Ureteral Stent Symptom Questionnaire: Development and Validation of a Multidimensional Quality of Life Measure

Article *in* The Journal of Urology · March 2003

DOI: 10.1097/01.ju.0000049198.53424.1d · Source: PubMed

0022-5347/03/1693-1060/0
THE JOURNAL OF UROLOGY®

Vol. 169, 1060–1064, March 2003
Printed in U.S.A.
DOI: 10.1097/01.ju.0000049198.53424.1d

URETERAL STENT SYMPTOM QUESTIONNAIRE: DEVELOPMENT AND VALIDATION OF A MULTIDIMENSIONAL QUALITY OF LIFE MEASURE

H. B. JOSHI, N. NEWNS, A. STAINTHORPE, R. P. MACDONAGH, F. X. KEELEY, JR. AND A. G. TIMONEY

From the Bristol Urological Institute, Southmead Hospital, Bristol, and Taunton and Somerset National Health Service Trust, Taunton, United Kingdom

ABSTRACT

Purpose: We developed the ureteral stent symptom questionnaire (USSQ), a psychometrically valid measure to evaluate symptoms and impact on quality of life of ureteral stents.

Materials and Methods: A total of 309 patients were asked to participate during different phases of our study. In phase 1 a structured literature search, 9 patient interviews and studies of 90 patients using existing instruments formed the foundation for the initial draft of our new questionnaire. In phase 2 the USSQ was pilot tested, reviewed by experts and field tested in 40 patients to produce a final 38-item draft. In phase 3 formal validation studies were performed in 55 patients to assess validity, reliability and sensitivity to change. Discriminant validation was performed by administering the questionnaire to 3 groups of patients without stents.

Results: The final draft addressed various domains of health (6 sections and 38 items) affected by stents covering urinary symptoms, pain, general health, work performance, sexual matters and additional problems. The validation studies showed the questionnaire to be internally consistent (Cronbach's $\alpha > 0.7$) with good test-retest reliability (Pearson's coefficient > 0.84). The questionnaire demonstrated good construct validity and sensitivity to change shown by significant changes in the score with and after removal of stents. The new USSQ discriminated patients with stents from healthy controls ($p < 0.001$) and patients with urinary calculi without stents and lower urinary tract symptoms.

Conclusions: Indwelling ureteral stents have a significant impact on health related quality of life. The new USSQ is a valid and reliable instrument that is expected to become a standard outcome measure to evaluate the impact and compare different types of stents.

KEY WORDS: stents, ureter, quality of life, questionnaires, treatment outcome

Placement of a ureteral stent is a common urological intervention. It has been more than 3 decades since the first description of a cystoscopically placed temporary ureteral stent,[1] and indications and use have continued to expand. However, side effects and patient morbidity associated with stents have been identified as major problems.[2–9] Despite improvements in stent designs and composition, in an effort to improve patient comfort and little or no morbidity, structured in-depth assessment of symptoms due to stents and their impact on daily life has not previously been performed to our knowledge. Such an assessment is best performed using patient self-report techniques, which measure subjective quality of life objectively and forms an important valid outcome measure, as long as the tool is appropriate, well developed and reliable.[10,11]

There are no such valid measures available to assess quality of life issues in patients with ureteral stents, which has hampered our understanding of such symptoms and their true impact. We developed a comprehensive, reliable and psychometrically valid multidimensional measure to evaluate health related quality of life in patients with ureteral stents. We describe the development and validation of the ureteral stent symptom questionnaire (USSQ), which is a self-administered measure designed for use in clinical and research settings.

PATIENTS AND METHODS

A total of 194 patients with and 115 without indwelling ureteral stents were asked to participate at various stages during the development and validation of the new questionnaire. The developmental phase included qualitative research methods. Only adults with unilateral ureteral stents placed for urinary calculi or ureteropelvic junction obstruction were included in this phase.

Phase 1. We performed a structured literature review using electronic data bases, hand searches and cross referencing to identify issues related to the use, symptoms and complications of ureteral stents.

We then conducted detailed interviews of 6 men and 3 women 18 to 70 years old. The interviews were audiotaped and transcribed to identify important themes related to the use of and problems with ureteral stents. Participants were allowed adequate opportunity to describe individual experiences with stents with emphasis on patient views and perception about stents. The interviews tried to identify the most appropriate words to describe symptoms, severity and bothersomeness. Frequency, patterns and daily variation of symptoms and their impact on quality of life were evaluated.

The transcripts were analyzed and the themes were identified by content analysis. The themes were grouped under symptom complexes or the broad health domains to which they were thought to be most appropriate (for example urinary symptoms, pain, general health and so forth). The transcripts and themes were reviewed by a panel of 3 clinicians (urologists), a staff nurse and a social science advisor so that further agreement could be sought about content analysis and categorization of the themes. Additional prospective studies were conducted to assess whether the existing instruments could identify the effects of stents on various domains of health, and were sufficiently specific and sensitive for this group of patients.

Accepted for publication September 6, 2002.

Phase 2. Based on the results of phase 1, an initial draft of the USSQ was developed. This version included a large pool of questions divided into 4 multi-item sections along with a validated generic measure Functional Status Questionnaire.[11] The investigators, clinicians and a select group of 5 patients reviewed this draft for content adequacy and relevance. It was revised to delete duplicated or obvious redundant items, and pilot tested by face-to-face interviews of 10 patients to identify problems or ambiguity related to the wording and clarity of the questions. The draft was further modified and administered to 40 patients with ureteral stents to evaluate its psychometric characteristics, and identify and retain the items that were most relevant and sensitive for the final version.

Phase 3. We evaluated the final draft with formal validation testing. The studies were performed to assess validity and reliability (internal consistency and test-retest repeatability) of the USSQ and its sensitivity to change by administering it to 55 patients with the stent (1 and/or 4 weeks after insertion) and 4 weeks after removal. Internal consistency was assessed (Cronbach's α) for the stent in situ scores. Test-retest reliability was evaluated by readministering the questionnaire 1 week after completion of the week 4 stent in situ questionnaire (25 patients). Sensitivity to change was assessed by comparing scores with and after removal of stents.

Validity was assessed using face content and construct (convergence and discriminant) assessments. Convergent validity was evaluated by correlating the responses to the questions in the USSQ to those assessing similar domains from the existing validated measures of Dartmouth COOP charts,[12] EuroQol[13] and Danish Prostate Symptom Score[14] questionnaires. Discriminant properties were evaluated by comparing the results from patients with ureteral stents to those from healthy volunteers, the cohort of patients with urinary (renal and/or ureteral) calculi who did not have stents and patients with lower urinary tract symptoms (45 in each group).

