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The Danish linguistic validation of the Ureteral Stent Symptoms Questionnaire

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ABSTRACT

INTRODUCTION. The aim of the study was to validate the Ureteral Stent Symptom Questionnaire (USSQ) in Danish for patients with indwelling ureteral stents.

METHODS. The linguistic validation of the original USSQ was performed following standardised multi-step translation procedures. Seventy patients with indwelling ureteral stents were asked to complete the Danish USSQ one and two weeks after stent placement and four weeks after stent removal.

RESULTS. A total of 65 patients (92.9%) completed the USSQ. Statistical evaluation revealed good internal consistency in all domains except work performance. Satisfactory convergent validity (<–0.4 or > 0.4) was demonstrated for urinary symptoms, body pain and global quality of life. The test-retest reliability-coefficient was statistically significant for urinary symptoms, general health, pain and sexual matters. Inter-domain associations were positive and monotone for all subscales. All sub-scores, except sexual matters, significantly decreased from one week after stent insertion to four weeks after stent removal ($p < 0.001$).

CONCLUSION. The Danish USSQ is a reliable and valid instrument with which to evaluate urinary symptoms and general health in patients with indwelling ureteral stents.

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TRIAL REGISTRATION.

The Danish National Ethics Committee and Region Syddanmark approved the study (Study approval number 20192000-168 and journal number 19-52219, respectively).

Ureteral stents are effective and indispensable in ensuring renal function and avoiding painful conditions in a wide range of patient groups. Unfortunately, ureteral stents give rise to many bothering symptoms in a large proportion of patients. In particular, symptoms include pain, disturbance of bladder function, lower urinary tract symptoms (LUTS) and haematuria [1-3]. Therefore, several studies have been conducted to elucidate how prominent stent-related symptoms are and to examine whether the design/material of the stent can be altered to reduce discomfort [4, 5]. For this purpose, Joshi et al. developed and validated a questionnaire, the Ureteral Stent Symptom Questionnaire (USSQ) [6]. The questionnaire has formed the basis of international studies that seek to elucidate and improve the condition of patients with ureteral stents. However, this form is not translated or validated into Danish or any other Scandinavian language. Therefore, in order to conduct studies including

Danish patients with ureteral stents, a translation and validation of the recognised USSQ form is required in Danish language.

METHODS

Translation process and pilot testing

Linguistic validation of the Danish version of the USSQ was performed according to Hutchinson's multistep process [7]. Two independent professional Danish native-speaking translators and a Danish-speaking healthcare professional translated the USSQ from English into Danish. Comprehensibility for patients with a low sociocultural level was strived for. This first Danish consensus version was then back translated into English by two independent bilingual professional translators and compared to the original version of the USSQ [6]. Small discrepancies were resolved and after a second consensus meeting, the final version of the Danish USSQ was edited and drafted. A pilot test study of the final Danish USSQ was then performed including interviews with five patients with indwelling ureteral stents to assess the questionnaire for comprehensibility. No additional remarks were added in this process and the Danish USSQ was considered usable to continue the validation process.

Patient selection

The Danish National Ethics Committee and Region Syddanmark approved the study (Study approval number 20192000-168 and journal number 19-52219, respectively).

Between June 2020 and June 2021, a total of 70 (44 males and 26 females) consecutive patients having a unilateral ureteral stent inserted at the Department of Urology, Vejle Hospital, Denmark, were recruited for enrolment in the study. Informed and signed consent was obtained from all patients. Inclusion criteria were patients between 18 and 80 years who underwent temporary unilateral JJ-stent insertion after ureteroscopy for renal or ureteral calculi. The exclusion criteria were 1) a history of or current medical treatment for LUTS or prostate cancer; 2) a history of or current medical treatment for urinary incontinence, overactive bladder syndrome or neurogenic bladder; 3) pregnancy; 4) permanent ureteral stenting; 5) bilateral ureteral stenting, 6) malignant conditions in the urinary tract; 7) medication with α-blockers, anticholinergics and analgesics interfering with lower urinary tract function; and 8) patient unable to understand given study information. Patients with major complications after ureteroscopy significantly affecting their clinical course were also excluded from the study.

