Research Article

Development of a validated questionnaire to assess knowledge and awareness among uncontrolled diabetic patients toward diabetes mellitus

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ABSTRACT

Background: Health literacy is an integral part of diabetes management. Patients with good knowledge of diabetes and its complications seek proper treatment and care and take charge of their health. **Objective:** This study was designed to develop and validate a questionnaire to assess the knowledge and awareness of uncontrolled diabetic patients toward diabetes mellitus (DM). **Methodology:** We developed a 15 item, two domain questionnaires to assess the knowledge and awareness among uncontrolled diabetic patients and examined for internal consistency, reproducibility, convergent, and discriminant validity using Cronbach's alpha, intraclass correlation, and corrected-item to total correlation scores, respectively. **Results:** The final version of the questionnaire was found to be statistically internally consistent, reproducible, and reliable and could be used to assess the awareness and attitude of patients toward self-management of DM. **Conclusion:** This questionnaire has been developed to quantify the awareness and attitude of uncontrolled diabetic patients toward diabetes mellitus and thereby arrive at outcomes to develop systematic strategies for promotion of knowledge, awareness, and self-care practices.

KEY WORDS: Awarness, Questionnaire, Uncontrolled diabetes mellitus, Validation

INTRODUCTION

Prevalence of type 2 diabetes is increasing globally, more so in developing countries like India due to rapid urbanization.[1] It is estimated that the prevalence of diabetes will rise to 5.5% in 2025 as compared to 4% in the year 1995. Patient education is likely to be effective if we know the characteristic of the patients in terms of knowledge, their attitude, and practices about diabetes.[2] Problems associated with diabetes mellitus (DM) can be minimized by early diagnosis and proper management. The primary aim of the management of DM is to delay the macro- and micro-vascular complications by achieving optimal glycemic control.[3] This involves lifestyle modification, including regular exercise, healthy diet and weight loss, and drug therapy. Therefore, health literacy is an integral part of diabetes management.[4] Patients with good knowledge of diabetes and its complications seek proper treatment and care and take charge of their health.[5] There is strong evidence that individuals who are educated and diligent with their diabetes self-care achieve better and durable diabetic control.[6] Many patients face low health literacy problem which affects their ability to manage their chronic illnesses. The association of low health literacy has been observed with worse glycemic control and poorer knowledge of the disease.[7] Moreover, knowledge is also a necessarily required factor to determine dissimilarities in medication adherence among diabetic patients.[8] Individual patient attitudes and intentions can influence adherence to the use of medical therapies diabetic foot care, and exercise.[9] Active attitude in relation to the disease is related to the prevention of complications through the management of the disease allowing people to live better with their condition.[10] A significant correlation between attitude and knowledge for people with diabetes suggested that more knowledge is associated with a predisposition to assume self-care which enables reduction of stress associated with the disease, higher receptivity to the treatment, trust of the multi-professional team, higher self-esteem and sense

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of self-efficacy, and a more positive perception of one's health, and social acceptance.[11] Assessment of knowledge, skill, attitude, health beliefs, psychosocial barriers, and education is part of an education plan for DM. Hence, this study was designed to develop and validate a questionnaire to assess the knowledge and awareness of uncontrolled diabetic patients toward DM.

METHODOLOGY

Study Site and Approval

This study was conducted for 5 months in a general medicine department of secondary care hospital located in Chennai. The protocol was reviewed and approved by the Institutional Ethics Committee before study commencement (Ref No. VISTAS-SPS/IEC/IX/2018/01). Consent from the authorities of the hospital was obtained before the administration of questionnaires to patients.

Subject Recruitment and Confidentiality

Uncontrolled diabetic patients whose HbA1c was >7.5 were requested participation. The study protocol was thoroughly explained to the participants by the investigator. Patients were enrolled in the study only on provision of written informed consent. All data were documented in specially designed case report forms, and access was restricted to the investigator to ensure non-violation of subject rights and confidentiality.

Study Design

This was a cross-sectional survey.

