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Development of a validated questionnaire to assess attitude of patient towards self-management among uncontrolled diabetic population in Tamil Nadu

Ashok Kumar M[1], Shanmugasundaram P*[2]

[1]Department of Pharmacy Practice, School of Pharmaceutical Sciences, Vels Institute of Science Technology and Advanced Studies, Pallavaram, Chennai-600117, Tamil Nadu, India
[2]School of Pharmaceutical Sciences, Vels Institute of Science Technology and Advanced Studies, Pallavaram, Chennai-600117, Tamil Nadu, India

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ABSTRACT

Diabetes mellitus is a chronic progressive metabolic disorder characterized by hyperglycemia. Adherence to the treatment regimen and self-management of diabetes mellitus form the nucleus of diabetic control. Empowerment is a patient-centred, collaborative approach tailored to match the fundamental realities of diabetes care. Patients need to learn about diabetes and how to safely care for it on a daily basis. Hence a questionnaire was developed and validated for assessment of patient attitude towards self-management of type II diabetes mellitus. The questionnaire was examined for internal consistency, reproducibility, convergent and discriminant validity using Cronbach's alpha, intraclass correlation and CITC scores respectively. 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 towards self-management of diabetes mellitus.

* Corresponding Author

Name: Shanmugasundaram P
Phone: +91-9840126575
Email: samsimahe@gmail.com

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INTRODUCTION

Diabetes mellitus is a chronic progressive metabolic disorder characterized by hyperglycemia and glucosuria with a global burden of more than 346 million people worldwide. As far as India is concerned, 32 million patients have diabetes mellitus (Yau, J. W., Rogers *et al*., 2012 and Diabetes Care., 2012). Uncontrolled diabetes mellitus is associated with several complications such as cardiovascular diseases, nephropathy, retinopathy and neuropathy, which can lead to chronic morbidities and mortality (Hirsch IB *et al*., 2005). Adherence to the treatment regimen and self-management of diabetes mellitus form the nucleus of diabetic control (Rawlings RA *et al*., 2011). Role of patients in diabetes management has increased with a widespread use of HbA1c (glycosylated haemoglobin) as an indicator and self-blood glucose monitors. Self-care behaviors and strong adherence to medication can have better treatment outcomes such as good glycemic control, reduction of complications and improvement in the quality of life (Marling CR *et al*., 2011). The importance of patients is becoming active and knowledgeable participants in their care. Empowerment is a patient-centred, collaborative approach tailored to match the fundamental realities of diabetes care (Clarke W *et al*., 2009). Patient empowerment is defined as helping patients discover and develop the inherent capacity to be responsible for one's own life (Monnier L *et al*., 2012). Since initially proposed in diabetes, there has been a growing recognition that, although health professionals are experts on diabetes care, patients are the experts on their own lives (Chin MH *et al*., 1998). This approach recognizes that

knowing about an illness is not the same as knowing about a person's life and that, by default, patients are the primary decision-makers in control of the daily self-management of their diabetes (Cramer JA *et al*., 2004 and, de Rekeneire N *et al*., 2003). Diabetes self-management education is an essential foundation for the empowerment approach and is necessary for patients to manage diabetes and make these decisions effectively. The purpose of patient education within the empowerment philosophy is to help patients make decisions about their care and obtain clarity about their goals, values, and motivations. Patients need to learn about diabetes and how to safely care for it on a daily basis (Dow WH *et al*., 1999). They also need information about various treatment options, the benefits and costs of each of these strategies, how to make changes in their behaviors, and how to solve problems. In addition, patients need to understand their role as a decision-maker and how to assume responsibility for their care (Frederick S *et al*., 2002). Hence, this study was designed to determine the awareness and attitude of patients towards self-management of type II diabetes mellitus.

METHODOLOGY

Study Site and Approval

This study was conducted for a period of 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 Committee before study commencement (Ref No. VISTAS-SPS/IEC/IX/2018/01). Consent from the authorities of the hospital was obtained prior to the administration of questionnaires to patients.

Subject Recruitment and Confidentiality

Uncontrolled diabetic patients whose HbA1c was greater than 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 the 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: Cross-sectional survey.

Sample Size

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

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 the 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 interclass 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 (AVE) 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

- Patients with underlying psychiatric or cognitive disorders and diabetic patients whose HbA1C is less than 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 (IBM – SPSS) 20.0 and Graph Pad Prism 6.0.

