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Original Research Article

Validation of a questionnaire for the assessment of knowledge, attitude, and practices in patients with irritable bowel syndrome

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ABSTRACT

Background: Irritable bowel syndrome (IBS) is a common disorder with a significant impact on the patients' quality of life. The objective if this study was to develop and validate knowledge, attitude, and practices (KAP) questionnaire in patients with IBS.
Methods: The questionnaire was developed by medical experts by a consultative process using available literature on KAP for patients with IBS. Contents of the questionnaire were validated based on content clarity and relevance using a 4-point ordinal scale. A cross-sectional survey of 100 individuals with IBS was carried out to establish internal consistency, followed by the establishment of the construct validity of the questionnaire.
Results: The original KAP questionnaire included 32 items categorized under the 3 domains of knowledge (22 items), attitude (6 items), and practices (8 items). During expert validation, 4 items from knowledge domain and 1 item from attitude domain were revised. For the original questionnaire, for the individual KAP domains and the overall questionnaire, the Cronbach's alpha raw values were 0.384, 0.215, 0.548, and -0.028, and standardized values were 0.395, 0.368, 0.490, and 0.119, respectively. Six items from knowledge domain and 1 item from attitude domain were deleted to strengthen the internal consistency without jeopardizing the purpose of study. For the questionnaire with 29 items, Cronbach's alpha values improved to 0.603, 0.314, 0.548, and 0.483 (raw values) and 0.586, 0.350, 0.490, and 0.414 (standardized values), respectively.
Conclusions: The validated questionnaire with 29 items had improved homogeneity as compared with the initial questionnaire with 36 items.

Keywords: Attitude, Inflammatory bowel syndrome, KAP questionnaire, Knowledge, Practices, Validation

INTRODUCTION

Irritable bowel syndrome (IBS) is a functional bowel disorder mainly characterized by abdominal discomfort, altered bowel habits, and poor quality of life (QoL).[1,2] The global prevalence of IBS has been reported to be 11.2%.[3] In India, the prevalence of IBS is estimated to be 4.2% to 7.9%. Globally, IBS affects more women than men; however, in India, male preponderance is reported.[4-6] Majority of the IBS patients either have insufficient

knowledge or have misconceptions regarding the disease, its risks, management, and prognosis.[7,8] As patients' knowledge and perceptions about their disease status might affect treatment compliance, it is important to identify and mitigate the knowledge gaps in order to improve the clinical outcomes and subsequently patients' QoL.[9] The knowledge, attitudes, and practices (KAP) surveys are beneficial in generating quantitative and qualitative data as well as unveiling misconceptions or misunderstandings that may represent potential barriers to behavior change and obstacles to the overall management of the disease.[10]

Although IBS is a common complaint at outpatient departments in India, scarce information is available on the knowledge, attitudes, and practices of patients with IBS. A validated and reliable questionnaire with adequate consistency can assess the KAP appropriately without biases being introduced by the measuring tool. Additionally, a validated questionnaire measuring different attributes of KAP can contribute to better-quality data, which can be used to lay the foundation for patient education programs. To the best of our knowledge, there is no validated and reliable KAP instrument presently available for IBS in India. Thus, the present study was conducted with the aim to develop and examine the validity and reliability of the questionnaire to assess KAP among newly diagnosed adult patients with IBS in India. The validated questionnaire will then be used to measure KAP in a larger sample of newly diagnosed patients with IBS.

METHODS

Questionnaire development

A multidisciplinary team of medical experts with experience in patient care and with knowledge about the perceptions prevalent in the community about IBS designed the questionnaire after reviewing the global literature on conceptions, attitude, and practices of patients with IBS. The questionnaire was reviewed, revised, and finalized after multiple rounds of consultative discussions among the experts. During these discussions, the question selection and framing under each domain was assessed to ensure appropriateness and accuracy, thereby confirming representativeness for the respective domains, viz., Knowledge, Attitude, and Practices. The final questionnaire had a total of 36 items distributed in three domains: 22 items in the Knowledge domain,6 items in the Attitude domain, and 8 items in the Practices domain.

