of correct answers and errors was used to analyze the reliability of the questionnaire and its sensitivity was measured in terms of percentage change. The “I don’t know” answers were also counted as errors. Ninety-nine patients were included, but 74 were excluded from the analysis because they only participated in the first 2 administrations. The 5 phases were completed by the sample of 25 patients planned for this stage of questionnaire development. Tables 1 and 2 show the characteristics of these patients.

Reliability was assessed between administrations 1 and 2 of the questionnaire (prior to the educational intervention); between administrations 3 and 4; and between 4 and 5 (after the intervention) (Figure). The values of the $\kappa$ statistic at each of the administrations were as follows: in the first 2 administrations of the questionnaire (before the intervention), 24 (96%) of the patients had $\kappa$ values between 0.41 and 1, and 1 patient had a $\kappa$ value of 0; for the third and fourth administrations (just after the intervention), 22 patients (88%) had $\kappa$ values between 0.81 and 1; and the results were similar between the fourth and fifth administration of the questionnaire. Table 3 shows the results for consistency assessed by direct calculation of coincident responses and Table 4 shows the indirect ($\kappa$ statistic) assessment for the same pairs of administrations.

The overall $\kappa$ value for multiple measurements by subject, according to the Fleiss method, $^2$ was 0.12 ($P<.05$) for the first and second administrations (before the educational intervention), and 0.43 ($P<.01$) for the third, fourth, and fifth administrations of the questionnaire (after the intervention).

Sensitivity to Change

The calculations of the percentage change were made between the first and third administrations of the questionnaire, and between the first and fifth (Figure). Each patient was found to answer more questions correctly after the educational intervention (third and fifth administrations) than before the program (first and second). The average number of correct answers was 12 (4) in the first administration, 19 (2) in the third, and 19 (1) in the third. The differences between the first and third applications of the questionnaire, and between the first and fifth, were statistically significant ($P<.05$, Table 5).

The median percentage change, an expression of sensitivity, was 67% and 10 patients showed an
improvement of between 81% and 233%. The sensitivity results measured as the percentage change are shown in greater detail in Table 6.

**Discussion**

For a questionnaire to be used in a clinical setting, it must be valid, reliable, and sensitive to change. It should also be easy to administer, and the results should be easy to code and interpret. In accordance with the proposed objective, we developed a questionnaire to test the asthma knowledge of an asthmatic adult or the parents or guardians of an asthmatic child. This questionnaire covered general concepts about asthma and its management in a simple and practical fashion. The questionnaire is useful for measuring the level of asthma knowledge; that is, it meets the criterion of face validity. Its characteristics and structure are appropriate and representative for the study population, and so it meets a further criterion, that of content validity. In addition, the expert consensus attained and the participation of asthmatic patients provided a rigorous framework to the expert consensus attained and the participation of representative for the study population, and so it meets the criterion of face validity. The questionnaire was developed and validated in a population with a wide age range. There was a predominance of adult patients and the percentage of parents or guardians of children with asthma was low (5%). This could be considered a methodological limitation that would affect the internal validity of the instrument. Nevertheless, similar results, with the corresponding statistically significant differences, were obtained when the questionnaire was analyzed excluding the parents and guardians of asthmatic children. We therefore think that this questionnaire is useful for a population representative of asthmatic patients in general.

Our instrument also showed consistency and accuracy, thus supporting its validity. Consistency is an intrinsic component of the validation process for any measurement index. In the case of this questionnaire, the consistency both before and after the educational intervention was somewhere between good and almost perfect in 96% of the patients (Table 4). The overall consistency between the 2 applications before the educational intervention was very much affected by a patient with a χ² statistic of 0. For the administrations after the educational intervention, 3 patients had χ² statistics between 0.01 and 0.40, and this also affected the overall χ², but not to the same extent as the effect of 0 for the administrations before the educational intervention (Table 4). Other questionnaires are not so rigorously assessed for reliability because patients do not undergo an educational intervention. Nevertheless, good reliability has been demonstrated for them, still other studies essentially focused on measuring interobserver variability. The reliability and validity of an instrument were determined in another study in a different setting to the one in which it was developed. The participants were health educators with formal training in asthma education, people without asthma who were studying for a university degree, and asthmatic adult patients in that study. That method was used to show that the questionnaire used was valid and reliable.

When designing the present study, we assumed the questionnaire was a multidimensional instrument lacking internal homogeneity because it expresses different attributes of a complex phenomenon. Therefore, we did not undertake a corresponding analysis to demonstrate this multidimensionality. Although factorial analysis of studies of questionnaires developed for parents of asthmatic children by Rodríguez Martínez and Sossa and Ho et al showed that asthma knowledge is multidimensional, this knowledge appeared as a unidimensional element in the analysis by Allen and Jones. Sensitivity to change is applied to determine scores on health status and quality-of-life scales when these are designed to detect a change over time. Clearly, these changes should be clinically relevant. For the purposes of our study, we needed to know whether the instrument...
could detect change, if present, after the educational intervention. We showed that the number of correct answers was, in general, much lower when the questionnaire was administered before the educational intervention whereas a significant increase (Pc<0.05) was observed afterwards.

