Original Article

Translation and Validation of Bahasa Malaysia Version of Urogenital Distress Inventory (UDI-6) and Incontinence Impact Quality of Life Questionnaires (IIQ-7), a Cross Sectional Study

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Abstract

***Background*: Urinary incontinence (UI) demonstrates major prevalence in women of different population groups. Reduced quality of life (QOL) is observed due to incontinence problems. Urogenital Distress Inventory (UDI-6) and Incontinence Impact Quality of Life (IIQ-7) are useful disease-specific questionnaires evaluating the impact of urinary incontinence on the QOL of women which is accepted internationally.**

***Objective*: This study aims to translate and validate UDI-6 and IIQ-7 in Malay language.**

***Methods:* A cross sectional study, which recruited 100 participants from two urogynecology clinics. Both questionnaires were initially translated from English to Bahasa Malaysia followed by back translation and final correction done by the professional translators. The participants were requested to maintain a urinary record of the upcoming week for three days that assisted in quantifying the severity of symptoms. None of the subjects were assigned any treatment during the study period. Validity and reliability of the translated questionnaires were determined by checking the internal consistency and also by doing test-retest.**

***Results:* The internal consistency levels of the UDI-6 and IIQ-7 Bahasa Malaysia questionnaires were 0.73 and 0.90 respectively with good test-retest (0.86 and 0.95). Incontinence episodes were strongly associated with obstructive, irritative, and stress symptoms. The factor of day time voiding had strong correlation with obstructive and irritative symptoms.**

***Conclusion:* UDI-6 and IIQ-7 did not measure similar outcomes; however, both questionnaires have their strengths in clinical settings. Analysis has also revealed that the Malaysian versions of both questionnaires had appropriate test-retest validity and reliability. Thus, it can be said that both of the questionnaires had great importance for screening patients with urinary incontinence in Malaysia.**

Keywords: *Urinary incontinence, Quality of Life, Bahasa Malaysia translation, Bahasa Malaysia Validation, Urogenital Distress Inventory, Incontinence Impact Questionnaire.*

Introduction

The prevalence of UI in women ranges from 10% to 46% in diverse population groups (1, 2). Most women who are affected are hesitant in disclosing and discussing it with their doctors. As a result, the problem remains unresolved in majority of the women (2,3). Individual assessment of the severity of UI such as symptoms distress and life impact holds great importance in evaluating UI. Researchers have developed well-constructed questionnaires that are now being used as tools for screening, symptom indices, and quality of life measurement. The diagnosis of UI in women might be improved by using both disease-specific and generic questionnaires (4). It should complement the conventional methods of assessment such as pad test and incontinence frequency volume.

IIQ-7 and UDI-6 were the two valid and consistent questionnaires for assessing the subjective phases of UI severity. They proved useful for the characterization of the severity of incontinence, accessing the success of the treatment, and making decisions about treatments (5). These questionnaires include items measuring symptoms and QOL (6).

The UDI-6 is composed of six items with three subscales. These include stress symptoms, discomfort/obstructive symptoms, and irritative symptoms. The items are scored from 0 to 4. A higher value in a question represents the increased level of disability. The questionnaire is regarded as reliable and valid means of the assessment of subjective aspects of incontinence severity in women (6). IIQ-7 is designed to evaluate distinctive domains of quality life impairment. IIQ-7 is composed of seven items which further subdivided into four domains of the lives of women. These include relationships, travel, emotional health, and physical activity. Each item of these questionnaires consists of a Likert scale that ranges from slight to moderate and from moderate to great. A higher score is the indication of reduced quality of life and severity of symptoms. The subjective information can be provided by UDI-6 items regarding urodynamic test results. The overall subscale score of IIQ-7 and UDI-6 are consistent with their descriptions (6).

The study emphasizes that these questionnaires might serve as an important evaluation device for the Malaysians as well as for the Malay speaking population from the neighbouring countries i.e. Indonesia and Singapore. These questionnaires will prove beneficial in the assessment process of the urinary incontinence influencing the quality of life of the women of Malaysia. Moreover, it also serves as an evaluation tool for measuring the treatment impact on incontinence. The main purpose of this research is to translate and validate Bahasa Malaysia version of IIQ-7 and UDI-6. Such questionnaires were also helpful for evaluating the influence of UI on the QOL of Malaysian women.

Definition of Terms

The definitions of the following terminologies are based on IUGA/ICS 2010 (7):

Urinary Incontinence (UI)

It is a commonly occurring and embarrassing condition characterized by the unintentional passing of urine due to the loss of bladder control.

Stress urinary incontinence (SUI)

It is characterized by the unintentional urine loss as a result of physical exertion or effort like sneezing, sports activities, heavy-lifting, coughing or running that will exert pressure on the bladder. Activity-related incontinence is used in few languages to distinguish this condition from psychological stress.

Mixed Urinary incontinence (MUI)

Mixed urinary incontinence refers to a condition in which people have both stress continence and urgency incontinence. It comprises of the symptoms of both and occurs as a result of urgency as well as the physical efforts i.e. coughing or sneezing.

