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Validation and results of a questionnaire for functional bowel disease in out-patients

Ioannis A Mouzas¹ ✉, Nikolaos Fragkiadakis¹ ✉, Joanna Moschandreas² ✉, Andreas Karachristos¹ ✉, Panagiotis Skordilis¹ ✉, E Kouroumalis¹ ✉ and Orestes N Manousos¹ ✉

¹ Gastroenterology Department, University Hospital, University of Crete, Heraklion, Greece

² Biostatistics Laboratory, Department of Social Medicine, University of Crete, Heraklion, Greece

✉ author email ✉ corresponding author email

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Abstract

Background

The aim was to evaluate and validate a bowel disease questionnaire in patients attending an out-patient gastroenterology clinic in Greece.

Methods

This was a prospective study. Diagnosis was based on detailed clinical and laboratory evaluation. The questionnaire was tested on a pilot group of patients. Interviewer-administration technique was used. One-hundred-and-forty consecutive patients attending the out-patient clinic for the first time and fifty healthy controls selected randomly participated in the study. Reliability (kappa statistics) and validity of the questionnaire were tested. We used logistic regression models and binary recursive partitioning for assessing distinguishing ability among irritable bowel syndrome (IBS), functional dyspepsia and organic disease patients.

Results

Mean time for questionnaire completion was 18 min. In test-retest procedure was obtained (kappa statistics 0.82). There were 55 patients diagnosed functional dyspepsia (Rome I criteria), 38 with organic disease. Location distinguishing factor, patients with functional dyspepsia having no lower (0.001). Significant factors distinguishing between IBS and functional dyspepsia by either antacids or defecation (19% vs 71% and 66% vs 0% respectively at night) was also a factor distinguishing between IBS and organic disease (< 0.01).

Conclusions

This questionnaire for functional bowel disease is a valid and reliable instrument to distinguish satisfactorily between organic and functional disease in an out-patient setting.

Introduction

Functional bowel disorders form a heterogeneous group of clinical syndromes of the gastrointestinal tract that present no histological, endoscopic or imaging evidence of the result of infectious or metabolic disease. Due to our limited understanding of their pathogenesis, functional bowel disorders remain largely a diagnosis of exclusion. This, together with a feeling of uncertainty on the part of the physician, may lead to unnecessary and expensive tests and examinations in order to rule out cancer or a specific organic disease [1,2]. If there is a situation where the medical history makes an impression towards reaching the correct diagnosis, this holds true for the patient with functional disorders. The need for simple and valid diagnostic criteria for these disorders, defined by their symptoms, has led to the search of clusters of positive symptoms that are as characteristic for patients with functional disorders [3,4]. A symptom-based classification system has recently been developed by multinational working groups as Rome Committees, resulting in diagnostic criteria for functional gastrointestinal disorders.

In order to elicit symptoms relevant to functional disorders, the administration of a questionnaire has been proved as valuable. It has been shown that a questionnaire is a valuable value in the gastroenterology outpatient setting, where functional bowel disorders are reported. Several questionnaires have been evaluated assessing the two disorders, i.e. the irritable bowel syndrome (IBS) and functional dyspepsia, and trying to distinguish them both from organic diseases and from each other.

The aim of the present study was 1) to evaluate a bowel disease questionnaire designed for Greek patients attending an out-patient gastroenterology clinic. 2) The data obtained.

Methods

Geography and health system

The island of Crete, which has approximately 550,000 inhabitants, is divided into 13 administration prefectures. Each prefecture has a local hospital but there is one central hospital: the University Hospital, in Heraklion. The prefecture of Heraklion has 280,000 inhabitants, of which 150,000 are urban and the remaining 130,000 are rural. The Gastroenterology Department of the University Hospital of Heraklion serves the gastrointestinal patients of the island. At the same time it fulfils the function of a central centre for subjects with gastrointestinal complaints who are residents of Heraklion. This is due to the structure of the Greek National Health System. All subjects from a prefecture are entitled to attend outpatient clinics of a tertiary hospital without referral from their general practitioners or rural physicians.