We thus assessed the sensitivity to change by measuring the percentage change in the number of correct answers. The fact that the instrument was able to detect change given that the median percentage change was 67% and 10 patients showed an improvement between 81% and 233%. These changes were well in excess of the percentage change expected for clinical relevance (40%). By measuring this change indirectly, the extent of learning is assessed. The higher the percentage change, the more the patient has learned. Sensitivity to change was not evaluated in the studies mentioned previously,11,13,26 except in the study of Rodríguez Martínez and Sossa,12 who, like us, detected a sensitivity to change after the educational intervention.

The association between the score on an asthma knowledge questionnaire and the impact on the different aspects of morbidity has been uneven, probably because any such association would be multifactorial. This lack of consistency may be due to factors such as the diversity of materials used for the development and validation of questionnaires as instruments for measuring knowledge. This point would certainly cover the content of the questionnaire itself, the type of responses, the way the answers were coded and assigned, the number of participants, the particular method used for validation and measurement of reliability and sensitivity, etc. The content of questions in our questionnaire about treating asthma, trigger factors, what to do during a crisis, allowed activities, and pathogenesis resembles that of Bertolotti et al,11 Allen and Jones,13 Rodríguez Martínez and Sossa,14 and Ho et al.26 Some of those questionnaires use questions with “true” or “false” answers,11,13,26 whereas others opted for a Likert scale.26 With regard to the validation and measurement of reliability, only 12 subjects were included to determine reproducibility in one of the most widely used questionnaires for parents of asthmatic children.9 In another study, participation in the integration of the content was limited to experts.16 In another, asthmatic patients also participated, but their numbers were limited to 7 and they only assessed the face validity.17; in contrast, 100 asthmatic patients participated in our study. On the other hand, other authors have taken a questionnaire developed and validated in another setting and used it in a different population, without investigating its validity.13

We will now comment on observations that were not formally evaluated using a sound scientific method. First, we should mention that the impact of education on the patients who participated in the development of this instrument goes beyond our findings, which are limited to objectively measuring or describing the properties of the questionnaire. That is, the patients show greater interest in participating in their treatment. Compliance is therefore improved and response to treatment is better, as measured by symptom relief and improved lung function. Interestingly, the low level of formal schooling in our study population did not influence the results obtained as the patients learned and modified their behavior towards self-management of the disease. This is probably because providing them with knowledge about the disease, its pathophysiology, and treatment options strengthened their motivation and helped them believe that the disease could be controlled. This observation has been confirmed in a study by Put et al,25 who used a previously validated questionnaire to assess this possibility. In contrast, Perępia et al13 obtained different results in studies specifically designed to assess the influence of motivation. They found that the patients’ desire to learn is not reflected in an interest in taking on an active role in decision-making, and that they prefer the physician to take responsibility.

In addition to the validity and sensitivity of our instrument, it also meets the requirements for a good questionnaire according to Stone34 in that it is appropriate and intelligible for the target population. None of the questions is ambiguous or open to different interpretations because if the patients have the relevant knowledge they will respond correctly. Finally, the questionnaire is easy to administer, the answers are readily coded, and the results are easy to interpret.

We have shown that this instrument is valid, reliable, and sensitive to change. The availability of such an instrument has enabled us to start a study to investigate whether the number of correct answers correlates with better long-term disease control, as measured by objective variables such as lung function tests, the number of crises and admissions to hospital, and the need for medication. Furthermore, it will be possible to assess other variables related to validity that we could not analyze in this study.

We are also using the questionnaire in daily clinical practice to assess how well asthmatic patients understand their disease and to focus the educational intervention on gaps in their knowledge, particularly when patients comply poorly with treatment.

We are aware that the process of educating asthmatic patients cannot be reduced to whether they correctly answer the questions in such an evaluation instrument or whether they attend several educational sessions. This process should be continuous; education should be imparted every day in the clinic, especially to improve the knowledge and skills required for appropriate use of inhalers and flow meters. At this point, we should mention that this questionnaire, with its design and content, cannot distinguish between skilled and unskilled users of these devices. However, questions on that point merely aim to stimulate patients’ or family members’ interest and make them aware that there is a technique for using inhalers and flow meters, that they have been trained in this technique, and that it should be followed correctly. This of course requires supervision and verification on the part of the physician and the nurses responsible for treating these patients.