Statistical analysis. The questionnaire responses were analyzed using cross tabulations and descriptive statistics. The sign and t tests were used to assess questionnaire responsiveness to change (comparison between stent in situ and after removal) and discriminant properties. Test-retest reliability and item associations were calculated using Pearson's product moment correlation coefficients. Cronbach's α was used to assess the internal consistency of the USSQ. Analyses were performed using the SAS statistical software (SAS Institute, Carey, North Carolina).

RESULTS

Phase 1. Patient interviews identified a range of symptoms and various issues affecting health related quality of life, including pain in the loin, bladder or other areas; mild to severe sexual dysfunction; bothersome storage, and voiding symptoms and incontinence. The stents appeared to have a significant impact on daily activities and general health that affected work performance. Due to differences in the assessment methods and lack of validated questionnaires, none of the studies in the literature was able to capture the whole impact reliably. The results of the studies, using existing questionnaires, identified a number of health domains affected by stents but none of the existing questionnaires revealed the complete impact and was intervention specific.[15,16]

Phase 2. The initial draft of the USSQ included 116 questions consisting of 48 symptom prevalence and 33 bother questions along with a 35-item Functional Status Questionnaire, an existing measure. The pilot testing resulted in changes to the wording of questions, resolved ambiguities, and improved patient understanding and acceptability. On further field testing, items with low (less than 0.20) or high endorsement frequencies and high Pearson's correlation coefficients (>0.95) were deleted. Similarly, the items that showed poor sensitivity to change ($p < 0.05$) were deleted. Apart from urinary symptoms, a high correlation between occurrence and associated bother of these symptoms was noted. Hence, the separate bother questions relating to these symptoms were eliminated.

Thus, a final draft of the USSQ with 38 scoring items was developed, which addressed various domains of health (6 sections) covering urinary symptoms, pain, general health, work performance and sexual matters with additional problems (see Appendix). The urinary symptom section included 11 items assessing storage and voiding symptoms along with incontinence, hematuria and dysuria. Two items assessed the impact of urinary symptoms on quality of life. The section on body pain retained 8 scoring items evaluating different dimensions of pain. A diagram with defined body zones was developed and the site(s) of pain was linked to the intensity levels using a Visual Analog Scale. The section on sexual matters included 3 comprehensive issues ("pain during sex," "overall satisfaction" and transient but "complete sexual dysfunction") applicable to both sexes.

The most relevant and sensitive items evaluating general health were selected and grouped into 2 separate sections evaluating work performance issues and general health domains. The section on work performance (7 items) included evaluation of functional limitation and quality of the work. The general health section (6 items) evaluated physical health, vitality, psychosocial impact and dependence. The section on additional problems (5 items) included a question to assess patient views on a balance between the need for and side effects of, stents.

Phase 3. The validation studies showed satisfactory results for both aspects of reliability testing (table 1). A high degree of internal consistency was observed for the majority of sections with the lowest results for the section on additional problems. The questionnaire demonstrated good test-retest reliability for all sections. Table 2 shows the results of interdomain (section) correlations for weeks 1 and 4 with the stent, and demonstrates variable relations between different sections.

The questionnaire had good convergent validity. The USSQ showed satisfactory correlation to the individual questions assessing similar domains (coefficients 0.61–0.85, $p = 0.001$) and total score (0.71, $p = 0.001$) from the Danish Prostate Symptom Score-I. Satisfactory correlations were observed between the USSQ and the Dartmouth COOP charts (0.64–0.83, $P = 0.001$) and the EuroQol questionnaire (0.56–0.77, $p = 0.001$). Significant changes in the score ($p < 0.005$) were observed across all domains with the stent (weeks 1 and 4) scores versus, after its removal, indicating good sensitivity except sexual domain scores (table 3).

The demographic characteristics of patients along with results of the discriminant validation are shown in table 4. Highly significant differences were observed for all domain scores between patients with stents and healthy volunteers. Clinically important sections in the USSQ (except for the total pain index score for the stone group) discriminated between patients with stents and those with stones and lower urinary tract symptoms. The scores for the section on sexual matters were high for the patients with stents, although the differences were not statistically significant when compared with the nonstent groups.

TABLE 1. *Reliability of USSQ section characteristics*

Domain	Internal Consistency (Cronbach's α)		Test-Retest Reliability (Pearson's correlation coefficient)
	Wk. 1 Stent In Situ	Wk. 4 Stent In Situ	
Urinary symptoms	0.96	0.94	0.97
Body pain	0.88	0.81	0.88
General health	0.90	0.89	0.96
Work performance	0.78	0.76	0.84
Sexual matters	0.70	0.71	0.92
Additional problems	0.60	0.61	0.82

TABLE 2. *Total domain correlations at weeks 4 and 1 with stent*

Domain Index Score	Urinary Symptoms Wk. 4/1	Body Pain Wk. 4/1	General Health Wk. 4/1	Work Performance Wk. 4/1	Sexual Matters Wk. 4/1	Additional Problems Wk. 4/1	Trade-Off Wk. 4/1
Urinary symptoms	1.00/1.00						
Body pain	0.67/0.82	1.00/1.00					
General health	0.77/0.85	0.85/0.88	1.00/1.00				
Work performance	0.38/0.68	0.53/0.64	0.54/0.70	1.00/1.00			
Sexual matters	0.30/0.13	0.32/0.18	0.27/0.10	0.29/0.15	1.00/1.00		
Additional problems	0.83/0.27	0.74/0.17	0.81/0.14	0.40/0.30	0.39/0.20	1.00/1.00	
Trade-off	0.81/0.69	0.72/0.54	0.83/0.56	0.44/0.30	0.21/0.21	0.76/0.81	1.00/1.00

TABLE 3. *Sensitivity to change: comparison of scores with stent and after its removal*

Domain	Wk. 1 Mean + SD	Wk. 4 Mean + SD	Post-Stent Mean + SD	p Value (wks. 1 and 4 vs. post-stent)
Urinary symptom index	26.9 + 8.9	28.3 + 7.8	16.2 + 3.0	0.001
Pain symptom index	23.05 + 10.38	22.2 + 9.6	10.9 + 3.4	0.001
General health index	10.73 + 6.99	12.8 + 5.0	7.25 + 3.1	0.001
Work performance index	9.90 + 7.5	15.0 + 13.0	3.83 + 0.28	0.003
Sexual matters	3.99 + 3.87	4.7 + 2.5	2.9 + 1.03	0.4 (wk. 1)/0.2 (wk. 4)

