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Original Research Article

Sensitivity and Responsiveness of Health Utility Indices (HUI2 and HUI3) Among Type 2 Diabetes Patients

Maxwell Ogochukwu Adibe* **and Cletus Nze Aguwa**
Pharmaceutical Outcomes Research Team, Department of Clinical Pharmacy and Pharmacy Management, Faculty of Pharmaceutical Sciences, University of Nigeria, Nsukka, Nigeria

For correspondence:* ***Email:* *Maxwell.adibe@gmail.com; maxwell.adibe@unn.edu.ng;* ***Tel:*** *+234 803 778 1479*

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Abstract

Purpose: *To assess the sensitivity and responsiveness of HUI2 and HUI3 among Type 2 diabetes patients.*
Methods: *This cross-sectional study was conducted in two purposively selected Nigerian tertiary hospitals. Six hundred and thirty-eight (638) adult patients were surveyed following their consent using the HUI2 and HUI3 (HUI23S4En.40Q) questionnaire. Patients' clinical characteristics such as age, co-morbidity, severity of disease, and utilization of hospital resources were postulated a priori to be associated significantly with utility scores of HUI2 and HUI3. Student's t-test and bivariate analyses were conducted to determine the diabetes-severity discriminatory ability of HUI2 and HUI3. The analyses were conducted with SPSS 14.0. A two-tailed significance level of 0.05 was used.*
Results: *Older patients had lower quality of life than younger patients. The overall health deficit of increasing age for HU13 was -0.2950 and that of overall HUI2 was -0.1553. The respondents without eye problem had higher quality of life than those with eye problem, in both HUI3 and HUI2 utility scores. Stroke was the most important patients' characteristic that negatively affected HRQOL. Patients with duration of diabetes > 4 years had lower quality of life scores than their counterparts (≤ 4years).*
Conclusion: *Health Utility Index Mark 2 and Mark 3 were sufficiently sensitive and responsive to diabetes severity among Type 2 diabetes patients.*

Keywords*: Health utility index, HUI2, HUI3, Quality of life, Diabetes.*

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INTRODUCTION

Health utility index mark 2 and mark 3 have been used to assess HRQOL of diabetes patients [1]. Both the HUI2 and HUI3 contain attributes that would likely be affected by diabetes and diabetes complications. For instance diabetic complications such as peripheral neuropathy would presumably affect the mobility and self care attribute of the HU12 and the ambulation and dexterity attributes of the HUI3. Neuropathy and myopathy would likely affect the pain and discomfort attribute of the HUI2 and HUI3 and the dexterity attribute of the HU13. Finally, retinopathy would likely affect the vision attribute of the HUI3 and the sensation attribute of the HUI2 [2]. Evidence of construct validity of the health utilities index mark 2 (HUI) and mark 3 (HUI3) in Type 2 diabetes [1,3], stroke and arthritis [4] had been generated in clinical samples. Thus, the HUI2 and HUI3 would be a reasonable choice of HRQOL measures for evaluating the impact of socio-demographics, co-morbid medical conditions and resource utilization on HRQOL in diabetes patients.

Health Utility Index (HUI) currently consists of two systems, HUI2 and HUI3, which together

describe almost 1,000,000 unique health states [4]. The two systems are independent but complementary. There is a growing trend for the use of HUI as a primary health outcome measure in the form of Quality Adjusted Life Years (QALYs) [5]. In diabetes, disease specific measures fail to capture the additional HRQOL deficits associated with co-morbidities that contribute to the disease burden [6]. Overall utility scores on the HUI2 can range from –0.03 to 1.0, with –0.03 representing the utility of the worst possible HUI2 health state, 0.0 representing dead, and 1.0 representing perfect health. Overall scores on the HUI3 can range from –0.36 to 1.0, with –0.36 representing the utility of the worst possible HUI3 health state (all attributes at the lowest level), 0.0 representing dead, and 1.0 representing perfect health [6]. For both instruments, differences of ≥ 0.03 on the overall scores and 0.05 or greater on the single attributes are considered to be clinically important. It is important to note, however, that differences in the content of overlapping attributes of the HUI2 and HUI3 may affect the performance of either instrument in Type 2 diabetes. Pain and emotion are likely to be affected by the severity of diabetes. The pain and discomfort attribute of the HUI2 is focused on the alleviation of pain through medication, whereas the pain attribute of the HUI3 is more focused on the degree of disruption of activities. The emotion attribute of the HUI2 focuses on worry and anxiety, whereas the emotion attribute of the HUI3 specifically assesses happiness versus depression. It is not clear which content would better reflect the pain and emotional deficits associated with diabetes. Overall, though, the HUI3 is less subject to floor effects than the HUI2 [4, 5, 6, 7, 8].

