

Assessing the reliability and validity of the ICECAP-A instrument in Chinese Type 2 Diabetes Patients

Yao Xiong

Southwestern University of Finance and Economics <https://orcid.org/0000-0002-7320-9708>

Hongyan Wu (✉ why_vivian@163.com)

<https://orcid.org/0000-0002-7338-2172>

Judy Xu

Southwestern University of Finance and Economics

Research

Keywords: ICECAP-A, EQ-5D-3L, Psychometrics, Reliability, China, Diabetes

Posted Date: October 23rd, 2020

DOI: <https://doi.org/10.21203/rs.3.rs-62440/v2>

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Version of Record: A version of this preprint was published on January 6th, 2021. See the published version at <https://doi.org/10.1186/s12955-020-01632-5>.

Abstract

Purpose We aimed to conduct psychometric tests for the Chinese version of ICECAP-A and compare the differences between ICECAP-A and EQ-5D-3L for patients with T2DM, and explore the relationship between clinical conditions and ICECAP-A through diabetes-related clinical indicators. **Methods** Data were collected from a sample of 492 Chinese T2DM patients. The reliability and validity of the ICECAP-A were verified. Exploratory factor analysis (EFA), correlation analysis and regression analysis were conducted for both the ICECAP-A and EQ-5D-3L. **Results** Our results show that the Chinese version of ICECAP-A has good internal consistency with an overall Cronbach's Alpha coefficient of 0.721. The mean scores of ICECAP-A and EQ-5D-3L are 0.85 vs. 0.94. A weak correlation ($r = 0.116$) was found between the ICECAP-A tariff and EQ-5D-3L utility. EFA showed that although the five dimensions of the ICECAP-A and EQ-5D-3L scales were loaded into two different factors respectively. However, the two scales captured different dimensions of quality of life and can complement each other. The ICECAP-A, EQ-5D-3L, and EQ-VAS scores showed differences across different socio-demographic characteristics and clinic conditions groups. **Conclusion** The Chinese version of the ICECAP-A capability instrument can be for assessing outcomes in adults with T2DM. It may capture more dimensions of QoL than traditional Health-related QoL (HRQoL) instruments and may be useful for economic evaluations of health care and social care for people with T2DM or other chronic diseases.

Key Points For Decision Makers

The ICECAP-A can be used to access the quality-of-life aspects of T2DM for the purpose of economic evaluation.

The combined use of capability of well-being and preference-based health-related quality of life can offer a broader space for assessing quality of life for T2DM patients to decision makers.

1 Background

Type 2 diabetes (T2DM) is one of the top chronic conditions in China which causes big burdens for both families and countries, with the total diabetes national prevalence in adults was 10.9%, of prediabetes, 35.7% [1]. The international diabetes federation (IDF) Diabetes Atlas 2019 estimated the total health expenditure due to diabetes was USD 109.0 billion in 2019 in China [2], and T2DM-related direct annual cost was USD 90.5 billion [3].

In addition, to raise levels of glucose in a patient's blood, most patients suffer from a variety of long-term complications, including microvascular complications (e.g., neuropathy, nephropathy, and retinopathy) and large vessel complications (e.g., myocardial infarction, angina, stroke, and amputation) [4].

Meanwhile, studies show that only 26% of Chinese T2DM patients received treatment, and of these, only 40% had adequate glycemic control [5, 6]. High untreated rate and poor blood glucose control raise the risk of long-term complications in Chinese T2DM patients.

T2DM not only makes patients endure abnormal biochemical indicators but also has a significantly negative impact on the general quality of life (QoL) and well-being due to the disease and complications. Therefore, appropriate exercise, diet, and self-management have played important roles in diabetes management besides pharmaceutical treatment. Furthermore, the purpose of treating T2DM has become more than the control and improvement of the biochemical indicators of the patient, the more important purpose is to prevent and delay the occurrence of chronic complications of diabetes and to alleviate the adverse symptoms and distress of the disease, that is, improve their general QoL and well-being.

