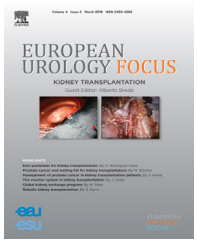
available at www.sciencedirect.com
journal homepage: www.europeanurology.com/eufocus



Urinary Stones and Intervention Quality of Life (USIQoL): Development and Validation of a New Core Universal Patient-reported Outcome Measure for Urinary Calculi

Hrishikesh B. Joshi [a,b,*], *Hans Johnson* [c], *Amelia Pietropaolo* [d], *Aditya Raja* [a,b], *Adrian D. Joyce* [e], *Bhaskar Somani* [d], *Joe Philip* [c], *Chandra Shekhar Biyani* [e], *Tim Pickles* [a]

[a] *School of Medicine, Cardiff University, Cardiff, UK;* [b] *Department of Urology, University Hospital of Wales, Heath Park, Cardiff, UK;* [c] *University of Bristol Medical School, Bristol, UK;* [d] *University Hospital Southampton NHS Foundation Trust, Southampton, UK;* [e] *Leeds Teaching Hospitals NHS Trust, Leeds, UK*

Article info

Associate Editor: Malte Rieken

Keywords:
urinary calculi
health related quality of life (HRQoL)
patient reported outcome

* Corresponding author. Department of Urology, University Hospital of Wales, Heath Park, Cardiff CF14 4XW, UK. Tel. +44 29 20745151.
E-mail address: hrishi.joshi@wales.nhs.uk (H.B. Joshi).

1. Introduction

Urolithiasis is a common condition with the prevalence of 2–3% among the general population and 50% of patients likely to form further stones within 5 yr [1]. The prevalence rates reported range from 7% to 13% in North America, 5–9% in Europe, and 1–5% in Asia [2]. The disease resulted in 550 000 emergency room visits in the USA in 2009 and more than 30 800 hospital admissions in England in a year [3,4]. Stone patients miss an average of 47.9 h of work per year, with additional hours lost due to ambulatory care visits [5]. There are different options for managing urinary calculi with expectant, medical, or interventional treatments [6], which can be multistaged and carry different risks and success rates. Temporary interventions such as indwelling ureteric stents add to the patient burden [7]. Urolithiasis and its treatment(s) have an adverse effect on health-related quality of life (HRQoL) and can compromise all areas of patient functioning [8–10].

A patient-reported outcome measure (PROM) is a report on a patient's health condition that comes directly from the patient [11]. In addition to their use in randomised controlled trials to assess treatment effectiveness, there is growing interest in the use of PROMs in routine HRQoL monitoring and medical audits [12]. A PROM can improve the evidence base as long as the measure is appropriate and in accordance with international standards [13]. American Urological Association guidelines state that treatment decisions about urinary calculi should incorporate patient preferences that are influenced by the HRQoL impact [14].

Attempts have been made to measure the HRQoL of patients with urolithiasis. Generic measures have been used for this, but often fail to elaborate on the clinically relevant domains [8]. In the recent past, PROMs specific to urolithiasis targeted at different subpopulations have been developed [15–17]. It is now recognised that modern psychometric methods based on Rasch measurement theory (RMT) should be integral to the development of such measures [18–20].

Our hypothesis was that the subjective QoL impact of stone disease and interventions can be measured objectively using a valid and reliable PROM developed using modern methodology. Our aim was to develop a core PROM, incorporating RMT, to evaluate the impact of the entire spectrum of upper-tract urinary calculi in a uniform way and facilitate cross-comparison of the HRQoL impact of urolithiasis and interventions.

https://doi.org/10.1016/j.euf.2020.12.011

Please cite this article in press as: Joshi HB, et al. Urinary Stones and Intervention Quality of Life (USIQoL): Development and Validation of a New Core Universal Patient-reported Outcome Measure for Urinary Calculi. Eur Urol Focus (2021), https://doi.org/10.1016/j.euf.2020.12.011

2. Patients and methods

We followed international PROM guidelines for the development and validation of the Urinary Stones and Intervention Quality of Life (USIQoL) measure that would also conform to the COSMIN (Consensus-based Standards for the Selection of Health Measurement Instruments) checklist [20]. The multicentre developmental process comprised five stages (ethical approval: 17/WA/0195, no. 138478, 217163). Adult patients with urolithiasis covering all index stone categories, representative of routine practice, were invited to participate. The participants included patients with renal or ureteric stones with or without treatment(s). The key steps are outlined in Fig. 1.

2.1. Development steps

2.1.1. Phases 1–3

The work in phases 1–3, with patient interviews involving many stakeholders, produced a working conceptual framework and an initial long draft of the questionnaire [8,21]. After pretesting, the revised draft was administered in field test 1.

