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TRANSLATION AND VALIDATION OF HINDI VERSION OF THE MULTIDIMENSIONAL QUESTIONNAIRE (MDQ) FOR QUALITY OF LIFE ASSESSMENT IN TYPE 2 DIABETES MELLITUS PATIENTS IN INDIAN POPULATION

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ABSTRACT: The present study was conducted to perform the translation and validation of Multi-Dimensional Questionnaire (MDQ) instrument for use in Indian type 2 diabetic patients. Validated English version of MDQ instrument was selected for the study. The instrument was subjected to forward and back translation to generate final version in the Hindi language. The instrument consists of three sections: Section I, general perceptions of diabetes and related social support measuring interference, severity and social support. Section II, social incentives related to self-care activities measuring positive reinforcing behaviors and misguided reinforcing behaviors and Section III, self-efficacy and outcome expectancies measuring self-efficacy and outcome expectancies. Validation was done in two hundred fifty Indian diabetic type 2 patients after the pilot testing (n=50). Internal consistency was assessed using Cronbach's alpha and value of 0.84 was gained for the summary score and alpha values of 0.81, 0.93 and 0.87 were observed for section I, II and III indicating high levels of internal reliability. The results of the study reveal the validation of the MDQ instrument in Hindi language and its use for further quality of life utility studies.

INTRODUCTION: Diabetes mellitus (DM) is a chronic illness that affects health related quality of life (QOL) of patients [1]. It is the illness which requires regular patient self-management education and continuous and medical care. Type 2 DM had showed significant impact on physical and psychological wellbeing of patients. Self-perceived QOL related to diabetes is an important outcome for diabetes education programs [2].

Psychological well-being appears to be an important goal of diabetes management and it should be taken into consideration in everyday diabetes care. Multiple factors such as glycemic control, types of treatment, numbers and types of complications and comorbid conditions, and demographic variables are studied to evaluate the association between health related quality of life (HRQOL) and these factors [3]. Qualitative and quantitative changes in the patient's relationships are seen in DM [4]. Good glycemic control could delay the onset and progress of complications [5, 7]. Social support [8, 11] problem-focused coping [12] and self-efficacy [8, 12-16] relate to good regimen adherence and glycemic control.

Taking into consideration the changes in relationship many instruments are designed to assess the QOL of patients where due importance is also given to assess physical, psychological and social functioning [17].

The instrument was originally developed and validated by Dr. Arie Nouwen in French language and had also been translated in English and German language to assess diabetes-related psychosocial issues. The instrument consists of three dimensions of MDQ: Section I general perceptions of diabetes and related social support measuring interference, severity and social support. Section II, social incentives related to self-care activities measuring positive reinforcing behaviors and misguided reinforcing behaviors. Section III, self-efficacy and outcome expectancies measuring self-efficacy and outcome expectancies.