Health-related quality of life (HRQoL) is a composite concept of a person's subjective evaluation of their health status, which could be measured by EQ-5D, SF-6D, etc. Currently, EQ-5D is the most commonly used HRQoL measurement instrument in China, including T2DM and other 17 chronic non-communicable diseases (CNCDS) [7]. As a universal preference-based HRQoL scale, EQ-5D has been widely used to measure the effects of T2DM, and EQ-5D tariff scores associated with T2DM and various comorbidities can be very useful in the economic assessment of model health status in T2DM patient health programs [8]. However, the impacts of disease and the effects of interventions on T2DM were not limited to the HRQoL but also encompassed broader QoL and well-being (similar to depressed populations). The HRQoL instrument may undervalue the outcomes of the integrated care of diabetes management and the wholly negative impact of T2DM.

The capability approach is an appropriate framework for conceptualizing these broader feelings of QoL and well-being into health decisions [9, 10]. In recent years, a family of generic instruments called Investigating Choice Experiences for the Preferences of Older People (ICEpop), that has developed to measure capability (CAP) to measure more general well-being than the traditional framework of HRQoL permits [11]. Unlike the popular HRQoL instruments of EQ-5D, ICECAP is designed to measure people's function and capability based on Sen's capability theory [12].

With a growing interest in using ICECAP instruments and the capability of a broader range of population groups, the ICECAP-A capability index has been developed to measure the generic QoL for the adult population. The ICECAP-A includes five dimensions of stability (feel settled and secure), attachment (have love, friendship and support), autonomy (be independent), achievement (achieve and progress), and enjoyment (have enjoyment and pleasure) [13]. Unlike most profile measures used in economic evaluations, the ICECAP-A focuses on wellbeing defined in a broader sense, rather than health. Most evidence shows that ICECAP-A is reliable and valid [14–17]. In addition to studies in the general population, which also involved the comparison of ICECAP-A tariff scores for diseases with healthy populations, such as knee pain [18], depression [19], and patients with other chronic conditions. It has the potential for economic evaluations of public health interventions as well as other social care in addition to clinical-focused medical services and pharmaceutical products.

ICECAP-A has been translated into Chinese with the adaptation of Chinese culture. A recent study shows that the Chinese version of ICECAP-A has good internal consistency and concurrent validity based on the general online population [11]. The study also shows that the ICECAP-A tariff scores reflected differences

across different socioeconomic groups as expected. However, it is not clear whether ICECAP-A can distinguish subpopulations with different health conditions (e.g., T2DM) in Chinese culture since it doesn't include respondents' objective health status. The aims of this study are 1) Conduct psychometric tests for the Chinese version of ICECAP-A and compare the differences between ICECAP-A and EQ-5D-3L for patients with T2DM; 2) Explore the relationship between clinical conditions and ICECAP-A through diabetes-related clinical indicators.

2 Methods

2.1 Research design and setting

The data is from the Community Diabetes Management Study (CDMS). Considering the geographical location, level of economic and social development, and accessibility, the CDMS survey respectively selected two community health service centers in Beijing and Chengdu to conduct interviews with T2DM patients. CDMS is a longitudinal panel study from June 2015 to December 2017, that includes a sample of 967 diabetes patients and 20 physicians who conduct disease management for them. The baseline survey was conducted in June 2015, the six follow-up surveys were conducted in September and December 2015, June and December 2016, and June and December 2017, respectively. That is the study had been conducted every 3 months in the first year and every 6 months in the second and later years, with a total of 7 wave surveys available now.

2.2 Data collection procedure and data sources

We retrieved health records from the local Center for Disease Control and Prevention and included all individuals with a previous diagnosis of T2DM living in four districts in Beijing and Chengdu as the sampling frame.

The participant inclusion criteria were: 1) aged 18 years or older; 2) clinically diagnosed with type 2 diabetes; 3) without any cognitive impairment and serious vision and hearing problems; 4) able to read and communicate in Mandarin; and 5) consent to participate in the study. Informed consent was obtained from all patients included in the study.

