Development and Validation of a Questionnaire for Assessing Medication Adherence in Type 2 Diabetes Mellitus in India

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Ensuring adherence to medications among patients treated for chronic illnesses is a challenge faced by healthcare providers around the world. The present study was performed to develop and validate a questionnaire for assessing medication adherence in Type 2 Diabetes Mellitus (DM) patients as this is one of the most prevalent chronic disease in India. The study included type 2 DM who were on antidiabetic a minimum duration of six months with or without co-morbidities, aged 18-65 years. Participants were asked 15 specifically designed questions. Items were validated using content validity and the internal consistency was assessed using coefficients of reliability such as Cronbach's alpha and Spearson Brown correlation correction. Of the 15 items in the questionnaire, one of the items was evaluated using a 5-point Likert scale and was considered as a sub-item of another main item; 14 items with dichotomous answers were included to assess the internal consistency. Out of 14 items, 2 were excluded to provide a Cronbach's alpha value of 0.927 which is suggestive of a good internal consistency amongst the questionnaire items. Spearson brown correlation correction performed on these final 12 items yielded a value of 0.91 which suggests good inter-item reliability. Given the validity and reliability of this 12-items questionnaire and its ease of use, it could serve as a screening tool in the outpatient setting to identify patients who are poorly adherent and therefore at risk of developing uncontrolled blood sugar levels.

Keywords: Anti-diabetic medications; Medication adherence; Questionnaire;
Type 2 diabetes mellitus; Validation.

Ensuring adherence to medication among patients treated for chronic illnesses such as diabetes mellitus and hypertension is a challenge faced by healthcare providers around the world. Medication adherence in patients may be defined as adherence to medications for an illness as prescribed. According to World Health Organization (WHO), non-adherence is measured by relating patients' medication taking behavior with the prescribed regimen.[1]

Adherence to medication is a crucial part of patient care and is an important factor in the effective management of chronic illnesses such as diabetes mellitus and hypertension. Different tools for assessing adherence have been designed and validated for different conditions, in different circumstances. WHO categorizes these tools as subjective and objective measurements.[2] Objective measures include direct measures such as direct measurement of the drug or its metabolite in body

fluids, secondary database analysis, Electronic Medication Packaging (EMP) devices such as Medication Event Monitoring System (MEMS), pill count, and subjective measures like clinician assessments using questionnaires and self-reports.

At least 45% of patients with type 2 diabetes mellitus do not achieve adequate glycemic control (HbA1c <7%) and one of the major contributing factors is poor medication adherence.[3] Adherence to diabetic medications is an important factor in achieving good diabetes control, decreasing morbidity and preventing mortality.[4] It has been found that non-adherence to antidiabetic medications is associated with poor glycemic control and increased costs through the use of healthcare resources.[5,6] Similarly adequate adherence to medications is essential for optimal control of blood pressure (BP) in chronic hypertensive patients. A survey conducted in 89 countries in 2018 found that only 60% of hypertensive patients who were on treatment had their BP controlled.[7] Patients with high adherence were 45% more likely to achieve BP control than those with medium or low compliance after controlling for age, gender, and comorbidities.[8] Assessment and ensuring adequate medication adherence, therefore, becomes vital for the management of chronic illnesses.

Questionnaires were first designed to minimize the limitations of other self-report methods by standardizing the measurement of adherence to a specific medication regimen.[9] Nguyen et al. have identified 43 validated self-report adherence scales, excluding those that were not in English.[10] Most analyzed scales have a recommended cutoff value while some scales, like the Medication Adherence Questionnaire (MAQ), the 8-item Morisky Medication Adherence Scale (MMAS), and the Brief Medication Questionnaire, rank the degree of adherence instead of defining an absolute cutoff for adherence.[10] But these questionnaires are not always validated to conform to the patients that we come across in our setup. Further, stringent copyright laws of the majority of these questionnaires interfere with the procurement and use of these questions. Having a questionnaire that will take into consideration the social, cultural and financial situation of the patients in our hospital setup becomes important for better understanding the barriers to adherence so that therapy can be tailored individually to improve medication taking behavior. Hence, the present study was performed to develop and validate a questionnaire for assessing medication adherence in Indian patients.