MATERIALS AND METHODS: The study was conducted in two hundred fifty outpatient clinics in Pune. Patient information leaflet was given to the individual patients and the written consent was obtained. The MDQ questionnaire was administered to diabetic patients twice during total study period. For translation procedure, one of the authors acted as the local project manager who carries out the cognitive debriefing interviews. He was a native speaker of the Hindi language and a resident of India. The study was designed as shown in **fig. 1**.
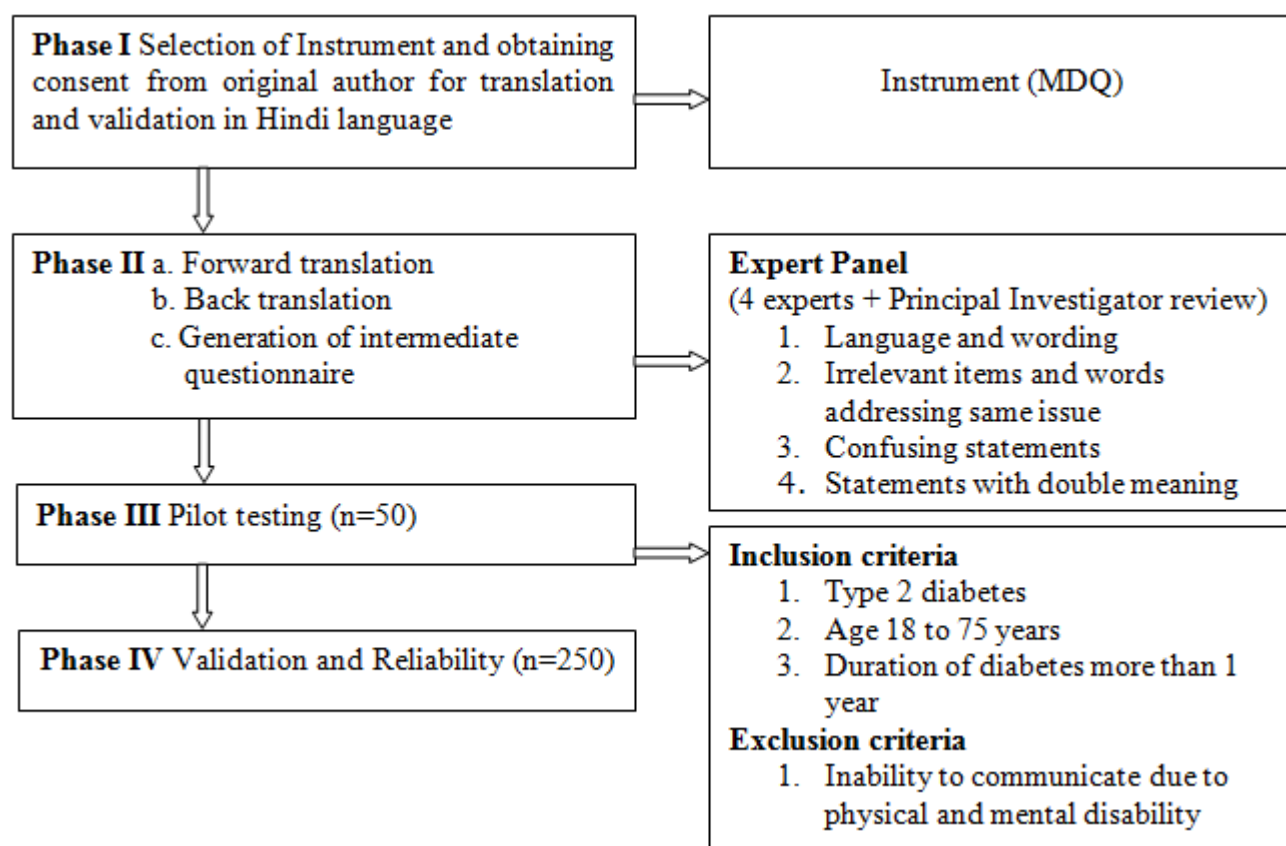

Phase I Selection of Instrument and obtaining consent from original author for translation and validation in Hindi language → Instrument (MDQ)

Phase II a. Forward translation
b. Back translation
c. Generation of intermediate questionnaire
→ **Expert Panel** (4 experts + Principal Investigator review)
1. Language and wording
2. Irrelevant items and words addressing same issue
3. Confusing statements
4. Statements with double meaning

Phase III Pilot testing (n=50) →
Inclusion criteria
1. Type 2 diabetes
2. Age 18 to 75 years
3. Duration of diabetes more than 1 year
Exclusion criteria
1. Inability to communicate due to physical and mental disability

Phase IV Validation and Reliability (n=250)

FIGURE 1: STUDY DESIGN

The suggested methodology was as follows:

Following two step were carried out to translate the original MDQ into Hindi language and produce a version that would be conceptually as close as possible to the original questionnaire.

Step I:

Forward translations: The English questionnaire was given to two translators. Translator I was an occupational language translator with Hindi as native language and had very good command over English. The translator II was a diabetologist who also was a native Hindi speaker and had extremely good command over English.

Step II:

Back translation: The intermediate MDQ was given to the two translators who had never seen the original MDQ before. Information was given regarding the

questionnaire explaining that it was a health related quality of life assessment tool specific for diabetes type 2. They were requested to formulate the questions in simple English language understandable to everyone. Translator I was an official translator having vast experience in language translation and translator II was a dialectologist who also was a native Hindi speaker. Both of them had extremely good command over English as well as Hindi language.