The observation exclusion criteria were: 1) loss to follow-up; 2) missing most data in socio-demographic characteristics; 3) illogical data (i.e. age was less than the duration of diabetes); 4) HbA1c = 0% or HbA1c > 20% (195 mmol/mol).

Patients were invited to the community health service centers for face-to-face paper-and-pencil interviews at baseline and every wave follow-up. At every interview, patients received a medical examination including blood pressure. A fasting blood sample was collected to test the blood lipids, HbA1c level, and fasting blood glucose level. Each participant was also asked to complete a long-form questionnaire, which consisted of 1) socio-demographic characteristics such as age, gender, marital status, monthly income, education level, work status, and health insurance; 2) personal health information, including self-

reported happiness, self-reported health status, other chronic diseases, and comorbidities; 3) QoL, which was measured by both the Chinese versions of ICECAP-A (ICECAP-A was firstly added in the 4th wave survey) and EQ-5D-3L.

The study adhered to the Declaration of Helsinki and ethics approval was obtained from the Institutional Review Board of the Fu Xing Hospital, Capital Medical University (Approval Number: 201FXHEC-KY). Written informed consent was obtained from each participant at the recruitment stage of the study.

The interviewers attended a one-day training session which included an introduction of the study, explanations for possible questions, and mock interviews. Throughout the data collection process, every filled questionnaire was checked by two other interviewers independently. A double-entry method was adopted to ensure the accuracy of data entry. The software for Windows, Stata version 15 (Stata Corp, College Station, TX, USA) is used for statistical analysis.

2.3 Psychometric Tests

2.3.1 Reliability test

The reliability for the questionnaire as a system can be tested to check the reliability of the ICECAP-A where Cronbach's alpha, with a value of > 0.70 is considered acceptable.

2.3.2 Validity test

Exploratory factor analysis (EFA) was conducted for both the EQ-5D-3L and ICECAP-A. We also conducted a Polychoric correlation analysis between the scores for the ICECAP-A, EQ-5D-3L, and EQ-VAS. We employed Polychoric correlation analysis instead of Pearson correlation because the former is employed when the measurement of variables was based on an ordinal scale.

In this study, socio-demographic characteristics and clinic conditions were used to construct known-group analyses. To test the discriminative validity of the ICECAP-A and EQ-5D-3L measures, a univariate analysis using one-way analysis of variance was carried out.

In the study, the overall ICECAP-A tariff score was calculated using the UK value set [20]. We used the EQ-5D-3L utility values set that was developed by Liu GG et al, based on the Chinese urban population [21]. Individual attributes for the ICECAP-A questionnaire ranged from the full capability level (4) to the no capability level (1), whereas each dimension of the EQ-5D-3L questionnaire ranges from the highest level (1) to the lowest (3). Therefore, the full capability status is (4,4,4,4,4) whilst the highest EQ-5D-3L status is (1,1,1,1,1). Because ICECAP-A and EQ-5D-3L did not exhibit the same ordinal direction for different dimensional levels, we transformed the EQ-5D-3L level values to facilitate comparison between the two scales, as a result, level (1) was reassigned as level (3) and level (3) was reassigned as level (1) in EQ-5D-3L, and the highest EQ-5D-3L status was (3,3,3,3,3).

3 Results

3.1 Descriptive Analysis

The socio-demographic characteristics and clinical condition of the participants are shown in Table 1. In total, there were 492 participants (mean age 64.02 (SD 9.57) years) included in our study, 60.6% (n = 298) were female. In this study, almost 86.2% (n = 424) of participants had a lower than college educational level. More than 90% of the participants were married. Regarding clinical condition, 82.7% (n = 407) of participants had been diagnosed with other chronic diseases, and 70.3% (n = 344) of participants did not report any complications.