2.1.2. Phase 4: field test 1

Field test 1 was undertaken to construct USIQoL scales and perform a preliminary psychometric evaluation in a large sample to select the most appropriate items.

2.1.3. Phase 5: field test 2

Field test 2 was undertaken to comprehensively evaluate the shortened version generated from phase 4 to produce the final draft. Patients also completed existing generic questionnaires and those with an indwelling stent completed the Ureteric Stent Symptoms Questionnaire (USSQ) [22].

2.2. Sample size considerations and statistical analysis

The rule-of-thumb sample size recommendations for traditional analysis (10 subjects/item of the largest subscale [18 items in the long draft; n = 180]) and Rasch analysis (n = 200 minimum and 400/500 maximum for four/five class intervals) were followed for all assessments during phases 4 and 5.

A combination of traditional and RMT assessments was conducted using a sophisticated mathematical measurement model [23]. SPSS 25 software (SPSS Inc., Chicago, IL, USA) was used to perform traditional (eg, Spearman correlations) analysis. Rasch analysis (polytomous extended response category, partial credit model) was performed using RUMM 2030 software.

2.3. Rasch analysis

Phase 4 assessed different properties of the USIQoL such as item and person locations, item fit (fit residuals and χ^2 statistics), Person Separation Index (PSI), response categories, and local dependence (Table 1) [24]. Misfitting items were removed in an iterative manner, with removal of a single item at a time, after which the analyses were run again.

In phase 5, in addition to the analyses in phase 4, we assessed: (1) differential item functioning (DIF) for the traits age (four groups), sex, stone site (kidney/ureter), type of intervention, presence or absence of symptoms, and history of previous stones; (2) Smith's test of unidimensionality [25]; and (3) the optimal scale structure and logit-based scoring.

2.4. Traditional analysis (internal consistency and validity)

In phase 4, interitem and corrected item-total correlations were calculated. Correlations between scales (EuroQoL EQ-5D-5 L instrument, Short-Form-12 questionnaire, Hospital Anxiety and Depression Scale, and Work Productivity and Activity Impairment Questionnaire [expected 0.3–0.5]) were assessed for criterion validity [26–29].

In phase 5, in addition to the analyses for phase 4, we conducted tests of reliability (test-retest, patients with stable disease completing the USIQoL twice, 24–72 h apart) and validity (convergent) including both within- and between-scale testing and responsiveness to change (subgroup completing the USIQoL before and after interventional treatments at an interval of 4–16 wk).

3. Results

3.1. Item generation

A total of 62/77 invited patients (mean age 51 yr) and 30 family members participated in phases 1 and 2, generating 106 themes and 10 broad headings. These were mapped to a conceptual framework, with removal of duplications to create item sets [8,21]. A five-point rating scale (ranging from "not at all" to "a lot") was selected for the initial draft (Fig. 1).

3.2. Pretesting

Forty patients evaluated USIQoL, with minor changes to the items providing preliminary evidence of its face content validity and clinical suitability. A review by clinicians confirmed its completeness. The revised versions, with 60 items including treatment items, were drafted for the first field test. This evaluated pain using different formats (frequency of mild to unbearable pain, intensity of worst, day-to-day as well as average pain; 10 items), physical and social health including sex life (18 items), psychological health (six

Please cite this article in press as: Joshi HB, et al. Urinary Stones and Intervention Quality of Life (USIQoL): Development and Validation of a New Core Universal Patient-reported Outcome Measure for Urinary Calculi. Eur Urol Focus (2021), https://doi.org/10.1016/j.euf.2020.12.011

Table 1 – Glossary of terms.