Sample Size

The sample size was estimated using the following formula for calculation of sample size for the quantitative variable.

$$\text{Sample size} = (Z_{1-\alpha/2})^2 (SD)^2/d^2$$

Sample size = 78

Where $Z_{1-\alpha/2}$ is standard normal variate as mentioned in the previous section, where SD is the standard deviation of a variable taken from previously done studies, d is the absolute error or precision.

Study Methodology

Validation of questionnaire

Reliability analysis

Internal consistency of individual items in each domain of the questionnaire was examined to assess the overall reliability. The homogeneity of questions in each domain was determined in terms of Cronbach's alpha (α) coefficient, whose value of 0.7 or above was considered for the questionnaire to be internally consistent. Reproducibility of answers was also examined through the administration of the questionnaire to mentally stable patients on day 1 (test arm) and day 15 (re-test arm: Washout period of 14 days) and computation of intraclass correlation coefficient (ICC). An ICC of 0.7 or above was considered significant for test-rest reproducibility.

Construct validity

Corrected-item to total correlation (CITC) scores and average variance extracted were computed to examine convergent and discriminant validity of the construct, respectively.

Inclusion Criterion

Uncontrolled diabetic patients (HbA1c >7.5) of either gender, who express willingness to participate in the study by providing written informed consent.

Exclusion Criterion

The following criteria were excluded from the study:

- Patients with underlying psychiatric or cognitive disorders and diabetic patients whose HbA1c is <7.5.
- Patients who do not undersign written informed consent.

Statistical Methods

Descriptive summary of demographic and clinical variables is presented either as mean ± SD or as median (minimum and maximum). Choice of the descriptive and inferential statistical method was based on distribution normality as determined through normal probability plot and Shapiro–Wilk test. Statistical analyses were performed using International Business Machines - Statistical Package for the Social Sciences 20.0 and GraphPad Prism 6.0.

RESULTS

Patients with type 2 DM who visited the hospital were requested participation. The printed version of the questionnaire was issued to 78 patients. 62 patients filled independent responses to the questions and returned the questionnaires to the investigator. Hence, the response rate was 79.5%. Descriptive summary of demographical parameters of the studied population is shown in Table 1.

Reproducibility of responses was examined through computation of ICC. Two sets of answers from the CPs in the test-retest arm were obtained and examined. A coefficient of 0.7 or higher was considered as a measure of significant reproducibility Table 2.

Purification of items was not carried out because the CITC of all individual items were >0.5 and the Cronbach's alpha of all the individual constructs was

Table 1: Summary of demographics (*n*=62)

Demographic	Category		Number of CPs (%)
	Range	Summary statistics	
Age (in years)	18–35	34 (24, 35)	8 (12.9)
	36–65	52 (41, 64)	54 (87.1)
Gender	Male		39 (62.9)
	Female		23 (37.1)
Literacy rate	Literate		51 (82.3)
	Illiterate		11 (17.7)
Location	Urban		52 (83.9)
	Rural		10 (16.1)
Smoking history	Smokers		20 (32.3)
Alcoholism	Alcoholics		24 (38.7)
Obesity	Normal		40 (58.1)
	Overweight		3 (4.8)
	Class I obesity		9 (14.5)
	Class II obesity		5 (8.1)

Table 2: Reliability analysis: Summary of tests for reproducibility

Domain	Maximum score	Median scores*		*P* value**	ICC
		Day 1	Day 15		
Knowledge	5	2 (0, 3)	2 (0, 3)	0.362	0.91
Awareness	10	3 (2, 5)	3 (2, 4)	0.711	0.96

*Data represented as median (minimum, maximum), ***P* value retrieved through Wilcoxon matched pairs signed-rank test, ICC: Intraclass-correlation coefficient