TABLE 4. *Discriminant properties of the ureteral stent symptoms questionnaire*

Domain	Stent Group (wk. 4)	Control Group	Stone Group	Lower Urinary Tract Symptom Group
No. pts.	44	20	37	36
Mean age + SD (median)	50.8 + 16.8 (50)	50 + 13.2 (50)	54 + 14.1 (56)	62.5 + 11 (64)
Male-to-female ratio	32:12	12:8	30:7	29:7
Mean domain scores mean + SD p values for 3 nonstent groups vs. stent group:				
Urinary symptom index	28.3 + 7.8	14.9 + 2.4 (<0.001)	20.9 + 5.5 (0.001)	23.3 + 5.8 (0.04)
Pain symptom index	22.2 + 9.6	0.6 + 3.0 (<0.001)	18.8 + 6.7 (0.11)	14.6 + 4.8 (0.002)
General health index	12.8 + 5.0	9.5 + 2.2 (0.001)	10.6 + 3.8 (0.04)	10.3 + 2.3 (0.01)
Work performance index	15.0 + 13.0	3.0 + 0.28 (<0.001)	7.9 + 7.7 (0.02)	3.4 + 1.2 (0.001)
Sexual matters	4.7 + 2.5	2.1 + 0.4 (0.02)	2.8 + 0.9 (0.1)	3.2 + 0.9 (0.6)

Scoring of the questionnaire. The scoring system for the questionnaire consists of a simple sum of the scores for individual questions in each section. Each section had a summary (index) score except for the questions on additional problems. Simple sum and multiplicative composite scoring systems were tried before finalizing the simple scoring, which was justified by the high degree of internal consistency for these sections. The high scores indicate worse outcomes.

DISCUSSION:

The new USSQ is a reliable and comprehensive instrument for evaluating the symptoms and impact on health related quality of life due to ureteral stents. Compared to other studies in the literature, we demonstrated that a combination of urinary symptoms and pain that affect physical and psychosocial health together with additional problems characterize a broad spectrum of impact associated with stents. The new USSQ has satisfactory validity with good evaluative and discriminant properties, which make it a valid outcome measure.

We tried to evaluate the need to develop a new instrument by asking patients and clinicians to assess suitability of the existing instruments and conducting prospective studies using those measures (phase 1), and the results justified the need. The USSQ was developed using a multi-step, multidisciplinary approach and adhered to the standard methods and rigorous guidelines of instrument development used in the field of measurement psychology.[17,18] The cognitive testing and validation studies of the USSQ gained the approval of patients and clinicians, which was further confirmed by statistical analysis of correlation and reliability assessments.

The selection of items for the urinary symptom section was based on objective and subjective evidence.[16] The features of the urinary symptoms, such as frequency, urge incontinence, hematuria and dysuria, which characterized stent experience were well captured in the USSQ. Pain associated with stents has remained a dynamic multidimensional experience, making it difficult to capture precisely and in a quantifiable format. We tried to capture different dimensions of pain, including behavioral measurement of pain, and symptoms that are supposed to characterize the experience of stent pain, such as pain related to micturition.

Patients were able to understand the scheme of answering the questions on the site(s) and severity of pain as noted during pilot testing and subsequent validation phases, with a less than 2% nonresponse rate. The responses to individual questions demonstrated that the diversity in the sites and intensity of pain, pain on voiding and interference in life were items characteristic for the patients with stents. Due to the presence or radiation of the pain associated with stents to external genitalia, especially in men, the diagram where patients mark the site(s) of the pain had to be different for the 2 genders but this is the only aspect of the questionnaire that distinguishes between the sexes.

Compared to many other groups of patients affected by urological conditions, a large proportion who need stent placement are actively employed. Hence, the impact of stents on functional capacity and work performance is covered separately in the section on work performance. The USSQ can be used with additional methods of economic evaluations to perform more detailed health economic assessments.

Simplicity in scoring the questionnaire was achieved using a system that added score of individual items to form an index score for each section. However, there is no single score for the whole questionnaire, as individual section scores represent separate domains and characteristics of the stent experience. Similarly, it is possible to interpret results of questions on an individual item basis depending on clinical needs (for example characteristics of hematuria or different sites of pain).

We validated the USSQ by administering the questionnaire at weeks 1 and 4 with the stent in situ. However, 4-week assessments, remained our main time frame to give

patients adequate chance to experience the impact of stents. Similarly, in our experience assessment of symptoms 4 weeks after stent removal represented patient baseline status satisfactorily. Adequate performance in test reliability, construct validity and treatment responsiveness needs to be demonstrated during psychometric validation before a new scale is applicable for general research or clinical use.[19] Overall, the USSQ has shown a strong internal consistency and high test-retest reliability. Results evaluating responsiveness to change, sensitivity and specificity indicated that the tool captures the impact of stents satisfactorily.

The USSQ differentiated patients with stents and healthy controls well. The impact of stents represents a spectrum of symptoms, many of which are common to other urological conditions, especially urinary calculi and lower urinary tract symptoms. However, when analyzed on an individual question basis, it became clear that many of the symptoms are highly prevalent and remain specific to patients with stents (for example hematuria, different locations of pain, loin pain during voiding). The USSQ captured these symptoms well. Similarly, the overall impact of stents, when measured across all domains of the USSQ, always discriminated patients with stents from all other groups. True criterion validation of the USSQ was difficult due to absence of an existing gold standard outcome measure for patients with ureteral stents.

It was important to compare the stent with nonstent (baseline) health status. In theory, comparing stent status with either pre-stent or post-stent status can achieve this objective. However, the pre-stent questionnaire assessment does not reflect the baseline status generally, tends to produce a significant noise-to-signal ratio and may not be psychometrically valid for the purposes of comparison. Hence, it is essential to evaluate patient baseline status by administering the questionnaire after the stent has been removed, thus patients act as their own controls.

There are certain limitations to our study. The development and validation study did not include patients with ureteral obstruction due to malignant pathology or stents inserted for long-term use (for example metal stents). The questionnaire performs short and brief assessment of general health domains and sexual function. In-depth evaluation of these domains can be performed using additional validated instruments. The questionnaire administration in a format other than paper, such as computer based administration, will need further evaluation. The current USSQ has been validated for use in the English speaking population. We anticipate further use of the scoring algorithms to define clinically significant change and stratify scores as mild, moderate or severe.

