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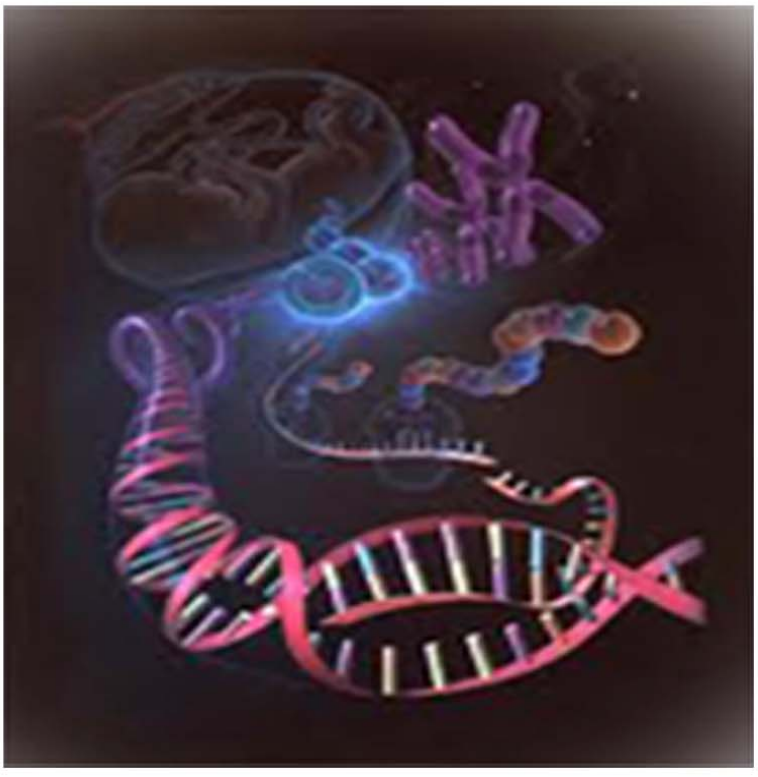

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Research Paper

QUALITY OF LIFE WITH TYPE2 DIABETES: TRANSLATION AND VALIDATION OF INDIAN VERSION OF DES-5

Shrikant S Pawar[1*] and Prasad A Thakurdesai[2]

Corresponding Author:* ***Shrikant S Pawar,* ✉ *shrikant_pawar12@rediffmail.com*

The present study was conducted to perform the cultural adaptation, translation and validation of Diabetes Empowerment Scale-5 (DES-5) instrument in Hindi language for use in Indian type 2 diabetic patients. Validated English version of DES-5 instrument was selected. Instrument was subjected to forward and back translation to generate final version in the Hindi language. The instrument consists of three dimensions of DES-5: Managing psychological aspects of diabetes, assessing dissatisfaction and readiness to change and setting and achieving diabetes goal. Validation was done in two hundred fifty Indian diabetic type 2 patients after the pilot testing (n=50). Internal consistency was assessed using cronbach alpha and value of 0.85 was gained for the summary score, indicating high levels of internal reliability. The results of the study revealed the validation of the DES-5 instrument in Hindi language. This translated Hindi version of DES-5 can be used for further quality of life utility studies.

Keywords: Diabetes, Quality of life, DES-5, Validation, Cronbach alpha

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a non-immune, complex, heterogenous and polygenic metabolic disease condition with serious short term and long term consequences (Solli *et al*., 2010). This disease results from a genetic predisposition and from life style, characterized by high calorie intake little exercise. It is a serious disease and cause for growing public health concern in both developed and developing countries. Globally, the number of diabetics is expected to double in 2030 while public awareness about this disease remains low (Zimmet, 2003). The number of deaths attributed to diabetes was previously estimated at just over 800,000. Many of these diabetes related deaths are from diabetes related complications like, retinopathy, neuropathy, myocardial infarction, angina pectoris and stroke etc.

Quality of life (QOL) is an important outcome of diabetes care to study the influence of diabetes on the patients self care activities which in turn

[1] Asst. Professor, Dept of Pharmacology, Sinhgad Technical Education Society's, Smt. Kashibai Navale College of Pharmacy, Kondhwa, (Bk) Pune-411048 and Research Scholar Karpagam University, Coimbatore.

