



Translation and validation of the Korean version of acute cystitis symptom score

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Purpose: Acute Cystitis Symptom Score (ACSS) is a simple self-reporting questionnaire initially developed in Uzbek language to help diagnose acute uncomplicated cystitis (AUC). The purpose of this study was to translate the ACSS to Korean and validate the Korean version of ACSS using Korean-speaking women.

Materials and Methods: The original version of ACSS in Uzbek was translated into the target (Korean) version according to internationally accepted guidelines for the translation and cultural adaptation. Cognitive interviews were then conducted for five women with symptoms of AUC and five women without AUC who were native speakers of the Korean language to investigate the clarity, understandability, and acceptability of the translation. The final Korean version of the ACSS was tested in 50 women (31 AUC patients and 19 controls) for clinical validation.

Results: Reliability test for 9 questions (6 questions about typical symptoms of AUC, and 3 questions on quality of life) showed high values (Cronbach's alpha=0.853). The sum score of typical symptoms showed the highest balance for diagnostic sensitivity and specificity (area under the ROC curve=0.935). Sensitivity and specificity to predict AUC were 90.3% and 89.5% at cut-off score 6 of the typical domain.

Conclusions: The Korean version of the ACSS showed high levels of reliability and validity, similar to other validated versions in different languages. It will play an important role in practice and/or clinical research for diagnosis and treatment efficacy monitoring of Korean-speaking women suffering from AUC.

Keywords: Cystitis; Questionnaire; Urinary tract infection

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INTRODUCTION

Urinary tract infection (UTI) is the most common bacterial infection in general practice [1-3]. Almost half of all women have at least one episode of UTI during their lifetime [4]. Acute uncomplicated cystitis (AUC) accounts for

the greatest number of UTIs, particularly in young sexually active women. AUC is usually diagnosed based on clinical symptoms and laboratory findings including pyuria or a positive urine culture in primary health care.

However, depending on types of hospitals, laboratory evaluation could not be performed. Thus, physicians are

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asked to prescribe empirical antibiotics based on only complaints of patients in the absence of urine culture and sensitivity data. Fortunately, the probability of AUC in a woman with dysuria, urinary frequency, or hematuria is reported to be about 50%. Specific combinations of symptoms raise the probability to be more than 90% [5]. Therefore, questionnaires and symptom scores can be used to assess the diagnosis and severity of AUC more accurately.

Acute Cystitis Symptom Score (ACSS) is a simple self-reporting questionnaire initially developed in Uzbek language to help diagnose AUC in primary healthcare settings [6]. ACSS questionnaire consists of an 18-item self-reporting questionnaire (6 questions about typical symptoms of AUC, 4 questions regarding differential diagnoses, 3 questions on quality of life [QoL], and 5 questions on additional conditions that might affect therapy). It was further translated into Russian [7], German [8], Hungarian [9], Italian [10], American English version [11], and so on (<http://www.acss.world>) and validated. Therefore, we aimed to develop a Korean version of the ACSS and validate it using Korean-speaking women.

MATERIALS AND METHODS

1. Translation and linguistic validation

Translation of original version (Uzbek) into the target version (Korean) was performed according to internationally accepted guidelines for the translation and cultural adaptation [12-14]. Forward translation of the Uzbek version of the ACSS into Korean language was carried out by two independent professional translators. Translations were then reconciled by the translators and the authors. A preliminary Korean version of ACSS was translated back into Uzbek language and reconciled by another Uzbek-speaking bilingual staff of the hospital to confirm proper forward translation of the ACSS. After comparison with the Uzbek version, quality control, and discussion by the authors, a complete Korean version of the ACSS questionnaire was obtained. Cognitive interviews were then conducted by five women with symptoms of AUC and five women without AUC who were native speakers of the Korean language to investigate the clarity, understandability, and acceptability of the translation. Participants were asked to comment on their understanding of each item and suggest alternative formulations in the case of problematic wording. All comments of participants were discussed between the translators and the authors. The final Korean version of the ACSS was confirmed.