Content validation of the questionnaire

The questionnaire was reviewed independently by a panel of five experts, which included 01 gastroenterologists, 01 general physicians, 01 consulting Physician/ Nephrologist who are primary caregivers, and 01 experts in social surveys. Each item of the questionnaire was rated for two criteria, viz., content clarity and content relevance. Content clarity was rated on a 4-point ordinal scale, where 1: very confusing, 2: confusing, 3: clear, and 4: very clear. Content relevance was also rated on a 4-point ordinal scale, where 1: highly irrelevant, 2: irrelevant, 3: relevant, and 4: highly relevant. Based on the scores given by the experts for each question on content clarity and content relevance, questions were either retained as original or reframed. The decision criteria used was based on the scores (Table 1).

Table 1: Scores for the questions and corresponding decisions for inclusion.

Score for each item in questionnaire	Decision
Score of 4	Question was retained as original
Score of 3 by at least 3 experts	Question was retained as original
Score ≤ 2 by any of the experts on the basis of clarity or content relevance or both criteria.	Question was modified

Internal consistency of the questionnaire

After expert validation, a cross-sectional survey was conducted among 100 adult patients newly diagnosed with IBS as per Asian criteria at five private gastroenterology clinics in Ajmer, Hyderabad, and Bhopal, between May and July 2018. Patients willing to sign the patient authorization form (PAF) to participate were included in this study. Asian criteria include recurrent abdominal pain, bloating, or other discomfort for ≥3 months associated with one or more of the following: (a) relief with defecation, (b) change in stool form (show patient the Bristol Stool Scale), and (c) change in stool frequency.[11] Patients with evidence of structural abnormality of the gastrointestinal (GI) tract or diseases/conditions, acute GI conditions (obstructions, bleeding, perforation), severe systemic disorders (cardiac, hepatic, neurological and renal), pregnant or lactating women, and patients unwilling or unable (at physician's opinion) to provide complete information per the questionnaire were excluded.

After obtaining informed consent to participate in this questionnaire validation process, the patients were requested to respond to the self-administered KAP questionnaire. The completeness of the questionnaire was ensured by the investigator or qualified designee. The internal consistency of the questionnaire was assessed by measuring Cronbach's alpha coefficients that depicted the closeness and relation among a set of items concerning the nature of IBS symptoms, attitude, and practices towards management of IBS in patients. Cronbach's alpha value is also considered to be a measure of scale

reliability, which uses variance of the items to calculate reliability. Cronbach's alpha value of 0.7 is considered to be acceptable, following which the instrument, or as in our study the questionnaire, can be considered to be consistently reliable. Two values, viz., raw and standardized, were reported for Cronbach's alpha correlation coefficient. Raw value was based upon item covariance. Variance is a measure of how a distribution of a single variable (item) spreads out. Covariance is a measure of the distribution of two variables. The correlation coefficient is directly proportional to covariance. Standardized value was based upon item correlation.

Interpretation of scores of the questionnaire

The scoring for responses to questions was segregated by the KAP domains. For 22 statements in the knowledge domain, responses were categorized as "True," "False," or "Do not know". Responses were then coded to the numeric scale for deriving alpha values. Each "Correct" answer was scored as 1, "Do not know" answer as 0, and "Incorrect" answer was scored as -1. The sum of all item scores represented the total score for the knowledge domain. The total domain score ranged from -22 to 22. The higher total domain score indicated good knowledge. The 6 statements in the attitude domain were used to understand patients' perceptions regarding impact of IBS on daily life, care-seeking behavior, and compliance to IBS management.

Responses to statements were categorized using a 5-point Likert scale ranging from 2 (strongly agree) to -2 (strongly disagree) for 5 statements and 2 (strongly disagree) to -2 (strongly agree) for 1 statement based on the level of agreement to the statements. The score for this domain ranged from -12 to 12. The higher total domain score indicated positive attitude or more concern towards IBS.

Practices domain included 8 statements indicating specific practices toward lifestyle changes because of IBS, consultations with healthcare providers, and IBS treatment. The responses representing positive practices were scored as 1 and negative practices were scored as 0. Total domain score ranged from 0 to 8.