[2] General Manager, Scientific Affairs, Indus Biotech Private Ltd., Pune.

can cause negative impact on diabetes control management. The study conducted in India reveals that the self confidence and family life are negatively affected by diabetes (Singh and Bradley, 2006).

Health is an important determinant of person's quality of life. Factors such as culture, region, environment, education and finance can affect quality of life but they are often beyond the scope of health care. In routine practice, there is also an ever increasing demand from patients that medical actions should improve their QOL, which involves the need to have indicators of healthcare outcome related to that variable (Miguel *et al.*, 2010).

DES-5 INSTRUMENT

The instrument was originally developed and validated by Anderson Robert (2000) in English language for USA to assess diabetes-related psychosocial self-efficacy. Translation and validation of DES-5 is also carried out in two foreign languages like Chinese and Spanish with an objective to determine the psychometric properties of the Swedish and Chinese version (Ann T Y Shiu *et al*., 2003) of the Diabetes Empowerment Scale (Swe-DES-23). The study outcomes showed acceptable validity and reliability and, thus, found to be a suitable tool in evaluating empowerment-based education programmes.

MATERIALS AND METHOD

The study was conducted in out patient's clinics in Pune. The study was conducted between December 2011 to June 2012. Patient information leaflet was given to the individual patients and the written consent was obtained. The DES-5 questionnaire was administered to diabetic patients twice during total study period.

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 resides in India. Following four phases were carried out for the study.

Phase I: Forward Translations

The aim of this step was to translate the DES-5 into Hindi and produce a version that would be conceptually as close as possible to the original questionnaire. 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.

Phase II: Back Translation

The intermediate DES-5 was given to the two translators who had never seen the original DES-5 before. They were given information 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.

Phase 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.

Phase IV: Pilot Testing

The final second intermediate DES-5 questionnaire was then administered to 50 patients with type 2 diabetes. These patients had never seen the DES-5 questionnaire before and were all native Hindi speakers. Patient population comprised of (42) male and females (8) with median age of years. All patients were having the history of diabetes were asked to fill DES-5 questionnaire and were then interviewed for difficulty in understanding the questions and their meaning. They were also asked for the questions that confused, divert and upset them during the filling of questionnaire.

VALIDATION

Study Population and Sample Size

Patients who participated in the validation study were Hindi speaking adults over the age of 18 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. The patients were asked to fill the questionnaire. After the interval of 4 weeks the same study population was asked to fill the questionnaire. Patients were on the regular treatment between visits.

Measurement of Outcomes

The DES-5 in diabetic patients was measured by using 28 item scales. The instrument consists of three dimensions of DES-5: Managing psychological aspects of diabetes (9 Items), all 9 items were measured on a 5-point response scale. Assessing dissatisfaction and readiness to change (9 Items), all 9 items were measured on a 5-point response scale from “strongly agree” to “strongly disagree” and setting and achieving diabetes goal (10 Items), all 10 items were measured on 5-point response scale from “strongly agree” to “strongly disagree” .

Statistical Analysis

Internal consistency and reliability of dimensions of the questionnaire were assessed using cronbach alpha coefficient (7). Alpha values equal to or greater than 0.70 were considered satisfactory. Item–total correlations over 0.07 were considered to show acceptable correlation between the items of questionnaire and the domain total to which they contribute. Test re-test i:e reproducibility was assessed across a 4-week interval on 250 patients using interclass correlation coefficient. Pearsons correlation coefficient was calculated for all the three subclasses. Significance was set to 0.05 for all analysis. All the statistical analysis was performed in SAS 9.1.