2. Clinical validation

Korean speaking women aged over 18 years with any

lower urinary tract symptoms from May to August 2021 were included. Patients who had major psychiatric disorder or neurological disorder were excluded from this study. All respondents underwent routine clinical investigations such as urinalysis and urine culture of a mid-stream urine sample. These participants were divided into two groups (AUC patients or controls) according to the physician's diagnosis based on presence or absence of typical symptoms, pyuria, and bacteriuria at the time of questionnaire completion. The URiSCAN Super Plus, fully automated urine analyzer (YD Diagnostics, Yongin, Korea), was used for urine reagent strip tests. UF-1000i flow cytometer (Sysmex Medical Electronics Co, Kobe, Japan) was used for counting total white blood cells and red blood cells. Pyuria was defined as 10 or more white blood cells/HPF and hematuria is defined as the presence of at least 5 red blood cells/HPF. Patients with bacteriuria $\geq 10^3$ CFU/mL were considered microbiologically significant.

3. Statistical analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS version 20.0 for Windows; IBM Corp, Armonk, NY, USA). Data are presented as mean±standard deviation or percentage according to the distribution of parameters. Mann-Whitney's U-test and Student's t-test were used for comparative analysis between AUC patients or controls. Reliability of the questionnaire was estimated by calculating internal consistency using Cronbach's alpha. To determine the validity of the questionnaire, predictive ability of the ACSS was measured by calculating sensitivity and specificity. Based on previous investigations, a sum score of 6 of typical symptoms was used as cut-off value for discriminating respondents into AUC patients and controls [6-11]. A p-value of <0.05 was considered statistically significant.

4. Ethical approval

This study was conducted at Bucheon St. Mary's Hospital in Korea. It was performed in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was received from each patient prior to their participation in this study. This study was approved by the Institutional Review Board of the Catholic University of Korea (approval number: HC21QISI0029; 16 April, 2021).

RESULTS

1. Translation and linguistic validation

The final Korean version of the ACSS used in this study

한국어 급성 방광염 증상 점수 설문지

첫 째 방문 - 파트 A (진단 파트) 작성 시각: : 작성 날짜: / / (년/월/일)

최근 24 시간 동안 경험한 아래와 같은 증상의 여부와 정도를 표시해 주십시오 (각 증상마다 1 가지 답만 표시해 주십시오)

		0	1	2	3
대표 증상	1 빈뇨 증상이 있음 <small>(화장실을 매우 자주 가야 함)</small>	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
	2 소변을 참기 힘든 급박뇨 증상이 있음	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
	3 소변 볼 때 통증 또는 화끈거림이 있음	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
	4 소변을 보고 난 뒤에도 잔노감이 있음	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
	5 하복부 통증 또는 불편함이 있음 (지골 상부/불우형)	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
	6 소변에 피가 섞임	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
"대표 증상" 점수 합계					점
간접 증상	7 요통 (주로 한쪽으로 치우친 통증)	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
	8 질 분비물 (특히 아침에)	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
	9 요도 분비물 (배뇨 시에는 제외)	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
	10 발열 및 오한 <small>(체온을 췌 경우 체크해 주십시오)</small>	<input type="checkbox"/> 아니오	<input type="checkbox"/> 약간 그렇다	<input type="checkbox"/> 그렇다	<input type="checkbox"/> 매우 그렇다
"간접 증상" 점수 합계					점
삶의 질	최근 24 시간 동안 상기 증상으로 인한 불편한 느낌이 어느 정도인지 체크해 주십시오 (제일 적절한 답을 1 가지만 고르십시오)				
	<input type="checkbox"/> 0 불편함 없다 (증상이 전혀 없다. 평상시와 똑같은 기분이다)				
	<input type="checkbox"/> 1 조금 불편하다 (평소보다 다소 안 좋은 기분이다)				
	<input type="checkbox"/> 2 불편하다 (매우 기분이 안 좋다)				
	<input type="checkbox"/> 3 많이 불편하다 (끔찍한 기분이다)				
	최근 24 시간 동안 상기 증상은 일상활동에 어느 정도 영향을 끼치는지 체크해 주십시오 (제일 적절한 답을 1 가지만 고르십시오)				
	<input type="checkbox"/> 0 방해하지 않았다 (평상시와 똑같다)				
	<input type="checkbox"/> 1 조금 방해하였다 (불편하지만 일상활동은 가능하다)				
	<input type="checkbox"/> 2 방해하였다 (일상활동에 많은 노력이 필요하다)				
	<input type="checkbox"/> 3 많이 방해하였다 (일상활동을 거의 못 하고 있다)				
	최근 24 시간 동안 상기 증상은 사회활동(모임 참석, 친구들과 만남 등등)을 어느 정도 방해했는지 체크해 주십시오 (제일 적절한 답을 1 가지만 고르십시오)				
	<input type="checkbox"/> 0 방해하지 않았다 (평소와 같이 사회활동을 하였다)				
<input type="checkbox"/> 1 조금 방해하였다 (일부의 사회활동을 못하였다)					
<input type="checkbox"/> 2 방해하였다 (대부분의 사회활동을 못하였다)					
<input type="checkbox"/> 3 많이 방해하였다 (사회활동을 전혀 못하였으며 거의 집에 있었다)					
"삶의 질" 점수 합계					점
추가 사항	오늘 기준으로 아래와 같은 상태에 해당되는지 체크해 주십시오				
	14 생리 중이십니까?	<input type="checkbox"/> 아니오	<input type="checkbox"/> 네		
	생리 전 증후군이 있으십니까?	<input type="checkbox"/> 아니오	<input type="checkbox"/> 네		
	경년기 증상이 있으십니까?	<input type="checkbox"/> 아니오	<input type="checkbox"/> 네		
	임신 중이십니까?	<input type="checkbox"/> 아니오	<input type="checkbox"/> 네		
	당뇨가 있으십니까?	<input type="checkbox"/> 아니오	<input type="checkbox"/> 네		