Table 1

Sample characteristics for the ICECAP-A and EQ-5D-3L scores and EQ-VAS by socio-demographic and clinic conditions groups of the sample

	ICECAP-A tariff score			EQ-5D-3L tariff score			EQ-VAS			
	N	mean	sd	p-value	mean	sd	p-value	mean	sd	p-value
Gender				0.725			0.154			0.036
Male	194	0.85	0.09		0.95	0.06		82.98	10.59	
Female	298	0.85	0.1		0.93	0.08		80.74	10.89	
Age				0.005			0.595			< 0.001
< 35	2	0.94	0.05		0.96	0		92.50	3.54	
35–44	14	0.89	0.07		0.94	0.07		85.00	9.58	
45–54	64	0.87	0.11		0.95	0.05		85.17	7.92	
55–64	140	0.85	0.11		0.94	0.07		81.64	13.66	
≥65	272	0.84	0.08		0.93	0.08		80.51	9.59	
Marital status				0.017			0.007			< 0.001
Married	448	0.86	0.09		0.94	0.06		82.19	10.55	
Unmarried	44	0.81	0.12		0.90	0.11		75.80	11.88	
Monthly income per capita				0.197			0.694			< 0.001
<¥1000	54	0.87	0.12		0.93	0.07		73.52	15.07	
¥1001-¥2000	57	0.86	0.09		0.92	0.12		78.75	11.87	
¥2001-¥3000	225	0.85	0.08		0.94	0.06		82.59	9.36	
¥3001-¥4000	120	0.85	0.1		0.95	0.05		83.78	8.68	
≥¥4000	36	0.83	0.11		0.93	0.11		85.03	10.29	

ICECAP-A ICEpop CAPability measure for adults, EQ-5D-3L EuroQoL Three-Dimension, sd standard deviation

There are 1, 3, 16, 42, 23 missing data which in the categories of self-reported happiness, number of complications, fasting blood glucose, two hours postprandial blood glucose, HbA1c, respectively.

	ICECAP-A tariff score			EQ-5D-3L tariff score		EQ-VAS		
Education	0.667			0.223				< 0.001
Primary school or below	122	0.85	0.11	0.92	0.09	75.73	13.03	
Middle school	132	0.85	0.09	0.93	0.08	82.34	9.72	
High or profession school	170	0.85	0.09	0.94	0.06	83.36	9.59	
College or above	68	0.86	0.09	0.96	0.02	86.47	6.11	
Work status	0.021			0.756				< 0.001
Other work status	99	0.86	0.08	0.94	0.07	84.96	6.37	
Working	63	0.89	0.07	0.94	0.06	86.25	7.83	
Leisure	330	0.84	0.1	0.94	0.07	79.74	11.82	
Health insurance	0.004			0.645				< 0.001
Government medical insurance	3	0.87	0.01	0.96	0	73.33	15.28	
Urban resident medical insurance	17	0.79	0.16	0.95	0.05	81.35	6.1	
Urban employee medical insurance	359	0.85	0.08	0.94	0.07	83.83	8.93	
New cooperative medical insurance	111	0.88	0.11	0.93	0.08	74.74	13.67	
No insurance	2	0.89	0.07	0.96	0	85.00	0	

ICECAP-A ICEpop CAPability measure for adults, EQ-5D-3L EuroQoL Three-Dimension, sd standard deviation

There are 1, 3, 16, 42, 23 missing data which in the categories of self-reported happiness, number of complications, fasting blood glucose, two hours postprandial blood glucose, HbA1c, respectively.