Table 3: Mean score, Cronbach's alpha, and intraclass correlation coefficient

Constructs	Items	Mean score (*n*=62)	Cronbach's alpha coefficient (*n*=62)	Intraclass correlation coefficient (*n*=62)
	Assessment of Knowledge	43.2	0.88	0.91
	Assessment of Awareness	28.1	0.92	0.92
Knowledge	Do you know the risk factors of diabetes mellitus?	33.9	0.87	0.85
	Can you differentiate and recognize the symptoms of hypoglycemia and hyperglycemia?	54.8	0.89	0.89
	Can diabetes mellitus cause life-threatening secondary complications?	29.0	0.94	0.92
	Do you know what HbA1c is?	33.8	0.85	0.95
	Do you know that HbA1c should be monitored once in 3 months?	64.5	0.87	0.98
Awareness	Are you aware of your target blood glucose level?	61.2	0.93	0.86
	Are you aware of the complications of uncontrolled diabetes mellitus?	16.1	0.91	0.97
	Do you know the importance of foot hygiene maintenance?	19.4	0.94	0.88
	Do you know that life style modification can aid in achieving target blood glucose level?	40.3	0.88	0.93
	Do you know that it is significant to adhere to the diabetic diet?	77.4	0.92	0.91
	Do you know the importance of hydration in diabetic control?	24.2	0.98	0.94
	Do you know that alcohol can peak blood sugar levels and lead to dangerous levels?	12.9	0.85	0.95
	Are you aware that persistent stress can have deteriorating effects on diabetes mellitus?	8.1	0.96	0.87
	Are you aware of foods with a low glycemic index?	3.2	0.94	0.95
	Are you aware that weight loss can improve diabetic control?	17.7	0.86	0.98

Table 4: Reliability analysis: Tests for internal consistency

S. No.	Questions	Factor loading	Corrected item-to-total correlation	Construct wise Cronbach's alpha
Domain I – Assessment of knowledge				
1.	Do you know the risk factors of diabetes mellitus?	0.688	0.789	0.97
2.	Can you differentiate and recognize the symptoms of hypoglycemia and hyperglycemia?	0.772	0.794	
3.	Can diabetes mellitus cause life-threatening secondary complications?	0.712	0.810	
4.	Do you know what HbA1c is?	0.821	0.709	
5.	Do you know that HbA1c should be monitored once in 3 months?	0.759	0.799	
Domain II – Assessment of awareness				
1.	Are you aware of your target blood glucose level?	0.808	0.686	0.93
2.	Are you aware of the complications of uncontrolled diabetes mellitus?	0.682	0.652	
3.	Do you know the importance of foot hygiene maintenance?	0.793	0.795	
4.	Do you know that life style modification can aid in achieving target blood glucose level?	0.846	0.876	
5.	Do you know that it is significant to adhere to the diabetic diet?	0.799	0.788	
6.	Do you know the importance of hydration in diabetic control?	0.675	0.808	
7.	Do you know that alcohol can peak blood sugar levels and lead to dangerous levels?	0.734	0.694	
8.	Are you aware that persistent stress can have deteriorating effects on diabetes mellitus?	0.855	0.761	
9.	Are you aware of foods with a low glycaemic index?	0.749	0.849	
10.	Are you aware that weight loss can improve diabetic control?	0.691	0.753	

Table 5: Factor structure analysis of individual constructs and convergent validity

Item	Assessment of knowledge	Assessment of awareness	Construct wise Cronbach's alpha
K_1	0.759		0.97
K_2	0.832		
K_3	0.791		
K_4	0.854		
K_5	0.773		
A_1		0.832	0.93
A_2		0.759	
A_3		0.827	
A_4		0.764	
A_5		0.843	
A_6		0.775	
A_7		0.836	
A_8		0.788	
A_9		0.805	
A_{10}		0.769	
Eigen value	1.927	2.338	
% of variance	4.99	4.09	16.83 (Total)

>0.8 suggesting the constructs to be consistent before purification itself Table 3-5.

Factor structures were accepted as the composite reliabilities and average variances extracted for individual constructs were above acceptable limits as shown in Table 6.

Discriminant Validity

The empirical distinction of individual constructs was examined through discriminant validation. The squared correlation of each pair was less than the variances extracted suggesting a significant empirical distinction between the constructs as shown in Table 7.