Generic patient-reported outcome measures
EQ-5D-3L: EuroQol 5-dimension, 3-level questionnaire. Descriptive system for health-related quality of life states in adults; a preference-based measure also used for economic appraisals to calculate quality-adjusted life years
SF-12: Medical Outcomes Study Short-Form-12 questionnaire. A 12-item self-reported outcome measure assessing the impact of health on an individual's everyday life. Also used for preference-based utility (economic) assessments.
Disease- and intervention-specific patient-reported outcome measures
USIQoL: Urinary Stones and Intervention Quality of Life questionnaire. Quality-of-life measure specific for urinary stone (upper tract) disease and interventions.
WISQoL: Wisconsin Stone Quality of Life questionnaire. Quality-of-life measure specific for kidney stone disease.
USSQ: Ureteral Stent Symptoms Questionnaire. Intervention-specific measure to assess the impact of ureteral stents on quality of life.
HADS: Hospital Anxiety and Depression Scale. Instrument used to measure anxiety and depression in a general medical population of patients.
WPAI: Work Productivity and Activity Impairment Scale. Instrument used to measure impairments in work.
Rasch measurement analysis terminology (item = question, trait = patient/disease characteristics)
Logit range: For information on the scale to the sample target, a measure of the match between the range of HRQoL (domains) measured with the USIQoL and the range of HRQoL in the patient sample.
Targeting and Person Separation Index (PSI): Used to measure the reliability of a scale. A questionnaire is perfectly targeted if the mean of the person is the same as the mean of the items on the shared metric. PSI represents the extent to which items distinguish between distinct levels of disease-specific bother.
Item fit: The χ^2 statistic is used to confirm that the central property of item invariance (the hierarchical ordering of the items) does not vary across the trait measured. Fit residuals are used to assess differences between the observed and expected data for each person and item.
Ordered thresholds: Consistent use of the scale that corresponds to evidence that the response categories represent increasing levels of the construct being measured (the correct ordering of the response categories is reflected in successive thresholds).
Residual correlation: The extent to which each item is independent of the others (helps to remove redundant questions).

Fig. 1 – Steps in the development (phases 1–2) and evaluation (phases 3–5) of Urinary Stones and Intervention Quality of Life (USIQoL).
HRQoL = health-related quality of life; EAU = European Association of Urology; BAUS = British Association of Urological Surgeons; AUA = American Urological Association; PROM = patient-reported outcome measure.
[a] Construct definition: PROM development underpinned by the theory (conceptual base) and

items), work performance (eight items), and travel/holiday issues (three items). Fourteen items addressed additional problems including treatments and help from health care providers and family members, and one item on global health.

3.3. *Field test 1: item reduction and scale development*

During the first field test, 212/250 patients completed the questionnaires (Table 2). We evaluated psychometric properties, considering this to be a single scale, and seven subscale formats.

Rasch analysis demonstrated important features of USIQoL, including limitations, requiring modifications. All scales indicated good to excellent reliability (PSI 0.62–0.89; Table 3). However, for almost all scales, more than 60% of the items had disordered thresholds (difficulty distinguishing between responses "quite a bit" and "very much") necessitating a change from five to four or two response categories. Each scale had items with significant fit residuals (12–60%), and residual correlations (50–90%), indicating item redundancy.

Traditional analysis showed that USIQoL is a reliable and valid measure of the impact of stones on different domains. Reliability was excellent (total scale, $\alpha = 0.9$, subscales, $\alpha = 0.6–0.9$). The corrected item total (0.3–0.8) and interitem (0.4–0.9) correlations were satisfactory. Preliminary analyses of criterion validity were as expected (correlations with generic measures, range 0.3–0.8), demonstrating satisfactory early item level validity.

Using an iterative approach, misfitting and redundant items were removed to generate the revised versions for stone disease and interventions (20 and 24 items, respectively). These included five scales for pain, social health (five items each), physical health, psychological health (four items each), and work (two items), with four treatment items ready for field test 2.

3.4. *Field test 2*

In total, 369/390 patients participated in phase 5 (409 observations, 61 patients completed >1 [pre- and post-treatment] questionnaires), with 24/30 patients completing the test-retest study (Table 2).

3.4.1. *Rasch analysis*

Rasch analysis demonstrated that most of the items in the scales mapped out continua of increasing bother (Table 3). The scales located items in a clinically sensible order with a good sample match. Deviations from model expectations were marginal.Items excluded were pain (life interference, average and mild pain), social (sex, social life, and holiday), psychological (worry about kidney failing), and treatment (diet and device). The two treatment items (medication, water intake) were combined with the social scale. This transformed the USIQoL into a final 15-item measure.

Please cite this article in press as: Joshi HB, et al. Urinary Stones and Intervention Quality of Life (USIQoL): Development and Validation of a New Core Universal Patient-reported Outcome Measure for Urinary Calculi. Eur Urol Focus (2021), https://doi.org/10.1016/j.euf.2020.12.011

Table 2 – Participant characteristics.