Step III:

Second intermediate Hindi questionnaire: The above two separate back translations were then compared to each other and also the original questionnaire. All questions by both the translators were similar (explaining same meaning) to each other and to original questionnaire.

Step V:

Pilot testing: The final second intermediate MDQ was then administered to 50 patients with type 2 diabetes. These patients had never seen the MDQ questionnaire before and were all native Hindi speakers. Patient population comprised of males 42 and females 8. All patients with history of diabetes were asked to fill MDQ questionnaire and were then interviewed for difficulty in understanding the questions and their meaning. They were also asked for the questions that confuse, divert and upset them during the filling of questionnaire**.**

Validation Study (Study population and sample size): Patients who participated in the validation study were Hindi speaking adults above the age of 18 years with a clinical diagnosis of diabetes mellitus type 2 at the time of the first study visit. A total of 250 diabetic patients (31 females and male 219) were scheduled to participate in the study. A consent form and Hindi version of MDQ was given to patients and they were asked to fill the same. After the interval of 4 weeks the same study population was asked to fill the questionnaire. Patients were on the regular treatment between visits.

Validation Study (Measurement of outcome): The MDQ in diabetic patients was measured by using 41 item scales. The instrument consists of three dimensions of MDQ: Section I general perceptions of diabetes and related social support measuring

interference, severity and social support (16 items) measured on a 6-point response scale from "Not at all" to "Extremely". Section II social incentives related to self-care activities measuring positive reinforcing behaviors and misguided reinforcing behaviors (12 items) measured on a 6-point response scale from " Never" to "Very often" and Section III self-efficacy and outcome expectancies measuring self-efficacy and outcome expectancies (13 items) measured on a 100 point response scale from "Not at all important" to "Very important".

Statistical analysis: Internal consistency and reliability of dimensions of the questionnaire were assessed using Cronbach alpha coefficient. Alpha values equal to or greater than 0.70 were considered satisfactory. Test re-test i.e. reproducibility was assessed across a 4-week interval on 250 patients using interclass correlation coefficient. Kruskal-Wallis H test results for multiple group comparison and Mann-Whitney test results for pairwise comparison was used. Pearsons correlation coefficient was calculated for each of the three sections and seven subs-domains. All statistical analyses were performed with the SAS software package (version 9.1 for Windows). Significance was set to 0.05 for all analysis.

RESULTS: Demographic and clinical data of the respondents indicates that out of two hundred eighty six people with diabetes type 2 that participated in the study, two hundred fifty (87.41 %) participants completed and returned the questionnaires. The study design is presented in Figure 1. Mean age was 58.0 (SD = 6.7) years (range=18-75). Other demographic characteristics of the patients are presented in **Table 1.**

Out of 250 patients 219 respondents were male and 31 were females. As per the demographic study 50.8 % of patients were without any diabetic complications while 49.2 % of patients were suffering from diabetes related complications. Out of 250 patients 16.8 % were found to be overweight and 3.2 % were obese. Average age of diagnosis with diabetes was 6.98 years (SD=1.73). The mean, standard deviations and reliability coefficients of the seven domains are presented in **Table 2**. Results indicate adequate internal consistency ranging from 0.71 to 0.91. Internal consistency was assessed using Cronbach's alpha and value of 0.84 was gained for the summary score (Section I, Section II and Section

III), indicating high levels of internal reliability. Alpha values for total ranged from 0.84 (maximum) to 0.82 (minimum). Alpha values for all the three sections, general perceptions of diabetes and related social support was 0.81, social incentives related to self-care activities was 0.93 and for self-efficacy and outcome expectancies it was 0.87 as shown in **Table 3**. Pearson correlation was assessed for all the three sections and the correlation was found to be significant for all (p< 0.05) as presented in **Table 4**. A higher correlation between all the three sections was observed. **Table 5** presents the correlations among the seven domains of MDQ. Statistically significant correlation (p<0.01) was observed between interference and positive reinforcing behavior, misguided reinforcing behavior, self-efficacy and outcome expectancies. Also significant correlation was found between severity and outcome expectancies. Misguided reinforcing behavior showed weak positive correlation with self-efficacy. Positive reinforcing behavior showed strong positive correlation with misguided reinforcing behavior and weak association with self-efficacy.