Awareness and attitude toward DM are significantly less among patients with uncontrolled diabetic patients. Inadequate knowledge of the disease state could precipitate the risk of treatment failure and unhealthy lifestyle measure. Hence, the knowledge, attitude, and practice of uncontrolled diabetic patients toward their disease state need to

Table 6: Acknowledgment of factor structure for individual constructs

S. No.	Construct	Number of items in the construct	Composite reliability	Convergent validity (AVE)
1.	Assessment of knowledge	5	0.885	0.578
2.	Assessment of awareness	10	0.891	0.694

AVE: Average variance extracted

Table 7: Discriminant validity and squared correlation between the constructs

Construct	Assessment of knowledge	Assessment of attitude
Assessment of knowledge	0.65[a]	
Assessment of awareness	0.54*	0.37[a]

*Denotes significant empirical distinction at 99% confidence interval ($P< 0.01$); [a]Denotes the average variance extracted of the constructs

be enhanced through one to one patient counseling sessions, mobile-based health applications, and/or mass educational programs.

DISCUSSION

American Diabetic Association has defined self-management education as the process of providing the person with diabetes the knowledge and skill that is needed to perform self-care, manage crises and make lifestyle changes. To achieve such a health-care system for the management of DM, patients, and doctor should work together. There is an emphasis on teaching pathophysiology and its relation with treatment, nutritional aspects, medications, complications, goal setting, and psychosocial adjustments. These standards were considered during the formulation of this questionnaire. Community's knowledge can help to assess causes, risk of diabetes and motivate them to seek proper treatment and care. A study in a rural population of Sudan showed 15% had adequate knowledge, identified genetics (57.2%) and nutritional habits (46.9%) as risk factors, and retinopathy (31.1%), and cardiovascular diseases (16%) as a complication.[12] In Kenya 27% of the respondents had good knowledge on diabetes, 75% had poor dietary practices and 72% did not participate in regular exercise, and over 80% did not monitor their body weight, good knowledge had an association with good practices.[13] In Debre Tabor, Ethiopia, 49% and 39.5% had good knowledge and good attitude toward DM, respectively; in addition, positive relationship between knowledge and positive attitude was seen.[14] There is evidence that poor attitude causes a deleterious effect on diabetes management. In one of the studies conducted among diabetic patients followed up in a tertiary care center in Sri Lanka had revealed around 75% use some form of herbal medicine with or without antidiabetic medications.[15] Few studies are available which explore the relationship between knowledge and practice among nondiabetic and T2DM groups. It has been reported that people living with DM have better KAP scores toward diabetes compared to non-DM subjects.[16] Quality and consistency of the questionnaire were determined by reliability analysis. The overall consistency of the questionnaire and individual domains was determined through Cronbach's alpha while the magnitude of the contribution of individual question toward Cronbach's alpha was determined through CITC scores. As the CITC score of all individual questions was >0.5 and the Cronbach's alpha of all the domains was >0.8, the questionnaire, on the whole, was found to be consistent. Hence, no question in the construct was dropped, and the questionnaire as such was subjected to further statistical validation. CITC scores were also interpreted to determine the convergent validity as they quantify the relationship between each of the questions and the total score of the individual domains. On the whole, the questionnaire exhibited acceptable internal consistency with overall Cronbach's alpha >0.8 and sufficient reproducibility with ICC >0.75.[17] In addition, we determined the empirical distinction of individual domains through discriminant analysis. The squared correlation of each pair was found to be less than variances extracted suggesting that each domain is empirically distinct from each other. This method of determining the empirical distinction between the domains of the questionnaire was adopted from previous literature.[18]

CONCLUSION

A 15-item containing, two domain questionnaires were developed and validated to assess the awareness and attitude of uncontrolled diabetic patients toward DM. This questionnaire has been developed to quantify the awareness and attitude of uncontrolled diabetic patients toward DM and thereby arrive at outcomes to develop systematic strategies for promotion of knowledge, awareness, and self-care practices. Patients play a crucial and irreplaceable role in the management of their disease states as the extent to which comply with medication advice can directly have significant effects on the treatment outcomes. Hence, this questionnaire could have significant roles in the assessment of awareness and attitude of uncontrolled diabetics toward DM.

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