후속 방문 - 파트 B (환자가평가결과) 작성 시각: : 작성 날짜: / / (년/월/일)

증상 변화	첫 째 설문지를 작성한 이후로 어떠한 증상의 변화를 겪었는지 체크해 주십시오				
	<input type="checkbox"/> 0 증세가 매우 좋아졌다 (모든 증상이 사라졌다)				
	<input type="checkbox"/> 1 증세가 많이 좋아졌다 (대부분의 증상이 사라졌다)				
	<input type="checkbox"/> 2 증세가 다소 좋아졌다 (증상이 일부 호전되었다)				
	<input type="checkbox"/> 3 증세의 변화가 거의 없다 (이전과 증상이 동일하다)				
<input type="checkbox"/> 4 증세가 나빠졌다 (증상이 악화되었다)					

파트 A 1-14 의 모든 질문은 파트 B 에서도 추적 조사합니다.

Fig. 1. Korean version of the Acute Cystitis Symptom Score (ACSS) questionnaire.

for diagnosis of AUC in women is presented in Fig. 1.

2. Clinical validation

1) Demographic data and baseline characteristics

Clinical validation for the Korean version of the ACSS was performed using 50 Korean-speaking women presenting with or without symptoms of AUC at the outpatient clinic. Although there was no standard sample size for the validity or reliability analysis of the questionnaire, more than 30 patients were planned to be recruited to confirm the normal distribution of AUC patients. Considering that about two-thirds of patients were actually diagnosed as AUC in the

examination for lower urinary tract symptoms, a total of 50 subjects were recruited. The mean age of these 50 patients was 54.4±15.5 years (range, 19–83 y). Thirty-one (62.0%) patients had proven AUC (AUC patients). Among these patients, the most common uropathogen was *Escherichia coli* (n=23). Four patients of them had UTIs with extended-spectrum β-lactamase producing organisms. There were no pregnant women among subjects. Detailed self-reporting questionnaire data for the Korean version of the ACSS, including the severity of typical symptoms, differential symptoms, and the QoL are shown in Table 1.