Sensitivity (also called the true positive rate) measures the proportion of actual positives which are correctly identified as such (e.g. the percentage of sick people who are correctly identified as having the condition). The ability of HUI2 &3 to discriminate patients with multiple or severe illnesses that affect QoL in diabetes patients has been documented [3]. For questionnaires to provide useful measures of clinical outcome they need to demonstrate adequate clinimetric properties. One of the most important clinimetric properties of a questionnaire is responsiveness, which is defined as the ability of an outcome measure to detect true change over time [9]. There are two main approaches to quantifying responsiveness: anchor-based (external responsiveness) and distribution- based methods (internal responsiveness) [10].

The aim of this study was to assess the sensitivity and responsiveness of HUI2 and HUI3 among Type 2 diabetes patients.

METHODS

Study design and area

This cross-sectional study was conducted in two purposively selected Nigerian tertiary hospitals. The hospitals were University of Nigeria Teaching Hospital, Ituku Ozalla (UNTH), and Nnamdi Azikiwe University Teaching Hospital, Nnewi (NAUTH). UNTH began early in the 20th century as a standard general Hospital for Africans built by the colonial administrators. It later metamorphosed into a general hospital on the attainment of Nigeria's independence in the 1960's. However, at the end of the Nigerian civil war in 1970, the then government of East Central State transformed it into a Specialist Hospital with effect from July 1, 1970. At this time, the hospital had a total of 50 doctors, 10 wards, and 300 beds and a chest bay of 60 beds. There were also 350 nurses working in the Hospital.

Today, the situation has changed dramatically. The bed capacity of the hospital in the permanent site is over 500 beds and the number of its personnel (professional and non – professional) has increased tremendously. The University of Nigeria Teaching Hospital became independent in July 1976 with the appointment of autonomous Management Board.

Altogether, there are 41 main departments in the hospital with three out – posts – Comprehensive Health Centers at Obukpa near Nsukka, Enugu State, Abagana in Njikoka Local Government Area of Anambra State and Isuochi in Abia State. There are nine training schools/programmes in the hospital viz: the School of Nursing, Midwifery, Medical Laboratory Science, Nurse Anesthetists, Community Health and Post Ophthalmic Nursing. Others are Peri–Operative Nursing, Cardiothoracic Nursing and Medical Records. These schools currently operate at the old site but plans are already on the ground to provide structures for them in the New Site as soon as possible. It is also worthy to mention that Community services rendered by University of Nigeria Teaching Hospital extend to various states in the country particularly those in the South–East Geopolitical zones.

The Nnamdi Azikiwe Teaching Hospital Nnewi was established by the Anambra State of Nigeria (ASN) edict No 10 of 1988. The hospital was commissioned on Friday 19th July, 1991.

The Nnamdi Azikiwe Teaching Hospital therefore is a multi-campus complex comprising of the Main Hospital at Nnewi, the Diagnostic/Primary Health Care Centre at Nneni and Guiness Eye Hospital Onitsha. The location of the Main Teaching Hospital at Nnewi is temporary. It is hoped that in future, the hospital will move over to its permanent site at Okofia Nnewi.