Overall, the results of this project highlighted the widespread impact of stents on health related quality of life. The new instrument characterizes the stent experience that has not been evaluated by previous studies and helps to quantify it satisfactorily. Details of the stent experience, based on its validation studies, along with its impact on work performance and utility analysis, are reported separately.[20]

The USSQ is now undergoing linguistic validation for use in languages other than English (German, Korean) and international evaluation within clinical trials to help evaluate its psychometric properties in further detail. Stents continue to evolve and new designs and materials are being tested. During all of this work assessment of patient morbidity and health related quality of life will remain an important issue.[21] This project has improved our understanding of various health related quality of life issues in patients with indwelling ureteral stents. Future studies using the USSQ will help us to understand the mechanisms underlying stent related symptoms and achieve effective patient communication. We expect the new USSQ to serve as an important outcome measure for future ureteral stent studies and in the search for an ideal stent.

Dr. Jenny Donovan, Department of Social Sciences, University of Bristol, provided advice on the design and conduct of study, and Dr. Vaughn Reed performed the statistical analysis.

APPENDIX

The following table can be considered as a guide to the calculation of the sample size for comparison of different types of stents with the USSQ as a main outcome measure. The guidelines are based on the results from the validation studies of the USSQ when the questionnaire was administered to patients with indwelling ureteral stents and a control group of (healthy) patients. Based on the differences in the mean domain score and standard deviation for the 3 important sections (urinary symptoms, pain and general health) the sample size was decided using a 2-tailed test ($p < 0.05$). The expected difference between different stent designs will need to be specified as a percentage difference (or difference in the index score) between 1 or more of the 3 important domains of the USSQ (urinary symptoms, body pain and general health).

Domain	% Difference in Mean Total Domain Score for 2 Samples	Difference in Mean Total Domain Score for 2 Samples	Power (number of patients in each arm)		
			80%	85%	90%
Urinary symptom index (difference between patients with the stents and controls = 46%, a score difference of 12)					
	30%	8	14	16	18
	20%	5	29	33	38
	15%	4	53	60	70
	10%	3	129	148	173
Pain index (the difference between patients with the stents and controls = 96.6%, a score difference of 19.30)					
	30%	6	64	73	85
	20%	4	129	148	173
	15%	3	252	288	337
	10%	2	700	800	935
General health index (the difference between patients with the stents and controls = 32%, a score difference of 4.3)					
	30%	4	38	43	51
	20%	2.6	79	90	105
	15%	2.05	129	148	173
	10%	1.3	393	456	526

The complete USSQ is available at www.bui.ac.uk/endourology and www.endourology.org

REFERENCES

1. Saltzman, B.: Ureteral stents. Indications, variations, and complications. Urol Clin North Am, **15:** 481, 1988
2. Pollard, S. G. and MacFarlane, R.: Symptoms arising from double-J ureteral stents. J Urol, **139:** 37, 1988
3. Bregg, K. and Riehle, R. A., Jr.: Morbidity associated with indwelling internal ureteral stents after shock wave lithotripsy. J Urol, **141:** 510, 1989
4. Thomas, R.: Indwelling ureteral stents: impact of material and shape on patient comfort. J Endourol, **7:** 137, 1993
5. Candella, J. V. and Bellman, G. C.: Ureteral stents: impact of diameter and composition on patient symptoms. J Endourol, **11:** 45, 1997
6. Irani, J., Siquier, J., Pires, C., Lefebvre, O., Dore, B. and Aubert, J.: Symptom characteristics and the development of tolerance with time in patients with indwelling double-pigtail ureteric stents. BJU Int, **84:** 276, 1999
7. Dunn, M. D., Portis, A. J., Kahn, S. A., Yan, Y., Shalhav, A. L., Elbahnasy, A. M. et al: Clinical effectiveness of new stent design: randomized single-blind comparison of tail and double-pigtail stents. J Endourol, **14:** 195, 2000
8. Preminger, G. M., Kettelhurst, M. C., Elkins, S. L., Seger, J. and Fetner, C. D.: Ureteral stenting during extracorporeal shock wave lithotripsy: help or hindrance? J Urol, **142:** 32, 1989
9. Spilker, B.: Quality of Life Assessments in Clinical Trials. New York: Raven Press, Ltd., pp. 3–10, 1990
10. Donovan, J. L.: The measurement of symptoms, quality of life and sexual function. BJU Int, suppl., **85:** 10, 2000
11. Jette, A. M., Davies, A. R., Cleary, P. D., Calkins, D. R., Rubenstein, L. V., Fink, A. et al: The Functional Status Questionnaire: reliability and validity when used in primary care. J Gen Intern Med, **1:** 143, 1986
12. Nelson, E., Wasson, J., Kirk, J., Keller, A., Clark, D., Dietrich, A. et al: Assessment of function in routine clinical practice: description of the COOP Chart method and preliminary findings. J Chronic Dis, suppl., **40:** 55s, 1987
13. EuroQol—a new facility for the measurement of health-related quality of life. The EuroQol Group. Health Policy, **16:** 199, 1990
14. Hansen, B. J., Flyger, H., Brasso, K., Schou, J., Nordling, J., Thorup Andersen, J. et al: Validation of the self administered Danish Prostatic Symptom Score (Dan-PSS-I) system for use in benign prostatic hyperplasia. Br J Urol, **76:** 451, 1995
15. Joshi, H. B., Okeke, A., Newns, N., Keeley, F. X., Jr. and Timoney, A. G.: Influence of ureteric stents on general health. Results from EuroQol and SF-36 multidimensional measure survey. J Endourol, suppl., **13:** A113, 1999
16. Joshi, H. B., Okeke, A., Newns, N., Keeley, F. X., Jr. and Timoney, A. G.: Characterization of urinary symptoms in patients with ureteral stents. Urology, **59:** 511, 2002
17. Guyatt, G. H., Kirshner, B. and Jaeschke, R.: Measuring health status: what are the necessary measurement properties? J Clin Epidemiol, **45:** 1341, 1992
18. Cella, D. F. and Tusky, D. S.: Measuring quality of life today: methodological aspects. Oncology, **4:** 29, 1990
19. Ware, J. E., Jr.: Standards for validating health measures: definition and content. J Chronic Dis, **40:** 473, 1987
20. Joshi, H. B., Stainthorpe, A., MacDonagh, R. P., Keeley, F. X., Jr. and Timoney, A. G.: Indwelling ureteral stents: evaluation of symptoms, quality of life and utility. J Urol, **169:** 000, 2003
21. Clayman, R. V.: Editorial comment. J Urol, **163:** 1619, 2000

0022-5347/03/1693-1065/0
THE JOURNAL OF UROLOGY®

Vol. 169, 1065–1069, March 2003
Printed in U.S.A.
DOI: 10.1097/01.ju.0000048980.33855.90

INDWELLING URETERAL STENTS: EVALUATION OF SYMPTOMS, QUALITY OF LIFE AND UTILITY

H. B. JOSHI, A. STAINTHORPE, R. P. MacDONAGH, F. X. KEELEY, JR. AND A. G. TIMONEY

From the Bristol Urological Institute, Southmead Hospital, Bristol, and Taunton and Somerset National Health Service Trust, Taunton, United Kingdom

ABSTRACT

Purpose: We report the prevalence of symptoms associated with ureteral stents, their impact on health related quality of life and utility analysis based on the validation studies of the new ureteral stent symptom questionnaire (USSQ).