Statistical analysis

The Cronbach's alpha raw and standardized values were calculated using PROC CORR procedure in SAS® version 9.4 for each of the three domains as well as for overall data. The Cronbach's alpha value was calculated for all three domains: knowledge (22 questions), attitude (6 questions), and practices (8 questions). An overall Cronbach's alpha value was also calculated for the data.

RESULTS

Content validation

In the knowledge domain, 2 items were rated as 'confusing' and 'irrelevant' by 1 and 2 experts, respectively. In the same domain, 3 items were rated as 'confusing' by 1 expert and 1 item was rated as 'irrelevant' by 1 expert. In practice domain, 1 item was rated as 'confusing' and 'irrelevant' by 1 and 2 experts, respectively. After expert validation for clarity and relevance, 4 questions in the knowledge domain and 1 question in the attitude domain required revision. The questionnaire finalized after content validation by experts was used to establish internal consistency in patients.

Internal consistency

Demographic profile

A total of 100 patients participated in the questionnaire validation process to establish internal consistency. The mean age of the patients was 41.07 years; 55 (55%) were men. Majority of the patients belonged to the upper middle socioeconomic class (80%), 14% of the patients belonged to the lower middle socioeconomic class. The socio-demographic profile of the patients is included in Table 2.

Table 2: Socio-demographic characteristics of the patients (n=100).

Variables	N (%)
Sex	
Female	45 (45.00)
Male	55 (55.00)
Age (in years)	
N	100
Mean	41.07
SD	9.89
Minimum	18.00
Median	42.00
Maximum	63.00
Socio-economic status	
Lower socioeconomic class	1 (1.00)
Lower middle socioeconomic class	14 (14.00)
Upper lower socioeconomic class	5 (5.00)
Upper middle socioeconomic class	80 (80.00)

N=number of subjects; SD=standard deviation

Statistical validation for internal consistency

The Cronbach's alpha values for each domain and the overall questionnaire were low as compared with the benchmark of 0.7.

The raw values for knowledge, attitude, and practices, and the overall questionnaire were as follows: 0.384,

0.215, 0.548, and -0.028, respectively. The corresponding standardized values were 0.395, 0.368, 0.490, and 0.119,

In order to improve the Cronbach's alpha value, the team comprising of statisticians and investigators decided to perform exploratory analysis to calculate Cronbach's alpha after deleting some questions without compromising the main purpose. This was achieved by checking the correlation of each question with the entire questionnaire and the alpha value if a particular question was deleted from the analysis (Table 1).

Since the knowledge domain had the maximum number of questions, it was decided to delete few questions from this domain. After discussion and testing, a total of 7 questions were deleted: 6 from the knowledge domain and 1 question from the attitude domain (Table 3).

The Cronbach's alpha values were re-calculated after deletion process. The Cronbach's alpha values after deleting each the questions are reported in the Supplementary Table 1.

Table 3: Details of the questions deleted from the questionnaire.

Domain	Question deleted	Question label
Knowledge	Question 8	IBS may occur because of the use of certain medications
	Question 15	Patients should immediately see their doctor if they notice blood in stools, experience weight loss and nighttime symptoms, develop fever, etc.
	Question 16	IBS can be diagnosed and treated by primary care physician (general practitioner)
	Question 19	IBS treatment requires surgery
	Question 21	IBS medications need to be taken for the entire span of life
	Question 22	IBS can be effectively managed to lead a good daily life
Attitude	Question 1	Patients can manage their IBS symptoms using over-the-counter medications

IBS, irritable bowel syndrome

Table 4: Cronbach's alpha values for each domain and overall.

Variables	Cronbach's alpha for Knowledge Domain (16 Questions)	Cronbach's alpha for Attitude Domain (5 Questions)	Cronbach's alpha for Practice Domain (8 Questions)	Cronbach's alpha for Overall Questionnaire (29 Questions)
Raw	0.603	0.314	0.548	0.483
Standardized	0.586	0.350	0.490	0.414

Table 5: Summary of responses by patients for the knowledge domain.