	ICECAP-A tariff score			EQ-5D-3L tariff score		EQ-VAS	
Income source							
			< 0.001		0.585		0.261
Salary	311	0.85	0.09	0.94	0.06	82.49	9.35
Agriculture production or business	21	0.88	0.08	0.95	0.04	77.05	11.36
Other source	127	0.83	0.1	0.93	0.1	80.40	13.31
Unkown	33	0.92	0.1	0.93	0.06	80.91	12.08
Self-reported happiness							
			0.012		0.022		0.001
Very happy	423	0.85	0.09	0.94	0.06	82.00	11.04
Fairly happy	66	0.85	0.09	0.92	0.11	80.17	8.25
fairly unhappy	3	0.55	0.08	0.81	0.05	60.00	0
Self-reported health status							
			0.013		0.002		< 0.001
Good health	314	0.86	0.09	0.95	0.06	84.37	9.5
Fair health	165	0.85	0.09	0.92	0.08	77.86	10.12
Poor health	12	0.74	0.15	0.87	0.14	62.42	16.98
Number of Other Chronic diseases							
			0.248		0.051		< 0.001
None	85	0.86	0.07	0.94	0.07	85.42	6.18
1	222	0.86	0.09	0.95	0.06	83.19	9.95
2 or above	185	0.84	0.11	0.93	0.08	78.02	12.36
Number of Complications							
			0.631		< 0.001		< 0.001
None	344	0.85	0.09	0.95	0.06	83.42	8.66
1	104	0.84	0.10	0.93	0.08	77.88	15
2 or above	41	0.85	0.08	0.89	0.1	76.20	10.64

ICECAP-A ICEpop CAPability measure for adults, EQ-5D-3L EuroQoL Three-Dimension, sd standard deviation

There are 1, 3, 16, 42, 23 missing data which in the categories of self-reported happiness, number of complications, fasting blood glucose, two hours postprandial blood glucose, HbA1c, respectively.

	ICECAP-A tariff score			EQ-5D-3L tariff score		EQ-VAS	
Fasting Blood Glucose	0.184			0.401		0.001	
< 6.1 mmol/L	256	0.85	0.08	0.94	0.06	83.78	7.85
6.1 ~ 7.0 mmol/L	87	0.85	0.11	0.94	0.06	83.81	7.74
≥7.0 mmol/L	133	0.86	0.11	0.93	0.09	77.83	14.38
Two hours Postprandial Blood Glucose	0.477			0.550		0.002	
< 7.8 mmol/L	88	0.84	0.10	0.94	0.05	83.76	8.75
7.8 ~ 11.1 mmol/L	270	0.85	0.09	0.94	0.07	83.24	8.08
≥11.1 mmol/L	88	0.86	0.10	0.93	0.09	77.18	15.26
HbA1c	0.020			0.248		0.010	
< 6.5%	328	0.84	0.09	0.94	0.06	83.12	8.74
≥6.5%	141	0.87	0.09	0.93	0.09	79.21	13.54
Overall sample		0.85	0.10	0.94	0.07	81.62	10.82
ICECAP-A ICEpop CAPability measure for adults, EQ-5D-3L EuroQoL Three-Dimension, sd standard deviation							
There are 1, 3, 16, 42, 23 missing data which in the categories of self-reported happiness, number of complications, fasting blood glucose, two hours postprandial blood glucose, HbA1c, respectively.							

The average ICECAP-A tariff score in samples was 0.85. Male participants had an equal ICECAP-A tariff score compared to female participants. Participants over 65 years old had the lowest ICECAP-A, EQ-5D-3L, and EQ-VAS scores compared to younger participants. Married participants and those with a higher level of education had a higher ICECAP-A, EQ-5D-3L, and EQ-VAS scores compared to those in other marital status and with lower education, respectively. Furthermore, based on the monthly income per capita, we found that high-income participants indicated the lowest ICECAP-A tariff score compared with low-income participants, but middle-income participants indicated the highest EQ-5D-3L score. Concerning clinical conditions, EQ-5D-3L and EQ-VAS scores in participants without complications or comorbidities were higher than those with complications. Furthermore, participants with higher HbA1c reported a higher ICECAP-A tariff score and lower EQ-5D-3L and EQ-VAS scores compared to those who had lower HbA1c.

The Kruskal Wallis test showed that the differences in the overall distribution of QoL among seven categories of the sample (e.g., age, marital status, work status, category of health insurance and level of HbA1c) were statistically significant ($P < 0.05$) for the ICECAP-A measure, and differences in the overall distribution of HRQoL among four categories of the sample (e.g., marital status, number of complications) statistically significant ($P < 0.05$) for the EQ-5D-3L measure.

