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## GYNAECOLOGY

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# Reliability and Validation of Thai-version of Urge-Urinary Distress Inventory Questionnaire

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### ABSTRACT

**Objectives:** To develop and test the reliability of a Thai version of the urge-urinary distress inventory (U-UDI) questionnaire and to correlate with overactive bladder symptom score (OABSS) and overactive bladder validated 8 question screener (OAB-V8) questionnaires.

**Materials and Methods:** During June 2019 and July 2020, 100 Thai women attending the female pelvic medicine clinic at King Chulalongkorn Memorial Hospital with overactive bladder were recruited. The original English of U-UDI was forward translated into a Thai version by one linguist from Chulalongkorn University and backward translated by another linguist then the content was validated by two urogynecologists at our department. The patients were asked to complete the Thai version of U-UDI, OABSS and OAB-V8 questionnaires at first visit and only Thai version U-UDI questionnaire at 2-week interval.

**Results:** All patients completed the study. The mean  $\pm$  standard deviation (SD) of age were  $61.1 \pm 11.8$  years. The mean  $\pm$  SD of the urge domain U-UDI summary score was  $1.6 \pm 0.8$  (first visit) and  $1.4 \pm 0.9$  (at 2 weeks). The weighted Kappa coefficients of the 9 items were 0.4-0.5. Test-retest reliability showed good reliability with intraclass correlation 0.8 (95% confidence interval 0.7, 0.8). The Cronbach's alpha of U-UDI was 0.8. The Pearson's correlation (r) of U-UDI to OABSS and OAB-V8 was 0.6 and 0.6.

**Conclusion:** A Thai version of U-UDI questionnaire was reliable and valid. It could be used as a tool for urinary urgency evaluation in Thai women.

**Keywords:** Thai version, Urgency, Urge, U-UDI, OABSS, OAB-V8

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## ความเที่ยงและความตรงของแบบสอบถามความรุนแรงของอาการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory questionnaire)

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### บทคัดย่อ

**วัตถุประสงค์:** เพื่อหาความเที่ยงของแบบสอบถามความรุนแรงของอาการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory, U-UDI) ฉบับภาษาไทย และหาสหสัมพันธ์เทียบกับแบบสอบถามคัดกรองอาการปัสสาวะเร่งรีบ (Overactive Bladder Symptom Score, OABSS และ Overactive Bladder Validated 8 Question Screener, OAB V-8) ฉบับภาษาไทย **วัสดุและวิธีการ:** ระหว่างเดือนมิถุนายน 2019 ถึง กรกฎาคม 2020 ได้ทำการศึกษาในสตรีไทย 100 คนที่ถูกวินิจฉัยว่ามีภาวะกระเพาะปัสสาวะไวเกินที่มารับการรักษาที่คลินิกเวชศาสตร์เชิงกรานสตรีและศัลยกรรมช่องคลอดเสริม โรงพยาบาลจุฬาลงกรณ์ สภากาชาดไทย โดยสตรีทุกคนจะตอบแบบสอบถามความรุนแรงของอาการปัสสาวะเร่งรีบ 9 หัวข้อ (Urinary Urgency Distress Inventory, U-UDI) เป็นฉบับภาษาไทยที่แปลโดยนักภาษาศาสตร์จากสถาบันภาษา จุฬาลงกรณ์มหาวิทยาลัย และแปลกลับเป็นภาษาอังกฤษโดยนักภาษาศาสตร์อีกท่าน โดยมีการตรวจสอบโดยนรีแพทย์ทางเดินปัสสาวะจากภาควิชาสูติศาสตร์นรีเวชวิทยา คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย โดยผู้เข้าร่วมวิจัยจะทำแบบสอบถามความรุนแรงของอาการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory, U-UDI) ฉบับภาษาไทย และแบบสอบถามคัดกรองอาการปัสสาวะเร่งรีบ (Overactive Bladder Symptom Score, OABSS และ Overactive Bladder Validated 8 Question Screener, OAB V-8) ฉบับภาษาไทยในสัปดาห์แรก จากนั้นจะมีการทำแบบสอบถามความรุนแรงของอาการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory, U-UDI) ฉบับภาษาไทยซ้ำอีกครั้งเมื่อครบ 2 สัปดาห์

