Development and validation of quality of life assessment instrument for diabetic patients

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ABSTRACT

Diabetic Mellitus is a reason for concern as it significantly increases one's risk of developing microvascular, and macrovascular complications and adversely affects the quality of life (QoL).QoL is a term used to appraise the patient's functional capacity, psychological, social health, and over all sense of well-being. For chronic illnesses like diabetes mellitus the therapeutic success is conventionally measured by disease-free and overall survival, and control of chief physical symptoms. Number of tools is available for assessing the quality of life in diabetes each with their advantage and disadvantages. The aim of this study was to design and test the reliability and validity of Modified Diabetes Quality of Life questionnaire (MDQoL-17) and to assess the quality of life of south Indian diabetic patients. The tool was developed and validated appropriately. The tool was translated into kannada for use in the local patients and appropriately validated for translation. The developed tool had appropriate reliability and internal consistency. Overall Quality of life of Diabetic patients was analyzed from the data collected of 100 patients and has shown moderate QoL by both the questionnaires. The QoL predicted by RAND-36, which consists of 36 questions, and MDQoL-17, which consists of 17 questions, was almost the same. This showed that MDQoL-17 was good enough to predict the Quality of life as RAND-36. The QoL score was correlated with demographic and other variables.This study showed that the developed MDQoL-17 questionnaire performed similar to the established RAND-36 and could be used as a tool to assess the quality of life in diabetic patients.

INTRODUCTION

Diabetes mellitus [DM] is a group of metabolic disorders where a patient is diagnosed with hyperglycemia, and also associated with abnormalities in carbohydrate, fat, and protein metabolism[1]. DM is a reason for concern as it significantly increases one's risk of developing microvascular, and macrovascular complications [2]. The prevalence of diabetes is rising all over the globe at an alarmingly fast rate. Over the past 30 years or so, the status of diabetes has changed from being thought as a mild disorder of the elderly to one of the major causes of morbidity and mortality affecting the young and middle-aged people[3].

Quality of life (QoL) is a term used to appraise the patient's functional capacity, psychological, social health, and over all sense of well-being. The World Health Organization Quality of Life (WHOQOL) group defined QoL as an individual's perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns[4]. For chronic illnesses like diabetes mellitus the therapeutic success is conventionally measured by disease-free and overall survival, and control of chief physical symptoms[5].

The ultimate aim of health care interventions is assessment of QoL in clinical practice and research settings. From various QoL research studies, several findings of clinical use have been reported. These include the ability to provide clinicians and patients with accurate expectations about the likely effect of treatments on well-being and functioning, the ability to identify common problems that will need to be addressed, and the ability to identify therapies and interventions effective in addressing these problems. In addition, findings also suggest that QoL data may improve clinicians' ability to predict treatment response and survival time in certain contexts. Routine assessment of quality of

life as part of clinical practice has the ability to improve communication between patients and providers, identify frequently overlooked problems, prioritize problems, and evaluate the impact of therapeutic efforts at the individual patient level [6].

Numerous generic and disease specific tools are available to evaluate QoL [7-9].

The general QoL assessment tools which can be applied to any disease are, Short Form 36 (SF-36 Health Survey), RAND-36 measure of health- related quality of life and the EuroQol (EQ) [10]. The various diabetes related assessment tools are Problem Areas in Diabetes (PAID) scale, the Diabetes Health Profile (DHP), the Diabetes Quality of Life Question-naire (DQOL), the Diabetes Care Profile (DCP), the Diabetes-39, the Audit of Diabetes-Dependent Quality of Life (ADDQoL), Well-being Enquiry for Diabetics (WED) [11]. RAND-36 is the most widely and commonly used HRQoL survey instrument in the world today, which assesses the health under eight domains [12].