Questionnaire creation and mode of administration

We created a questionnaire based on the symptom-oriented questionnaire used in the study of...

al [9], with several adaptations, and the consensus Rome I criteria [10]. related questions was formulated by a physician with extensive experier gastrointestinal outpatients (NF). Two gastroenterologists (IM, PS) revis necessary changes by eliminating ambiguous questions and expressions and relevant questionnaire. After reaching the final version, the questi pilot group of 30 out-patients using self-administration technique. Only questionnaire forms were adequately filled-in so as they could be further get reliable results we decided to continue the study using the interview technique. Our decision was buttressed by the fact that in a group of 15 possible to use both administration techniques, we obtained identical res: all patients was a final year medical student (AK).

Participants

One-hundred-and-forty consecutive patients attending the outpatient Ga the University Hospital of Heraklion for the first time and complaining of a or disturbed stool movements were invited to provide responses to the a refusal rate of 8.6% (12 patients). Fifty healthy controls were randomly the Orthopedic department of the same hospital. None of them had visit gastrointestinal symptoms during the last three years. After one to two was given to be completed for a second time in 12 patients whose symp during this period and in 6 controls in order to check for the concordance (reliability). After a period of one to three month of clinical evaluation an was provided by two experienced gastroenterologists (IM, NF). Respons were not used for the final diagnosis. Healthy controls did not undergo a diagnosis was made independently of the questionnaire responses and of the clinical and laboratory investigation. All patients underwent endos or/and lower digestive tract, and ultrasound of upper abdomen, while CT when needed. The Rome I diagostic criteria as described in [10] were us the followings: at least 3 months of continuous or recurrent symptoms of discomfort that is a) relieved with defecation; and/or b) associated pain frequency of stool and/or c) associated with a change in consistency of s more of the following, at least one-fourth of occasions or days: a)altered altered stool form; c)altered stool passage; d)passage of mucus; e) bloat abdominal distention [10]. Patients were reached by telephone call 1.5– a further confirmation of the final diagnosis. In four cases no conclusive Fourteen patients were lost to follow-up.

Statistical analysis

Pearson's chi-square tests were performed to assess whether the patier control subjects with respect to qualitative sociodemographic variables. gender, marital status, occupation, birth rank, educational and area of re the age distribution between patients and controls were made using the way analysis of variance (one-way ANOVA) was used to assess possible distribution between the patient groups. Subsequently, the applicability questionnaire in distinguishing between the three bowel disease groups Initially, logistic regression models were fitted to examine differences in disease groups for each of the questionnaire items separately, having a and sex effects. The significance of each of the factors was obtained by c deviance when the factor was included in the model (given the null mode only) and comparing this to the appropriate chi-square distribution. In th abdominal pain, a separate category was included within each item for t respond that they had abdominal pain more than six times in the previou

In order to determine whether the three patient groups could be separa questionnaire responses, classification rules for the diagnostic groups b

were derived. Models were fitted using binary recursive partitioning. With models, the initial split is on the most significant predictor and the constraint the next split in an optimal way. In order to determine whether the model is parsimonious without sacrificing its goodness-of-fit, the least important predictor is removed. The cost-complexity measure $D_\alpha(T') = D(T') + \alpha \text{size}(T')$, where $D(T')$ is the deviance of T' , $\text{size}(T')$ is the number of terminal nodes of T' and α is the cost-complexity parameter. In the present study, with three classification groups, taking $\alpha = 4$ enables one to select the model with the minimum Akaike's Information Criterion, (this criterion penalizes minus two times the number of independent parameters) [11]. Finally, cross-validation was performed by splitting the data into ten mutually exclusive sets.

The test-retest reliability of the questionnaire was judged with the use of kappa to assess concordance between questionnaire responses on two separate occasions. A value of 1 corresponds to a perfect concordance and a value of 0 to a concordance by chance [12].

The statistical packages used were SPSS version 7.5 and S-Plus (version 6.0).

Results

The mean time for interview and completion of the questionnaire was 18 minutes. All who participated understood and answered the questions easily. On re-interview performed on 18 persons at an interval of 7–14 days, significant agreement was obtained. Median kappa statistic for all questions was 0.82 (range 0.56 to 1.0).