RESULTS

Patients with type II diabetes mellitus who visited the hospital were requested participation. The printed version of the questionnaire was issued to

Table 1: Summary of Demographics (n=62)

S. No	Demographic	Category		Number of Patient (%)
1.	Age (in years)	*Range*	*Summary Statistics*	
		18-35	34 (24, 35)	08 (12.9)
		36-65	52 (41, 64)	54 (87.1)
2.	Gender	Male		39 (62.9)
		Female		23 (37.1)
3.	Literacy rate	Literate		51 (82.3)
		Illiterate		11 (17.7)
4.	Location	Urban		52 (83.9)
		Rural		10 (16.1)
5.	Smoking History	Smokers		20 (32.3)
6.	Alcoholism	Alcoholics		24 (38.7)
7.	Obesity	Normal		40 (58.1)
		Overweight		03 (4.8)
		Class I obesity		09 (14.5)
		Class II obesity		05 (8.1)

Table 2: Reliability Analysis: Summary of Tests for Reproducibility

Domain	Maximum Score	Median Scores*		P-value**	ICC
		Day 1	Day15		
Lifestyle Modifications	16	3 (-8, 5)	3 (-9, 5)	0.568	0.942
Treatment	12	1 (-5, 6)	2 (-5, 7)	0.385	0.926

78 patients. 62 patients filled independent responses to the questions and returned the questionnaires back 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 intraclass correlation coefficient. Two sets of answers from the patients in the test-retest arm were obtained and examined. A coefficient of 0.7 or higher was considered as a measure of significant reproducibility as shown in Table 2, 3 and 4.

Purification of items was not carried out because the CITC of all individual items were above 0.5 and the Cronbach's alpha of all the individual constructs was above 0.8 (Table 5) suggesting the constructs to be consistent before purification itself.

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 the Table. 7.

Majority of the patients possess inadequate awareness and negative attitude towards self-management of diabetes mellitus. This necessitates the need to promote awareness and attitude of patients towards self-care management.

DISCUSSION

Diabetes is a chronic disease that requires a person with diabetes to make a multitude of daily self-management decisions and to perform complex care activities. Diabetes self-management education and support provides the foundation to help people with diabetes to navigate these decisions and activities and has been shown to improve health outcomes (Fuchs V *et al*., 1982). A gap currently exists between the promise and the reality of diabetes care. In spite of the great strides that have been made in the treatment of diabetes in recent years, many patients do not achieve optimal outcomes and still experience devastating complications that result in a decreased length and quality of life (Glasgow REP *et al*., 2001). Traditionally, the success of patients to manage their diabetes has been judged by their ability to adhere to a prescribed therapeutic regimen. A great deal of effort has been spent in developing methods for measuring compliance and techniques and strategies to promote adherence. Unfortunately, this approach does not match the reality of diabetes care (Glasgow REP *et al*., 2001). The serious and chronic nature of diabetes, the complexity of its management, and the multiple daily self-care decisions that diabetes requires mean that being adherent to a predetermined care program is generally not adequate over the course of a person's life with diabetes. Intervention strategies that enable patients to make decisions about goals, therapeutic options,

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)
Lifestyle Modifications	Attitude towards Lifestyle Modifications	40.2	0.92	0.90
	Attitude towards Treatment	50	0.89	0.91
	Smoking can increase blood sugar levels.	45.2	0.88	0.89
	Smoking aggravates the risk of cardiovascular and renal disorders.	27.4	0.89	0.86
	Aerobic physical activity can aid inadequate management of blood sugar levels.	58.1	0.97	0.93
	Adhering to the recommended diabetic diet can have major positive effects on diabetic control.	51.6	0.94	0.95
	Foot should be routinely washed and monitored for abrasions or wounds.	48.4	0.97	0.97
	Footwear should be checked thoroughly before wearing.	46.8	0.88	0.93
	It is ok to occasionally walk barefoot for short distances for justifiable reasons.	41.9	0.89	0.88
Treatment	Skipping meals or starving can bring down blood sugar levels.	54.8	0.95	0.86
	Drugs cannot be skipped if blood glucose is found to be within limits.	50.0	0.90	0.87
	Drugs need not be taken continuously and to be taken only when symptoms are felt, or blood sugar levels are found to be high.	43.5	0.94	0.96
	Dose can be doubled or tripled if the preceding dose is unintentionally or intentionally missed.	56.5	0.86	0.93
	It is ok to occasionally eat carbohydrate-rich foods and sweets.	40.3	0.91	0.86
	Insulin dose can be self – adjusted based on the carbohydrate intake and physical activity.	54.8	0.88	0.96
	Routine self-monitoring of glucose is necessary to have a track of blood sugar	51.6	0.87	0.91