According to the Diabetes Atlas 2006 published by the International Diabetes Federation, the number of people with diabetes in India currently around 40.9 million is expected to rise to 69.9 million by 2025 unless urgent preventive steps are taken [3]. Certain reports states that the existing health assessment tools does not exactly consider the QoL issues in diabetes [13], this suggests that there is a need for development of specific tool which will be capturing the QoL related issues in diabetic patients. Furthermore such tools has to be validated in the local languages to make it suitable for Indian scenario and especially in Southern India as studies have confirmed the prevalence of diabetes is much higher in South India [3]. In this context we developed and validated MDQoL-17 questionnaire in English and Kannada for assessing the QoL of diabetic patients. The aim of the study was to design and test the reliability and validity of Modified Diabetes Quality of Life questionnaire (MDQoL-17) and to assess the quality of life of south Indian diabetic patients.

METHODOLOGY

The study site was tertiary care teaching hospital in south India, a 2000 bedded hospital with various specialties and super specialties where approximately 2000 diabetic patients are admitted each year to various medicine units. The study was conducted between the months of September 2009 to May 2010. This Prospective observational study was conducted after Ethical Clearance was obtained from the Manipal University Ethics Committee.

Following procedure is used to develop and validate quality of life questionnaire for diabetic patients. RAND questionnaire is a generic questionnaire that laps eight concepts which include: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. It also includes a single item that provides an indication of perceived change in health. All items are scored so that a high score defines a more favorable health state. Each item is scored on a 0 to 100 range so that the lowest and highest possible scores are set at 0 and 100, respectively. Scores represent the percentage of total possible score achieved [14]. This is used for study purpose.

Step 1. : Validation of Kannada Translated RAND Questionnaire:

RAND Questionnaire was translated into Kannada, which is a local language preferred by the patients and was validated using back translation and expert's opinion methodology.

Step 2. : Development of Questionnaire to assess QoL of Diabetic patients:

The MDQoL-17(Appendix-1) was developed based on some tools available for diabetes like Problem areas in diabetes (PAID), which is a measure of diabetes specific emotional stress. Items like fear and depression were taken from PAID. Few items like freedom to eat, working life, family life, social life were taken from ADDQoL 19, an individualized measure of the impact of diabetes on quality of life. While few other items related to social domain like feeling embarrassed to manage diabetes in public and problems while planning for a trip were included from a publication by *Hill Briggs et al* [13] and were modified to include the questions relevant to our set up. The developed questionnaire was validated by experts' opinion, and was translated into Kannada. The quality and appropriateness of Kannada tool was validated using back translation to English. The back translation method ensures that both the original version and back-translated version are conveying similar meaning like their English counterparts. [4]

Step 3. : Evaluating both Kannada RAND-36 and Developed Questionnaire MDDQoL-17:

4 experts 2 physicians, and 2 pharmacists reviewed it. The Questionnaire was revised based on experts' suggestions for minor changes.

Step 4. : Pilot study:

A total of 10 diabetic patients were chosen, the study was described, and after obtaining their consent they were provided with RAND-36 and MDQoL-17 Kannada versions and were asked to fill the questionnaires. After the questionnaire was filled the internal consistency and reliability was assessed using Cronbach's Alpha.

Step 5. : FullStudy:

Among all the DM patients admitted in hospital during the study period, records of eligible patients were screened and those who were eligible were explained about the study. In those patients who were willing to participate and give consent, enrolled in to the study. A total of subsequent 100 enrollments were taken for the study. Demographic details, laboratory parameters, complaints, treatment details were documented and were asked to fill in RAND-36 questionnaire. After two days patients were asked to fill MDQoL-17 questionnaire. Both English and Kannada versions were used based on the language of the patient. The patients have taken approximately 8-10 min of time to fill the RAND-36 questionnaire and 4-5 min of time to fill MDQoL-17 questionnaire. The questionnaires after being filled were collected back for evaluation.

Statistical Analysis

Reliability and internal consistency of the questionnaires was assessed using Cronbach's alpha, which is a widely applied index of internal consistency.