The distribution of responses to the ICECAP-A instrument is presented in Table 2. There were no more than 30% of the participants who reported full capability in the attributes of Stability and Attachment. Meanwhile, only 15.5% ($n = 76$) of the participants could make achievements and progress in all aspects of their life. On the contrary, more participants had full capability performing completely independently (52.9%) and enjoyment (36.4%).

Table 2
Response to ICECAP-A questionnaire

Attributes	Level 4		Level 3		Level 2		Level 1	
	n	(%)	n	(%)	n	(%)	n	(%)
Stability	138	28.1	334	67.9	20	4.1	0	0.0
Attachment	120	24.4	317	64.4	55	11.2	0	0.0
Autonomy	260	52.9	167	33.9	65	13.2	0	0.0
Achievement	76	15.5	275	55.9	139	28.3	2	0.4
Enjoyment	179	36.4	299	60.8	14	2.9	0	0.0

Different from the distribution of responses to the ICECAP-A instrument, more than 91% of the participants reported no problem in all the five attributes in the EQ-5D-3L (Table 3).

Table 3
Response to EQ-5D-3L questionnaire

Attributes	Level 3		Level 2		Level 1	
	n	(%)	n	(%)	n	(%)
Mobility	457	92.9	34	6.9	1	0.2
Self-care	480	97.6	12	2.4	0	0.0
Usual activities	471	95.7	20	4.1	1	0.2
Pain/ discomfort	452	91.9	39	7.9	1	0.2
Anxiety/ depressed	481	97.8	11	2.2	0	0.0

3.2 Reliability test

Each item of the ICECAP-A and EQ-5D-3L in Chinese is independent as the correlation factor ranges from 0.063 to 0.637(Supplementary Table 1 and Table 2). Moreover, both the Cronbach's Alpha coefficients are more than 0.7, which suggests an appropriate level of reliability.

The correlation between dimensions of the two scales was weak-to-moderate (polychoric correlation range - 0.335 ~ 0.561) (Supplementary Table 3). Specifically, the Anxiety/depressed dimension has higher correlations with the four other dimensions except for Autonomy, where the correlation with Stability and Enjoyment exceeds 0.5. Autonomy has higher correlations with Mobility, Self-care, and Usual activities than the other ICECAP-A dimensions, where the correlation with Self-care and Usual activities exceeds 0.5. We found the weak correlations of ICECAP-A items with EQ-5D-3L tariff score, and EQ-VAS score (polychoric correlation range - 0.214 ~ 0.367). Weak correlations of ICECAP-A tariff score were also observed with the EQ-5D-3L tariff score, EQ-VAS score (polychoric correlation of 0.116 and 0.218, respectively).

3.3 Validity test

3.3.1 Exploratory factor analysis

The factor load obtained after the promax rotation is shown in Table 4. It can be found that the five dimensions of the ICECAP scale are mainly loaded on factor 1, and the five dimensions of the EQ-5D-3L scale are mainly loaded on factor 2. The factor correlation is 0.258, meaning the promax rotation was an appropriate choice for the analysis. The results indicated that there is a different construct between the two scales, providing different meaning information in T2DM.

Table 4
Exploratory factor analysis comparing the ICECAP-A and EQ-5D-3L

Rotated promax		
	Factor 1	Factor 2
ICECAP-A		
Stability		0.347
Attachment		0.099
Autonomy		0.208
Achievement		0.224
Enjoyment		0.279
EQ-5D-3L		
Mobility	0.189	
Self-care	0.225	
Usual activities	0.428	
Pain/ discomfort	0.117	
Anxiety/ depressed	0.192	
Factor correlation(s)	0.258	
Loadings of < 0.09 are dropped from the table to allow easy interpretation of results		