The Nnamdi Azikiwe Teaching Hospital Nnewi is a tertiary health institution which was set up to provide the students of the college of Health Sciences, Nnamdi Azikiwe University Nnewi the facilities for clinical training. It also aims at providing specialized medical attention/treatment to the citizens of Anambra State in particular and Nigeria in general. In addition to out-patient services, the Teaching Hospital also provides services and training in specialty areas such as Internal Medicine, Obsterics and Gynaecology, Paediatrics, and Surgery (Orthopaedic, Dental, Ophthalmic and General Surgery).

The main branch of the Teaching Hospital has a bed capacity of two hundred (200). Since the conversion to a teaching hospital the staff strength and attendance of patients have grown astronomically.

Inclusion criteria

Six hundred and thirty-eight (638) adult patients attending outpatient clinics of the hospitals that satisfied the inclusion criteria were surveyed following their oral consent. Inclusion criteria were: 18 years and above, diagnosed Type 2 diabetes of at least one year, understanding of English Language, and not too ill to answer the questions. Investigators briefed the respondents on the purpose of the study and oral consent was obtained from the respondents.

Ethical considerations

Ethical clearances with reference numbers: UNTH/CSA.329/Vol.6 and NAUTH/CS/66/VOL. 4/124 were obtained from UNTH and NAUTH respectively. Confidentiality and anonymity of the patients' information were maintained throughout the study. This complete set of HUI23S4En.40Q instruments used in study were fully licensed and granted by Health Utility Inc.

Data collection

Administration and retrieval of (HUI23S4En.40Q) questionnaire was continuous for six weeks in each of the hospitals. The study was conducted from November 2010 to March 2011.

Socio-demographic and clinical characteristics of the patients were obtained using another data collection form. Data obtained were on age, sex, marital status, occupational status, highest level of education, and smoking status. Self reported clinical characteristics were duration of diabetes, mode of glycemic control (e.g., oral medication, insulin and diet), utilization of hospital resources (e.g. overnight hospitalization in the past one year, emergency room visit and number of absenteeism from work in the past 6 months), and co-morbidities (e.g., hypertension, eye problem, stroke, depression and heart diseases).

Analysis of data

The derivation of health status classification levels, health states, single-attribute level utility scores and overall health-related quality of life for HUI2 and HUI3 were performed according to the algorithm presented in procedure of the manual (HUI23-40Q.MNL). In order to determine the diabetes-severity discriminatory ability of HUI2 and HUI3, some hypotheses were postulated *a priori,* based on their relevance to diabetes and their ability to test the performance of the overall scores of HUI2 and HUI3. Demographic data (increasing age), co-morbidity (stroke; heart disease: hypertension, coronary heart diseases, congestive heart failure; eye problem and additional number of medical conditions > 1), severity of disease (use of insulin, use of oral medication, longer duration of diabetes and greater number of absenteeism from work in previous 6 months), and utilization of hospital resources (overnight hospitalization, more contact with physician in emergency room and physician visit) were postulated to be associated with significant health related quality of life (HRQOL) deficits [1-3, 11]. These were stratified using dichotomous events - 'respondents with characteristics in question – Yes' and 'respondents without the characteristics – No'. Two-sample comparisons were made using Student's *t*-test for normally distributed variables or Mann–Whitney *U*-tests for non-normally distributed data, to determine the ability of each instrument to discriminate between 'Yes' and 'No' responses, as specified in the *a priori* hypothesis. Bivariate analysis was conducted to examine the specific effects of patients' characteristics on single attributes of HUI2 and HUI3. Data analysis was conducted with SPSS 14.0® (Chicago, Illinois, USA). A two-tailed significance level of 0.05 was used.

RESULTS

The results generally revealed that the studied population was mostly female, middle-aged,

moderately educated, mostly self-employed and many of the diabetes patients had heart-related diseases, (Table 1). Increasing age was significantly associated with HUI2 single attributes deficits in sensation (r = -0.364; p < 0.01), mobility (r = -0.265; p < 0.01), self-care (r = -0.179; p < 0.05), cognition (r = -0.203; p < 0.01) and pain (r = -0.212; p< 0.01), (Table 2). In HUI3 single attributes, increasing age also significantly affected vision (r = -0.315; p < 0.01), cognition (r = -0.245; p < 0.01), ambulation (r = -0.274; p < 0.01) and pain (r = -0.192; p < 0.01). These deficits were both statistically and clinically significant. The HRQOL deficits imposed by increasing age were more on HUI2 than HUI3 (Tables 2 and 3).