There were 55 patients diagnosed as having IBS, 18 patients with functional dyspepsia, 18 patients with organic disease according to the Rome criteria [13], and 38 patients with organic disease (18 with ulcer or gastroesophageal reflux disease, 7 with diseases of the biliary tract, 7 with bowel disease, 2 with self-limited infectious colitis, 3 with bacterial overgrowth, and 1 with Crohn's disease), remaining 6 patients with various diseases, among these 2 malignancies (1 of the stomach, and of the colon). The one patient who was diagnosed as having functional dyspepsia and organic disease was excluded from the statistical analysis. Also excluded were 14 patients that did not complete the evaluation (14 lost to follow-up and 4 with no diagnosis).

The demographic characteristics of the patients and controls are presented in Table 1. There was no significant difference in age or in sex ratios between patients (median age 50 years, 58% males) and controls (median age 50 years, 58% males). More patients than controls were educated at most to primary level; 74% of patients (95 observed, 100 expected) versus 46% (23 observed, 33 expected) of the control group ($\chi^2 = 12.81$ on 1 df, $p = 0.002$). More expected patients came from rural areas ($p = 0.012$), 73 observed versus 83 expected (1 df). The homogeneity between the patient groups with regard to their demographic characteristics is indicated by the percentages presented in Table 1. The differences between groups was with respect to age distribution, with organic disease patients being older than those suffering from IBS ($p = 0.002$).

Table 1. Demographic characteristics of patients and controls answering both questionnaires

The prevalence of symptoms in the subgroups of patients with IBS, functional dyspepsia, organic disease and also in the control group is presented in table 2. Having had pain on at least six occasions in the previous year was a very common symptom in all groups. It can be seen that the location of the abdominal pain is a significant factor, with patients with functional dyspepsia having no lower abdominal pain. Significant factors distinguishing the IBS from the functional dyspepsia group were pain relief by antacids (19% in IBS, 71% in functional dyspepsia patients) and pain relieved on defecation (66% in IBS, 0% in functional dyspepsia patients) and when the pain began (49% in IBS, 6% in functional dyspepsia patients).

disease comparisons, awaking from the pain at nighttime was significant in patients with organic disease (26% in IBS, 61% in organic disease patients).

Table 2. Prevalence of signs and symptoms in patients with IBS, functional or organic disease and controls, and comparisons of IBS with dyspepsia and organic disease patients using logistic regression models.

An example of classification using the model provided in fig. 1 is as follows: a subject presenting with pain in the lower abdomen which he/she has had for less than 3 months, is bloated, the pain not being related to eating a meal, would be classified as having IBS (probability greater than 0.99) as opposed to having functional dyspepsia. If the same subject stated that the pain was related to eating a meal, he/she would be classified as having IBS using the model, but the probability is now 0.625 versus 0.99 for organic disease. When the model in fig. 1 was subjected to cost-complexity pruning (with nine terminal nodes, with the splits following the pain reflection question, feeling bloated and the subject's age). The cost of increasing the simplicity of the model (the misclassification rate rose from 20% to 24%). Cross-validation of the model indicated that perhaps the most important questions contained in the questionnaire were the presence and location of the abdominal pain and having loose bowel



Figure 1. A graphical depiction of the recursive partitioning model used for classifying gastrointestinal patients as having IBS, functional dyspepsia or organic disease based on responses to a questionnaire.

Discussion

In this study we evaluated a questionnaire that was developed for patients in the Gastroenterology out-patient Clinic in Greece. In the design of our questionnaire, instruments proposed by other authors were taken into account [4,8,14]. In previous studies performed in selected populations, the questionnaires have been validated and the results might not be representative for persons belonging to other groups. To elaborate an instrument that could differentiate among patients with irritable bowel syndrome and organic gastrointestinal disease. We had to adapt the instrument to use within the Greek linguistic and cultural milieu. To provide a disease classification for respondents belonging to other groups requires adaptation, modification and validation within a different cultural context [21].