**ผลการศึกษา:** ผู้เข้าร่วมวิจัยทั้งหมด 100 คน ได้ทำแบบสอบถามและตอบกลับ พบว่าอายุเฉลี่ยคือ  $61.1 \pm 11.8$  ปี และมีค่าเฉลี่ยของแบบสอบถามความรุนแรงของอาการปัสสาวะเร่งรีบ (Urge Urinary Distress Inventory, U-UDI) ฉบับภาษาไทยอยู่ที่  $1.6 \pm 0.8$  ในครั้งแรก และ  $1.4 \pm 0.9$  ใน 2 สัปดาห์ถัดมา และมีความสอดคล้องโดยใช้สัมประสิทธิ์ Kappa ของแบบสอบถามทั้ง 9 หัวข้ออยู่ที่ 0.4 ถึง 0.5 และมีความเที่ยงของการทดสอบซ้ำอยู่ที่ โดยใช้สัมประสิทธิ์สหสัมพันธ์ภายในชั้นอยู่ที่ 0.8 โดยมีค่าความสอดคล้องของแบบสอบถาม (Cronbach's Alpha) อยู่ที่ 0.8 ส่วนค่าความสอดคล้องสัมประสิทธิ์สหสัมพันธ์เชิงอันดับ Pearson เมื่อเทียบกับแบบสอบถามคัดกรองอาการปัสสาวะเร่งรีบ (Overactive Bladder Symptom Score, OABSS และ Overactive Bladder Validated 8 Questions Screener, OAB V-8) ฉบับภาษาไทยอยู่ที่ 0.6

**คำสำคัญ:** ปัสสาวะเร่งรีบ, แบบสอบถามภาษาไทย, ปัสสาวะไวเกิน

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## Introduction

Overactive bladder (OAB) is defined as a symptom syndrome of urinary urgency, with or without urge incontinence, usually with urinary frequency and nocturia, in the absence of infection or obvious pathologic features<sup>(1)</sup>. It has a negative impact on the quality of life, interfering with daily activities, travel, and sleep<sup>(2-4)</sup>. Urinary urgency definition is the complaint of a sudden compelling desire to pass urine, which is difficult to defer<sup>(5,6)</sup>. Currently, the diagnosis of OAB is based on urinary urgency symptom rather than objective measure so the clarify symptoms is the best way to assessed the patient understanding and severity of the symptoms. Many questionnaire are developed to measure the patient's symptoms such as overactive bladder symptom score questionnaire (OABSS) and overactive bladder validated 8 question screener questionnaire (OAB V-8)<sup>(7, 8)</sup>. The English version of OABSS was reported with the intraclass correlation coefficient of the total OABSS score of 0.7 and the Cronbach's alpha coefficient of 0.5<sup>(7)</sup>. The Thai version of OABSS was reliable and valid, had an intraclass correlation coefficient of the total OABSS score of 0.8 and the Cronbach's alpha coefficient of 0.3<sup>(9)</sup>, while the Thai version of OAB V-8 had the Cronbach's alpha coefficient above 0.7 and the intraclass correlation coefficient of 0.6<sup>(8)</sup>. Both Thai version OABSS and OAB V-8 have been used as screening and follow-up tools<sup>(10, 11)</sup>. Those two OAB questionnaires contained only one question per each questionnaire about the urgency symptom. In order to focus specifically on urgency symptom, a specific questionnaire is required. The International Consultation on Incontinence (ICI) has recommended the standard questionnaire for measure urinary urgency symptoms such as an urge-urinary distress inventory (U-UDI)<sup>(12)</sup>. The U-UDI questionnaire is designed specifically for urinary urgency evaluation. This questionnaire is beneficial for the comparison of the urinary urgency symptoms domain for the evaluation of OAB disease treatment due to the good

psychometric property and easy to use format. It is a grade A questionnaire recommended by ICI which comprised of nine questions. It composed of two domains. A urinary urgency domain is questions number 1, 2, 3, 5, 8 and 9. Also, Urinary incontinence domain is questions number 4, 6 and 7. The scores ranged from 0 (no symptom) to 4 (most bothersome) according to the degree of bothersomeness. The summary score was calculated by averaging the non-missing scores. In the original study, a U-UDI questionnaire has a good reliability, validity and responsiveness (Cronbach's alpha 0.7, test-retest reliability 0.5). Consequently, it is commonly used in urinary urgency studies as comparison of urgency symptoms before and after treatment<sup>(13-16)</sup>. Currently, there is no study or translation of U-UDI questionnaire in Thailand. Therefore, we realized the importance of the urinary urgency symptoms. This study aimed to develop and test the reliability of a Thai version U-UDI questionnaire. Besides, we also studied the correlation with OABSS and OAB V-8 as the secondary objective.