Having eye problems significantly affected HUI2 single attributes deficits in sensation (r -0.270; P< 0.01), mobility (r = -0.336; p < 0.01), self-care (r = -0.281; p < 0.01), cognition (r = -0.310; P< 0.01) and pain (r = -0.375; p < 0.01), Table 2. In HUI3 single attributes, having eye problems was also significantly affected vision (r = -0.383; p < 0.01), speech (r = -0.230; p < 0.01), dexterity (r = -0.300; p < 0.01) cognition (r = -0.312; p < 0.01), ambulation (r = -0.320; p < 0.01) and pain (r = -0.353; p< 0.01). The health deficit for HUI3 was -0.3589 while HUI2 deficit was -0.2100, (Table 2). The trends in the 'having eye problems' were the same as that of age, but eye problem was apparently more disabling than age as it had high negatively correlates with utility scores in both HUI2 and HUI3 (Table 4). The effect of eye problems was more on HUI3 than HUI2.

Heart diseases significantly affected two HUI2 single attributes in sensation (r = -0.208; p< 0.01), and self-care (r = -0.157; p < 0.05), Table 3. In HUI3 single attributes, heart diseases also significantly affected vision (r = -0.174; p < 0.05), emotion (r = -0.144; p < 0.05), ambulation (r = -0.228; p < 0.05) and pain (r = -0.216; p < 0.05).
Stroke significantly affected HUI2 single attributes deficits in sensation (r = -0.142; p< 0.05), mobility (r = -0.467; p < 0.01), self-care (r = -0.606; p < 0.01), cognition (r = -0.487; p< 0.01) and pain (r = -0.557; p < 0.01), Table 2. In HUI3 single attributes, stroke significantly affected vision (r = -0.155; p < 0.05), speech (r = -0.505; p < 0.01), dexterity (r = -0.472; p < 0.01), emotion (r = -0.209; p < 0.01) cognition (r = -0.392; p < 0.01), ambulation (r = -0.505; p < 0.01) and pain (r = -0.537; p < 0.01).

Those respondents that had absenteeism of > 6 days in the previous 6 months had lower utility scores than those that had ≤ 6 days absenteeism from work. Patients that had overnight hospitalization, more contact with physician or nurse in emergency room (ER), and those that visited their physicians more often (> 12 times) in the previous 12 months had lower overall health utilities scores and single attributes utility scores in both HU13 and HU12. Visiting physicians for more 12 times affected all the HUI2 single attributes and 5 of 8 HUI3 single attributes; Emergency room contact affected 4 of 6 HUI2 and 6 of 8 HUI3 single attributes significantly. The HUI2 and HUI3 instruments could capture, identify and discriminate this group of patients who used more of the hospital resources (Table 2-4).

The instruments discriminated the quality of life of patients in different age groups, duration of diabetes, severity of diabetes, co-morbidity, and utilization of hospital resources.

DISCUSSION

The HUI2 and HUI3 were able to capture debilitating effect of age on respondents by differentiating health deficits associated with young and old with greater deficits placed on the elderly. The older patients had lower quality of life than those of younger patients. This result is consistent with other studies conducted by Eljedi *et al* [12] in Gaza strip camp and Issa *et al* [13] in Nigeria, which showed that being old was associated with lower quality of life.

The instruments were able to detect the similarities and differences in the interrelated and overlapping attributes in each of the instruments, this trend was similar all the patients' characteristics examined. They captured the differences in the health deficits associated with having an eye problem and without. This is consistent with a study performed in Canada [14] which concluded that, the illness burden experienced by individuals with diabetes is not only associated with diabetes itself, but largely with co-morbid medical conditions. This eye problem could be attributed to diabetic retinopathy, which is a complication of diabetes.

