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Research Article

THE DEVELOPMENT, TRANSLATION AND VALIDATION OF AN INSTRUMENT USED IN A TOBACCO CESSATION INTERVENTION STUDY AMONG PATIENTS WITH DIABETES

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ABSTRACT

Objective: In diabetes care, smoking cessation is a very important component that should be addressed in order to facilitate effective blood glucose control and to limit the development of complications associated with diabetes. This raises the need to evaluate patients' knowledge, attitudes, and perception toward their physicians' practices. This study aimed to develop, translate and validate a tool that can be used to evaluate diabetic patients' knowledge of diabetes, the effect of smoking on the disease, their perception of physicians' practices and their attitudes toward smoking cessation intervention.

Methods: The questionnaire was developed using information from the literature. A standardized translation procedure was then used to develop a Malay version from the original English version of a previously developed questionnaire entitled, "Survey on diabetes and tobacco smoking among diabetes patients." A convenience sample of 85 out-patients with diabetes who were smokers was identified. All data were collected from the Penang General Hospital in Penang, Malaysia. The instrument consisted of items on the knowledge of the disease and the patient's attitude as well as items on physicians' practices regarding the smoking habits of the diabetic patients.

Results: The mean age and body mass index of the study participants was 54.29±12.8 years and 26.40±7.6 kg/m^2, respectively. Reliability was tested for both the English and Malay versions for internal consistency of the questionnaire items using Cronbach's alpha coefficient (Cronbach's alpha=0.905).

Conclusion: The instrument is a reliable and valid measure of diabetes and smoking knowledge, attitude and physician practice.

Keywords: Diabetes mellitus, Reliability, Translation, Validation, Smoking cessation.

INTRODUCTION

Diabetes mellitus is a chronic disease that continues to increase globally and has become an epidemic that threatens all nations, including those in the developing world. An approximately 51% increment in its prevalence is expected worldwide by 2030, likely due to population growth, aging, obesity and urbanization, which are linked to lifestyle changes (e.g., decreased physical activity, dietary habits shifted to the high energy foods) [1]. According to the International Diabetes Federation (Diabetes Atlas) in 2011, there were 366 million people worldwide with diabetes, a number that is expected to rise to 552 million by 2030. In 2011, Malaysia, one of the middle-income countries in Southeast Asia, had a prevalence of diabetes of 12.1% (adjusted to the world population) and 11.7% (adjusted to the national population). This prevalence is expected to increase to 13.7% by 2030 (adjusted to the world diabetes population), which becomes 13.3% when adjusted to the national population [1]. Tobacco smoking is the most preventable cause of premature death in developed countries [2]. The prevalence of tobacco use is similar among people with diabetes and those in the normal population [3], despite the fact that its complications are not equal. The risk for complications from diabetes among smokers is four times higher than that for non-smokers [3]. Tobacco smoking is thought to be a reason for a worsening of diabetes control, insulin resistance as well as for all-cause mortality [4,5]. Smoking is also an independent risk factor in the development of macro vascular complications [6] and micro vascular diseases, especially nephropathy and neuropathy [7,8]. The burden of tobacco smoking among diabetic patients is enormous, and health care providers do not deliver tobacco cessation interventions consistently and comprehensively to this vulnerable population [9]. To the best of our knowledge, there is currently a lack of tools in the Malay language to assess knowledge that can be used for smoking cessation programs among diabetics; therefore, this work aims to develop, translate and validate a 41-item questionnaire used to evaluate diabetic patients' knowledge of their disease, the effect of smoking on diabetes, their perception of physicians' practices and their attitudes towards smoking cessation intervention. This tool will provide information that can be used in the future to design and evaluate smoking cessation interventions for people with diabetes. This tool may also generate an evidence base in the modification of the tobacco-smoking behavior of diabetics by changing their thoughts and beliefs towards the dangerous effects of tobacco smoking and the abilities of their physicians to help them overcome this behavior.

METHODS

We developed a 41-item questionnaire based on information drawn from the literature on diabetes care and the potent negative effects of smoking on diabetes by entering these words as keywords in a Google search. A substantial number of questions was adapted and modified from the published literature [10-14]. The questionnaire was initially developed in the English language and was later translated into the Malay language (the national language of Malaysia). Questions about tobacco smoking were adapted and modified from previous reports [10-14].