Questions number	Knowledge	Correct knowledge N (%)	Incorrect knowledge N (%)	No knowledge (don't know) N (%)
Q1	Irritable Bowel Syndrome (IBS) is always a hereditary disease	54	7	39
Q2	IBS affects only women	89	4	7
Q3	IBS is a life-threatening condition	57	24	19
Q4	IBS increases the risk of developing cancer of the colon and/or rectum	11	53	36
Q5	IBS symptoms considerably affect patient's daily life	91	2	7
Q6	IBS is more common than chronic diseases such as high blood pressure (hypertension)/high sugar (diabetes)	12	48	40
Q7	Patients with IBS may develop symptoms because of allergy to various foods	57	17	26
Q8	IBS may occur because of the use of certain medications	15	38	47
Q9	IBS develops because of increase in stress/anxiety	41	18	41
Q10	Patients with IBS develop symptoms because they have a motility disorder (a muscle or nerve problem) of their gastrointestinal (GI) tract	49	16	35
Q11	IBS is associated with symptoms such as abdominal pain/discomfort, constipation/diarrhea, bloating	77	12	11

Continued.

Questions number	Knowledge	Correct knowledge N (%)	Incorrect knowledge N (%)	No knowledge (don't know) N (%)
Q12	Abdominal pain in IBS is severe, continuous, and lasts for weeks	21	64	15
Q13	IBS is also associated with other GI disorders such as acidity (Gastroesophageal reflux disease [GERD])	45	21	34
Q14	IBS may also be associated with joint pains, rashes, muscle pain, fatigue, etc.	27	24	49
Q15	Patients should immediately see their doctor if they notice blood in stools, experience weight loss and nighttime symptoms, develop fever, etc.	82	4	14
Q16	IBS can be diagnosed and treated by primary care physician (general practitioner)	19	78	3
Q17	IBS symptoms can be improved by changing the diet	85	3	12
Q18	IBS can also be managed by managing stress/anxiety and other lifestyle changes	56	6	38
Q19	IBS treatment requires surgery	38	25	37
Q20	Alternative medications (home remedies/Ayurvedic preparations) can improve IBS symptoms	27	51	22
Q21	IBS medications need to be taken for the entire span of life	45	30	25
Q22	IBS can be effectively managed to lead a good daily life	80	16	4

Table 6: Summary of responses by patients for the attitude domain.

Questions number	Attitude	Desirable attitude N (%)	Undesirable attitude N (%)	Neutral N (%)
Q1	Patients can manage their IBS symptoms using over-the-counter medications	63	33	4
Q2	For treating IBS, medication should be taken in consultation with physicians only	87	0	13
Q3	Dietary and lifestyle changes are critical to manage IBS symptoms	80	9	11
Q4	Controlling stress/anxiety is as important as taking regular medications for IBS management	70	5	25
Q5	IBS management requires good compliance to drugs prescribed by your physician	81	0	19
Q6	You should report change/worsening of your symptoms immediately to the doctor	96	0	4

Table 7: Summary of responses by patients for the practice domain.

Questions number	Practice	Desirable practice N (%)	Undesirable Practice N (%)	No answer N (%)
Q1	Do you avoid certain foods that are known to trigger IBS symptoms	96	4	0
Q2	Do you perform yoga/meditation to minimize the stress/anxiety?	50	50	0
Q3	Do you exercise regularly to prevent IBS symptoms?	62	38	0
Q4	Do you avoid eating gluten (e.g., wheat, barley, and rye)-containing food products that might worsen your symptoms?	59	41	0
Q5	Do you have adequate sleep?	96	4	0
Q6	Do you take your medications prescribed for IBS regularly?	70	30	0
Q7	Do you skip medications after few days of symptom relief?	69	31	0
Q8	After following advice from your physician regarding diet, lifestyle, and medications, do you feel that your daily life is less affected now?	80	20	0

BS, irritable bowel syndrome; N, number of patients.

The raw alpha value for the knowledge domain with 22 questions was 0.384, which improved to 0.603 for when 6 questions were deleted. The corresponding standardized alpha value also increased from 0.395 to 0.586 (Table 4). The raw alpha value for the attitude domain with

6 questions was 0.215, which improved to 0.314 when 1 question was deleted. The corresponding standardized alpha value also increased slightly from 0.368 to 0.350 (Table 4). As all questions were retained from the original questionnaire in the practice domain, the raw and standardized alpha values remained unchanged at 0.548 and 0.490, respectively (Table 4). For the overall questionnaire, the raw alpha value increased from -0.028 with 36 questions to 0.483 with 29 questions; the corresponding standardized alpha value increased from 0.11 to 0.414 (Table 4).