Materials and Methods: A total of 85 consecutive adult patients with unilateral indwelling ureteral stents who were asked to participate during the validation phases of the USSQ were considered for this analysis. They were asked to complete the USSQ and the EuroQol, a weighted utility instrument, 4 weeks after stent insertion and removal. In addition, 40 patients were asked to complete these questionnaires 1 week after stent insertion to assess the prevalence of symptoms and utility values at different times.

Results: Of the 85 patients 62 (73%) with a mean age of 50 years completed the necessary questionnaires. Urinary symptoms and pain that affected work performance and general health were important stent related problems. Of the patients 78% reported bothersome urinary symptoms that included storage symptoms, incontinence and hematuria. More than 80% of patients experienced stent related pain affecting daily activities, 32% reported sexual dysfunction, and 58% reported reduced work capacity and negative economic impact. The mean EuroQol utility values, which indicate patient satisfaction with treatment, were significantly reduced following stent insertion.

Conclusions: Urinary symptoms and pain associated with indwelling ureteral stents interfere with daily activities and result in reduced quality of life in up to 80% of patients. Stents are associated with negative functional capacity and reduced utility values. The results have implications in terms of routine clinical practice, patient counseling and future stent research.

KEY WORDS: stents, ureter, signs and symptoms, patient satisfaction, quality of life

The work done during developmental phases of the new ureteral stent symptom questionnaire (USSQ) and the review of the literature have clearly shown that ureteral stents are associated with a variety of urinary tract symptoms, stent related pain and additional problems.[1–4] The stents appear to affect physical and psychosocial health, and also have a negative impact on functional capacity and work performance.

The studies performed during validation of the USSQ quantified the wide ranging impact of stents in a thorough, comprehensive and reliable manner.[5] We present from its validation studies the evidence of symptoms associated with stents and the impact they have on general health domains. Because of the significant impact of stents on work performance, we evaluated this issue using the EuroQol questionnaire,[6] a validated instrument to perform comparative health status and cost utility analysis, in addition to the USSQ.

We combined economic and health related quality of life evaluations to define a broad picture of the impact of stents. The results are compared to those obtained from healthy controls, as well as other urological patient cohorts who participated during validation studies, to present a comparative analysis of the impact of stents in relation to different patient groups and health states.

PATIENTS AND METHODS

A total of 85 consecutive adult patients with unilateral indwelling ureteral stents who participated during the validation phases of the USSQ were considered for this analysis.

Accepted for publication September 6, 2002.

They were asked to complete the USSQ and EuroQol questionnaire, a weighted utility instrument, 4 weeks after stent insertion and 4 weeks after stent removal. In addition, 40 patients from this cohort were asked to complete these questionnaires 1 week after stent insertion to assess symptoms and utility values at different times. Similarly, a group of 25 healthy volunteers, 45 patients with renal calculi who did not have stents and 45 patients with lower urinary tract symptoms were asked to complete these questionnaires during part of the validation studies.

The USSQ has 6 sections to evaluate the impact of stents on health related quality of life in a comprehensive manner, and the EuroQol instrument has 6 items. The responses to the EuroQol questions were replaced by an appropriate valuation of each health state (utility values). The thermometer scale in the questionnaire indicated patient rating of their health status on a scale from 0 (death) to 100 (perfect health). The EuroQol utility values were derived using the time trade-off technique. Results of both questionnaires with the stent were compared with those after stent removal, and with controls and the 2 other patient groups without stents.

The questionnaire responses were analyzed using cross tabulations and descriptive statistics. The prevalence of various symptoms is presented in the categories of (never, occasionally, sometimes, most of the time and all of the time). Simple sums were obtained to derive an index score for each section of the USSQ. The differences between responses to week 4 stent in situ individual section (t test), work performance (sign test) and EuroQol utility (McNemar's test) questions and post-stent status were tested for statistical signif-

icance. Fisher's exact test and chi-square tests were used to compare differences in the work performance questions for the stent group, control group and patients with stones or lower urinary tract symptoms. Kruskal-Wallis test was used to compare EuroQol utility scores for these groups. Relations among age, sex and utility scores were assessed by Spearman's rank correlation coefficients.

RESULTS

Of the 85 patients who were asked to participate in the study 39 men and 23 women with a mean age of 50.2 years completed the necessary questionnaires. Of the 40 patients asked to complete questionnaires with the stent for 1 week 28 (70%) returned them. The age, sex distribution and details of employment status of the stent and nonstent groups are presented in table 1.

Urinary symptoms. Table 2 shows the percentage of patients reporting various urinary symptoms. Of the patients with the stent for 4 weeks 76% voided every 2 hours or less during the day and 58% awoke 2 times or more at night to void. A high proportion of patients with stents reported frequency, urgency, dysuria and hematuria, which interfered with daily activities. The differences between the prevalence of urinary symptoms associated with stents as well as their impact on quality of life compared to post-stent status reached statistical significance ($p \leq 0.01$) except for the symptom of nonurge incontinence. These symptoms were also significantly worse compared to the nonstent groups.

Pain. More than 80% of patients reported stent related pain (table 3). Pain occurred in the loin/flank region in 60% of patients, bladder region in 38%, external genitalia in 32%, groin in 28% and anterior side of the kidney (lumbar/hypochondriac) region in 26%. Stent related pain was reported in 1 site by 24% of patients, 2 sites by 48% and 3 sites by 16%.

Of the patients 38% experienced stent related pain during vigorous activities only, while 40% suffered it during activities of moderate severity or during basic activities, and 7% reported pain while resting. Only 15% of patients did not experience pain or discomfort due to stents during physical activities. More than 70% of patients with the stent reported the need for analgesics (35% more than two-thirds of the time) to control pain. The incidence of body pain was significantly higher compared with that of the healthy controls and patients with lower urinary tract symptoms. The total pain score, as measured by the USSQ, was higher for the stent group than for the stone group, although the difference did not reach statistical significance. However, 77% of patients in the stone group reported body pain, with 68% experiencing it in the loin region only and no one having pain in the external genitalia. Overall intensity of the pain in the stone group was lower (mean score 7 versus 20 with the stent for all sites combined together) compared with stent related pain. These differences were statistically significant and revealed specific aspects of stent related pain.