These questions included the number of cigarettes smoked per day and smoking tobacco history (duration of smoking tobacco) [15]. Questions regarding the factors that affect diabetes control, including food, exercise, medications, alcohol, and smoking tobacco, were modified from the literature [10,16]. Questions regarding the deterioration and increased risk for many diseases related to smoking tobacco in the diabetic patients were modified from the literature [16]. Questions related to the doctors' practices were suggested based on 5A's protocol [17]; 5A's protocol helps smokers to quit smoking tobacco, and quitting smoking tobacco is one of the important goals in the management of diabetes. Some questions were modified from the original sources, including, "have you been asked about your tobacco smoking status?" [13,18]. Questions about receiving advice from their physicians, follow-up to determine their tobacco smoking status, the type of the advice delivered, and patients' interpretations of the messages were also modified [18]. All participants were asked about their willingness to participate in the study, and all patients subsequently read the patient information sheet and signed the patient consent form. To ensure face and content validity, the English version of the questionnaire was reviewed by six pharmacists, five of whom are faculty members with experience and expertise in pharmacy education. Some reviewers suggested converting some of the knowledge and practice questions into multiple choice questions, moving some of the knowledge questions to the practice section, adding more questions to the knowledge domain and lastly, putting the attitude questions in a table format with a Likert scale, which would be easier to understand. The questionnaire was modified according to the suggestions provided and sent for a second review. Readability tests were performed using Microsoft Word version 2010 to enhance the questionnaire's validity; the questionnaire was found to be readable by respondents with at least a Grade 6 education level. The translation of the questionnaire into Malay was validated using the standard forward and backward method [19]. The questionnaire was forward translated into the Malay language by two independent translators at the Language Centre of University Sains Malaysia (USM). Reconciliation of the two forward translations into one forward translation was done by one native speaker of the Malay language who is a faculty member with experience and expertise in pharmacy education and research. The backward translation of the reconciled translation into the source language, which is English, was performed by two different translators. A review of the backward translation against the source language (English) was conducted by two native speakers of Malay, who are faculty members with experience and expertise in pharmacy education and research. In order to ensure conceptual equivalence between the English and Malay translations, harmonization of the new translation and the source version was achieved by three native speakers of Malay who are faculty members with experience and expertise in similar research fields. Cognitive debriefing for the newly translated version was performed in nine diabetic patients (smokers and ex-smokers) at the USM clinic to assess the level of comprehensibility and cognitive equivalency, to resolve any translation problems, and to highlight any item that may cause confusion. A review of the results from the cognitive debriefing and a finalization as well as proofreading was all accomplished by a single native speaker. Following the previous steps outlined above, a new Malay version was developed and became ready for reliability testing.

Statistical analyses

The collected data were analyzed using the SPSS (version 18.0) software package (SPSS Inc., Chicago, IL). Almost all questions were calculated as proportions and percentages because they are categorical variables. In addition, continuous variables, including age, duration of diabetes, period of smoking tobacco, and number of attempts to stop, were calculated as the mean±standard deviation. Reliability analyses tests included Cronbach's alpha, split-half reliability method, Spearman–Brown, and Guttman split-half.

RESULTS AND DISCUSSION

The questionnaire (English and Malay versions) was first tested on a convenience sample of 85 patients who were randomly selected (diabetic smokers and/or ex-smokers) and who attended the out-patient clinic at the Hospital Pulau Pinang from February to March 2012. The respondents were able to answer the questionnaire within 10-15 minutes. The mean age and body mass index of the study participants was 54.3±12.8 years and 26.4±7.6 kg/m^2, respectively. The patients had been diagnosed with diabetes 10.9±8.2 years before, and they had been smokers for 25.3±12.4 years. Of the 85 diabetic patients who were smokers, 97% were males; the sample also contained a relatively equal proportion of Malays and Chinese. Approximately, 78% of the participants started smoking before they had been diagnosed with diabetes, and 39% of them did not know, which type of diabetes they had. Table 1 provides additional details regarding the socio-demographic characteristics of the participants.

Table 2 demonstrates that half of the patients tried to quit smoking due to their health condition whereas approximately 15% of them tried to quit smoking because of advice given by their families and friends. Approximately, 24% of them reported other smokers' habits as a reason for their relapse, while 12% considered their depression as the main cause. However, 45% of the study population continued smoking simply because it was a habit.

Table 3 shows the reliability test for each item using Cronbach's alpha. A reliability analysis of the questionnaire showed an internal consistency reliability of 0.9 for the attitude domain. The reliability of the 4-item knowledge domain was measured by split-half reliability; the Spearman–Brown coefficient was 0.6 and the Guttman split-half coefficient was 0.56 (Table 4). Cronbach's alpha can measure items that are highly correlated and can measure the same parameter, and, therefore, it was used for the attitude domain only.