Characteristic	Field test 1 (n = 212/250)	Field test 2 (n = 345/360) [a]
Mean/median age (yr)	52.5/52	53.8/56
Age range (yr)	19–89	18–90
Age group, n (%)		
16–40 yr	64 (30)	98 (29)
41–64 yr	92 (43)	166 (48)
65–80 yr	50 (24)	74 (21)
>80 yr	6 (3)	7 (2)
Sex, n (%)		
Male	135 (64)	241 (69)
Female	77 (36)	103 (31)
Not recorded		1
Bothersome pain, n (%)		
Yes	127 (65)	204 (60)
No	73 (35)	138 (40)
Not recorded	12	3
Site of stone, n (%)		
Kidney	147 (68)	225 (63)
Ureter	62 (32)	115 (35)
Not recorded	3	5
Previous stones, n (%)		
Yes	116 (56)	176 (52)
No	84 (44)	162 (48)
Not recorded	12	7
Paid employment (n)		
Yes	125	230
No	81	115
Not recorded	6	
Current treatment(s), n (%)		
Medical (metabolic disorder)	13 (6)	28 (8.1)
Shockwave lithotripsy	73 (34.4)	122 (35.3)
Surgical interventions (eg, URS/PCNL)	37 (18.3)	79 (22.8)
Observation (± short-term medical treatment, eg, tamsulosin, analgesics)	88 (41.3)	117 (33.8)
Stent in situ	16 (7.5)	33 (9.6)

URS = ureteroscopy; PCNL = percutaneous nephrolithotomy.
[a] Test-retest data not included.

Table 3 – Psychometric testing results from the Rasch analysis for field test 1 and field test 2.

USIQoL scale	Items (mean) [a]		Persons (mean) [a]		PSI	Fit statistics [b]		Disordered thresholds [c]	Residual correlation [d]
	Locations (logit range)	FR	Locations (logit range)	FR		Items with FR outside ±2.5 SD (n)	Items with χ^2 $p > 0.001$ (n)		Items with r score range > +0.3 (n)
Field test 1 (n = 212)									
Total (59 items)	0.0	−0.08–0.27	−0.45	0.88	14	55	56		
Pain (10 items)	0.0	−0.94–0.36	−0.69	0.84	4	6	7		
Physical + social (18 items)	0.0	−0.46–0.08	−0.60	0.89	4	16	12		
Psychological (6 items)	0.0	−0.88–0.34	−0.98	0.89	1	0	3		
Work (8 items)	0.0	−0.85–1.10	−0.62	0.81	7	8	6		
Travel (3 items)	0.0	−0.87–0.66	−0.50	0.62	0	3	2		
Field test 2 (n = 345 with 409 observations)									
Pain and Physical Health (6)	0.00	−0.88	0.08	−0.61	0.72 (−2.0 to +1.3)	0	0	0 (−0.3 to+0.07)	
Psychosocial Health (7)	0.00	−0.58	0.31	−0.55	0.70 (−1.0 to +0.3)	0	0	0 (−0.4 to +0.06)	
Work (2)	0.00	−1.14	−2.58	−1.05	0.83 (−1.3 to −0.9)	0	0	0 (−0.98)	

PSI = person separation index (measures the reliability of the scale; 0.7 is adequate); FR = fit residual; SD = standard deviation.
[a] Logit range: for information on the scale to the sample target, the match between the range of HRQoL measured with the USIQoL and the range of HRQoL in the patient sample.
[b] Item fit measured in terms of (1) fit residual (expected to lie between a mean of 0 and ±2.5 SD) and (b) χ^2 statistic (should be less than the Bonferroni-corrected significance level).
[c] Disordered thresholds: response categories not working as intended (measured using item response curves and threshold maps).
[d] Residual correlation: the extent to which each item is independent of the others (should be <0.3 above the mean).
[e] Smith's test of unidimensionality within scales. This identifies if the person estimates derived from the most diverse subsets of items are significantly different using principal component analysis. If the proportion, or the lower bound of the 95% confidence interval of significant ($p < 0.05$) t tests, is less than 5%, this indicates unidimensionality.

Please cite this article in press as: Joshi HB, et al. Urinary Stones and Intervention Quality of Life (USIQoL): Development and Validation of a New Core Universal Patient-reported Outcome Measure for Urinary Calculi. Eur Urol Focus (2021), https://doi.org/10.1016/j.euf.2020.12.011

3.4.2. Revised scaling

Items had superior fits when the five-scale structure was changed to a three-scale form, combining pain and physical health domains (PPH; six items), psychological and social health domains (PSH; seven items), and the work domain (two items). Fig. 2 demonstrates satisfactory item-threshold distribution maps for the subscales.

3.4.3. DIF and unidimensionality

We evaluated all 15 questions and three scales against different patient subpopulations (Supplementary Table 1). This confirmed good performance across traits. All three scales were unidimensional.