Overactive bladder (OAB)

Urine urgency is the central feature of Overactive bladder, which is usually associated with nocturia. It may result in frequency of urine either with or without the urinary incontinence. It may be a symptom of a more serious problem such as urinary tract infection or other pathologies.

Urgency Urinary Incontinence (UUI)

The most frequent type is urge incontinence that is characterized by an overactive bladder and an urgent need for urination. It may result in passing of urine before a person can reach the toilet.

Methods

It was a cross-sectional study involved two tertiary centers situated in East Coast and West Coast of Peninsular Malaysia.

Translation Phase

IIQ-7 and UDI-6 were independently translated from English language to Bahasa Malaysia by two of the researchers who are fluent in both languages and an expert in the field of urogynecology. A single version was developed

by reviewing the two translated versions and examining the discrepancy items. Two translators whom did not have access to the original edition of the questionnaires did the back-translation. Both the original and back-translated editions were compared to develop the final version of UDI-6 and 11Q-7 Bahasa Malaysia versions.

Validation Phase

The participants were women age 18 years and above who attended urogynecology clinic at two tertiary centers in West Coast and East Coast of Malaysia. There were newly diagnosed or having a pre-existing urinary incontinence with or without treatment. All the research participants were requested to fill the form containing UDI-6 and IIQ-7 questionnaires after obtaining their written approval. Socio-demographic and clinical data was collected regarding the age, parity, menstrual status, and marital status. The research assistant helped those individuals in completing the questionnaire who were unable to read or write. Women whose mental capacity would preclude completion of the questionnaire and those who refused to participate were excluded from the study.

The physician provided consultation to the patients without any information about the questionnaires. They maintained a bladder diary of three days in the next week that assisted in quantifying the severity of symptoms. In order to measure reliability, patients were reassessed on UDI-6 and IIQ-7 after two to four weeks. None of the subjects were assigned any treatment as all of them had stable symptoms.

Sample Size and Statistic

The recommended ratio of subject to item evaluation level must be 5:1 or above it [8,9]. Therefore minimum required sample size for UDI-6 was 30 samples and IIQ-7 required at least 35 samples. Internal consistency was measured using Cronbach's alpha. A value of greater than 0.7 was considered as acceptable (10). Interclass Correlation Coefficient (ICC) was used to measure the reliability of measurements (11). ICC > 0.7 was considered as a good reliability. Criterion validity was checked using Pearson's correlation coefficient test with number of incontinence episodes and urinary frequency (as measured by the urinary bladder). The overall analysis was carried out using the IBM SPSS Statistics for Windows version 20.0. (IBM Corp. Released 2011. Armonk, NY). The level of significance was set at $P<0.05$.

Results

One hundred patients of urinary incontinence were recruited in this research based project. Nine percent of the patients were excluded because of improper completion of the questionnaires as well as bladder diary thus leaving a total of 91 patients. Majority (56%) of the population were from the Malay ethnic group. The patient's socio demographic details and diagnosis is shown in Table 1. Majority of the participant were postmenopausal (63.7%) and had secondary education (94.37%). The mean (standard deviation) age of patients was 55 years (SD = 13.5) while the mean parity was 3.7.

Reliability Statistic

Cronbach's alpha for UDI-6 and IIQ-7 were 0.73 and 0.90 respectively. ICC for UDI-6 and IIQ-7 were 0.85 and 0.95 respectively (Table 2).

Criterion Validity

A positive relationship existed among subscales of irritative, obstructive, and stress symptoms. An optimistic connection was seen involving day time void incidence and nocturia along with the obstructive and irritable symptoms UDI-6 subscales. On the other hand, in case of IIQ-7, only a positive correlation was found between nocturia along with the emotional subscales, and physical activity (Table 3).

Discussion

The two disease-specific questionnaires are UDI- 6 and IIQ-7, which are the concise editions of the original UDI-6 and IIIQ-7 correspondingly. These have shown promising outcomes within the evaluation of symptoms distress, health-related quality of life. They have also proved significant in characterizing the diverse kinds of established urinary incontinence within the clinical surroundings (12). It is a measuring tool which is suitable to be used at any age due to the growing prevalence specifically in older adults (13). The original editions of the questionnaires are comprised of 30 and 19 questions respectively. Although, they are validated and are found to be useful in the assessment of treatment efficacy but they have still proved ineffective in terms of the

Table 1: Patient demographic

	n [%]	Mean	SD	Min	Max
Age		55.05	13.5	19	81
Race					
Malay	51[56.0]				
Indian	26 [28.6]				
Chinese	14 [15.4]				
Level of education					
Primary	35 [38.5]				
Secondary	43 [43.7]				
Tertiary	13 [14.3]				
Diagnosis					
SUI	34 [37.4]				
OAB	15 [16.5]				
MUI	26 [28.6]				
POP	16 [17.6]				

Table 2: Internal consistency and reliability of UDI-6 and IIQ-7

	Internal consistency Cronbach's alpha	Intraclass correlation coefficients
UDI-6	0.73	0.86
Irritative	0.47	0.76
Stress	0.48	0.81
Obstructive	0.58	0.85
IIQ-7	0.90	0.95
Physical activity	0.80	0.93
Travel	0.84	0.91
Social	-	0.81
Emotional	0.91	0.96

*$P < 0.001$ for all coefficients

duration of period requisite for the completion of the questionnaire (14). It led to the creation of short editions of UDI-6 and IIIQ-7 comprising of 7 and 6 questions respectively which demonstrated higher correlation with lengthy forms (15).