## Materials and Methods

This psychometric test, cross-sectional study was conducted at The Female Pelvic Medicine and Reconstructive Surgery Clinic, King Chulalongkorn Memorial Hospital (KCMH), a tertiary care center in Bangkok, Thailand, between June 2019 and July 2020. The inclusion criteria was patients with OAB symptoms for more than three months and at least one episode of urgency with or without urinary incontinence in a past week during the study period. A total of 100 female participants were recruited based on a volunteer basis. All participants must be able to read and write in Thai language. The exclusion criteria were: patients with indwelling catheters, practicing intermittent self-catheterization, evidence of a symptomatic urinary tract infection, chronic inflammation, previous or current malignant disease of the pelvic organs, bladder stones, any neurological bladder disease, diabetic neuropathy,

quitted or changed.

### **Translation process**

After permission from the original study's authors, the English version of U-UDI was forward translated into Thai language by a linguist from Language institute, Chulalongkorn University and backward translated by another linguist. The content validation was done by the two urogynecologists (SB, PR). Two urogynecologists reviewed all the translations to confirm that the meanings were similar to the original version. In case of the any discrepancy to the original questionnaire, the translation questionnaire was sent back to the linguists for the correction until there was no discrepancy. The final translated Thai version of U-UDI questionnaire was pretested in 20 participants. Each subject completed the questionnaire, and was interviewed to probe about what she thought was meant by each questionnaire item and the chosen response. Both the meaning of the items and responses were explored to confirm the understanding meaning of the original English version by the authors. The OABSS and OAB-V8 questionnaires were used for score correlation for the criterion validity.

The patients were asked to complete the self-administration Thai version of U-UDI, OABSS and OAB-V8 questionnaires at first visit. The thirty minutes period was given for all questionnaire completion. The completeness of all items was checked and only Thai version U-UDI questionnaire were given and sent back by mail at 2-week interval.

### **Statistical analysis**

Descriptive statistics (mean, median standard deviation, interquartile range). The weighted Kappa coefficients were used for item analysis. Intraclass correlation was used for the test-retest reliability. Pearson's correlation was used for criterion validation. Cronbach's alpha was used for the internal consistency. The statistical analysis was

done by SPSS version 22.0. For sample size calculation, rule of thumb formula for estimation of sample size for psychometric test study were used<sup>(17)</sup>. Total of 90 participants were needed. After adding 10% dropout, therefore 100 participants in total were needed.

## **Results**

Between June 2019 and July 2020, 100 patients from the Female Pelvic Medicine and Reconstructive Surgery Clinic, King Chulalongkorn Memorial Hospital (KCMH) completed the Thai version U-UDI, OABSS and OAB V-8 questionnaires at first visit whereas Thai version U-UDI questionnaire was given and sent back at 2-week interval. There was no drop out at the second week of the study. All participants completed the questionnaires at first and two weeks interval. The mean  $\pm$  standard deviation (SD) of age were  $61.1 \pm 11.8$  years, 62% were Buddhist, 6% were Islam, and 1% was Christianity. Most women (63%) had middle level of education. The majority were primary school (36%), secondary school (16%) and vocational certificate (11%), with the remainder having had bachelor degree or higher (37%). Sixty-two percent of women had body mass index of 18-25 kg/m<sup>2</sup>. Fifty-two percent of women were married. Most of the participants were currently employed (50%), retired (40%). Multiparous was documented in 59 women (59%). Fifty percent of women had symptoms within a year. The other demographic and clinical characteristics are shown in Table 1.

The mean  $\pm$  SD of the total U-UDI summary score was  $1.5 \pm 0.7$  (first visit) and  $1.4 \pm 0.8$  (at 2 weeks interval) while the urge domain U-UDI summary score was  $1.6 \pm 0.8$  (first visit) and  $1.4 \pm 0.9$  (at 2 weeks interval) (Table 2). For the primary outcome, the test retest reliability of the Thai version U-UDI questionnaire was 0.8 (95% confidence interval 0.7, 0.8).

**Table 1.** Patient's characteristics (n = 100).

	Mean ± SD
Age at informed consent	61.1 ± 11.8
	n (%)
Body mass index	
Less than 18 kg/m <sup>2</sup>	1 (1)
18 to 25 kg/m <sup>2</sup>	62 (62.6)
25 to 30 kg/m <sup>2</sup>	26 (26.3)
More than 30 kg/m <sup>2</sup>	10 (10.1)
Education	
Vocational certificate	11 (11)
Primary school	36 (36)
Secondary school	16 (16)
Bachelor degree or higher	37 (37)
Occupation	
Business career	29 (32.2)
Employee	21 (23.3)
Retired	40 (44.4)
Religion	
Buddhist	91 (92.9)
Islam	6 (6.1)
Christianity	1 (1)
Number of children	
Nulliparous	27 (27)
1 children	14 (14)
2 children	28 (28)
3 children	20 (20)
More than 3 children	11 (11)
Duration of symptoms	
Within 1 year	50 (50)
1-2 years	25 (25)
More than 2 years	25 (25)