MATERIALS AND METHODS

This study was conducted on 30 patients with type 2 diabetes mellitus, aged between 18-65 years, at the Department of Endocrinology in a tertiary care hospital, between Jan 2019 to June 2019 after obtaining Ethics Committee approval from the Institutional Ethics Committee. A Written informed consent was taken from all the patients who expressed their willingness to participate in the study. Data on demographic profile, medical history, clinical examination, anthropometric measurements such as weight, body mass index were documented. Routine investigations such as fasting/random blood sugar, and glycosylated hemoglobin (HbA1c) were also noted. The patients were asked in their local language to answer the questionnaire. Type 2 diabetic patients who were on antidiabetic medications for a minimum duration of six months with or without co-morbidities were included in the study. Patients with psychiatric illness were excluded. The collected data were analyzed statistically using SPSS 18.0.[11] The items in the questionnaire were validated by two independent experts to assess the relevance of the questions. Coefficients such as Cronbach's alpha and Spearson Brown correlation correction (Split half method) were employed to understand the reliability of the questionnaire.

RESULTS

This study classified the patients based on age, gender, education status, number of drugs taken per day, intake of fixed dose combination and duration of illness, as shown in Table 1. Of the 30 patients included in the study, majority of the patients (n=18; 60%) were above the age of 50 years. The mean age of the study participants was 51.4 ± 10.5 years.

Validity

The validity of any questionnaire is its ability to measure what it is intended to measure i.e., how valid are the results of the questionnaire.[12] Content validation of the items in the questionnaire

was conducted in order to assess the relevance of the items as well as to ensure important aspects in the context of medication adherence were included in the questionnaire. Expert opinion was sought to assess the completeness of the questionnaire. Two experts independently judged whether the items adequately measured the construct intended to assess i.e., medication adherence and whether the items were sufficient to measure the domain of interest. Upon reviewing the questionnaire, the experts concluded that the questions were easy and simple to understand, did not violate the privacy of the participants in any way, covering all the relevant aspects of medication adherence, and did not have any missing items.

Reliability

Coefficients such as Cronbach's alpha and Spearson Brown correlation correction (Split half method) were employed to understand the reliability of the questionnaire. This questionnaire had 15 questions- one of the questions was evaluated using a 5-point Likert scale and was considered as a sub-question of another main question, while the other 14 questions were dichotomous, having either "YES" or "NO' as the answer. Hence, it was proposed to include only these 14 items for the reliability assessment.

Initially, Cronbach's alpha was computed for the 14 items; however, it revealed a very low reliability value. Hence, based on permutations and combinations - Cronbach's alpha was calculated for a different combination of items. A combination consisting of 12 items revealed a high Cronbach's alpha value of 0.927 (Table 2), which is supposed to represent a good internal consistency between the items. The items were also assessed for an individual item to a total correlation which yielded satisfactory values. (Table 3)

Question number 4 (Table 3) was followed by a sub-question for those participants who answered the question with the answer "yes", to assess the frequency of forgotten doses, which was assessed by a 4-point Likert scale (1- once a month, 2- once a fortnight, 3- once a week and 4- every other day). Out of 9 (30%) patients who answered "yes" for that main question, seven answered once a month whereas two patients answered once in a fort night.

Further, split half methodology was employed to evaluate the reliability of these 12

Table 1. Classification of study subjects based on demographic and clinical characteristics

Demographic and clinical Characteristics		Frequency (%)
Age (years)	< 30	01 (03.33)
	31 - 50	11 (36.67)
	> 50	18 (60.00)
Gender	Female	18 (60.00)
	Male	12 (40.00)
Education status	Illiterate	04 (13.33)
	Primary school	02 (06.67)
	Secondary school	15 (50.00)
	Graduation	08 (26.67)
	Post-graduation	01 (03.33)
Number of drugs taken per day	1	08 (26.67)
	2	11 (36.67)
	3	05 (16.67)
	4	04 (13.33)
	5	02 (06.67)
Fixed dose combination	No	19 (63.33)
	Yes	11 (36.67)
Durations of illness (Year)	< 1	02 (06.67)
	1 - 5	14 (46.67)
	6 - 10	09 (30.00)
	> 10	05 (16.67)