Much has been written on what topics an asthma educational program should cover. In general, we believe these topics are covered by our educational program, and also, though in brief fashion, by the questionnaire that we have developed.

Despite the widespread publication of guidelines on diagnosis and treatment of asthma and the educational strategies implemented in different countries, the translation of questionnaires and administration to patients in our
treatment setting is difficult because the process requires validation of a new translated version and few of these instruments are suitable for Spanish-speaking populations.

Our questionnaire may be useful in Latin American populations because that such populations have common medical terminology and practices. This would make it easier for physicians to administer and enhance comprehension by Spanish-speaking patients.

In conclusion, the asthma knowledge questionnaire for asthmatic patients and parents and guardians of asthmatic children covers general concepts about the disease and its management in a simple and practical fashion. It has proved valid, reliable, and sensitive to change, and so is useful in research and health care of Spanish-speaking asthmatic patients.

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REFERENCES

## Appendix

English Translation, for Informative Purposes, of the Mexican Spanish Asthma Knowledge Questionnaire

(Original Available in the Spanish Version of the Article)

### Instructions:
- Indicate the correct answer (a or b) with an “X.” If you do not know, mark “c.”

### Questions

1. **Asthma is**
   - (a) contagious.
   - (b) not contagious.
   - (c) I don’t know.

2. **Asthma symptoms are due to**
   - (a) bronchial inflammation that causes the bronchi to close.
   - (b) the bronchi opening.
   - (c) I don’t know.

3. **When an asthmatic patient is exposed to cold, does exercise, or suffers from flu, this**
   - (a) is not problem.
   - (b) could lead to an asthma crisis.
   - (c) I don’t know.

4. **What is the aim of treating an asthmatic patient?**
   - (a) To completely cure him or her.
   - (b) To control the disease.
   - (c) I don’t know.

5. **Asthma medication is important, but just as important is**
   - (a) recognizing and avoiding triggers of a crisis.
   - (b) never exercising.
   - (c) I don’t know.

6. **A person with controlled asthma can**
   - (a) work, go to school, and take exercise.
   - (b) only walk, rest, and eat.
   - (c) I don’t know.

7. **Asthma medication helps to**
   - (a) reduce inflammation and open the bronchi.
   - (b) strength the bronchial wall and dilute the mucus.
   - (c) I don’t know.

8. **Indicate to what group the asthma medications for reducing the number of crises belong.**
   - (a) Medications for opening the bronchi.
   - (b) Preventative medications.
   - (c) I don’t know.

9. **Do you know how to use the inhalers for treating asthma properly?**
   - (a) Yes.
   - (b) No.

10. **A medication to be avoided by asthmatic patients is**
    - (a) aspirin.
    - (b) antibiotics.
    - (c) I don’t know.

11. **The best route of administration for asthma medication is**
    - (a) oral (pills or syrup) and by injection (vials).
    - (b) inhaled, or as an aerosol.
    - (c) I don’t know.

12. **Indicate what the 2 types of medication for asthma are.**
    - (a) Preventative and for opening the bronchi.
    - (b) Primary and secondary.
    - (c) I don’t know.

13. **Some patients who use medication for opening the bronchi suffer side effects such as**
    - (a) nervousness, palpitations, hand tremor.
    - (b) diarrhea and fever.
    - (c) I don’t know.

14. **Peak expiratory flow**
    - (a) is an individual measurement for each patient that changes as the disease evolves.
    - (b) always has the same value for each and every patient.
    - (c) I don’t know.

15. **A flow meter**
    - (a) can be used easily at home and is a useful guide for treatment.
    - (b) is only measured in hospital and is of limited use in asthma.
    - (c) I don’t know.

16. **An accessory for improving inhaler technique for aerosol medication is**
    - (a) a vaporizer.
    - (b) a spacer.
    - (c) I don’t know.

17. **Asthma is a disease in which**
    - (a) discomfort remains constant over time.
    - (b) the symptoms and condition of the patient are constantly changing.
    - (c) I don’t know.

18. **In the self-management program for the asthmatic patient**
    - (a) the physician and patient take active part in decision making.
    - (b) only the patient is active in the decision making.
    - (c) I don’t know.

19. **In what circumstances should a patient with asthma go to the emergency room?**
    - (a) When the flow meter shows a reading indicated as dangerous but he or she is in little discomfort.
    - (b) When he or she has difficulty speaking without pausing, is taking more than 25 breaths per minute, has a pulse rate of 110 or more per minute, and the flow meter is marking dangerous levels.
    - (c) I don’t know.

20. **If the flow meter readings decrease day after day, discomfort persists, and no relief can be obtained with the medication for opening the bronchi, what should you do?**
    - (a) Increase the dose of inhaled anti-inflammatory medication and see a doctor.
    - (b) Take bed rest.
    - (c) I don’t know.