Table 1. Self-reporting questionnaire data for the Korean version of the ACSS

Questionnaire		Total (n=50)	Controls (n=19)	AUC patients (n=31)	p-value ^a
Age (y)		54.4±15.5	51.5±16.4	56.2±14.8	0.669
Typical symptoms					
1. Urinary frequency	0 (None)	4 (8.0)	4 (21.1)	0 (0.0)	<0.001
	1 (Mild)	17 (34.0)	8 (42.1)	9 (29.0)	
	2 (Moderate)	18 (36.0)	7 (36.8)	11 (35.5)	
	3 (Severe)	11 (22.0)	0 (0.0)	11 (35.5)	
2. Urinary urgency	0 (None)	8 (16.0)	5 (26.3)	3 (9.7)	0.002
	1 (Mild)	21 (42.0)	11 (57.9)	10 (32.3)	
	2 (Moderate)	14 (28.0)	3 (15.8)	11 (35.5)	
	3 (Severe)	7 (14.0)	0 (0.0)	7 (22.6)	
3. Dysuria	0 (None)	18 (36.0)	12 (63.2)	6 (19.4)	<0.001
	1 (Mild)	14 (28.0)	7 (36.8)	7 (22.6)	
	2 (Moderate)	11 (22.0)	0 (0.0)	11 (35.5)	
	3 (Severe)	7 (14.0)	0 (0.0)	7 (22.6)	
4. Incomplete bladder emptying	0 (None)	11 (22.0)	8 (42.1)	3 (9.7)	<0.001
	1 (Mild)	24 (48.0)	10 (52.6)	14 (45.2)	
	2 (Moderate)	8 (16.0)	1 (5.3)	7 (22.6)	
	3 (Severe)	7 (14.0)	0 (0.0)	7 (22.6)	
5. Pain in lower abdomen	0 (None)	19 (38.0)	11 (57.9)	8 (25.8)	0.004
	1 (Mild)	18 (36.0)	7 (36.8)	11 (35.5)	
	2 (Moderate)	10 (20.0)	1 (5.3)	9 (29.0)	
	3 (Severe)	3 (6.0)	0 (0.0)	3 (9.7)	
6. Hematuria	0 (None)	34 (68.0)	16 (84.2)	18 (58.1)	0.018
	1 (Mild)	8 (16.0)	3 (15.8)	5 (16.1)	
	2 (Moderate)	4 (8.0)	0 (0.0)	4 (12.9)	
	3 (Severe)	4 (8.0)	0 (0.0)	4 (12.9)	
Differential symptoms					
7. Flank pain	0 (None)	36 (72.0)	15 (78.9)	21 (67.7)	0.480
	1 (Mild)	6 (12.0)	2 (10.5)	4 (12.9)	
	2 (Moderate)	6 (12.0)	1 (5.3)	5 (16.1)	
	3 (Severe)	2 (4.0)	1 (5.3)	1 (3.2)	
8. Abnormal vaginal discharge	0 (None)	36 (72.0)	15 (78.9)	21 (67.7)	0.378
	1 (Mild)	11 (22.0)	3 (15.8)	8 (25.8)	
	2 (Moderate)	1 (2.0)	1 (5.3)	0 (0.0)	
	3 (Severe)	2 (4.0)	0 (0.0)	2 (6.5)	
9. Urethral discharge	0 (None)	40 (80.0)	16 (84.2)	24 (77.4)	0.229
	1 (Mild)	6 (12.0)	3 (15.8)	3 (9.7)	
	2 (Moderate)	2 (4.0)	0 (0.0)	2 (6.5)	
	3 (Severe)	2 (4.0)	0 (0.0)	2 (6.5)	
10. High body temperature	0 (None)	45 (90.0)	19 (100.0)	26 (83.9)	0.067
	1 (Mild)	5 (10.0)	0 (0.0)	5 (16.1)	
	2 (Moderate)	0 (0.0)	0 (0.0)	0 (0.0)	
	3 (Severe)	0 (0.0)	0 (0.0)	0 (0.0)	
Quality of life					
11. Discomfort because of symptoms	0 (None)	2 (4.0)	1 (5.3)	1 (3.2)	0.027
	1 (Mild)	31 (62.0)	15 (78.9)	16 (51.6)	
	2 (Moderate)	13 (26.0)	3 (15.8)	10 (32.3)	
	3 (Severe)	4 (8.0)	0 (0.0)	4 (12.9)	

Table 1. Continued

Questionnaire		Total (n=50)	Controls (n=19)	AUC patients (n=31)	p-value ^a
12. Interference with everyday activities	0 (None)	9 (18.0)	5 (26.3)	4 (12.9)	0.066
	1 (Mild)	34 (68.0)	13 (68.4)	21 (67.7)	
	2 (Moderate)	3 (6.0)	1 (5.3)	2 (6.5)	
	3 (Severe)	4 (8.0)	0 (0.0)	4 (12.9)	
13. Interference with social activities	0 (None)	29 (58.0)	13 (68.4)	16 (51.6)	0.136
	1 (Mild)	15 (30.0)	5 (26.3)	10 (32.3)	
	2 (Moderate)	3 (6.0)	1 (5.3)	2 (6.5)	
	3 (Severe)	3 (6.0)	0 (0.0)	3 (9.7)	

ACSS, Acute Cystitis Symptom Score; AUC, acute uncomplicated cystitis.

^a:p-values between AUC group and control group.