3.3.2 Regression Results

Several sociodemographic characteristics of the participants were shown to significantly influence the ICECAP-A tariff scores and EQ-VAS in the multiple regression analysis (Supplementary Table 4), mostly in line with the results of the univariate analysis presented above in Supplementary Table 1. The older participants had lower EQ-5D tariff scores and EQ-VAS scores. But higher education contributed to a significantly better capability for the participants in our study. The variables about clinical conditions were all shown to not significantly influence the ICECAP-A tariff score except for self-reported happiness and self-reported health status. Not surprisingly, participants with better self-reported happiness and self-reported health status had a higher ICECAP-A tariff score. The R^2 statistics indicate that the demographics and health conditions accounted for approximately a fifth of the variance in QoL index scores (ICECAP-A = 22.4% and EQ-5D-3L = 13.7%).

4 Discussion And Conclusion

This study was conducted to assess the reliability and validity of ICECAP-A in Chinese T2DM patients and explore the correlations of the ICECAP-A with the EQ-5D-3L. Despite cross-cultural differences between countries, our study suggested that the Chinese version of the ICECAP-A was able to measure QoL of T2DM in China. The results provided supporting evidence for the reliability and validity of the adapted version of the ICECAP-A.

4.1 Main Findings

The statistic results of the T2DM patients on two instruments were reported mean values of capability score and HRQoL score, and both values were higher than those in the general population [11] and other diseases population (e.g. Asthma, Cancer, Hearing, Arthritis, Heart disease) [22]. The capability score and HRQoL score were influenced by some factors, such as disease and age [16, 23–26]. In terms of the effect of disease, the lower score might be due to disease, but on the other hand, the score may not be significantly lower or higher due to the population's adaptation to disease; in terms of the effect of age, some studies show a positive or negative effect on the score with increasing age, with the reasons that the increased impact of disease with age, especially in the elderly population, and the increased adaptability of the population with age [16, 27]. Across the five dimensions in ICECAP-A, the T2DM patients had the least number of people at the full capability level in the Achievement dimension and the most number of people at the full capability level in the Autonomy dimension, consistent with the results of the Chinese general population [11].

In terms of reliability, the Cronbach's alpha coefficient was 0.72 for the ICECAP-A and EQ-5D-3L, which was lower than the previous results in the Chinese general population (0.80) [11], German T2DM patients (0.83), and English T2DM patients (0.86) [16]. However, the results of the Cronbach's alpha coefficient for omitting each item showed that the internal consistency of the questionnaire was high.

Overall, the dimensions of the two scales were weakly to moderately correlated (0.2–0.6), which is consistent with the general population [11, 17] and women with irritative lower urinary tract symptoms [15]. However, in significant contrast to these studies, we also observed weak negative correlations among ICECAP-A, EQ-5D-3L, and EQ-VAS. The possible reasons are as follows: Among the five dimensions of EQ-5D-3L, Mobility, Self-care, Physical activities, and Pain/discomfort are more related to physical health, and among these dimensions, the Chinese population perceives that the three dimensions of Mobility, Self-care, and Physical activities had a significantly greater impact on health-related quality of life than the Pain/discomfort dimension [28], the problems appearing in the dimensions of Mobility, Self-care, and Usual activities will not only affect patient's QoL, but will also significantly affect that family members engage in a multitude of essential activities for patients, some of which need time, energy, material and physical demands, and if such health problems persist over time, they can also significantly reduce the well-being of the entire family, and thus negatively affect the patient's own sense of Stability, Attachment, Autonomy, and Enjoyment, and appear problems on the Pain/discomfort dimension, which may only be considered relatively minor health problems (especially discomfort), so