**Table 2.** Item response of Thai version U-UDI scores (n = 100).

Items	Visit	
	week 0 (n (%))	week 2 (n (%))
1. Do you experience frequent urination?		
Not disturb at all	9 (9)	11 (11)
Slightly disturbed	31 (31)	32 (32)
Moderately disturbed	27 (27)	26 (26)
Greatly disturbed	13 (13)	5 (5)
No	20 (20)	26 (26)
2. Do you experience a strong feeling of urgency to empty your bladder?		
Not disturb at all	11 (11)	14 (14)
Slightly disturbed	29 (29)	27 (27)
Moderately disturbed	25 (25)	22 (22)
Greatly disturbed	12 (12)	9 (9)
No	23 (23)	28 (28)

**Table 2.** Item response of Thai version U-UDI scores (n = 100). (Cont.)

Items	Visit	
	week 0 (n (%))	week 2 (n (%))
3. Do you experience difficulty in holding your urine?		
Not disturb at all	17 (17)	12 (12)
Slightly disturbed	27 (27)	29 (29)
Moderately disturbed	20 (20)	19 (19)
Greatly disturbed	12 (12)	9 (9)
No	24 (24)	31 (31)
4. Do you experience any urine leakage?		
Not disturb at all	19 (19)	21 (21)
Slightly disturbed	35 (35)	25 (25)
Moderately disturbed	16 (16)	21 (21)
Greatly disturbed	4 (4)	0 (0)
No	26 (26)	33 (33)
5. Do you experience urine leakage related to the feeling of urgency?		
Not disturb at all	12 (12)	11 (11)
Slightly disturbed	30 (30)	22 (22)
Moderately disturbed	15 (15)	22 (22)
Greatly disturbed	6 (6)	3 (3)
No	37 (37)	42 (42)
6. Do you experience urine leakage related to physical activity, coughing or sneezing?		
Not disturb at all	14 (14)	20 (20)
Slightly disturbed	28 (28)	22 (22)
Moderately disturbed	9 (9)	11 (11)
Greatly disturbed	9 (9)	7 (8)
No	40 (40)	40 (40)
7. Do you experience urine leakage not related to urgency or activity?		
Not disturb at all	17 (17)	16 (16)
Slightly disturbed	18 (18)	23 (23)
Moderately disturbed	14 (14)	12 (12)
Greatly disturbed	1 (1)	2 (2)
No	50 (50)	47 (47)
8. Do you experience nighttime urination?		
Not disturb at all	16 (16)	17 (17)
Slightly disturbed	31 (31)	37 (37)
Moderately disturbed	33 (33)	27 (27)
Greatly disturbed	10 (10)	10 (10)
No	10 (10)	9 (9)
9. Do you experience bedwetting?		
Not disturb at all	22 (22)	26 (26)
Slightly disturbed	5 (5)	4 (4)
Moderately disturbed	3 (3)	3 (3)
Greatly disturbed	0 (0)	1 (1)
No	70 (70)	66 (66)
	<b>Mean ± SD</b>	
Total (Items 1-9) U-UDI summary score	1.5 ± 0.7	1.4 ± 0.8
Urge domain (Items 1, 2, 3, 5, 7 and 9) U-UDI summary score	1.6 ± 0.8	1.4 ± 0.9

U-UDI: urge-urinary distress inventory, SD: standard deviation

The weighted Kappa coefficients of the 9 items were ranged between 0.4-0.5. The Cronbach's alpha was 0.8 (Table 3). For the

secondary outcome, the Pearson's correlation (r) of U-UDI to OABSS and OAB-V8 was 0.6 and 0.6 (Table 4).