TABLE 1: DEMOGRAPHIC INFORMATION FOR SURVEY RESPONDENTS (N = 250)

Demographic parameters	Value
Age (years)	58.09
Men to Women ratio	219/31
Patients with diabetic complications (%)	49.3
Years since diabetes diagnosis	6.98
Received diabetes patient education (%)	55.60
Years of school completed	
Eighth grade or less	2
Some high school	38
High school graduate	26
Some college	184

TABLE 2: SCALE MEANS, STANDARD DEVIATIONS AND CRONBACH ALPHA

	No of Items	Mean	Standard deviation	Cronbach alpha
Section I				
Interference	9	3.4	1.1	0.91
Severity	3	3.9	1.6	0.76
Support	4	4.6	0.8	0.71
Section II				
Positive reinforcing behavior	8	4.5	1.0	0.90
Misguided reinforcing behavior	4	4.5	0.9	0.84
Section III				
Self-efficacy	7	87.8	9.1	0.81
Outcome expectancies	6	91.3	9.9	0.78

TABLE 3: CRONBACH ALPHA OF ALL THREE SECTIONS

Section	Description	No. of Items	Cronbach alpha		
			Total	Min	Max
Section I	General perceptions of diabetes and related social support	16	0.81	0.73	0.83
Section II	Social incentives related to self-care activities	12	0.93	0.93	0.92
Section III	Self-efficacy and outcome expectancies	13	0.87	0.86	0.87

TABLE 4: PEARSON CORRELATION BETWEEN MDQ SECTIONS

Subscales/Sections	Section I	Section II	Section III
Section I	1	0.26**	0.22**
Section II		1	0.32**
Section III			1

Section I: General perceptions of diabetes and related social support; **Section II:** Social incentives related to self-care activities, **Section III:** Self-efficacy and outcome expectancies, ** Correlation is significant at the 0.01 level (2-tailed)

TABLE 5: PEARSON CORRELATION BETWEEN SEVEN MDQ SUBDOMAINS

Subscale	I	S	SS	PRB	MRB	SE	OE
I	1	0.10	0.04	0.22**	0.20**	0.24**	0.20**
S		1	-0.22**	-0.01	-0.10	0.10	-0.09
SS			1	0.35**	0.35**	0.005	0.07
PRB				1	0.92**	0.41**	0.11
MRB					1	0.42**	0.11
SE						1	0.68**
OE							1

I, Interference; S, Severity; SS, Social Support; PRB, Positive Reinforcing Behavior; MRB, Misguided Reinforcing Behavior; SE, Self Efficacy; OE, Outcome Expectancies. **$p<0.01$ for all values shown as Pearson's correlation coefficients.

DISCUSSION: MDQ was developed to facilitate data integration and was not designed to provide a comprehensive assessment. It is comprised of self-report measures that can be used along with other assessment procedures including medical, behavioral, or any other relevant psychosocial measures. MDQ is comprised of three sections focusing on general perceptions of diabetes and related social support, social incentives, self-efficacy, and outcome expectancies in relation to self-care activities. The present study assessed the validity and reliability of the Hindi version of MDQ in 250 patients with type 2 diabetes. This validation was performed in four phases I to IV. MDQ questionnaire was subjected to pilot study (n=50) after forward and backward translation.

The internal consistancy of questionnaire for the summary score was high with cronbach's alpha coefficient (0.84). The internal consistancy of three subscales were also satisfactory ($\geq$0.7) and adequate internal consistancy for all seven domains were observed from (0.71 to 0.91) whereas the study of Arie Nouwen et al showed the internal consistancy ranging from (0.70 to 0.91). The interclass correlation coefficients also indicate good reproducibility of questionnaire which supports the study of Arie Nouwen *et al*.

Our study provides preliminary support for the reliability and validity of the translated Hindi version of MDQ.

CONCLUSIONS: In conclusion, the results of this study indicate that the Indian version of the MDQ was reliable. Thus the translated instrument helps to study the psychological performance of diabetic patients towards diabetes. The present study demonstrated that the Hindi MDQ is useful for assessing quality of life of type 2 diabetes patient's in clinical settings. The study carried out indicates that this validated Hindi version of MDQ in Indian type 2 diabetec patients can be further incorporated for utility study.

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