The scores of both RAND-36 and MDQoL-17 were converted to a range of 1 to 10 for the ease of comparison and analysis. The demographic data was expressed as Mean and standard deviation using Microsoft Excel software package. The RAND-36 and MDQoL-17 scores were also expressed as mean and standard

deviation. When the scores of RAND-36 and MDQoL-17 were assessed in terms of covariates like age, gender, duration of illness etc for comparing two mean values unpaired 't' test and comparison of means of three or more groups one-way ANOVA was used. These statistical tests were performed using GraphPad Prism 5 [Computer Program], Version 5.03, La Jolla (CA): GraphPad Prism Inc.

RESULTS

For validation of MDQoL-17, a total of 100 diabetic patients were enrolled in the study. Among which, 89% were males and 11% were females. The mean age of the study group was found to be 55.84±9.71 years (meanS.D). 7% were newly diagnosed Diabetes Mellitus patients, and 64% had a history of 2-10 years of diabetes. The average duration of hospitalization was 9.427.19 days due to either diabetic complications or co-morbidities prolonging the length of stay. Majority patients (67%) were managed with Insulin and 33% were on Oral hypoglycemic agents. The mean Post Prandial Blood Sugar (PPBS)which was done on admission was found to be 263.22mg/dl (S.D=109.65) and the mean Fasting Blood Sugar (FBS) which was done during discharge was found to be 126.6 mg/dl (S.D=50.64).The study population was categorized into three groups. Details are given in Table 1

The reliability and internal consistency of the questionnaire was measured using Cronbach's alpha in both the questionnaire taking 10 patients first and later for 100 patient data and the results have shown significant reliability in both the questionnaire. The values are given in Table 2.

Overall Quality of life of Diabetic patients was analyzed from the data collected of 100 patients and has shown moderate QoL by both the questionnaires. The QoL predicted by RAND-36, which consists of 36 questions, and MDQoL-17, which consists of 17 questions, was almost the same. This shows that MDQoL-17 was good enough to predict the Quality of life as RAND-36. The results are tabulated in the Table 3.

Correlation of QoL with demography of patients:

The QoL of patients based on their demographic details was measured for both RAND-36 and MDQoL-17 questionnaire. Even though differences could be observed based on demographic variables, most of them were statistically insignificant. Females have shown better QoL compared to males in both the questionnaires. There was a slight decrease in the QoL with increasing age in both the questionnaires. The QoL was better in patients who were on less than 2 diabetic medications rather than more than 2 drugs according to MDQoL-17 while no big difference was seen in RAND-36. There was negative correlation for presence of co-morbidities in both the questionnaires. There was no remarkable change found in the QoL related to duration of illness, but patients with duration of illness ranging between 21-30 years have reported poor quality of life. The QoL of life in case of length of stay in hospital did not show a great change but patients whose stay was for more than 20 days have relatively shown poor QoL. The QoL of patients with insulin was better in RAND-36 and was poor in MDQoL-17, the patients who were on oral hypoglycemic agents had poor QoL in RAND-36 and better QoL in MDQoL-17. There was negative correlation between patients with Diabetes alone, Diabetes with its complications, Diabetes and other co morbidities in both the questionnaires. Table 4 represents the analysis and comparison of RAND-36 scores and MDQoL-17 scores respectively for identifying covariates influencing scores.

Table 1. Diabetic complications and Co-morbidities

Complication	No of Patients (N=100)
DM	7 (7%)
DM with its complications	44 (44%)
DM with co morbidities	49 (49%)

Table 2. Cronbach's Alpha values

No of DM patients	Cronbach's value	
	RAND-36	MDQoL-17
10 patients	0.95	0.85
100 patients	0.57	0.87

Table 3. Overall QoL of Diabetic patients:

QOL scores (Mean ± S.D)		p values
RAND-36	MDQoL-17	
5.39±1.81	5.40±1.80	>0.05

Table 4. Comparison of scores obtained from RAND-36 and MDQoL-17for identifying covariates influencing scores.