General health. Stents had a variable degree of impact on all general health domains (table 3). A high percentage of patients reported tiredness and an inability to feel calm and peaceful with the stent. Similarly, stents affected physical activities and resulted in reduced enjoyment of social life and the need for extra help performing daily activities. The impact of stents on general health was significantly worse compared to post-stent status and correlated well with the incidence of urinary symptoms and/or stent related pain. The stents had a more negative impact on health related quality of life compared with lower urinary tract and stone groups.

Sexual health. Results of the USSQ revealed problems due to stents (at week 4) in 35% of patients who were sexually active, which were commonly experienced in the form of physical pain (mild 24%, moderate to severe 11%). However, stents also affected other sexual health domains such as desire and enjoyment. Of 70% patients who reported to be sexually active the severity of stent related symptoms resulted in temporary, but total, sexual dysfunction in 14%. Regarding overall satisfaction with sex, 18% of patients expressed mixed feelings and 14% were dissatisfied at the end of 4 weeks of an indwelling stent. Assessments at week 1 with the stent were limited by the short period. Compared with patients in the stone and lower urinary tract groups, the differences were not statistically significant as the number of sexually active patients was low.

Work performance. With the stent in place for 4 weeks 26% of patients spent more than 2 days in bed (range 3 to 14) and 42% had to reduce activities by more than 3 half days or more (4 to 28 half days). Similarly, the presence of the stent resulted in a reduction in the quality of work. This impact was significantly worse compared to the 3 groups without stents. Table 4 shows the impact of the stent by comparing the results before and after its removal.

EuroQol analysis. The EuroQol analysis evaluating general health domains revealed a significant association between the stent and post-stent state responses regarding mobility, ability to perform usual activities and presence of pain or discomfort ($p < 0.001$). This relationship was also true when compared with healthy controls ($p < 0.001$) and patients with stones and lower urinary tract symptoms ($p < 0.01$).

The results of the EuroQol utility and thermometer analyses revealed a decrease in the utility scores in greater than 85% of patients with the stent (tables 1 and 4). The range of the EuroQol scores varied between −0.18 and 1.0, indicating wide variation in the impact of stents. There was no significant difference in the median utility scores with the stent for 1 and 4 weeks. The utility and thermometer scores were lower with the stent compared to the other groups without stents ($p < 0.01$, except stone group).

Additional problems. Of the patients 68% experienced symptoms of a urinary tract infection (27% less than a third of the time, 41% more than a third of the time) due to 4 weeks

TABLE 1. *Demographic details and comparative analysis of work performance and utility scores*

	Stent Group	Control Group	Stone Group	Lower Urinary Tract Group
Mean age + SD	50.2 ± 16.1	50 ± 13.2	54 ± 14.1	62.5 ± 11
Male-to-female ratio	39:23	12:8	30:7	29:7
% Employment status:				
Full-time	54	45	44	30
Part-time	4	20	14	12
Retired	32	30	36	58
Other	10	5	6	0
Work performance (p value vs. stent group)		≤0.001	≤0.01	≤0.01
% Frequent work rest ($p \leq 0.01$)	52	0	40 (not significant)	13
% Work change ($p < 0.01$)	59	0	25	20
% Reduced work hours ($p = 0.008$)	52	8	25	7
EuroQol Scores (p value vs. stent group)		<0.01	0.01	0.01
Median utility (quartiles)	0.76 (0.62–0.94)	1.00 (0.80–1.00)	0.80 (0.76–1.00)	0.88 (0.73–1.00)
Median thermometer (quartiles)	78 (60–85)	85 (80–95)	80 (65–87.5) (not significant)	80 (70–90) (not significant)

TABLE 2. *Characteristics of urinary symptoms with the stent and after its removal*

	% Never			% Occasionally			% Sometimes			% Most of the Time			% All of the Time		
	Wk. 1	Wk. 4	Post-Stent	Wk. 1	Wk. 4	Post-Stent	Wk. 1	Wk. 4	Post-Stent	Wk. 1	Wk. 4	Post-Stent	Wk. 1	Wk. 4	Post-Stent
Symptoms:															
Urgency	28	20	42.5	48	44	50	12	20	7.5	12	11	0	0	5	0
Urge incontinence	80	44	81.5	12	44	17.5	4	6	2.5	4	6	0	0	0	0
Non urge incontinence	80	73	92.5	16	18	5	4	9	2.5	0	0	0	0	0	0
Incomplete emptying	34	18	72.5	44	44	15	24	19	7.5	8	14	2.5	0	5	2.5
Dysuria	4	30	81.5	44	28	12.5	28	16	0	16	21	0	8	5	0
Hematuria frequency	52	40	97	16	26	3	12	14	0	16	18	0	4	2	0
Interference in life*	12	18	75.5	48	28	20	20	24	4.5	16	25	0	4	5	0
Hematuria amount†	52	42	97	36	48	3	4	2	0	8	8	0			
Quality of life impact‡	10	12	65	12	30	15	78	40	20	0	18	0			

* Described as none, little, moderate, quite a bit and extreme, respectively.
† Described as no blood, slight blood staining, heavy blood staining and heavy bleeding and clots, respectively.
‡ Described as mostly satisfied, mixed feelings, dissatisfied-unhappy and terrible, respectively.

TABLE 3. *Characteristics of stent related pain and impact of stents on general health*

	% Never			% Occasionally			% Sometimes			% Most of the Time			% All of the Time		
	Wk. 1	Wk. 4	Post-Stent	Wk. 1	Wk. 4	Post-Stent	Wk. 1	Wk. 4	Post-Stent	Wk. 1	Wk. 4	Post-Stent	Wk. 1	Wk. 4	Post-Stent
Symptoms:															
Sleep disturbance	48	40	90	32	28	0	6	18	0	10	10	0	4	4	0
Pain voiding	24	5	87.5	12	27	12.5	14	20	0	40	28	0	12	20	0
Painkillers	36	26	82.5	28	38	12.5	24	16	5	8	14	0	8	6	0
Pain in kidney area at voiding*	64		64		0		36	36		0					
Overall bother†	10	14	83	55	30	15	15	20	2	10	26	0	10	10	0
General health domains:															
Vitality (feeling tired)	8	26	40	56	28	52	20	24	8	12	18	0	4	4	0
Feeling calm and peaceful	20	5	50	28	58	4	12	9	2	36	17	44	4	11	50
Social life enjoyment	16	26	0	24	38	0	16	12	4	28	8	36	16	16	60
Need extra help	52	34	82	28	30	18	8	22	0	4	14	0	8	0	0
Physical activities:‡															
Light	68	64	100	20	20	0	8	14	0	4	2	0	0	0	0
Heavy	28	38	80	20	28	4	4	8	0	32	24	0	16	12	16

* Described as no pain and pain, respectively.
† Described as none, a little, moderate, quite a bit and extreme, respectively.
‡ Described as no difficulty, some difficulty, much difficulty, did not do due to stent and did not do for other reasons, respectively.

