Original Article

Validity and Reliability of a Questionnaire Designed to Assess Risk Factors of Pancreatic Cancer in Iran

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Abstract

Background: The objective of this study is to develop a questionnaire to study risk factors of pancreatic cancer in Iran and to assess its reliability and validity.

Methods: Following a comprehensive literature search and consulting with six expert gastroenterologists,these domains were included in the questionnaire: demographic variables; anthropometric indices; socioeconomic status indicators; signs and symptoms of the current disease; occupational history and exposure to certain physical and chemical agents; medical and drug history; family history of cancer; history of alcohol, tobacco, or opium use; history of tea and coffee consumption; pregnancy and menstrual data (only for women); and dietary habits and cooking methods. Atotal of 113 questions were developed and included in the questionnaire.

Content validity was assessed by six gastroenterologists, three lay experts, and one methodologist. Reliability was evaluated using test-retest. Ten case subjects and 15 control subjects completed the questionnaire twice with time intervals of two or three weeks.

Results: Overall, the validity and reliability of the questionnaire were acceptable. Item content validity index for clarity was above the predetermined level of 0.80 or higher for 112 (out of 113) questions. The corresponding index for relevancy was 0.80 or higher for 111 (out of 113) questions. The overall scale validity index for clarity and relevancy were 0.97 and 0.96, respectively. Inter-rater agreement for clarity and relevancy were 0.81 and 0.83 respectively. The scale comprehensiveness score was 100%. Regarding reliability, the intraclass correlation coefficients and kappa statistics were above the predetermined level of 0.70, except for four items. For the small minority of items that did not meet the predetermined standards (0.80 for validity and 0.80 for reliability), modifications were made based on consensus.

Conclusion: The questionnaire can be used for research purposes in the relevant studies.

Keywords: Iran, pancreas cancer, questionnaire design, reliability and validity

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Introduction

With over 250,000 deaths per year, pancreatic cancer is the 8th most common cause of cancer mortality worldwide.[1]

Given the dismal prognosis of pancreatic cancer, studies which attempt to identify its risk factors are important, as they may provide a chance to reduce its incidence. Thus far, several risk factors have been identified for pancreatic cancer, including tobacco smoking,[2] diabetes mellitus,[3,4] obesity,[4] heavy alcohol drinking,[5] family history,[6] certain genetic polymorphisms,[7,8] and chronic pancreatitis.[9] A host of other factors, such as high intake of red meat or exposure to *H. pylori*,[10] have been associated with higher risk of pancreatic cancer; these associations, however, have not been consistent across studies and remain controversial.

To our knowledge, no previous epidemiologic study has systematically studied risk factors of pancreatic cancer in Iran; a task which may be important, partly to confirm the established risk factors, and partly to study local and yet unidentified risk factors in this country. For other cancers, local risk factors have been identified. For example, while tobacco and alcohol are the main risk factors for esophageal squamous cell carcinoma in most parts of the world,[11] they play a less significant role in certain areas of Iran with high risk of this cancer[12] and, instead, opium has been emerging as a risk factor.[13,14] Therefore, we planned a case-control study of pancreatic cancer in Iran to assess potential risk factors. Since this is the first case-control study of this type in Iran, a new instrument needs to be developed. The objective of this study is to describe the methods for the development and assessment of validity and reliability of a questionnaires designed to assess risk factors for pancreatic cancer in Iran.

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Material and Methods

Development of the questionnaire content

The questionnaire was developed using a comprehensive litera-

ture search, comparisons with questionnaires developed for other cancer studies in Iran and the world, and consulting with expert gastroenterologists. A search was conducted to determine the theoretical and operational definitions for the domains of interest, with an emphasis on potential risk factors for pancreatic cancer. The literature reviews included gastroenterology and oncology textbooks and relevant databases such as PubMed, Scopus, and Web of Science. Based on the literature search and questionnaires from Golestan Cohort Study (which focuses primarily on esophageal and gastric cancer in Iran)[15,16] various domains that could be potentially included in the questionnaires (e.g., demographics, tobacco smoking history, and opium consumption history) were suggested. Six expert gastroenterologists, who were all faculty members of Tehran University of Medical Sciences, were consulted for the suggested domains. After this consultation, a final decision was made for domains to be included, and questions were developed for each domain. The investigators discussed each question to improve its clarity and determine itsorder.