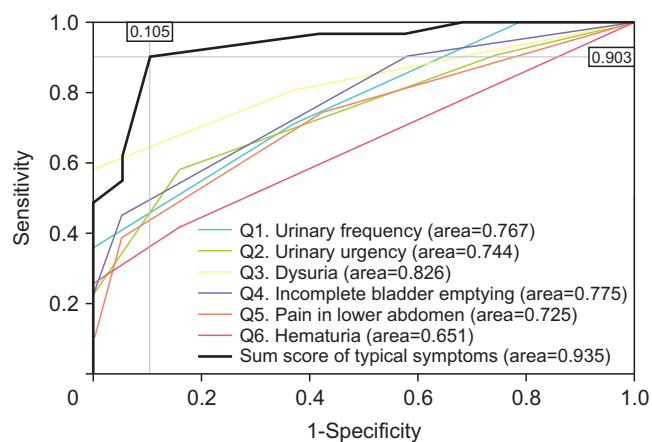


Fig. 2. Receiver operating characteristic (ROC) curves of the individual typical symptoms and the sum score of the typical symptoms.

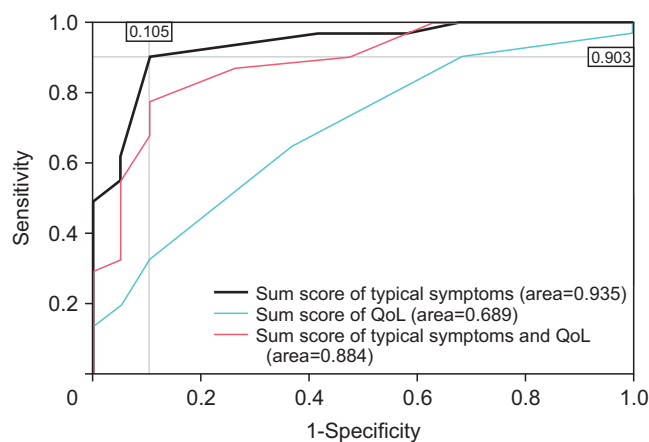


Fig. 3. Receiver operating characteristic (ROC) curves of the sum score of the typical symptoms, the sum score of quality of life (QoL), and the sum score of the typical symptoms and QoL.

2) Reliability and validity

Reliability test for 9 questions (6 questions about typical symptoms of AUC, and 3 questions on QoL) showed high values (Cronbach’s alpha=0.853). Cronbach’s alpha of the entire questionnaire including 4 questions of differential diagnoses was 0.823.

Fig. 2 showed the receiver operating characteristic (ROC) curves of the individual typical symptoms and the sum score of the typical symptoms. Among them, the sum score of typical symptoms showed the highest balance for diagnostic sensitivity and specificity (area under the ROC curve=0.935). Fig. 3 showed the ROC curves of the sum score of the typical symptoms, the sum score of QoL, and the sum score of the typical symptoms and QoL. Similarly in this analysis, the sum score of typical symptoms showed the best balance between sensitivity and specificity. Sensitivity and specificity to predict AUC were 90.3% and 89.5%, respectively, at cut-off score 6 of typical domain. The sum score of the typical symptoms, the sum score of QoL, and the sum score of the typical symptoms and QoL between AUC patients and controls are presented in Fig. 4.

DISCUSSION

The diagnosis of AUC is usually based on clinical symptoms and laboratory findings including pyuria or a positive urine culture in primary health care. However, as recommended in various guidelines, an accurate diagnosis of AUC needs to focus on a history of lower urinary tract symptoms (dysuria, frequency and urgency) and the absence of vaginal discharge or irritation [15]. In addition, depending on types of hospitals, laboratory evaluation could not be performed. Physicians in primary care clinics are often asked to prescribe empirical antibiotics only based on complaints of patients in the absence of urine culture and sensitivity data. Under such health care environments, questionnaires and symptom scores can be used to perform the correct diagnosis of AUC.