Sl.no	Covariate factors		QOL scores (Mean ± S.D)		p values
			RAND-36	MDQoL-17	
1	Gender	Male	5.34±1.80	5.37±1.77	>0.05
		Female	5.75±1.95	5.57±2.09	
2	Age in years (no of patients)	21-30 (2)	4.94±0.22	6.07±0.40	NA
		31-40 (3)	4.68±2.14	4.40±2.28	
		41-50(22)	6.26±1.43	6.39±1.64	>0.05
		51-60 (43)	5.51±1.93	5.53±1.90	
		61-70 (24)	4.79±1.62	4.63±1.29	
		71-80 (6)	4.21±1.96	4.09±1.63	
3	No. of diabetic medications	2≤	5.38±1.75	5.45±1.72	>0.05
		≥2	5.43±2.27	5.00±2.36	
4	Co-morbidity	Present	5.43±1.89	5.50±1.86	>0.05
		Absent	5.35±1.73	5.30±1.76	
5	Duration of Illness (years)	1<	4.75±0.61	5.01±0.69	>0.05
		2-10	5.52±1.78	5.54±1.87	
		11-20	5.56±2.03	5.39±1.79	
		20-30	3.35±0.61	3.76±1.49	
6	Length of stay in hospital (days)	5<	5.73±1.58	5.39±1.74	>0.05
		6-10	5.16±1.93	5.38±1.70	
		11-20	5.52±1.68	5.51±1.87	
		>20	5.27±2.42	4.94±3.01	
7	Patients with and without Insulin	Insulin	5.45±1.71	5.25±1.62	>0.05
		Oral hypoglycemic agents	5.27±2.01	5.69±2.12	
8	Complications	DM	5.05±2.52	5.05±2.52	>0.05
		DM + its complications	5.30±1.66	5.30±1.66	
		DM + co morbidities	5.52±1.85	5.52±1.85	

Determination of Quality of Life based on different Domains:

In Energy/Fatigue, Social, General domains the patients have reported moderate quality of life for RAND-36, while relatively poor quality of life for role physical, role emotional domains, and slightly poor QoL for physical and general domain in RAND-36. Moderate quality of life was reported in MDQoL-17 questionnaire for Energy/Fatigue and Social domains. In comparison to all domains patients have reported relatively better QoL for Emotional domain in both the questionnaires. A

significant difference was found between the scores rated in RAND-36 and MDQoL-17 for Role Physical, Physical, Role Emotional and General domains. Table 5 represents Quality of life based on domains.

Analysis of RAND-36 scores and MDQoL-17 scores based on diagnosis:

The QoL using RAND-36 scores and MDQoL-17 scores was measured based on diagnosis and the results have shown moderate QoL, but the quality of life was relatively poor in

Table 5. QoL based on Domains

Sl.no	Domains	QOL scores (Mean ± S.D)		p values
		RAND-36	MDQoL-17	
1	Physical	5.94±2.80	4.73±3.73	>0.05
2	Role Physical	3.45±3.69	5.58±3.16	<0.05
3	Role Emotional	4.13±3.85	5.15±2.36	>0.05
4	Energy/Fatigue	5.24±2.42	4.58±3.27	>005
5	Social	5.76±2.56	5.99±1.94	<0.05
6	Emotional	6.38±2.09	6.29±2.34	>0.05
7	General	5.38±2.10	4.67±2.09	<0.05
8	Pain	5.53±2.70	-	NA

Table 6. RAND-36 scores and MDQoL-17 scores based on the diagnosis:

Sl.no	Complaints on Admission		QOL scores (Mean ± S.D)		p values
			RAND-36	MDQoL-17	
1	Retinopathy	Present (n=24)	5.72±1.98	5.24±1.82	>0.05
		Absent (n=76)	5.28±1.75	5.44±1.80	
2	Neuropathy	Present (n=13)	5.54±2.01	5.27±1.69	>0.05
		Absent (n=87)	5.37±1.79	5.41±1.82	
3	Nephropathy	Present (n=17)	5.23±1.81	5.17±1.50	>0.05
		Absent (n=83)	5.42±1.81	5.44±1.85	
4	Cardiovascular disorders	Present (n=12)	4.62±1.70	4.89±1.20	>0.05
		Absent (n=88)	5.49±1.80	5.46±1.86	
5	Urinary tract infections	Present (n=8)	5.43±1.91	5.40±1.83	>0.05
		Absent (n=92)	5.39±1.81	5.40±1.81	
6	Hypertension	Present (n=42)	4.93±1.84	5.12±1.57	<0.05 Rand scores shows sig diff
		Absent (n=58)	5.72±1.72	5.60±1.94	
7	Foot problems	Present (n=22)	5.38±1.64	4.72±1.48	<0.05 MDQoL scores shows sig difference
		Absent (n=78)	5.39±1.86	5.59±1.84	