Table 1: Patients' demographic characteristics

Item description	Frequency	Percentage
Race		
Malay	51	40.5
Chinese	44	34.9
Indian	30	23.8
Others	1	0.8
Gender		
Female	6	4.8
Male	120	95.2
Marital status		
Married	96	76.2
Single	24	19
Divorced/widowed	6	4.8
Education level		
No formal education	1	0.8
Primary	12	9.5
Secondary	86	68.3
Tertiary	27	21.4
Diabetes type		
Type I	13	10.3
Type II	35	27.8
I don't know	78	61.9
Start of smoking in relation to diabetes		
Before disease onset	119	94.4
After disease onset	7	5.6
Cigarette type		
Manufactured cigarette	120	95.2
Leaves	5	4
Cigar	1	0.8
Exercise frequency/week	28	22.2
Never	56	44.4
<3 times	18	14.3
3 times	24	19.0
More than 3 times	96	54.8
Support of family and friends		
Yes	69	30.2
No	38	15.1
Not applicable	19	0.8

Table 2: Factors affecting patients' smoking habits

Items	Frequency	Percentage
Factors motivating tobacco cessation		
Health issues	66	52.4
Family advice	17	13.5
Physician advice	3	2.4
Financial	5	3.9
Desire to quit	12	9.5
Religious	2	1.6
Other	2	1.6
Not applicable	19	15.1
Factors promoting relapse after quitting		
Other smokers	43	34.1
Alcohol	1	0.8
Depression	19	15.1
No family support	2	1.6
Weight gain	2	1.6
Addiction	3	2.4
Habit	19	15.1
Stress	18	14.3
Not applicable	20	15.9
Factors promoting the continuation of smoking tobacco		
Habit	82	56.1
Feel happy	8	6.3
Don't know	5	3.9
Addiction	2	1.6
Stress	22	17.5
Relaxing	7	5.6

Table 3: Reliability test

Questions	Mean±SD	Corrected item-total correlation	Cronbach's alpha if item deleted
The importance of quitting for diabetes management	3.7±1.2	0.737	0.892
Doctor's repeated advice helps patients quit	3.8±1.04	0.772	0.883
Doctor's assessment helps patients quit	3.8±1.04	0.871	0.862
Doctor's assistance helps patients quit	3.7±1.1	0.594	0.918
Doctor's follow-up helps patients quit	3.7±1.1	0.865	0.863

Table 4: Reliability statistics table

Reliability test	Number of items	Co-efficient
Cronbach's alpha	5	0.905
Spearman-Brown		
Equal length	4	0.648
Unequal length		0.649
Guttman split-half	11	0.563

To select items that would enter the main study analyses, running the exploratory factor analyses was needed, which resulted in a data reduction and which produced six factors. These six factors were distinctly subdivided from the original three, but they still fulfilled the criteria of the main divisions. Knowledge was satisfied by three factors (knowledge about the relationship of smoking and other diseases, knowledge toward factors effecting diabetes control, and knowledge regarding the existence of smoking cessation clinics and medications used to help people to quit). On the contrary, the doctors' practices category was met by two factors (advice given by doctors regarding diabetes and smoking cessation and doctor intervention regarding smoking), while the patients' attitudes were met by one factor only. After extracting the variables, the Kaiser–Meyer–Olkin value became reasonable (0.720), and the first factor represented 16.267% of the overall variance; the sixth variable had 6.988% of the overall variance.

To assess the goodness of fit, SPSS counted the proportion of residuals with high residuals; we found that 29% of the residuals had absolute values >0.50; therefore, a good model fit was expected. Cronbach's alpha after the data reduction was 0.876.

This study involved the translation of this questionnaire from the original English into a Malaysian language version by following standardized translation guidelines [19]. The translated form of the questionnaire contained simple, easily comprehensible language that even low-educated patients can understand. After the questionnaire was translated, the reliability and validity of the newly translated version were demonstrated. This study is a translation and validation study of a self-reported instrument for the measurement of the knowledge of the impact of smoking on diabetes as well as physicians' practices toward tobacco cessation. A major approach in translation is required in which the cultural and language equivalence is checked. The 41-item questionnaire is a relatively suitable and straightforward questionnaire; its reliability was confirmed using internal consistency and split-half tests, and the validity was examined through known group validity. Our study of Malaysian diabetic patients can be considered one of the few studies that has investigated this issue among diabetic patients who smoke [12,20,21]. Moreover, the Malaysian and English versions of the questionnaire proved to be acceptable to patients; it is a simple questionnaire that can be administered by a trained nurse in face-to-face interviews to overcome non-responses by those who cannot read, although the original questionnaire is a self-administered instrument.

CONCLUSION

Our findings from this study indicate that this novel tool is a reliable and valid measure of knowledge of diabetes, patients' attitudes, and physicians' practices, which can now be used in a clinical setting.