3.4.4. Traditional analysis

Traditional analysis confirmed that all three USIQoL scales are reliable and valid measures for assessment of important

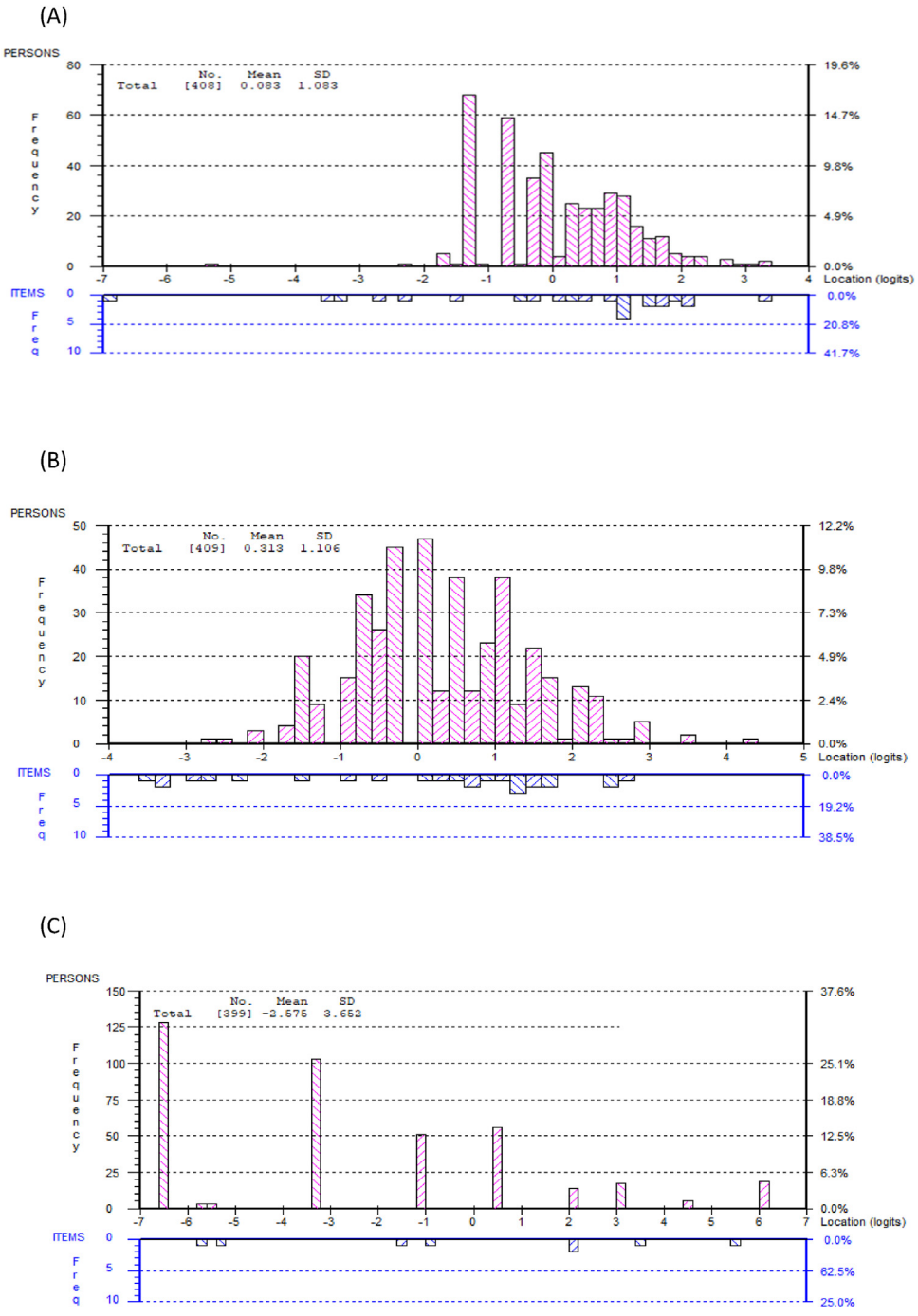


Fig. 2 – Person-item threshold distribution map for (A) Pain and Physical Health Scale (grouping set to interval length of 0.20, making 55 groups), (B) Psychosocial Health Scale (grouping set to interval length of 0.20, making 45 groups), and (C) work (grouping set to interval length of 0.20, making 70 groups).
SD = standard deviation.

Please cite this article in press as: Joshi HB, et al. Urinary Stones and Intervention Quality of Life (USIQoL): Development and Validation of a New Core Universal Patient-reported Outcome Measure for Urinary Calculi. Eur Urol Focus (2021), https://doi.org/10.1016/j.euf.2020.12.011

domains across patient groups. Corrected item-total and interitem correlations supported the hypothesis that items within scales measured a common underlying construct with good reliability. Test-retest correlations were excellent (0.81–0.92), indicating good scale stability (Table 4).

Criterion validity was tested extensively and hypothesised correlations between scores for USIQoL scales and existing generic and domain-specific measures were consistent. We showed that there was very good correlation with the relevant domains between the USIQoL and USSQ scales. The USIQoL was responsive to change, as shown by a significant positive effect for all scale scores after intervention.