Study design and data collection

The Danish version of the USSQ was self-administered to all cases according to the following study setup:

USSQ1 = USSQ administered to patients one week after stent insertion

USSQ2 = USSQ administered to patients two weeks after stent insertion

USSQ3 = USSQ administered to patients four weeks after stent removal.

Moreover, the Danish Prostate Symptom Score (DanPSS) [8] was completed by male participants one week after stent insertion; the International Consultation on Incontinence (ICIQ) [9] was completed by female participants one week after stent insertion and the Short Form Health Survey version 2 (SF-36v2Short) [10] was completed by both males and females one week after stent insertion. The DanPSS is developed and validated in Danish, and the ICIQ and SF-36 are translated and validated in Danish. All questionnaires were administered electronically or in paper versions according to the patients' preference.

Finally, 5- or 6-French JJ stents (Percuflex, Boston Scientific) with lengths according to the patients' heights were inserted by experienced urologists.

Statistical analyses

Baseline patient characteristics were evaluated by means of descriptive statistics: frequencies (percentages), mean (normally distributed variables) or median (interquartile range) (non-normally distributed variables). Individual mean substitution was used in the scoring of the USSQ subscales if the number of missing items within a domain did not exceed 25%.

Internal consistency was evaluated by Cronbach's α of USSQ1 and USSQ2 as well as test-retest reliability (using Interclass Correlation Coefficient (ICC)) of USSQ1 and USSQ2. Measures > 0.70 were considered to show sufficient consistency and reliability.

Assessment of inter-domain association of USSQ subscales was established by Spearman's rank-correlation with 95% confidence intervals (CIs). Likewise, convergent validity was examined using Spearman's rank correlation (95% CI) of USSQ1 subscales with selected SF-36, ICIQ and DanPSS subscales. Spearman correlations were considered moderate to strong if the absolute values were ≥ 0.40. Due to the departure from normal distribution, the confidence intervals of Spearman's rank correlation were estimated using bootstrapping procedures with 20,000 repetitions.

The sensitivity to change was evaluated by comparing the medians of subscale scores of USSQ1 with those of the post-stent USSQ assessment. The Wilcoxon's signed rank test was used for statistical testing. Moreover, the distribution of relevant single items was compared before and after stent removal.

Stata Statistical Software Release 16 (StataCorp 2019, College Station, TX) was used for all statistical analyses and significance levels were set to 0.05.

Trial registration: The Danish National Ethics Committee and Region Syddanmark approved the study (Study approval number 20192000-168 and journal number 19-52219, respectively).

RESULTS

Seventy patients were included in the study; of these, 65 patients (42 males and 23 females (92.9%)) responded to the USSQ1.

Internal consistency and reliability

Internal consistency measures (Cronbach's α) were high for USSQ1 urinary symptoms, pain and general health, suggesting overall good reliability (α's range: 0.85-0.96) but somewhat lower for sexual matters (α = 0.77) (**Table 1**). Work performance did not demonstrate sufficient consistency (α = 0.56). Test-retest reliability coefficients demonstrated similar patterns, where sufficient reliability was reached for the subscales of urinary symptoms, pain, general health and sexual matters (ICCs between 0.88 and 0.95), but reliability was only 0.68 for work performance.

TABLE 1 Internal consistency and test-re-test reliability for each domain of the Ureteral Stent Symptom Questionnaire.

	Internal consistency Chronbach's α		Test-retest reliability,
	USSQ week 1 [n]	USSQ week 2 [n]	ICC (95% CI) [n]
Urinary symptoms	0.83 [64]	0.86 [62]	0.88 (0.80-0.93) [59]
Body pain	0.96 [62]	0.97 [55]	0.92 (0.86-0.95) [53]
General health	0.85 [64]	0.87 [62]	0.90 (0.83-0.94) [56]
Work performance	0.56 [29]	0.69 [28]	0.68 (0.25-0.87) [23]
Sexual matters	0.77 [10]	0.60 [11]	0.95 (0.73-0.99) [7]

CI = confidence interval; ICC = Interclass Correlation Coefficient; USSQ = Ureteral Stent Symptom Questionnaire.

Inter-domain association

Inter-domain associations are reported in **Table 2.** Positive, monotonic relationships were demonstrated for body pain, urinary symptoms and general health with Spearman's correlation coefficients ranging from0.56 to 0.80.