**Table 3.** Reliability of Thai version U-UDI score.

Items	weighted Kappa (95%CI)
1. Do you experience frequent urination?	0.5 (0.4 - 0.6)
2. Do you experience a strong feeling of urgency to empty your bladder?	0.5 (0.4 - 0.6)
3. Do you experience difficulty in holding your urine?	0.5 (0.3 - 0.6)
4. Do you experience any urine leakage?	0.5 (0.4 - 0.6)
5. Do you experience urine leakage related to the feeling of urgency?	0.5 (0.4 - 0.6)
6. Do you experience urine leakage related to physical activity, coughing or sneezing?	0.5 (0.4 - 0.7)
7. Do you experience urine leakage not related to urgency or activity?	0.4 (0.3 - 0.6)
8. Do you experience nighttime urination?	0.5 (0.4 - 0.6)
9. Do you experience bedwetting?	0.4 (0.3 - 0.6)
	<b>ICC (95%CI)</b>
Test-retest reliability (ICC = Intraclass correlation)	0.8 (0.7 - 0.8)

U-UDI: urge-urinary distress inventory, SD: standard deviation

**Table 4.** Correlation of Thai version U-UDI score with other measurements.

Items	Pearson's Correlation Coefficient (r)	p value
Total U-UDI total score vs OAB-v8 total score	0.6	< 0.001
Total U-UDI total score vs OABSS total score	0.6	< 0.001
Urge domain U-UDI summary score vs OAB V-8 total score	0.6	< 0.001
Urge domain U-UDI summary score vs OABSS total score	0.6	< 0.001

U-UDI: urge-urinary distress inventory, OABSS: overactive bladder symptom score, OAB-v8: 8-item overactive bladder symptoms score questionnaire.

Total U-UDI item = items 1-9, Urge domain U-UDI items = items 1, 2, 3, 5, 8 and 9

## Discussion

Findings from the current study demonstrated that this Thai version U-UDI questionnaire had a good test-retest reliability (The ICC is 0.8) which was consistent with the original study of U-UDI questionnaire that had a test-retest reliability of 0.59<sup>(12)</sup>. The Cronbach's alpha (0.8) in this study was also consistent with the original study<sup>(12)</sup>. When compared to the previous study of the test- retest reliability of U-UDI questionnaire reported by Borello-France<sup>(18)</sup>, the mean scores of the urge domain U-UDI summary score (1.8 at baseline and 1.7 at the re-test period) were similar to our study (1.6 at baseline and 1.4 at the re-test period).

These low U-UDI total score and urge domain score reflect the mild symptoms of urinary urgency domain. However, these findings were not affected the psychometric property in this study. The test-retest reliability (ICC) from our study was 0.8 which was also higher than the ICC of 0.6 as reported by Borello-France<sup>(18)</sup>. The higher ICC from our study can be explained the better understanding when translated into Thai for Thai women with OAB. When compared to the other urgency questionnaires that translated into Thai language such as OABSS, we found the similar test-retest reliability<sup>(9)</sup>. This supports the good understanding of Thai language translation of the OAB questionnaire.

And also the small numbers of the items (Only 9 items) made it easy to administer. We also found the similar good internal consistency (Cronbach's alpha 0.8) from our study when compared to the OAB V-8 questionnaire<sup>(8)</sup>. We found similar weighted Kappa (0.4-0.5) in all items of Thai version U-UDI which showed moderate agreement to the original study<sup>(12)</sup>. And when compared to the scores to the other OAB questionnaires, there was a moderate correlation between Thai version U-UDI questionnaire vs OABSS and OAB V-8 questionnaires (these are the standard questionnaires for urinary symptoms of OAB). From these psychometric test results, we can confirm that this translated questionnaire is reliable and can reflect the urinary urgency symptoms in Thai patients. As up to now, there is no translation in other language, our report is the first international translation of this U-UDI questionnaire so that there might be more translation process for using this urinary urgency questionnaire in the future. As this questionnaire is recommended by International Consultation on Incontinence (ICI) for urgency evaluation and research (grade A recommendation) and focused specifically in the urinary urgency symptoms. Although this questionnaire should be used in the evaluation of urinary urgency symptoms in the treatment of overactive bladder rather than using general questionnaire for OAB symptoms such as OABSS or OAB V-8 questionnaires, it was designed specifically for urinary urgency evaluation so it was not directly suitable for evaluation of other OAB symptoms such as urinary frequency or urinary incontinence when compared to OABSS or OAB V-8 questionnaire.

### **Strengths in this study**

This study was the first translated Thai version of the standard questionnaire specifically focused on the urinary urgency questionnaire in Thailand and there was no missing data in our study.

### **Limitation in this study**

Due to the time restraint, there was no study of the responsiveness conducted in this study. Further prospective study with correlation to the changes of clinic symptoms of OAB is advocated.

## **Conclusion**

This study demonstrated that this Thai version U-UDI had a good reliability, validity and correlated with OABSS and OAB V-8. It could be used as a tool for urinary urgency evaluations such as screening patients, determining the severity of symptoms and using in further clinical research.

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## **Potential conflicts of interest**

The authors declare no conflict of interest.

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