Identification of higher burdens (health deficits) in patients with heart diseases than those patients without heart diseases shows that heart disease is a common co-morbidity associated with diabetes. This is in accordance with a study which demonstrated that diabetes patients are 2 to 4 times more likely to develop cardiovascular disease than those without diabetes [15]. This conforms to a study that found out that the presence of cardiovascular complications as co-morbidities with diabetes led to deficit in health related quality of life [16].

Table 1: Characteristics of the patients

Demographic data	N = 638
Age – mean (SD)	51.70 (6.81)
Age (years)	%
≤ 52	31.50
> 52	68.50
Sex (%) Male	45.00
Level of education	**%**
No formal education	26.00
Primary school	28.00
Secondary school	27.50
University	18.50
Marital status	**%**
Currently married	60.00
Widowed	25.00
Separated	6.00
Single	9.00
Occupation	**%**
Student	4.00
Self employed	44.50
Employee	24.50
Retired	27.00
Number of absenteeism from school/work in last 6 months (if not retired)_mean (SD)	6.20 (2.53)
number of absenteeism (days)	%
≤ 6	52.90
> 6	47.10
Smoking status	%
Current smoker	23.50
Non – smoker	76.50
Duration of diabetes (years) – mean (SD)	4.30 (1.87)
Duration of diabetes (years)	%
≤ 4	59.30
> 4	40.70
Family history of diabetes (%)- Yes	47.50
Number of medical conditions_ mean (SD)	1.90 (0.76)
Number of additional medical condition	%
=1	59.30
> 1	40.70
Has eye problem (%) Yes	47.50
Suffers the effect of stroke (%) Yes	14.50
Has heart disease (%) Yes	85.50
Overnight hospitalization (%) Yes	51.50
Contact with physician or nurse in ER (%) Yes	17.00
Number of physician visits in previous 12 months – mean (SD)	11.62 (4.76)
Physician visits	%
≤ 12	59.30
> 12	40.70
Use of insulin (%) yes	47.50
Use of medication (%) Yes	95.00
Self-rated health	**%**
Excellent	7.00
Very good	20.00
Good	30.00
Fair	27.00
Poor	16.00

Table 2: Impact of patients' characteristics on single attributes of HUI2 (Bivariant correlation)

Patients' characteristics	Sig[a]	Sensation	Mobility	Self care	Emotion	Cognition	Pain
Medication use	1	-0.167*	-0.126	-0.088	-0.125	-0.131	-0.137
Smoking status -Yes	1	-0.115	-0.115	-0.162*	0.090	-0.112	-0.127
Has heart disease	2	-0.208**	-0.105	-0.157*	0.085	-0.132	-0.099
Overnight hospitalization	4	-0.144*	-0.191**	-0.008	0.096	-0.229**	-0.207**
Contact with physician in ER	4	-0.132	-0.321**	-0.165*	0.075	-0.389**	-0.322**
Use of insulin	4	-0.162*	-0.230**	-0.093	0.400	-0.219**	-0.347**
Stroke	5	-0.142*	-0.467**	-0.606**	-0.059	-0.487**	-0.557**
Eye problem	5	-0.270**	-0.336**	-0.281**	-0.050	-0.310**	-0.375**
Age > 52 years	5	-0.364**	-0.265**	-0.179*	0.021	-0.203**	-0.212**
medical condition >1	5	-0.283**	-0.331**	-0.242**	0.019	-0.281**	-0.366**
Duration of diabetes > 4 years	5	-0.246**	-0.318**	-0.198**	-0.037	-0.360**	-0.193**
Physician visit > 12	6	-0.251**	-0.204**	-0.208**	0.152*	-0.302**	-0.413**

**p < 0.05; ** p < 0.01*; Sig[a] = Number of single attributes out of 6 attributes that were significantly correlated with specific patients' characteristics in increasing order.