3.4.5. *Final USIQoL measure and scoring*

The final USIQoL (three scales and 15 items; Supplementary Table 2) is intended for self-administration, whereby patients rate the amount of bother attributed on a 4-point scale (1 = not at all, 2 = a little, 3 = quite a bit, and 4 = a lot). The disease and intervention versions are similar and differ only in the title time frame (since your "current stone problems" or "current or most recent stone treatment") to make the versions psychometrically valid. Scale scores are generated by summing items and transferring to a 0–100 (logit) scale, with high scores indicating greater patient bother.

4. Discussion

The recurrent nature of urolithiasis and ensuing interventions can result in a cumulative negative HRQoL impact. The impact can be assessed using PROMs, but this involves measurement challenges. Generic measures fail to capture this impact comprehensively. Hence, urolithiasis-specific PROMs have recently been developed. The Wisconsin Stone Quality of Life (WISQoL, 28 items) was the first measure developed to assess the impact of stable urolithiasis and medical therapies [15–17]. It has undergone linguistic validations, with wide applications in different studies.

It is well recognised that measures that comply with modern psychometric methods based on item response theory (RMT) are of higher quality [20]. In this respect, the development of recent PROMs had a focus on specific subgroups and involved only traditional methods. These do not cover key criteria in the COSMIN guidelines (content development, sample size, use of RMT, unidimensionality).

The new USIQoL is the first PROM to capture the HRQoL impact of urolithiasis (acute and chronic) and interventions. It was developed using a combination of classical and RMT approaches, with very few such measures in urology. In the Rasch model, the probability of a specified response (right/wrong answer) is modelled as a function of person and item parameters. This is a unique mathematical modelling approach based on a latent trait for which item values

Table 4 – Summary of traditional psychometric analysis: field test 2.

Test criterion	USIQoL scales		
	PPH (6 items)	PSH (revised 7-item scale; *n* = 156)	Work performance (2 items)
Cronbach's α	0.82	0.75	0.94
Interitem correlation range	0.29–0.56	0.11–0.59	0.89
Item total correlation range	0.51–0.62	0.0.35–0.58	NA
Test-retest (*n* = 24)	0.91	0.83	0.80
Construct validity (correlation coefficient)			
EQ-5D-3 L (*n* = 346)			
Utility-total	−0.41	−0.36	0.02
Pain/discomfort	0.49	0.39	0.12
Mobility	0.26	0.24	−0.11
Usual activities	0.40	0.42	0.02
Anxiety/depression	0.28	0.51	0.12
EQ-5D-Thermometer	−0.39	−0.45	0.01
SF-12			
Physical health (PCS, *n* = 296)	−0.53	−0.54	−0.00
Mental health (MCS, *n* = 302)	−0.37	−0.46	−0.15
WPAI (*n* = 67)	0.46	0.62	0.7
HADS			
Anxiety (*n* = 166)	0.47	0.52	0.08
Depression (*n* = 163)	0.54	0.52	−0.00
USSQ			
Pain (*n* = 14)	0.71	0.30	NA
Urinary symptoms (*n* = 14)	0. 84	0.56	NA
General health (*n* = 14)	0.62	0.87	NA
PPTS effect size (*n* = 57) [a]	0.6	0.123	0.35

PPH = Pain and Physical Health; PSH = Psychosocial Health; EQ-5D-3L: EuroQol 5-dimension, 3-level questionnaire; SF-12 = Medical Outcomes Study short-form questionnaire; PCS = physical component summary; MCS = mental component summary; WPAI = Work Productivity and Activity Impairment Scale; HADS = Hospital Anxiety and Depression Scale; USSQ = Ureteral Stent Symptoms Questionnaire; PPTS = pre–post-treatment scale; NA = not applicable.

[a] We assessed the responsiveness of USIQoL by calculating effect sizes in a comparison of pre-intervention and post-intervention scale scores. We expected these to be positive, confirming a post-treatment improvement leading to reduced bother, but did not hypothesise a magnitude given the relatively smaller sample and the first application of the scales.

Please cite this article in press as: Joshi HB, et al. Urinary Stones and Intervention Quality of Life (USIQoL): Development and Validation of a New Core Universal Patient-reported Outcome Measure for Urinary Calculi. Eur Urol Focus (2021), https://doi.org/10.1016/j.euf.2020.12.011

are calibrated, and person abilities are measured on a shared continuum that accounts for the latent trait. This provides an internally valid measure that is independent of the particular sample; the findings for the sample can be extrapolated to the population for measurement of clinically meaningful differences [30,31].