Validity assessment

Three groups of experts (6 gastroenterologists, three lay experts, and one methodologist) determined the validity of each question as well as the entire questionnaire. Two indices (relevancy and clarity) were assessed for each question, and four indices (relevancy, clarity, inter-rater agreement, and comprehensiveness) were calculated for the entire questionnaire. For each question and the entire questionnaire, the experts scored each of the abovementioned indices from 1 to 4, with 1, 2, 3, and 4 corresponding to poor, fair, good, and excellent, respectively. Once scoring was complete, the following indices were calculated: 1) item content validity index, which shows validity for each question; 2) scale validity index, which shows validity for the entire questionnaire; 3) inter-rater agreement, which shows how well experts agree on the validity of the questionnaire; and 4) comprehensiveness score, which shows what percentage of experts agree that the questionnaire is comprehensive. To calculate the item validity index, the scores were dichotomized into two groups: good or excellent vs. fair or poor. The item validity index for each question (for both clarity and relevancy) was calculated as the percentage of experts who rated the question as good or excellent. For each index, a cutoff point of 0.80 was considered as acceptable validity. For questions with validity indices less than 0.80, the question was revised or excluded.

The scale validity index was calculated using the average item-level method,[17] in which the average of clarity or relevancy score from all questions is calculated. The inter-rater agreement was calculated as the percentage of questions considered excellent or good by all experts. The scale comprehensiveness score was defined as the percentage of experts who considered the comprehensiveness of the questionnaire as good or excellent, rather than poor or fair. Therefore, it was calculated as the number of experts who rated the questionnaire as good or excellent divided by the number of all experts.

Reliability assessment

The test-retest method was used to evaluate reliability. General practitioners administered the questionnaire to 10 case subjects and 15 control subjects twice, with a 2 or 3-week interval between the two administrations. Intra-Class Correlation coefficients (ICC) and kappa statistics were used to determine reliability. For each of these statistics, a cutoff point of 0.70 was considered as denoting acceptable reliability. After calculating the index, in consultation with experts, questions with reliability values of less than 0.70 were revised or excluded.

Statistical methods

Statistical analyses were conducted using SPSS, version 19. The indices calculated included item validity index for clarity, item validity index for relevancy, scale validity index for clarity, scale validity index for relevancy, inter-rater agreement, scale comprehensiveness scale, ICC for quantitative variables, and kappa statistics for categorical variables, as noted above.

Ethical considerations

Informed consents were obtained from each of the study participants, including the 10 pancreatic cancer cases and 15 control subjects. The conduct of this study was approved by the Institutional Review Board of the Digestive Disease Research Institute, Tehran University of Medical Sciences.

Results

Selected Domain and questions

Following a comprehensive literature search and consulting with six expert gastroenterologists, these domains were included in the questionnaire: demographic variables; anthropometric indices; socioeconomic status indicators; signs and symptoms of the current disease; occupational history and exposure to certain physical and chemical agents; medical and drug history; family history of cancer; history of alcohol, tobacco, or opium use; history of tea and coffee consumption; pregnancy and menstrual data (only for women); and dietary habits and cooking methods. After choosing the domains, a total of 113 questions were developed and included in the questionnaire.

Content validity for items

The item content validity index for clarity was 0.80 or higher for 112 (out of 113) questions. The corresponding index for relevancy was 0.80 or higher for 111 (out of 113) questions. The questions that received a score below 0.80 for either clarity (one question) or relevancy (two questions) were evaluated and discussed again by the researchers and content experts, and slight modifications were made based on consensus.