Participant patients' responses for each domain

The summary of responses for total 36 questions in knowledge, attitude, and practices domain by participating patients is presented in Table 5, 6, and 7, respectively.

DISCUSSION

This study is first-of-its-kind study to validate a KAP questionnaire in newly diagnosed patients with IBS. We conducted a 2-tier validation of IBS-KAP questionnaire, viz, content clarity and relevance check by the experts followed by validation for internal consistency.

Expert validation did not recommend deletion of any question item; however, four questions from the knowledge domain and 1 question from the practices domain were revised in terms of question construct and framing.

In the second stage, analyses of patient data from the revised self-administered questionnaire showed that internal consistency reliability coefficients of individual domains as well as for the overall questionnaire were low (knowledge domain [0.384], attitude domain [0.215], and practices domain [0.548], overall questionnaire [-0.028]). The major reasons for low Cronbach's alpha value could be less number of questions, poor inter-relatedness, or heterogeneity among the questions. Literature suggests that the low Cronbach's alpha value due to poor correlation between questions can be improved by deleting or revising few questions.[12] Since the study did not satisfy the generally accepted criteria of 0.7 Cronbach's alpha value, an iterative process was initiated to check the individual question that contributed to overall raw and standardized Cronbach's alpha values. For example, in the knowledge domain, question number 20, 'Alternative medications (home remedies/Ayurvedic preparations) can improve IBS symptoms,' was found to have the strongest relation with the entire questionnaire (r=0.2896). The alpha value would drop to -0.1699, if this question was deleted. Finally, the consensus was to delete a total of 7 questions, which reduced the total number of questions to 29. The deleted questions were either less relevant or appeared to be repetition of other items in one or other domains. Additionally, the medical expert confirmed that deletions of the questions will not jeopardize the purpose of the KAP survey.

Thus, the removal of questions increased the Cronbach's alpha value to 0.4. Although it improved the homogeneity of the resultant questionnaire, it still did not reach the desired level of 0.7 for internal consistency. Further deletion of additional questions from a list of 29 questions improved the Cronbach's alpha by an insignificant value, thus no further questions were deleted. Hence, the revised questionnaire with 29 items was considered validated for use in the main KAP survey. One of the reasons that may have affected the Cronbach's alpha was use of "Do not know" as one of the response options; there is little distinction between "Do not know" and wrong information. Although IBS is a common condition, the community may not have scientific knowledge on etiology and symptoms of IBS. Answering as "Do not know" for few questions and providing a wrong answer to some other questions in the same domain might have added to heterogeneity.

Though the sample size was very small, we unearthed some interesting facts regarding KAP in this patient population, which will be further assessed in a larger survey. IBS patients generally have misconceptions about their disease, specifically with regard to concerns over risk of developing a more serious illness such as cancer of the colon and/or rectum. Lacy et al reported that 15.3% of patients believed that IBS will develop into cancer, and 21.5% of patients believed that IBS raises the chances of developing colorectal cancer.[8] In our study 11% patients had correct knowledge where as more than half (53%) had incorrect knowledge regarding this issue , suggesting prevalent misconception in Indian community.

Majority of subjects had proper knowledge regarding IBS affecting daily life (91%), association with diet (85%), and its major symptoms (77%). Very few patients knew that IBS is more common than other chronic diseases, such as hypertension and diabetes. The study by Lacy et al also demonstrated that 75.1% of patients believed that IBS was associated with dietary factors, and 28.7% of patients recognized abdominal pain as the cardinal symptom of IBS. In this validation study, most of the patients showed desirable attitude and practices toward medication, dietary habits, lifestyle, and symptom reporting similar to a cross-sectional study conducted by Algabr et al demonstrating that 100% of patients with IBS had positive attitude regarding diet, medications, and counselling.[13] In a study by Harris et al, 82% of patients had desirable attitude for lifestyle change or diet changes for IBS management.[9] The information regarding IBS as a hereditary disease was correct in 38% patients, and 37% patients had no knowledge which was lower than study

by Lacy et al demonstrating 52.1% of the patients having correct knowledge regarding role of genetic defect as an etiology for developing IBS in subset of patients.[8]

The language of the questionnaire was a limitation; the survey questionnaire could be answered by only English-speaking patients. Also, revalidation of the revised questionnaire could not be performed by experts.