The final 15-item selection for USIQoL was based on appraisals of the analyses against clinical relevance and measurement criteria. The psychometric evaluation showed that all three scales satisfy criteria for acceptability, validity, and reliability. The logit scoring for each scale offers different scores that allow clearer identification of the impact across different domains. This would help in future comparative studies and sample size calculations.

The results from traditional validity assessments alone suggested that the long draft of the USIQoL satisfied most of the criteria, until RMT demonstrated many targeting problems (disordered responses, item redundancies). This highlighted the value of RMT in conducting item-level analyses that guide precise item selection and rectify problems with scales. Our analysis demonstrated that the five-stage mixed-methods approach was important because of the complex assessments involved.

4.1. *Strengths and limitations*

Many aspects important to different stakeholders were considered for the conceptual framework and subsequent steps. Apart from construction of the necessary items and scales based on the key themes, we carefully evaluated whether there was a need for separate instruments for renal and ureteric stones, as well as the disease and interventions. We also looked at the demonstrable applicability of the PROM and the uniformity of the performance across the entire disease spectrum. Our work indicated that QoL in relation to different sites, diseases, and treatments is interlinked and separate measures can pose psychometric difficulties. The USIQoL development phases demonstrated that formulation of a single integrated PROM gave a better model of item fit and performed well across patient, disease, and intervention groups, making USIQoL an appropriate core instrument.

All three scales of the USIQoL demonstrated very good performance with proven unidimensionality. It was observed that pain, along with physical symptoms, which drive most of the clinical assessments, have more visible impact. The domain of pain, which is the most complex to assess, was tested extensively before finalising its appropriate format for inclusion. Similarly, issues regarding work are important to all stakeholders. The psychosocial scale is likely to be a good indicator of issues not evaluated routinely and the longer-term impact of the condition, which could drive treatment choices. USIQoL captures all these dimensions well, with the results quantified using modern psychometric techniques. USIQoL can also help in reliable combined HRQoL evaluation for stent subgroups.

There are certain limitations of the study and future work would help to address these. USIQoL was developed and validated in the English-speaking population of the UK and its wider application would need linguistic and cross-cultural validation. Its application with existing measures, such as WISQoL, could help in capturing a broader picture. Further USIQoL application, including in daily practice, will investigate scale sensitivity to develop clinically relevant thresholds. There is scope for adaptations to undertake economic appraisals and compare emergent treatments and service evaluations that would guide patient-centred care.

5. Conclusions

In conclusion, USIQoL is a new three-scale, 15-item, single-page self-report instrument that measures the HRQoL impact of stone disease and interventions. It has been developed using modern psychometric methods. It is fit for valid and reliable comparisons at the micro level (patients) and meso level (treatment groups, institutions). We expect USIQoL to serve as a core PROM for studies looking at and comparing the effectiveness of treatments, observational strategies, and quality of care, as well as an adjunct to medical audits. This PROM is expected to improve the evidence base and help toward better patient communication and shared decision-making.

Author contributions: Hrishikesh B. Joshi had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Joshi.

Acquisition of data: Johnson, Pietropaolo, Raja, Joshi.

Analysis and interpretation of data: Joshi, Raja, Pickles.

Drafting of the manuscript: Joshi, Biyani, Somani, Philip, Pickles.

Critical revision of the manuscript for important intellectual content: Joshi, Joyce, Biyani, Pickles.

Statistical analysis: Joshi, Pickles.

Obtaining funding: Joshi.

Administrative, technical, or material support: Biyani, Joshi, Joyce, Pickles.

Supervision: Joshi, Biyani, Somani, Philip.

Other: None.

Financial disclosures: Hrishikesh B. Joshi certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: None.

***Funding/Support and role of the sponsor*:** This work was supported by funding from the Urology Foundation. The sponsor played a role in the design and conduct of the study.

***Acknowledgments*:** We thank the Urology Foundation for partial funding. We are grateful to Prof. K. Sarica, Dr. F. Sangueodolce (European Association of Urology), Mr. A. Dickinson and BAUS Endourology Committee Members, Prof. M. Monga, and Dr. Sri Sivalingam (American Urological Association). We also thank Prof. S. Salek for help with the study design.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:https://doi.org/10.1016/j.euf.2020.12.011.