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ETHICAL APPROVAL

Approval for the conduction of this study was granted by the Medical Research Ethics Committee of the Ministry of Health, Malaysia and the Clinical Research Centre at Hospital Pulau Pinang, Malaysia (NMRR-11-477-9538).

REFERENCES

1. Whiting DR, Guariguata L, Weil C, Shaw J. IDF diabetes atlas: Global estimates of the prevalence of diabetes for 2011 and 2030. Diabetes Res Clin Pract 2011;94(3):311-21.
2. Centers for Disease Control Prevention. Tobacco Use: Targeting the Nation's Leading Killer. At a Glance 2011. Atlanta, GA: Centers for Disease Control Prevention; 2011.
3. Wen CP, Cheng TY, Tsai SP, Hsu HL, Chan HT, Hsu CC. Exploring the relationships between diabetes and smoking: With the development of glucose equivalent concept for diabetes management. Diabetes Res Clin Pract 2006;73(1):70-6.
4. Solberg LI, Desai JR, O'Connor PJ, Bishop DB, Devlin HM. Diabetic patients who smoke: Are they different?. Ann Fam Med 2004;2(1):26-32.
5. Adepu R, Ari SM. Influence of structured patient education on therapeutic outcomes in diabetes and hypertensive patients. Asian J Pharm Clin Res 2010;3:174-8.
6. Haire-Joshu D, Glasgow RE, Tibbs TL. Smoking and diabetes. Diabetes care 1999;22(11):1887-98.
7. Ikeda Y, Suehiro T, Takamatsu K, Yamashita H, Tamura T, Hashimoto K. Effect of smoking on the prevalence of albuminuria in Japanese men

with non-insulin-dependent diabetes mellitus. Diabetes Res Clin Pract 1997;36(1):57-61.
8. Sands ML, Shetterly SM, Franklin GM, Hamman RF. Incidence of distal symmetric (sensory) neuropathy in NIDDM. The San Luis Valley diabetes study. Diabetes Care 1997;20(3):322-9.
9. Kvyls R. Impact of clinical pharmacist provided patient education on QOL outcome in type II diabetes mellitus in rural population. Asian J Pharm Clin Res 2011;4(4):15-20.
10. Ding CH, Teng CL, Koh CN. Knowledge of diabetes mellitus among diabetic and non-diabetic patients in Klinik Kesihatan Seremban. Med J Malaysia 2006;61(4):399-404.
11. Kaliyaperumal K. Guideline for conducting a knowledge, attitude and practice (KAP) study. Community Ophthalmol 2004;4(1):7-9.
12. Ibrahim H, Norkhafizah S, Attitudes and practices in smoking cessation counselling among dentists in Kelantan. Arch Orofac Sci 2008;3(1):11-6.
13. Tolonen H, Kuulasmaa K, Laatikainen T, Wolf H. Recommendation for indicators, international collaboration, protocol and manual of operations for chronic disease risk factor surveys, 2002. Available from: http://www.ktl.fi/publications/ehrm/product2/part_iii2.htm. [Last cited on 2011 Dec 14].
14. Hoch E, Muehlig S, Höfler M, Lieb R, Wittchen HU. How prevalent is smoking and nicotine dependence in primary care in Germany?. Addiction 2004;99(12):1586-98.
15. Canga N, De Irala J, Vara E, Duaso MJ, Ferrer A, Martínez-González MA. Intervention study for smoking cessation in diabetic patients: A randomized controlled trial in both clinical and primary care settings. Diabetes Care 2000;23(10):1455-60.
16. Fitz-Patrick D. Diabetes Knowledge Test; 1996. Available from: http://www.endocrinologist.com/diabtest.htm. [Last cited on 2012 Dec 11].
17. US Public Health Service, Treating Tobacco Use and Dependence: 2008 Update. Rockville, MD: US Department of Health and Human Services, Public Health Service; 2008.
18. Thresia CU, Thankappan KR, Nichter M. Smoking cessation and diabetes control in Kerala, India: An urgent need for health education. Health Educ Res 2009;24(5):839-45.
19. Wild D, Grove A, Martin M, Eremenco S, McElroy S, Verjee-Lorenz A, et al. Principles of Good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: Report of the ISPOR Task Force for translation and cultural adaptation. Value Health 2005;8(2):94-104.
20. Hasimah NM, Nurhanani MN, Ramli M. Medical complications among type 2 diabetes mellitus patients at a general hospital in east coast Malaysia. Int Med J 2010;9(1):15-9.
21. Rampal S, Rampal L, Rahmat R, Zain AM, Yap YG, Mohamed M, et al. Variation in the prevalence, awareness, and control of diabetes in a multiethnic population: A nationwide population study in Malaysia. Asia Pac J Public Health 2010;22(2):194-202.