In the present study we took these steps under the guidance of a panel of experts in functional bowel disease. The instrument was validated in subjects having irritable bowel syndrome in the Gastroenterology Department and coming from a referral area of 250.000 patients and urban. Rural residents and subjects with only primary educational level were included in the patients' group than in that of healthy controls, the latter consisting of hospitalized patients. This fact reflects the constitution of the patients' group and is representative of the whole referral area, in contrast to the controls who were recruited from the area of the Hospital. Besides, the control group represented a random sample of the general population, thus explaining the fact that several of the controls met the Rome IBS criteria. It is also reminded that surveys of Western populations have revealed IBS in 15–20% of adults [22].

Due to a low yield of answered questionnaires when self-administered questionnaires were used we used the interviewer-administered technique. All respondents underwent the questionnaire with difficulty. The instrument was shown to discriminate well among the diseases: organic disease, functional dyspepsia and irritable bowel syndrome. For reasons of applicability of the results of this study, we used the Rome I criteria for II

for functional bowel disease was shown to be reliable: persons who were on occasions gave comparable answers.

Concerning the symptoms differentiating between IBS and functional dyspepsia, the most important features in our patients were 1) the location of pain, 2) whether the pain was relieved on defecation or by antacids and 3) whether there were more stools when the pain was relieved. In distinguishing between IBS and organic disease, the most prominent features were the location of the pain at night and whether the pain was relieved by defecation or by antacids, and especially the criterion referring to pain being relieved by defecation or by antacids. This further validation of the Rome II criteria distinguishing IBS from other gastrointestinal disorders.

When trying to interpret our results, the recursive partitioning model offers a simple way of simplification. Figure 1 is a graphical representation of the model used to distinguish between the three disease groups forming the hospital outpatient sample. The discriminant probabilities of being in each disease group are presented at the nodes. The model has a correct classification rate of 80% (22 patients misclassified). The most significant binary split in the discrimination process is the question of abdominal pain, and more specifically whether pain is present in the upper abdomen. On the basis of this question alone, the model splits the patients in two groups: those with organic disease and those with functional dyspepsia or organic disease. The most significant factors in distinguishing between possible IBS and organic disease patients are the duration of time for which they have had such a pain, the frequency of the pain and whether pain is relieved on defecation.

Having determined the localization of pain, significant factors in distinguishing between functional dyspepsia and organic disease are the presence of loose stools, whether the pain was reflection of pain to the spine, the presence of bloating and the age of the patient. An important advantage of the recursive partitioning approach over logistic regression is that the IBS, functional dyspepsia and organic disease groups to be modeled are not modeled at the same time, the rules derived are easy to interpret. A summary of the rules is provided in 1: Appendix.

There are a few drawbacks in this study, some of them being shared with the recursive partitioning model we used. The model we used assumes that patients fall into exactly one of the three conditions, a possibility that a patient may not have any of the three conditions or may have more than one. In fact, only one patient in this study had both organic and functional disease. It may not be a rarity in other, differently selected, populations, it constitutes a limitation of the model. A more important point may be the finding that the results of the questionnaire were not reproduced in comparable and unselected populations. The diagnostic value of our instrument may also have little external validity. A limitation of this study may be the small number of the sample, especially the group with organic disease. This fact may influence the validity of the comparisons concerning functional dyspepsia and those concerning functional as opposed to organic diseases. At last, self-administered questionnaire, a process that is considered both unbiased for the patient and for the doctor, was not feasible in the context of this study. None the less, the use of a self-administered questionnaire is to be time-saving and to give a better yield of answers and a minimal rate of non-response to the questions.

In conclusion, our study showed that the questionnaire for functional bowel disease developed is a valid and reliable instrument in the particular cultural and clinical context of our patients. This questionnaire can distinguish satisfactorily between organic disease and functional dyspepsia. The classification oriented model derived from the evaluation of the results of the questionnaire can be interpreted and it could be used in the out-patient setting.

Additional file. Appendix. Rules for the classification of gastrointestinal patients into one of three disease groups derived from a recursive partitioning model.

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Competing interests

None declared.

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