TABLE 4. *Comparison of work performance and EuroQol scores after stent removal and with stent*

	After Stent Removal		Stent (wk. 4)		Median Difference (lower quartile-upper quartile)	p Value
Mean bed days + SD	0.12 + 0.33		1.5 + 2.7		0.0 (−2.0–0.0)	0.0005
Mean half days or more + SD	0.77 + 1.3		6.9 + 9.52		0.0 (−7.5–0.0)	0.0001
Work performance	Less than 1/3 of time	More than 1/3 of time	Less than 1/3 of time	More than 1/3 of time		
% Frequent work rest	19	0	19	50	0.0 (−2.0–0.0)	0.0024
% Work change	14	0	4.5	71	−2.0 (−3.0–0.0)	0.0002
% Reduced work hours	9	0	28	42	0.0 (−2.0–0.0)	0.0037
EuroQol analysis:						
Median thermometer (quartiles)	85 (80–100)		75 (60–100)		8.0 (0.0–20.0)	0.0001
Median utility score (quartiles)	1.00 (0.80–1.00)		0.76 (0.62–0.90)		0.2 (0.0–0.3)	0.0001

of indwelling stent. Similarly, 37% took 1, 10% 2 and 2.5% more than 2 courses of antibiotics other than those they received at the time of stent insertion. Of the patients 37.5% had to seek assistance from health care professionals (37.5% once, 12.5% twice and 2.5% more than twice), while 5% visited the hospital once due to stent related problems.

The responses to the question evaluating patient feelings about "the need to use stents in the future" revealed negative impact of stents as only 8% were pleased (3% post-stent), 10% were mostly satisfied (5% post-stent), 32% had mixed feelings (22% post-stent), 19% were mostly dissatisfied (22% post-stent), 21% were unhappy (34% post-stent) and 10% thought it was terrible (14% post-stent). Further analysis of the results revealed no relationship between age and utility score (Spearman's rank correlation coefficient −0.01), and no difference between the median utility scores of female and male patients (Wilcoxon test $p = 0.52$). Finally, the utility score and job status (divided into 3 categories of employee, employer/self-employed, not employed) also showed no difference (Kruskal-Wallis test $p = 0.35$).

DISCUSSION

The results of our study indicated that urinary symptoms and stent related pain were predominant domains affected by stents, which in turn had a marked impact on general health. Stents also resulted in significant reduction in the utility values, which improved after stent removal. The side effects of stents had a negative impact on physical and psychosocial health, which was worse than symptoms and quality of life in patients with lower urinary tract symptoms or urinary calculi without stents.

Evaluation of urinary symptoms revealed that storage problems, incontinence, dysuria and hematuria interfered

with social life and resulted in a reduced quality of life. These results help to characterize urinary symptoms associated with stents. Although the incidence of dysuria was higher at week 1 and that of urge incontinence at week 4 with the stent, the overall differences in the urinary symptoms at these 2 times were not significantly different.

Pain associated with stents was unpredictable in terms of location, severity and frequency. Our results revealed that such pain could be present at multiple sites and diverse in its site as it was experienced in the groin and external genitalia. When compared with the nonstent groups stent related pain appeared to be a more dynamic and intense experience. This pain had an impact on physical health, sleep, daily activities and general health. Patients with stents had a higher intensity of pain, pain during voiding and a greater interference with daily life due to pain. A high proportion of patients required analgesia, which demonstrates the high morbidity of ureteral stents. Presence of pain in the kidney region while voiding, which appeared to be a symptom peculiar to the stents, may indicate reflux as observed in other studies.[7,8] Assessment of these aspects of stent related pain would help to evaluate new stent designs. It appeared that the impact of stent related pain on quality of life worsened as the stent indwelling time increased.

Sexual health, although affected by stents, might have been perceived as a less important problem. It was not a major problem with short stent indwelling time (week 1) but it became important as the stent indwelling time increased. The impact of stents was not only related to the pain during sexual activity, but also appeared to be more widespread affecting overall sexual satisfaction with sex. Stents had a wide ranging impact on general health. The most important domains affected were physical health, normal activities and pain. Stents also affected social life and vitality. The results confirmed the assumption that urinary symptoms had an impact on social life and that pain added to limitations in physical activities.

In a large proportion of patients with stents significant work hours were lost due to days in bed or the number of half days or more lost. Also, the quality of work performance was affected by the presence of a stent. Since a significant proportion of patients who require insertion of stents are actively employed, these issues need to be considered before a stent is placed.

Utility is a concept used in economics and decision analysis, and refers to the level of satisfaction experienced by the consumer of the goods or services.[9] Utility measures facilitate broad comparisons of the effects of different diseases and allow patients to evaluate the positive treatment effects and the negative side effects. The results revealed significantly worse utility values due to the stents compared with the post-stent status, as well as with the other groups without stents.

Additional problems (for example symptoms of a urinary tract infection and requiring additional help) could have resulted in increased dependence and negative work performance. These issues have implications in terms of the use of health care resources. Evaluation of patient views on the trade-off between the benefits and side effects of stents revealed their dissatisfaction with the stent experience in general and their reluctance to undergo another stent experience. It was interesting to note that a proportion of patients reported various symptoms (urgency, incomplete emptying and vitality), although with a significantly smaller frequency and/or intensity, after removal of the stents. This finding possibly demonstrates the prevalence of symptoms in the background population and the residual effects of treatment, and may have somewhat overestimated baseline symptoms.

The cumulative effect of various symptoms makes them much more significant resulting in a negative impact on health related quality of life even when compared with other urological conditions. We agree that stents serve a useful purpose in preventing upper tract obstruction by various mechanisms, allowing tissue healing, dilating the ureter and possibly assisting stone passage. Alternative treatment options (for example percutaneous nephrostomy tubes) when applicable are not without their problems.[10–12] However, current stent designs and materials are problematic, especially from the patient point of view, and considerable improvement is required. Our study has documented the extent of the underlying problem.

Our study has limitations in that only a single stent design was evaluated, which was a requirement for the validation of the new questionnaire. It is possible that nonresponders might have had worse stent experience which is difficult to assess. In this respect, the impact of different types of stents needs to be evaluated. Similarly, many issues related to the use of stents, such as indications for their use, optimum indwelling time and mechanisms related to symptomatology remain unclear. Our study demonstrates the possibilities for different stent designs to undergo uniform assessments.