Table 7. Analysis of QoL based on number of other Co morbidities diagnosed:

No of Complaints		QOL scores (Mean ± S.D)	
		RAND-36	**MDQoL-17**
No of other co-morbidities diagnosed	0 (n=45)	5.40±1.73	5.25±1.82
	1 (n=46)	5.33±1.86	5.53±1.78
	2 (n=8)	5.72±1.68	5.45±2.21
	3 (n=1)	4.83	5.21

patients who were diagnosed to have with nephropathy, cardiovascular disorders, hypertension, and foot problems. Presence of cardiovascular disorders had shown significant effect on quality of life. Details are given in Table 6 below.

Analysis of QoL based on number of other co-morbidities diagnosed:

The QoL using RAND-36 and MDQoL-17 was measured based on number of other co morbidities diagnosed, the results have shown gradual decrease in QoL scores indicating poor QoL as the number of co-morbidities diagnosed were increasing. Details are given in Table 7.

DISCUSSION

This study was aimed to develop a questionnaire (MDQoL-17), which was translated to Kannada to make it suitable for local population. The MDQoL-17 comprises of 17 diabetes specific questions and this was compared with RAND-36, which is a generic QoL questionnaire containing 36 questions. The sample size was 100 patients. In a study by Filipa Alvis da Coasta in Portuguese language 100 subjects were used to validate their QOL tool. MDQoL-17 questionnaire was found to be internally consistent and reliable when assessed using Cronbach's alpha values[15]. The calculated result was similar to the study by Thomas EB et al where they have reported a value of 0.85 for their tool[16]. Results have shown that there was no significant difference between the scores of RAND-36 and MDQoL-17, which clearly showed that MDQoL-17 was good enough to assess the quality of life as RAND-36. Analysis was carried out using scores of both the questionnaire to correlate QoL with demographics but no significant correlation was found. Females have shown better QoL compared to males in both the questionnaires. But gender cannot be considered as a predictor for QoL in this case as there were more men (89%) compared to women(11%).A trend of decreased QoL was observed when the number of co-morbidities increased but it was not statistically significant. This observation was in line with the observations reported by Rodrigo et al[17].There was a slight decrease in the QoL with increasing age in both the questionnaires suggesting that older age group had poor QoL. There was no significant association between duration of illness and QoL. Patients having a history of more than 20 years of Diabetes mellitus reported of poor QoL. This might be because the duration of illness increases the complications of the diabetes and thereby diminishing the QoL. The QoL did not correlate well with the length of stay. Patients whose stay was more than 20 days were reported of poor QoL. This might be because such patients had complications like

foot ulcers or other diabetic complications like nephropathy and cardiovascular complications. In comparison to all domains patients have reported relatively better QoL for Emotional domain in both the questionnaires. Analysis based on different domains showed that patients had relatively lower quality of life in physical, role physical, role emotional and energy/fatigue domains. Further analysis showed that co-morbidities like hypertension and foot ulcers resulted in significantly poor quality of life. The limitation of this study was less sample size as the study was time bound and carried at a single study site.There is a need to validate the tool using more number of native Kannada experts as in some studies they have used up to 15 experts to validate tools.

CONCLUSION

The present study showed that the developed MDQoL-17 questionnaire performed similar to the established RAND-36 and could be used as a tool to assess the quality of life in diabetic patients. The translated version in one of the Indian language Kannada used in this study was suitable for use in patients. This questionnaire is a shorter one compared to RAND-36 thereby making it easier for patients. This tool could be translated to other Indian languages and validated so that it can be used in any study that needs to assess the health related quality of life in diabetic patients.

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