Table 2. Reliability statistics

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	Number of items
0.927	0.986	12

items. We divided these 12 questions into 2 equal parts – odd and even questions. For each patient, the total score was recorded along with the sum of the scores for the even questions and the sum of the scores for the odd questions. To estimate the reliability of these 12 items, we applied

Table 3. Item-total correlation

Serial No.	Questions	Corrected Item-Total Correlation
1	Do you take your medicines on time every day?	0.998
2	Do you obey the follow-up orders as per your treating physician?	0.998
3	Do you continue to take your medications for chronic diseases (DM, Hypertension) when you are feeling sick?	0.999
4	Have you ever forgotten to take your medications?	0.961
5	Do you carry your medicines while travelling?	0.998
6	Do you take your medicines on days when your normal routine is disturbed for example when you attend a family function/ festival?	0.997
7	Do you stop/skip a dose when you are feeling better?	0.806
8	Do you stop taking your medicines when you feel any discomfort (side effects) without consulting your doctor?	0.820
9	Do you modify the dosage of medicines based on home glucose monitoring without consulting your doctor?	0.869
10	Do you modify the dosage based on changes in your diet or food intake without consulting your doctor?	0.869
11	Do you have difficulty following your treatment plan when you have to take multiple drugs at different times of the day?	0.898
12	Do you skip buying the medicines when you have financial troubles?	0.812

the Spearman-Brown correlation correction. It revealed a value of 0.91. This value suggests a very good inter-item reliability between the chosen 12 items.

DISCUSSION

Despite the availability of newer classes of medications, increased efforts towards patient education and targeted interventions addressing adherence, medication adherence remains poor in patients with type 2 diabetes mellitus. Adherence to medication is vital to achieve adequate glycemic control. This study reports development and validation of one such tool that can assess the adherence among Indian patients with type 2 diabetes mellitus on anti-diabetic medication.

This questionnaire is simple and easy to administer and can be quickly used even in outpatient settings to assess patients for their medication taking behavior. Patients with low adherence and uncontrolled blood sugar levels can be identified, so that tailored measures such as educating the patient regarding diabetes care, creating awareness by correcting misunderstandings and incorrect beliefs regarding diabetes treatment, addressing stress to improve coping skills among patients, or establishing a treatment regimen to improve medication adherence.[13]

There are several factors that affect the patient's adherence towards intake of prescribed medications in diabetic patients. Understanding these factors will help in improving medication adherence in diabetic patients. A study by Rubin[14] says that the patient's comprehension of the pharmacologic therapy regimen and its benefits, medication adverse effects, medication cost, regimen complexity and the patient's emotional well-being may all influence the adherence to anti-diabetic treatment among the patients with type 2 diabetes mellitus.

Given the validity, reliability and ease of use of this 12-item questionnaire, it could serve as a screening tool in the outpatient setting to identify patients who are poorly adherent and therefore at risk of developing uncontrolled blood sugar levels. Using a questionnaire such as this 12-item questionnaire would be economical and provide real-time information about a patient's medication taking behavior while helping us assess the various barriers to medication adherence that can be addressed to ensure better patient care. The knowledge of adherence, along with blood sugar control data, could be useful in the clinical decision-making process. However, the limitation of this study is the inability to assess the predictive validity of the items as it requires a larger sample size. This tool could further be tested in other chronic illnesses such as hypertension, bronchial asthma, thyroid disorders to assess patient adherence.

CONCLUSION

Medication adherence is important for the better management of chronic illnesses. Developing and using of a validated questionnaire which is simple and easy for patient use such as the one in the present study to evaluate adherence will help the patients with diabetes mellitus in receiving better treatment and the clinicians in providing better healthcare as well. It also helps us better understand the barriers to adherence.

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