family members engage in more emotional and psychological support. Whereas more than 80% of the respondents in this study were over 55 years old and 55% were older than 65 years, in China, most older people live with their children, and when they experience mild discomfort such as Pain/discomfort, their families and children can give them more emotional and psychological family supports, therefore, these respondents may experience higher capability on the dimensions of Stability, Attachment, Autonomy, and Enjoyment. It was also observed in the study that the Pain/discomfort dimension was positively correlated with the Achievement dimension, which was closely related to respondents' capability. EQ-VAS was negatively correlated with the Autonomy dimension and the correlation coefficient exceeded 0.2, possibly because the Autonomy dimension represented the independent of the respondent's capability, a larger proportion of the respondents in this study were older, and this population may need more family support, and therefore its higher capability in terms of independence did not necessarily mean the overall QoL was higher (EQ-VAS score was higher). The correlation coefficients of ICECAP-A with EQ-5D-3L and EQ-VAS were lower than those in knee pain [18] and irritative lower urinary tract symptoms [15], but consistent with these studies, ICECAP-A was weakly correlated with EQ-5D-3L than with EQ-VAS [29].

In terms of discriminative validity, there were statistically significant associations between measured capability and age, marital status, work status, insurance, income source, and HbA1c, while there were only significant associations between measured HRQoL and marital status and number of complications, but both the two instruments were significant associations with self-reported health status and self-reported happiness. However, based on the results in regression, the independent variables with statistically significant coefficients in ICECAP-A were similar to EQ-VAS.

In terms of construct validity, although the Anxiety/depressed dimension had the highest correlation with the four dimensions in the ICECAP-A, the Anxiety/depressed dimension was still loaded with factor 1 with the other four dimensions of the EQ-5D-3L in the factor analysis, which was different with the general population [11, 17] and patients with knee pain [18], where the Anxiety/depressed dimension was loaded with another factor with the five dimensions of the ICECAP-A.

4.2 Limitations and future direction

This study has a few limitations that are worthy of discussion. First, the ICECAP-A instrument was not included in the previous waves' questionnaires and therefore test-retest reliability could not be assessed in this study. Further investigation can be undertaken to use longitudinal data to test the correlation of ICECAP-A changes and diabetes clinical outcome changes. Second, the sample size for this study is small and concentrated in patients who are older than 65-years old. Thus, the conclusion should be cautious when it is promoted and applied to T2DM patients nationwide. Further studies with other chronic patients and compared to the ICECAP-O instrument are needed to add evidence to the international literature on the validity and use of the ICECAP-A. Third, the ICECAP-A tariff score is based on the UK value set, and studies have shown that the numerical differences in the EQ-5D scores obtained from the conversion tables of different countries are statistically significant [30-32]. For this reason, it is

necessary to develop a Chinese ICECAP-A value set to conduct economic evaluation. Finally, a self-reported health survey may suffer reporting heterogeneity [33], different populations have different understandings of the meaning of the same concept, e.g., women consider more emotional aspects of health than men when making self-assessment of overall health [34]; even if there is a consistent understanding of the meaning of the measured health concept, different groups may have different judgments about the actual level represented by a uniform response option [35]. This was not explored in the current work but could however be investigated by using anchoring vignette method to examine the effects of response heterogeneity in the self-reported capability survey. In this study, when the ICECAP-A scale was validated in the T2DM population, there were differences in the correlation with the EQ-5D-3L scale and factor loading with the general population and other disease populations and may be partly due to heterogeneity of disease or population. Therefore, studies on the measured properties of ICECAP-A in other disease populations could be conducted in the future.

5 Conclusion

This is the first paper to provide evidence that the use of a capability instrument in Chinese T2DM patients and aims to explore the ICECAP-A for measuring border well-being and QoL. Although despite some limitations, the results demonstrate the appropriateness of ICECAP-A for the reflection of diabetes capability.

Declarations

Authors:

Yao Xiong^{1,2,†}, Hongyan Wu^{3,†,*}, Judy Xu^{1,2}

Affiliations:

¹ School of Public Administration, Southwestern University of Finance and Economics, Chengdu, 611130, China;

² Center of Health Policy and Governance, Southwestern University of Finance and Economics, Chengdu, 611130, China

³ School of Medicine and Health Management, Guizhou Medical University, Guiyang, 550025, China;

*Correspondence: why_vivian@163.com

†Equal contributors

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