Both of these questionnaires are applied worldwide and have been validated in most of the languages including Chinese, Turkish, Swedish, and Arabic (16,17,18). Malaysia is a country with multiethnic society and Bahasa Malaysia is the national language. Each ethnic has their own mother tongue i.e. Tamil, Mandarin, Cantonese ect. The questionnaires have been validated in Bahasa Malaysia. It was tested on Malaysians who have Malay, Chinese and Indian ethnicity.

The study was conducted at two centers in diverse regions of Malaysia, named as East Coast and Federal area (west coast) to provide a representation to all the Malaysians having different dialects of Bahasa Malaysia. This study showed good response of Bahasa Malaysia editions of UDI-6 and IIQ-7. Internal consistency of IIQ-7 and UDI-6 was found excellent i.e. 0.73 and 0.90 respectively. Conversely, the UDI-6 subscales were found reasonable ranging from 0.47 to 0.58 when compared to the excellence of IIQ-7 subscales ranging from 0.80 to 0.90.

Cronbach's alpha internal consistency was interpreted above 0.7 that shows reliability and validity. Cronbach's Alpha was introduced by Lee

Table 3: Correlation of UDI-6 and IIQ-7 with measures of clinical severity

	Incontinence	*P*	Frequency	*P*	Nocturia	*P*
UDI-6	0.379	< 0.001	0.321	< 0.05	0.190	NS
Irritative	0.224	<0.05	0.350	<0.001	0.211	<0.05
Stress	0.425	<0.001	0.104	NS	0.003	NS
Obstructive	0.278	<0.05	0.294	<0.05	0.207	<0.05
IIQ-7	-0.041	NS	0.196	NS	0.275	<0.05
Physical Activity	0.042	NS	0.178	NS	0.247	<0.05
Travel	-0.022	NS	0.141	NS	0.149	NS
Social	0.049	NS	0.197	NS	0.169	NS
Emotional	-0.132	NS	0.139	NS	0.302	<0.05

* Pearson's correlation test

Cronbach in the year 1951, to offer a way to measure the internal consistency of a scale or test. The internal consistency describes an extent to which every item of the test measures the similar thought or construct. Therefore, the inter-relatedness of the items present in the evaluation is associated with it (19). The correlation of the items in a test demonstrates increased value of alpha. However, a high degree internal consistency is not indicated by the high coefficient alpha as alpha gets affected by the length of the test (10,20). The value of alpha gets diminished with the short length of the test. Hence, to raise the bar of alpha more relevant testing items should be included in the test to analyze the similar concept. Although, higher correlation between the items existing in an instrument is desirable, high reliability will not be generally expected for such short questionnaires like IIQ-7 and UDI-6 as Cronbach's alpha elevates the count of items despite of the correlations (10).

Arabic validation of IIQ-7 and UDI-6 survey demonstrated comparable results, even though the internal stability of UDI-6 subscales were near to the ground but were considered as consistent and applicable. It holds an immense significance in the facilitation of population-based epidemiologic analysis within this region. Excellence is shown in the test-retest dependability of both UDI-6 and IIQ-7 i.e. 0.86 as well as 0.95 correspondingly (18).

It has been observed that significant and proper correlation has been present between UDI-6 and measures of clinical severity. It demonstrated that UDI-6 can classify the conditions into stress and irritative symptoms. However, a diverse perspective was concluded for IIQ-7 which showed weak and irrelevant correlation. Malaysian women were found distinctive on the globe while their social norms and lifestyle might be diverse. Therefore, to comply with the Malaysian culture some items of IIQ-7 must be modified for instance, offering prayers and other activities like gardening, etc.

A similar study was conducted in Egypt, which demonstrated the same results as that of this study. Majority of the women were Muslims who complained about the urinary incontinence during their prayers that cause disruption in offering prayers. Muslims are required to perform ablution as a purification practice before each prayer and micturition is one of the actions that can invalidate it. Therefore, an item [prayer] has been added in IIQ-7 to comply with their culture. Moreover, one more item i.e. social activities were modified with the deletion of other i.e. entertaining activities (18).

Limitations

This study has focused on the issue of urinary incontinence (UI) in women. It might limit the estimation of the results as UI conditions in males were not studied. Another limitation is that the small scale hospital-based study may not represent a proper generalization of the results covering adults. A broad level analysis should be conducted to discover the quality of life approach and health-care seeking practices in the society (18).

Conclusion

Diverse psychometrical results were demonstrated by UDI-6 and IIQ-7. Both of these are recommended and are applicable to clinical settings and provide ease to control the tools.

Bahasa Malaysia editions of UDI-6 and IIQ-7 demonstrated excellent test-retest reliability and validity but showed reduced internal reliability. These could hold greater significance in the facilitation of population-based epidemiologic research within this region.

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