CONCLUSION

Currently, no other validated questionnaire is available to assess KAP regarding IBS in India. We developed a new questionnaire and did not replicate or validate any other KAP questionnaires or data. Our questionnaire demonstrates an ideal real-world clinical scenario for IBS patients in India and therein lies its strength. The questionnaire holistically assesses knowledge, attitude, and practices regarding IBS in Indian patients. This tool focuses on the etiopathogenesis, risk factors, symptoms, diagnosis, and management of IBS in the Indian population. By analyzing the score of individual domains, the clinicians can identify the areas which needs to be addressed while counselling the patient to make management of IBS more effective. This validated KAP questionnaire will also help us generate valuable data as part of a larger survey, and plan for mass awareness and patient educational programs at the community level.

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ANNEXURE

IBS KAP questionnaire with 29 items.

Knowledge (Please answer whether you consider the following statements to be true or false.)				
S.no.	**Statements**	**True**	**False**	**Do not know**
1	IBS is always a hereditary disease	□	□	□
2	IBS affects only women	□	□	□
3	IBS is a life-threatening condition	□	□	□
4	IBS increases the risk of developing cancer of the colon and/or rectum	□	□	□
5	IBS symptoms considerably affect patient's daily life	□	□	□
6	IBS is more common than chronic diseases such as high blood pressure (hypertension)/high sugar (diabetes)	□	□	□
7	Patients with IBS may develop symptoms because of allergy to various foods	□	□	□
8	IBS develops because of increase in stress/anxiety	□	□	□
9	Patients with IBS develop symptoms because they have a motility disorder (a muscle or nerve problem) of their gastrointestinal (GI) tract	□	□	□
10	IBS is associated with symptoms such as abdominal pain/discomfort, constipation/diarrhea, bloating	□	□	□
11	Abdominal pain in IBS is severe, continuous, and lasts for weeks	□	□	□
12	IBS is also associated with other GI disorders such as acidity (Gastroesophageal reflux disease [GERD])	□	□	□
13	IBS may also be associated with joint pains, rashes, muscle pain, fatigue, etc.	□	□	□
14	IBS symptoms can be improved by changing the diet	□	□	□
15	IBS can also be managed by managing stress/anxiety and other lifestyle changes	□	□	□
16	Alternative medications (home remedies/Ayurvedic preparations) can improve IBS symptoms	□	□	□

Attitude (Please tick the appropriate option for the below statements.)		
1	For treating IBS, medication should be taken in consultation with physicians only	□ Strongly agree □ Agree □ Neutral □ Disagree □ Strongly disagree
2	Dietary and lifestyle changes are critical to manage IBS symptoms	□ Strongly agree □ Agree □ Neutral □ Disagree □ Strongly disagree
3	Controlling stress/anxiety is as important as taking regular medications for IBS management	□ Strongly agree □ Agree □ Neutral □ Disagree □ Strongly disagree
4	IBS management requires good compliance to drugs prescribed by your physician	□ Strongly agree □ Agree □ Neutral □ Disagree □ Strongly disagree
5	You should report change/worsening of your symptoms immediately to the doctor	□ Strongly agree □ Agree □ Neutral □ Disagree □ Strongly disagree

Practices (please tick the appropriate option for the below statements.)			
S. no.		**Yes**	**No**
1	Do you avoid certain foods that are known to trigger IBS symptoms?	□	□
2	Do you perform yoga/meditation to minimize the stress/anxiety?	□	□
3	Do you exercise regularly to prevent IBS symptoms?	□	□
4	Do you avoid eating gluten (e.g., wheat, barley, and rye)-containing food products that might worsen your symptoms?	□	□
5	Do you have adequate sleep?	□	□
6	Do you take your medications prescribed for IBS regularly?	□	□
7	Do you skip medications after few days of symptom relief?	□	□
8	After following advice from your physician regarding diet, lifestyle, and medications, do you feel that your daily life is less affected now?	□	□