Table 3: Impact of patients' characteristics on single attributes of HUI3 (bivariant correlation)

Parameter	Sig[a]	Vision	Hearing	Speech	Dexterity	Emotion	Cognition	Ambulation	Pain
Smoking status -Yes	1	-0.121	0.082	-0.152*	-0.056	0.071	-0.123	-0.124	-0.113
Medication use	4	-0.149*	-0.081	-0.074	-0.142*	-0.055	-0.165*	-0.108	-0.139*
Overnight hospitalization	4	-0.063	-0.108	-0.210**	-0.041	-0.091	-0.178*	-0.210**	-0.189*
Age > 52 years	4	-0.315**	-0.126	-0.129	-0.132	-0.126	-0.245**	-0.274**	-0.192**
Has heart disease	4	-0.174*	0.033	-0.128	-0.035	-0.144*	-0.116	-0.228*	-0.216*
Physician visit > 12	5	-0.096	-0.105	-0.144*	-0.222*	0.047	-0.302**	-0.254**	-0.380**
Use of insulin	5	-0.076	-0.059	-0.194**	-0.217**	0.056	-0.240**	-0.263**	-0.340**
Contact with physician in ER	6	-0.067	-0.084	-0.314**	-0.231**	-0.143*	-0.336**	-0.314**	-0.278**
Eye problem	6	-0.383**	0.019	-0.230**	-0.300**	-0.134	-0.312**	-0.320**	-0.353**
medical condition >1	6	-0.151*	-0.013	-0.153*	-0.206**	-0.095	-0.210**	-0.377**	-0.312**
Duration of diabetes > 4 years	6	-0.252**	-0.109	-0.346**	-0.192**	-0.120	-0.372**	-0.346**	-0.397**
Stroke	7	-0.155*	-0.117	-0.505**	-0.472**	-0.209**	-0.392**	-0.505**	-0.537**

**p < 0.05; ** p < 0.01;* Sig[a] = number of single attributes out of 8 attributes that were negatively correlated with specific patients' characteristics in increasing order

The high negative correlates of stroke with utility scores were prominent in both HUI2 and HUI3 single attributes, with self-care single attribute mostly affected in HUI2 and pain in HUI3. The instruments ability to capture these deficits associated with stroke is in agreement with other previous studies [17,18].

Having more than one medical condition to diabetes followed the same trends of 'having heart diseases', this similarity might be due the fact that most of the additional medical conditions were heart related diseases. HUI2 and HUI3 were able to capture this similarity and it differentiated the patients with co-morbidity from those without. This conforms to study by Maddigan *et al* [19] which concluded that social and environmental factors are important determinants of health of health of diabetes patients, but co-morbidities have the largest impact on HRQOL among people with Type 2 diabetes. It also captured the increasing burden (HRQOL deficit) associated with additional co-morbidities in Nigerian diabetes patients as reported in several studies [17-19].

Effect of duration of diabetes indicates that diabetes imposes more burdens to the patients as individuals and reduces the country's productivity profile as man-hour loss due diabetes is high.

As the disease progresses to more severe situation, treatment option changes from diet to use of oral medication and/or insulin. This result is consistent with a study [15] which demonstrated that the longer the duration of diabetes, the higher chances of a patient developing overt nephropathy and other micro-complications of diabetes which might require insulin treatment, thus, the HRQOL of the patients is lowered.

Table 4: Impact of patients' characteristics on overall utility scores of HUI3 and HUI2