TABLE 2 Inter-domain association. Spearman's rank correlation with 95% confidence intervals (CI).

	ρ (95% CI) [n]					
	urinary symptoms	body pain	general health	work performance	sexual matters	global quality of life
Urinary symptoms	1.00					
Body pain	0.66 (0.46-0.78) [62]	1.00				
General health	0.67 (0.48-0.80) [64]	0.80 (0.69-0.87) [62]	1.00			
Work performance	0.33 (–0.11-0.64) [29]	0.26 (–0.18-0.63) [28]	0.62 (0.30-0.82) [29]	1.00		
Sexual matters	0.81 (0.31-0.99) [10]	0.24 (–0.50-0.83) [10]	0.65 (0.09-0.93) [10]	0.89 (0.61-1.00) [5]	1.00	
Global quality of life	0.56 (0.33-0.73) [64]	0.56 [0.35-0.72) [62]	0.58 (0.36-0.73) [64]	0.29 (–0.16-0.62) [29]	0.21 (–0.70-0.83) [10]	1.00

Convergent validity

The USSQ domains showed good correlations for body pain and SF-36 body pain, urinary symptoms and DanPSS urinary symptoms score and global quality of life and DanPSS quality of life score (**Table 3**). USSQ correlations to the ICIQ sum score were generally weak as was the correlation between USSQ general health and SF-35 physical functioning.

TABLE 3 Convergent validity. Spearman's rank correlation with 95% confidence intervals.

	ρ (95% CI) [n]
USSQ urinary symptoms versus	
ICIQ (female)	0.24 (–0.26-0.67) [21]
IPSS (male)	0.77 (0.50-0.90) [25]
USSQ body pain versus	
SF-36 v2 body pain	–0.43 (–0.61–-0.19) [58]
USSQ general health versus	
SF-36 v2 physical functioning	–0.21 (–0.47-0.09) [55]
USSQ work performance versus	
SF-36 v2 role-physical	–0.31 (–0.63-0.10) [27]
USSQ global QoL versus	
ICIQ QoI (female)	0.21 (–0.32-0.65) [21]
IPSS QoL (male)	0.50 (0.10-0.77) [25]

ICIQ = International Consultation on Incontinence Questionnaire; IPSS = International Prostate Symptom Score; QoL = quality of life; SF-36 v2 = Short Form Health Survey version 2; USSQ = Ureteral Stent Symptoms Questionnaire.

Sensitivity to change

All sub-scores, except sexual matters, demonstrated significant decreases from one week after stent insertion (USSQ1) to four weeks after stent removal (USSQ3) (**Table 4**). Most notably, body pain had a median of 22.1 one week after stent insertion and a median of zero after stent removal. Generally, fewer urinary problems, less pain, better general health and less need for work-related changes due to symptoms were reported one week after stent insertion.

TABLE 4 Sensitivity to change: USSQ1 vs USSQ3.

		Score, median (IQR)		
Domain	n	USSQ1: 1 wk after stent insertion	USSQ3: 4 wks after stent removal	p-value
Urinary symptoms	51	32 (26-38)	19 (15-23.1)	< 0.001
Body pain	48	22.1 (13.25-28.5)	0 (0-12.7)	< 0.001
General health	52	17 (13-19.5)	10 (7-12.5)	< 0.001
Work performance	24	9 (5-10.5)	4.5 (3-7)	0.002
Sexual matters	8	3.5 (2-5)	3 (2.5-3)	0.13

IQR = interquartile range; USSQ = Ureteral Stent Symptoms Questionnaire.

DISCUSSION

In 2018, a total of 10,735 ureteral stent procedures were performed in Denmark [11]. Despite improvements in stent design and materials, stent-related symptoms remain a major problem [12, 13]. Therefore, it is highly relevant to develop a valid instrument for measuring the symptom complex in Danish patients with indwelling ureteral stents.

So far, the USSQ has been successfully translated and validated in several other languages [14-16]. The original English version possesses excellent psychometric properties and a high discriminant power, providing good validation outcomes in other languages [15, 17-20]. Hence, we chose a study setup similar to that of Joshi. For assessment of convergent validity, well-known questionnaires previously validated in Danish (SF-36, DanPSS and ICIQ) were chosen. The SF-36, DanPSS and ICIQ have been used in other validations of the USSQ [6, 14, 15].