Previously, the Urinary Tract Infection Symptoms Assessment (UTISA) questionnaire from Bayer Health Care Pharmaceuticals Global Health Economics and Outcome Research, a 14-item self-reporting questionnaire about the

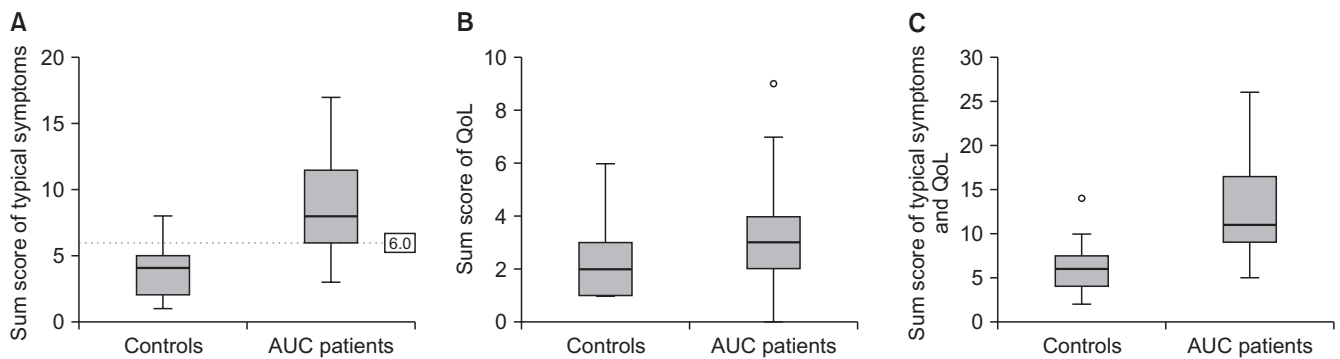


Fig. 4. The sum score of the typical symptoms, the sum score of quality of life (QoL), and the sum score of the typical symptoms and QoL between acute uncomplicated cystitis (AUC) patients and controls.

severity and bothersomeness of seven key uncomplicated UTI symptoms [16], has been translated into Korean with linguistic validation. However, statistical information such as predictive and discriminative ability were not evaluated [17]. Thus, it is still not widely used in practice or clinical research in Korea. On the other hand, the ACSS has been translated and validated into various languages.

The ACSS questionnaire was initially developed in Russian and Uzbek language [6]. In a combined analysis for both versions, Cronbach's alpha for reliability of the ACSS was 0.89. Sensitivity and specificity to predict AUC were 94% and 90%, respectively, at cut-off score of 6 for 'Typical' domain. Cronbach's alpha for the Russian version of the questionnaire was 0.86 and the area under the curve in the ROC analysis was 0.96. Symptom scores were positively correlated with laboratory results [7]. In European countries, Cronbach's alpha for the German ACSS was 0.87. A cut-off score of 6 for the 'Typical' domain significantly predicted AUC with a sensitivity of 94.7% and a specificity of 82.4% [8]. The Hungarian version also showed high levels of reliability and validity with sensitivity and specificity of 90% and 97%, respectively, at cut-off score of 6 for the 'Typical' domain [9]. The Italian version of the ACSS reported a sensitivity of 92.5% and a specificity of 97.8% at a cut-off score of 6 for the domain of typical symptoms [10]. Recently, the American-English ACSS showed excellent results of psychometric parameters and diagnostic values in clinical validation [11]. Our results are also consistent with validation results of ACSS in other languages. The Korean version of the ACSS showed high levels of reliability and predictive ability. And the sum score of typical symptoms show the highest balance for diagnostic sensitivity and specificity. However, the individual typical symptoms such as urinary urgency, pain in lower abdomen, and hematuria showed low levels of reliability and predictive ability (area under the ROC curve=0.744, 0.725, and 0.651, respectively).

The shortcomings of the study are (1) performed in a single center, and (2) in a limited number of patients (n=31) and controls (n=19). For all typical symptoms and QoL items, however, a significant difference could be found between patients and controls. Nevertheless, confirmation of the results in a larger multicenter study would be desirable. Finally, the original ACSS was composed of a diagnostic part (part A) and a follow-up part (part B). The follow-up part included a domain of 'dynamics' with five questions about changes of symptoms in addition to the same questions as those in the diagnostic part [18]. Therefore, further studies are needed to investigate applicability of the ACSS as a practical questionnaire for patient-reported outcome assessment in Korea.

CONCLUSIONS

In this study, a Korean version of the ACSS was tested in 50 women (31 AUC patients and 19 controls). It showed high levels of reliability and validity, similar to other validated versions of the ACSS in different languages. Thus, it will play an important role in practice and/or clinical research for the diagnosis and treatment efficacy monitoring of Korean-speaking women suffering from AUC.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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AUTHORS' CONTRIBUTIONS

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