References

[1] Pearle MS, Calhoun EA, Curhan G. Urologic diseases in America project: urolithiasis. J Urol 2005;173:848.
[2] Sorokin I, Mamoulakis C, Miyazawa K, Rodgers A, Talati J, Lotan Y. Epidemiology of stone disease across the world. World J Urol 2017;35:1301–20.
[3] National Health Service. Hospital episodes statistics data. Vol. 2014. NHS. 2015.
[4] Bultitude M, Rees J. Management of renal colic. BMJ 2012;345:e5499.
[5] Saigal CS, Joyce G, Timilsina AR, et al. Direct and indirect costs of nephrolithiasis in an employed population: opportunity for disease management? Kidney Int 2005;68:1808–14.
[6] Türk C, Neisius A, Petrik A, Seitz C, Skolarikos A, Thomas K. EAU guidelines: urolithiasis. Arnhem, The Netherlands: European Association of Urology; 2020. http://uroweb.org/guideline/urolithiasis
[7] Joshi HB, Stainthorpe A, McDonagh RP, et al. Indwelling ureteral stents: evaluation of symptoms, quality of life and utility. J Urol 2003;169:1065–9.
[8] Raja A, Hekmati Z, Joshi Hb. How do urinary calculi influence health-related quality of life and patient treatment preference: a systematic review. J Endourol 2016;30:727–43.
[9] Penniston KL, Nakada SY. Treatment expectations and health-related quality of life in stone formers. Curr Opin Urol 2016;26:50–5.
[10] Patel N, Brown RD, Sarkissian C, De S, Monga M. Quality of life and urolithiasis: the patient - reported outcomes measurement information system (PROMIS). Int Braz J Urol 2017;43:880–6.
[11] US Food and Drug Administration. Patient reported outcome measures: use in medical product development to support labelling claims. Guidance for Industry. Rockville, MD: US FDA; 2009.
[12] Department of Health. Equity and excellence: liberating the NHS. London, UK: The Stationery Office; 2010.
[13] Aaronson N, Alonso J, Burnam A, et al. Assessing health status and quality of life instruments: attributes and review criteria. Qual Res 2002;11:193–205.
[14] Assimos D, Krambeck A, Miller NL, et al. Surgical management of stones: American Urological Association/Endourological Society guideline, part I. J Urol 2016;196:1153–60.
[15] Penniston KL, Nakada SY. Development of an instrument to assess the health related quality of life of kidney stone formers. J Urol 2013;189:921–30.
[16] Tran Mgb, Sut Mk, Collie J, et al. Development of a disease-specific ureteral calculus patient reported outcome measurement instrument. J Endourol 2018;32:548–58.
[17] Ragab M, Baldin N, Collie J, et al. Qualitative exploration of the renal stone patients' experience and development of the renal stone-specific patient-reported outcome measure. BJU Int 2020;125:123–32.
[18] Lord FM. Applications of item response theory to practical testing problems. Hillsdale. NJ: Erlbaum; 1980.
[19] Rasch G. Probabilistic models for some intelligence and attainment tests (expanded edition). Chicago, IL: University of Chicago Press; 1980.
[20] Terwee CB, Prinsen CAC, Chiarotto A, et al. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. Qual Life Res 2018;27:1159–70.
[21] Raja A, Wood F, Joshi HB. The impact of urinary stone disease and their treatment on patients' quality of life: a qualitative study. Urolithiasis 2020;48:227–34.
[22] Rasch G. Probabilistic models for some intelligence and attainment tests. Copenhagen, Denmark: Danish Institute for Educational Research; 1960.
[23] Smith Jr EV. Metric development and score reporting in Rasch measurement. J Appl Meas 2000;1:303–26.
[24] The EuroQol Group. EuroQoL—a new facility for the measurement of health related quality of life. Health Policy (New York) 1990;16:199.
[25] Gandek B, Ware JE, Aaronson NK, et al. Cross-validation of item selection and scoring for the SF-12 health survey in nine countries: results from the IQOLA project. J Clin Epidemiol 1998;51:1171–8.
[26] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatrica Scand 1983;67:361–70.
[27] Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of a work productivity and activity impairment instrument. Pharmacoeconomics 1993;4:353–65.
[28] Joshi HB, Newns N, Stainthorpe A, MacDonagh RP, Keeley Jr FX, Timoney AG. Ureteral stent symptom questionnaire: development and validation of a multidimensional quality of life measure. J Urol 2003;169:1060–4.
[29] Smith Jr EV. Detecting and evaluating the impact of multidimensionality using item fit statistics and principal component analysis of residuals. J Appl Meas 2002;3:205–31.
[30] Granger CV. Rasch analysis is important to understand and use for measurement. Rasch Meas Trans 2007;21:1122–3.
[31] Hobart J, Cano S. Improving the evaluation of therapeutic interventions in multiple sclerosis: the role of new psychometric methods. Health Technol Assess 2009;13(12):1–200.

Please cite this article in press as: Joshi HB, et al. Urinary Stones and Intervention Quality of Life (USIQoL): Development and Validation of a New Core Universal Patient-reported Outcome Measure for Urinary Calculi. Eur Urol Focus (2021), https://doi.org/10.1016/j.euf.2020.12.011