The founders of the USSQ pointed out that patients with indwelling stents most often are affected by urinary symptoms and pain. This is reflected by high internal consistency measures for these domains in our study. All domains but work performance showed a satisfactory high consistency (Cronbach's $\alpha > 0.7$), which may be explained by a low response rate in the work performance domain (n = 29). Accordingly, high test-re-test reliability measures were reached for subscales pain, urinary symptoms, general health and sexual matters when comparing the USSQ one and two weeks after insertion. Work performance is a more variable domain depending on several factors not necessarily related to an indwelling ureteral stent, which may also explain the weak internal consistency in this domain. These findings are in line with those of the Chinese and English USSQ validations [6, 17].

All inter-domain associations demonstrated positive monotonic relationships; however, with varying strengths. Generally, the association of sub-scores sexual matters and work performance were weaker and did – in several cases – not reach the sufficient strength. This may be explained by the fact that only 29 patients were active in the labour market, leading to a lower statistical power of this domain. Similarly, only ten patients were sexually active and the correlation between sexual matters and pain was correspondingly low. Similar results were found in the German, French and Korean translations, maybe also indicating that other symptoms such as pain and micturition disturbances may have a stronger influence on quality of life than sexual matters [15, 18, 20]. As pointed out by the original authors, patients with an indwelling ureteral stent are affected mostly by urinary symptoms and pain that eventually affect their general health by impacting social life and limiting physical activities.

Good correlation was found with other validated symptom measures. Correlations between USSQ urinary

symptoms and DanPSS urinary symptoms, USSQ body pain and SF-36 body pain and USSQ global QoL and DanPSS QoL were excellent. A weak convergent validity was detected when comparing USSQ General Health and SF-36 Physical Functioning. The USSQ subscale General Health focuses on tiredness and social life activities, whereas the SF-36 focuses on the ability to walk stairs and walking distance. These discrepancies may explain the low correlation between the subscales. Also, correlations with ICIQ measures were generally low, which may be explained by a different content-related focus as the ICIQ only focuses on urinary incontinence. The USSQ urinary symptoms include dysuria and frequent voiding during daytime, which is probably more exhaustive in terms of describing the symptoms that ureteral stents may cause. Conclusively, a better comparator than the ICIQ could have been chosen. The ICIQ was also used as comparator in both the Spanish and the German USSQ validation models where comparable low strengths in the Urinary Symptoms domain were identified [15, 16].

Sensitivity to change was satisfactory for all domains except sexual matters when comparing the USSQ1 and USSQ3, $p < 0.001$ for urinary symptoms, body pain and general health.

Our study has some limitations. We refrained from including a healthy control group as we concluded that testing a cohort of 70 patients before and after removal of the stent would sufficiently cover assessment of discriminant validity. This is in accordance with the methodology used in the German validation of the USSQ [15], concluding that a control group would provide only negligible additional data in this context. Other validations of the USSQ including healthy control groups have found significant differences for all subscales but sexual matters [16, 17, 19, 20]. Only a limited proportion of patients had an active sex life and less than half of patients were active in the labour market.

This study validated the USSQ for use in patients with unilateral stents after kidney stone treatment. Inclusion was not limited to any special length or diameter of the stent as stent-related symptoms are considered to be fully comparable regardless of stent size. Only patients with a “double-J” stent of polyurethane, 5 or 6 French, were included (no “suture” or “string” stents, no silicone stents).

CONCLUSION

Overall, statistical analyses showed good and consistent validation results. The Danish version of the USSQ is a reliable and robust measure capable of evaluating ureteral stent-associated morbidity for both male and female patients. The questionnaire is suitable for self-administration and can be used in future clinical trials as well as in daily clinical practice for better understanding and assessment of stent-related symptoms and for comparison of different stent types.

Copies of the questionnaire can be obtained from the author corresponding author.

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Conflicts of interest Potential conflicts of interest have been declared. Disclosure forms provided by the authors are available with the article at ugeskriftet.dk/dmj

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