Although it is possible that some of the symptoms associated with stents may vary with increasing stent indwelling time,[7] the prevalence and overall impact of the symptoms on quality of life in this study remained remarkably constant as long as the stent was in place. However, more frequent assessments will help to evaluate temporal progression of symptoms with the stent in-situ.

An important application of these results is the provision of adequate patient information or counseling about ureteral stents. A significant reduction in anxiety can result when many stent related symptoms are explained to the patients beforehand. They can then make necessary arrangements at work and provide necessary information to employers. Similarly, dissemination of this information within the primary care network can also lead to easier management of some of the stent related problems at that level.

CONCLUSIONS

We suggest that indwelling ureteral stents are associated with a range of urinary tract symptoms and pain affecting the general health of patients. Their use results in a negative functional capacity and utility values, and a reduced quality of life in up to 80% of patients. Our results have implications in terms of routine clinical practice, patient counseling, evaluation of different stent designs and future stent research.

Dr. Jenny Donovan, Department of Social Sciences, University of Bristol, provided advice on the design and conduct of the study, and Dr. Vaughn Reed and Miss Charlotte Carmichael performed the statistical analysis.

REFERENCES

1. Tolley, D.: Ureteric stents, far from ideal. Lancet, **356:** 872, 2000
2. Saltzman, B.: Ureteral stents: indications, variations and complications. Urol Clin North Am, **15:** 481, 1988
3. Borboroglu, P. G., Amling, C. L., Schenkman, N. S., Monga, M., Ward, J. F., Piper, N. Y. et al: Ureteral stenting after ureteroscopy for distal ureteral calculi: a multi-institutional prospective randomized controlled study assessing pain, outcomes and complications. J Urol, **166:** 1651, 2001
4. Hollenbeck, B. K., Schuster, T. G., Faerber, G. J. and Wolf, J. S., Jr.: Routine placement of ureteral stents is unnecessary after ureteroscopy for urinary calculi. Urology, **57:** 639, 2001
5. Joshi, H. B., Newns, N., Stainthorpe, A., MacDonagh, R. P., Keeley, F. X., Jr. and Timoney, A. G.: Ureteral stent symptom questionnaire: development and validation of a multidimensional quality of life measure. J Urol, **169:** 000, 2003
6. EuroQol—a new facility for the measurement of health related quality of life. The EuroQol Group. Health Policy, **16:** 199, 1990
7. Irani, J., Siquier, J., Pires, C., Lefebvre, O., Dore, B. and Aubert, J.: Symptom characteristics and the development of tolerance

with time in patients with indwelling double-pigtail ureteric stents. BJU Int, **84:** 276, 1999
8. Candella, J. and Bellman, G. C.: Ureteral stents: impact of diameter and composition on patient symptoms. J Endourol, **11:** 45, 1997
9. Feeney, D. H., Torrance, G. W. and Labelle, R.: Integrating economic evaluations and quality of life assessments. In: Quality of Life and Pharmacoeconomics in Clinical Trials, 2nd ed. Edited by B. Spilker. Philadelphia: Lippincott-Raven Publishers, pp. 84–95, 1996
10. Pearle, M. S., Pierce, H. L., Miller, G. L., Summa, J. A., Mutz, J. M., Petty, B. A. et al: Optimal method of urgent decompression of the collecting system for obstruction and infections due to ureteral calculi. J Urol, **160:** 1260, 1998
11. Joshi, H. B., Adams, S., Obadeyi, O. O. and Rao, P. N.: Nephrostomy tube or 'JJ' ureteric stent in ureteric obstruction: assessment of patient perspectives using quality-of-life survey and utility analysis. Eur Urol, **39:** 695, 2001
12. Mokhmalji, H., Braun, P. M., Martinez Portillo, F. J., Siegsmund, M., Alken, P. and Köhrmann, K. U.: Percutaneous nephrostomy versus ureteral stents for diversion of hydronephrosis caused by stones: a prospective, randomized clinical trial. J Urol, **165:** 1088, 2001

EDITORIAL COMMENT

This pair of articles describes the development, validation and use of an instrument to measure the health impact of therapeutic ureteral stents. The instrument development involved considerable input from patients and clinicians, which is an important methodological step to ensure that all aspects of the stent experience are being captured. Readers interested in this topic would be well advised to read the articles after downloading the 38-item questionnaire from the authors' web site.

The questionnaire consists of 3 "stent specific" batteries dealing with urinary symptoms, pain (the pain section is gender specific) and "additional problems," and 3 "general" batteries covering general health, work performance and sexual matters. Scores for each domain are calculated by simple addition. The "additional problems" items are heterogeneous enough that one could predict the relatively low value of Cronbach's α, a test of how well the items "hang together," and raise doubts whether they should be scored together. Moreover, the "sexual matters" domain scores correlate poorly with the other domain scores, and do not change significantly after stent removal, weakening the case for including this battery. One special challenge in measuring stent related symptoms is for respondents to separate the effects of the stent from the effects of the underlying urological problem. The inability of the pain symptom index to discriminate patients with stents from patients with no stent and nephrolithiasis (a common clinical situation calling for a stent) highlights this difficulty, although discriminant validity may not be important for some uses of such questionnaires. The relative complexity of the instrument may have contributed to the nonresponse rates of 25% to 30% described in the latter article. These concerns notwithstanding, this questionnaire is an important step in achieving a better understanding of the ureteral stent experience from the patient point of view, as reflected in the interesting data presented in the second latter report. Further work needs to be done to refine and possibly simplify the instrument before using it, say, as an outcome measure in clinical trials.

Michael J. Barry
Medical Practices Evaluation Center
Massachusetts General Hospital
Boston, Massachusetts

REPLY BY AUTHORS

As stated in our first article, due to the relatively low value of Cronbach's, we do not advise adding scores for the items in the section on additional problems to give an index score. These are to be reported separately. We believe that the sexual matters domain is relevant, although there is a relatively small proportion of patients with stents in whom this is important, which affects its sensitivity to change. Sexual dysfunction becomes more pronounced when the stent indwelling time gets longer. Inclusion of this domain was also considered relevant from the point of evaluative properties of the questionnaire.

It is important to note that it is only the difference in the pain index score between patients with stents and the stone group which did not reach statistical significance. Many individual questions in this section perform this discrimination satisfactorily. Similarly, the overall stent experience (across all domains) captured by the USSQ discriminates patients with stents from those with no stent and nephrolithiasis. We agree with the comment regarding further work in that the application of the USSQ in clinical (field) trials will help to evaluate its psychometric properties in further detail and achieve greater refinement of the instrument.