and self-care behaviors and to assume responsibility for daily diabetes care are effective in helping patients care for themselves (Goldman DP *et al*., 2002). Quality and consistency of the questionnaire were determined by reliability analysis. The overall consistency of the questionnaire individual domains was determined through Cronbach's alpha while the magnitude of the contribution of individual question towards Cronbach's alpha was determined through CITC scores. As the CITC score of all individual questions was above 0.5 and the Cronbach's alpha of all the domains was above 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 above 0.8 and sufficient reproducibility with intraclass correlation coefficients above 0.75 (Tavakol *et al*., 2011). 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 (Benning *et al*., 2005).

Table 4: Reliability Analysis: Tests for Internal Consistency

S. No	Questions	Factor loading	Corrected item-to-total correlation	Constructwise Cronbach's Alpha
	Domain I – Attitude towards Lifestyle Modifications			
1.	Smoking can increase blood sugar levels.	0.789	0.673	
2.	Smoking aggravates the risk of cardiovascular and renal disorders.	0.776	0.564	
3.	Aerobic physical activity can aid inadequate management of blood sugar levels.	0.875	0.789	
4.	Adhering to the recommended diabetic diet can have major positive effects on diabetic control.	0.921	0.673	
5.	Foot should be routinely washed and monitored for abrasions or wounds.	0.832	0.895	0.97
6.	Footwear should be checked thoroughly before wearing.	0.920	0.651	
7.	It is ok to walk with barefoot for short distances for justifiable reasons occasionally.	0.863	0.708	
8.	Skipping meals or starving can bring down blood sugar levels.	0.755	0.790	
	Domain II – Attitude towards Treatment			
9.	Drugs cannot be skipped if blood glucose is found to be within limits.	0.769	0.652	
10.	Drugs need not be taken continuously and to be taken only when symptoms are felt, or blood sugar levels are found to be high.	0.872	0.861	
11.	Dose can be doubled or tripled if the preceding dose is unintentionally or intentionally missed.	0.783	0.874	
12.	It is ok to occasionally eat carbohydrate-rich foods and sweets.	0.850	0.811	
13.	Insulin dose can be self – adjusted based on carbohydrate intake and physical activity.	0.925	0.590	
14.	Routine self-monitoring of glucose is necessary to have a track of blood sugar profile.	0.874	0.677	

Table 5: Factor Structure Analysis of Individual Constructs and Convergent Validity

Item	Lifestyle Modifications	Treatment	Construct wise Cronbach's Alpha
A_{11}	0.768		
A_{12}	0.890		
A_{13}	0.907		0.97
A_{14}	0.776		
A_{15}	0.873		
A_{16}	0.752		
A_{17}	0.879		
A_{18}	0.825		
A_{21}		0.765	
A_{22}		0.788	
A_{23}		0.861	0.93
A_{24}		0.809	
A_{25}		0.911	
A_{26}		0.842	
Eigenvalue	2.367	2.777	
% of Variance	7.38%	6.40%	13.79% (Total)

Table 6: Acknowledgment of Factor Structure for Individual Constructs

S. No	Construct	No. of Items in Construct	Composite Reliability	Convergent Validity (AVE)
1.	Lifestyle Modifications	8	0.956	0.724
2.	Treatment	6	0.908	0.879

AVE: Average Variance Extracted

Table 7: Discriminant Validity and Squared Correlation between the Constructs

S.No.	Construct	Lifestyle Modifications	Treatment
1.	Lifestyle Modifications	0.572[a]	
2.	Treatment	0.337*	0.480[a]

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

CONCLUSION

A 14-item containing; two domain questionnaire was developed and validated to assess the knowledge and attitude of uncontrolled diabetic patients towards self-management of diabetes mellitus. This questionnaire has been developed to quantify the awareness and attitude of uncontrolled diabetic patients towards self-management of diabetes mellitus and thereby arrive at outcomes to develop systematic strategies for promotion of self-management of type II diabetes mellitus. This questionnaire can be used in an interventional study set up to quantify the effect of educational programs to promote the role of self-management of diabetes mellitus in uncontrolled diabetic patients. Patients play a crucial and irreplaceable role in the pharmacotherapy of diabetes mellitus. Hence this questionnaire could have significant roles in the assessment of awareness of patients towards self-management of diabetes mellitus and thereby promote their involvement in pharmacotherapy.

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