Content validity for the questionnaire: Using the average approach, the overall scale validity index for clarity and relevancy were 0.97 and 0.96, respectively. Theinter-rater agreement for clarity and relevancy were 0.81 and 0.83 respectively. All 10 experts rated the comprehensiveness of the questionnaire as good or excellent, thus yielding an overall comprehensiveness score of 100%.

Reliability

The ICC for quantitative items ranged from 0.72 to 1.0. The kappa coefficients for the large majority of categorical items were above the predetermined acceptable level (0.70), with the only exceptions being the time of onsetof symptoms of the current disease (0.51), history of Endoscopic Retrograde Cholangiopancreatography, (ERCP) (0.68), eating pickled vegetable (0.61), and water source before access to piped water (0.45). These questions were either slightly modified or retained as they were where low

reliability was due to factors that were not relevant to the way the question was asked. Further details are provided in the Discussion section.

Discussion

This study examined the content validity and test-retest reliability of a questionnaire designed to study risk factors of pancreatic cancer in Iran. This assessment was completed as part ofthe feasibility study of a case-control study onpancreatic cancer. The findings suggest that the questionnaire is comprehensive, has content validity, and the results are replicable over a two or three-week period. Moreover, the findings indicate that individual questions are clear and relevant, necessitating only minor modifications to the questionnaire.

The questionnaire probably owes part of its success to the fact that it is built on the backbone of a similar questionnaire used for studying risk factors of esophageal and gastric cancers in northeastern Iran.[16,18] Although that questionnaire was not formally tested for content validity or test-retest reliability, it was piloted for a relatively extended period of time on over 1,000 people before it was adopted for the main phase of a case-control and a cohort study.[15] Also, for some items, the validity of responses was measured against blood or urine biomarkers. For example, responses to opium consumption were validated against urine metabolites of morphine.[19]

Determination of content validity is somewhat subjective, as it depends on the reviewers' opinions. Nevertheless, the fact that this questionnaire received high scores for validity indices, based on opinions of six content experts (gastroenterologists), three lay experts, and one research methodologist, strongly suggests that it includes much of what needs to be covered in studies of risk factors of pancreatic cancer (comprehensiveness), that the questions can be understood accurately and clearly (clarity), and that items are not redundant (relevancy). Furthermore, as mentioned above, similar (but not identical) questionnaires have been successfully used in previous large-scale case-control and cohort studies in Iran. Alterations were made to the previous questionnaires in order to focus on the risk factors and symptoms of pancreatic cancer, rather than those of esophageal or gastric cancers.

Intra-class correlation coefficients for continuous variables and kappa statistics for categorical variables suggest acceptable test-retest reliability for the large majority of questionnaire items. A few items were less reliable, including history of ERCP, eating pickled vegetable, and water source before access to piped water. Undergoing ERCP was evaluated by both questioning the participants and examining their medical documents. As some participants were interviewed on the phone for the second time, their medical documents were not available for examination by the physicians, which may have resulted in a lower kappa value. Pickled vegetables are not main food items for most people; therefore, study participants may not accurately remember or report their consumption. An accurate report of water source before access to piped water depends on remote memory, which again may be responsible for the low kappa.

This assessment has some advantages and limitations. Inclusion and close involvement of three groups of experts (content experts, lay experts, and a methodologist) in designing and assessing the questionnaire is a strong point. A comprehensive literature search and using similar successful questionnaires is probably another advantage. One limitation is that reliability was tested on only 10 patients with pancreatic cancer and 15 participants without the disease. Also, part of the re-test was done over the phone, not in person. Nevertheless, we can still be confident that the questionnaire has acceptable reliability.

In summary, this study showed that the questionnaire developed to examine the risk factors of pancreatic cancer in Iran is comprehensive and reliable, and has content validity. Therefore, the questionnaire can be used in relevant studies.

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