RESULT

Out of two hundred eighty six people with diabetes type 2 participated in the study, two hundred fifty (87.41 %) participants completed and returned the questionnaires. Mean age was 58.09 (SD = 6.77) years (18-75). Other demographic characteristic of the patients were displayed 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 diabetic complications while 49.2 % of patients were suffering from diabetes related complications. From 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). Internal consistency was assessed using cronbach alpha and value of 0.86 was gained for the summary score, indicating high levels of internal reliability. Alpha values for total ranged from 0.87 (max) to 0.841 (mini). Alpha

Table 1: Demographic Information for Survey Respondents (n = 250)	
Age (years)	58.09
Men/women	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

values for subscale Managing Psychological Aspects of Diabetes ranged from 0.84 (max) to 0.77 (min), Assessing dissatisfaction and readiness to change from 0.83 (max) to 0.60 (mini) and Setting and Achieving Diabetes Goal from 0.81 (max) to 0.76 (min) as mentioned in Table 2. Pearson correlations were assessed for all the three subscales and the correlation was found to be significant for all ($p < 0.05$) (Table 3).

Relationship between different dimensions of quality of life (QOL) and post prandial blood glucose level, diabetes related complications, duration of diabetes and education was observed. Significant ($p<0.05$) as per Table 3. Relationship between managing psychological aspects of diabetes and post prandial blood glucose level was observed. Patients who failed to control blood glucose level showed lower scores which indicate the inability of the patients to have a control over the psychological aspects of diabetes. Also the significant ($p<0.05$) relationship was observed between hypertension cataract and managing psychological aspects of diabetes. Patients with cataract demonstrate lower score for QOL, thus presence of cataract can affect the QOL of diabetic patients. Significant ($P < 0.05$) relationship was observed between education and dimensions of QOL. Lower scores were observed in patients with higher education which indicates that patient with higher education can also have low QOL. No significant relationship was observed between treatment and different dimensions of QOL as mentioned in Tables 4 and 5.

Table 2: Scale Means, Standard Deviations and Cronbach Alpha				
Subscales	No of Items	Mean	SD	Cronbach Alpha
Managing psychological aspects of diabetes	9	2.0	0.6	0.83
Assessing dissatisfaction and readiness to change	9	2.3	0.3	0.71
Setting and achieving diabetes goal	10	2.0	0.6	0.74

Table 3: Pearson Correlation Between all Three Sections			
Subscales	Managing Psychological Aspects of Diabetes	Assessing Dissatisfaction and Readiness	Setting and Achieving Diabetes Goal to Change
Managing psychological aspects of diabetes	1	0.87**	0.85
Assessing dissatisfaction and readiness to change		1	0.15*
Setting and achieving diabetes goal			1
Note: ** Correlation is significant at the 0.01 level (2-tailed). * Correlation is significant at the 0.05 level (2-tailed).			

DISCUSSION

The present study assessed the validity and relaibility of the Hindi version of DES-5 in 250 patients with type 2 diabetes. DES-5 questionnaire was subjected to pilot study (n = 50) after forward and backward translation. The internal consistency of questionnaire for the summary score was high with cronbach's alpha coefficient (0.85). The

Table 4: Total Relationship Between Different Dimensions Quality of Life (QOL) and Clinical Demographic Variables

Variable	Managing Psychological Aspects of Diabetes	Assessing Dissatisfaction and Readiness to Change	Setting and Achieving Diabetes Goal
Post Prandial			
<140	37.2(4.7)	33.0(2.6)	38.8(3.2)
>140	34.6(4.5)*	32.2(2.5)	38.7(3.8)
Hypertension			
<=120	34.7(4.7)	32.3(2.6)	38.7(3.9)
121>140	36.0(4.6)	33.0(2.5)	39.3(3.4)
>=140	35.0(4.6)*	32.2(2.6)	38.3(3.4)
Nephropathy			
Yes	34.6(4.2)	32.2(2.4)	39.0(4.3)
No	35.2(4.7)	32.5(2.6)	38.7(3.5)
Angina			
Yes	35.5(4.4)	32.8(2.4)	39.2(3.8)
No	34.9(4.7)	32.3(2.6)	38.6(3.6)
Cataract			
Yes	33.3(4.1)	31.8(2.2)	39.7(4.4)
No	35.9(4.6)*	32.5(2.6)	38.6(3.5)
Age			
<=50	34.9(4.6)	31.9(2.6)	38.3(3.5)
51-60	35.6(4.6)	32.8(2.6)	38.7(3.5)
>60	34.5(4.6)	32.1(2.5)	39.0(3.9)
Duration of diabetes			
3-5	35.0(4.7)	32.6(2.7)	38.6(3.6)
6-7	35.1(4.9)	32.3(2.6)	38.4(3.4)
>=8	35.1(4.2)	32.5(2.5)	39.3(3.9)
Education			
1-2	33.7(1.2)	32.7(0.7)	45.0(3.1)
3	36.2(4.7)	32.8(2.7)	38.1(1.6)
4	29.4(1.6)*	29.4(1.5)*	33.8(3.1)*