Patient characteristics	Overall utility score (HU13) [a]N=235-321			Overall utility score (HU12) [a]N= 274-346		
Demographic/Clinical Characteristics	Yes; Mean±SD	No; Mean±SD	[b]Mean diff. (Yes - No)	Yes; Mean±SD	No; Mean±SD	[b]Mean diff. (Yes - No)
Age (>52 years)	0.320 ±0.424	0.615 ±0.376	-0.295**	0.563 ±0.268	0.719 ±0.229	-0.155**
Eye problem	0.224 ±0.403	0.584 ±0.383	-0.359**	0.502 ±0.263	0.712 ±0.227	-0.210**
Heart disease	0.381 ±0.427	0.606 ±0.408	-0.226*	0.601 ±0.267	0.678 ±0.250	-0.077
Stroke	-0.091 ±0.252	0.499 ±0.395	-0.590**	0.296 ±0.195	0.666 ±0.237	-0.370**
>1 medical condition	0.200 ±0.399	0.496 ±0.416	-0.296**	0.475 ±0.267	0.666 ±0.246	-0.191**
Use of insulin	0.278 ±0.425	0.535 ±0.401	-0.257**	0.546 ±0.278	0.672 ±0.240	-0.126*
Use of medication	0.3919 ±0.429	0.819 ±0.223	-0.427*	0.597 ±0.262	0.898 ±0.163	-0.301**
Duration of diabetes (>4 year)	0.196 ±0.392	0.565 ±0.392	-0.369**	0.490 ±0.261	0.698 ±0.235	-0.208**
Absenteeism from work	0.378 ±0.448	0.618 ±0.371	-0.240	0.642 ±0.256	0.714 ±0.225	-0.073
Overnight hospitalization	0.337 ±0.438	0.494 ±0.410	-0.158*	0.579 ±0.275	0.648 ±0.252	-0.069
Emergency Room visit	0.118 ±0.404	0.474 ±0.412	-0.356**	0.460 ±0.279	0.643 ±0.253	-0.183**
>12 visits	0.237 ±0.411	0.536 ±0.403	-0.300**	0.524 ±0.259	0.672 ±0.255	-0.147**

Overall utility Score and single attributes utility score (for all the respondents)

	HUI3 single attributes			HUI2 single attributes	
	Mean	SD		Mean	SD
Overall HUI3	0.4130	(0.0346)	Overall HUI2	0.6122	(0.1878)
Vision	0.8140	(0.0176)	Sensation	0.7706	(0.1597)
Hearing	0.9304	(0.0139)	Mobility	0.8655	(0.1632)
Speech	0.9730	(0.0060)	Emotion	0.7959	(0.0247)
Ambulation	0.8265	(0.0211)	Cognition	0.8264	(0.1639)
Dexterity	0.7858	(0.0231)	Self -care	0.8810	(0.0221)
Emotion	0.8739	(0.0159)	Pain	0.7531	(0.0182)
Cognition	0.7442	0.0229)	NA	NA	NA
Pain and discomfort	0.6325	(0.0267)	NA	NA	NA

*[a]N varied depending on number of respondents with missing data for each patients' characteristics in HUI2 and HUI3. NA= Not applicable to HUI2; ** p < 0.001 and *p <0.05 for comparison between Yes and No; [b]Mean difference ≥ 0.03 and ≥ 0.05 for overall utility score and single attributes scores respectively are clinically significant.*

Limitations of the study

The major limitations of this study were missing data, selection bias, and self-reported data. Missing data presented the most daunting challenge in demographic and clinical characteristics. Among the outcomes measured, utility scores were the most important. Fortunately, this measure did not suffer from missing data because the questionnaires were interviewer administered. Investigators' bias was a potential limitation, though this was minimal as the investigators were trained before the study. Selection bias was a problem as participation was voluntary, though all the patients who were eligible and willing to participate were surveyed. It remains possible that patients who chose to participate in the study may have differed in some important ways from those who did not participate, which could affect the external validity or generalizability. Data were self-reported, however, self-reported data about diabetes status have been established to be both valid and reliable [20].

CONCLUSION

Health Utility Index Mark 2 and Mark 3 were sufficiently sensitive and responsive to diabetes severity among Type 2 diabetes patients. These instruments can be used in clinical studies for a wide variety of conditions. HUI2 and HUI3

provide comprehensive, reliable, responsive and valid measures of health status and HRQL for subjects which can be compared across the countries. The widespread use of HUI facilitates the interpretation of results and permits comparisons of disease and treatment outcomes, and comparisons of long-term sequelae at the local, national and international levels. Utility scores of overall HRQL for patients are also used in cost-utility and cost-effectiveness analyses.

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CONFLICT OF INTEREST

The authors declare that they have no competing interests

AUTHORS' CONTRIBUTIONS

MOA and CNA designed the study. MOA carried out the statistical analysis. Both authors were involved in preparing the manuscript, and also read and approved the final copy of the manuscript.

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