Note: Values are Mean (SD) * indicates $p<0.05$, Kruskal-Wallis H test results for multiple groups comparison and Mann-Whitney test results for pairwise comparison. Higher values indicate good quality of life.

Table 5: Relationship Between Different Dimensions Quality of Life (Qol) and Oral Hypoglycemic Treatment

Variable	Managing Psychological Aspects of Diabetes	Assessing Dissatisfaction and Readiness to Change	Setting and Achieving Diabetes Goal
Treatment			
DPP4 I	35.5(4.5)	31.7(2.8)	37.6(2.7)
MET	35.5(4.6)	32.8(2.5)	38.8(3.8)
MGN	34.4(4.9)	32.5(3.0)	39.0(3.3)
SU	35.1(4.6)	32.3(2.5)	38.8(3.6)
TZD	32.2(3.9)	33.0(1.8)	38.6(3.9)

Note: DPP4I: Dipeptidyl peptidase-4, MET: Metformin, MGN: Meglitinides, SU: Sulfonyl Ureas, TZD: Thiazolidinediones. Values are Mean (SD). Higher values indicate good quality of life.

internal consistancy of three subscales were also satisfactory ($\geq$0.7). As compare to the value of original validation study (α = 0.96) our study gain less value (α = 0.85) but in acceptable range. The interclass correlationship coefficient also indicate good reproducibility of questionnaire. As per the demographic study more number of patients (49.2 %) are suffering form the diabetes related complications and this may become the major cause affecting the quality of life of patients. The original English version of DES-5 with 28-item DES-5 showed (α = 0.96) with three subscales: Managing the Psychosocial Aspects of Diabetes (α = 0.93), Assessing Dissatisfaction and Readiness to Change (α = 0.81), and Setting and Achieving Diabetes Goals (α = 0.91). The Chinese version of DES showed (α = 0.93) for Managing the Psychosocial Aspects of Diabetes with 9 items; (α = 0.81) for Assessing Dissatisfaction and Readiness to Change with 9 items; and (α = 0.91) for Setting and Achieving Goals with 10 items. The Indian Hindi version of DES showed (α = 0.83) for Managing the Psychosocial Aspects of Diabetes with 9 items; (α = 0.71) for Assessing Dissatisfaction and Readiness to Change with 9 items; and (α = 0.74) for Setting and Achieving Goals with 10 items. Patient with high blood glucose level with cataract have shown lower QOL, while education does not affect QOL of diabetic patients. Also no significant relationship was found between diabetes related complications like hypertension, nephropathy, angina and age. Previous study from India had showed that duration of diabetes did not have a significant influence on well-being (Sridhar and Madhu, 2002) and same results were observed in our study.

The comparison of our Hindi version of DES-5 with original English version and Chinese version help to confirm the reliability and validity of the instrument.

CONCLUSION

The present study demonstrate that the Hindi version of DES-5 is useful for assessing quality of life of type 2 diabetes patient's in clinical settings. This intrument is developed in such a way that the patient can go for self administration. The study carried out indicates that this validated Hindi

version of DES-5 in Indian type 2 diabetic patients and can be further incorporated for utility study.

Our study provides preliminary support for the reliability and validity of the translated Hindi version of DES-5.

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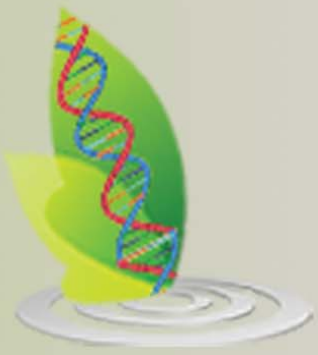

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