

Urinary Stones and intervention quality of Life (USIQoL): Development and validation of a new universal patient reported outcome measure

H. Joshi^{1,2}, A. Raja,^{1,2} H. Teleb², D. Bratt³, S. Biyani³, S. Bolomytis⁴, B. Somani⁵, J. Philip⁴, F. Wood¹

¹ School of Medicine, Cardiff University, ² Department of Urology, University Hospital of Wales, ³ St. James's University Hospital, ⁴ North Bristol Hospital, ⁵ Southampton General Hospital UK

BACKGROUND

- Urolithiasis and many treatment options which can have significant impact on patients' health-related quality of life (HRQoL).
- There is a need for a valid patient reported outcome measure (PROM) to evaluate this impact and evaluate treatments.

AIMS

To develop 'Urinary stones and Intervention quality of life' (USIQoL), a universal multidimensional PROM, using modern methods, to serve as an outcome measure

MATERIALS & METHODS

- Adult patients with urinary (renal and ureteral) stones covering all index stone categories (AUA) asked to participate
- Phase 1 included literature review and qualitative research (semi-structured and focus group interviews 80 pts, 30 family members) with thematic analysis. This formed the foundation for the initial long draft of the USIQoL
- Phase 2 included cognitive debriefing, pilot testing (n=40) alongside review by a panel of healthcare professionals (EAU/AUA/BAUS, n=20)
- Phase 3 involved instrument calibration and fit assessments with Rasch (internal construct) analysis (partial credit model) and validity and reliability (external construct) assessments by administering to the patients in the different phases of treatments as well as no active treatments (235 patients)
- Patients also completed existing tools (SF12, EuroQoL, HADS, USSQ) to evaluate concurrent validity to develop the final draft of the measure.

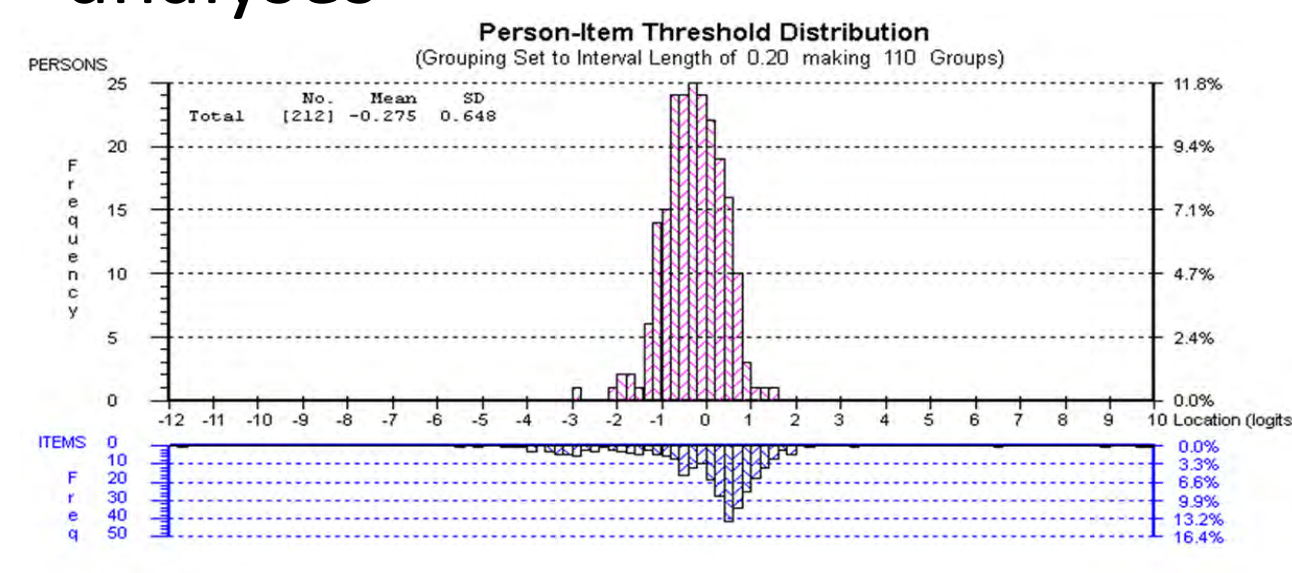
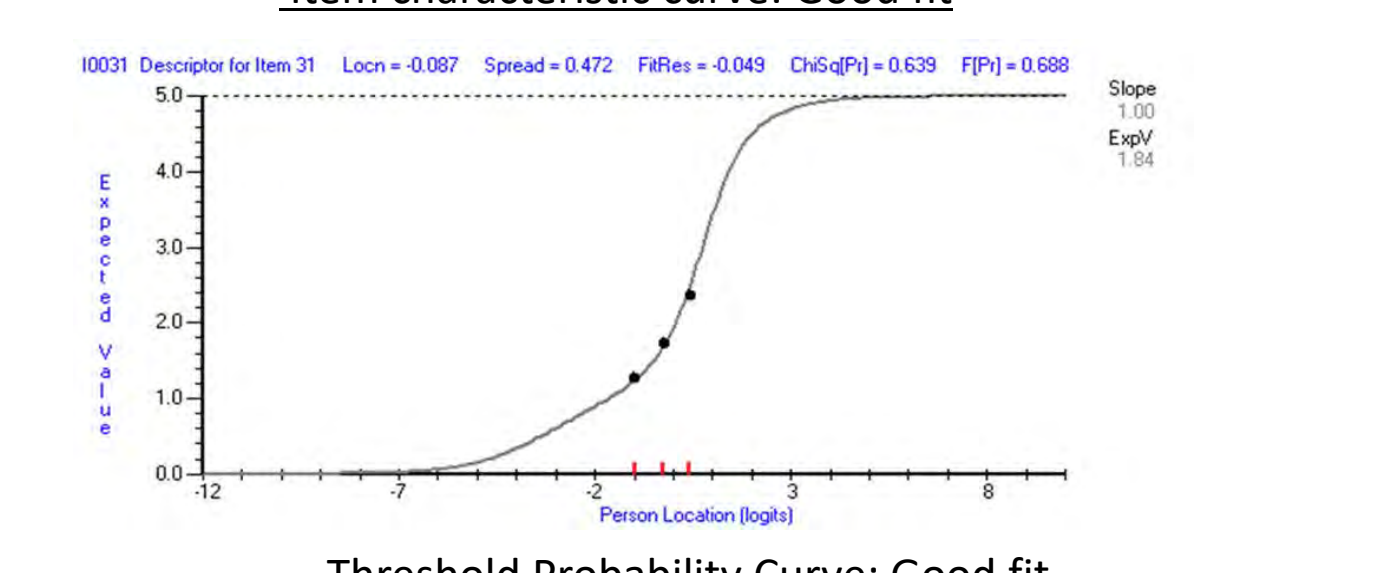
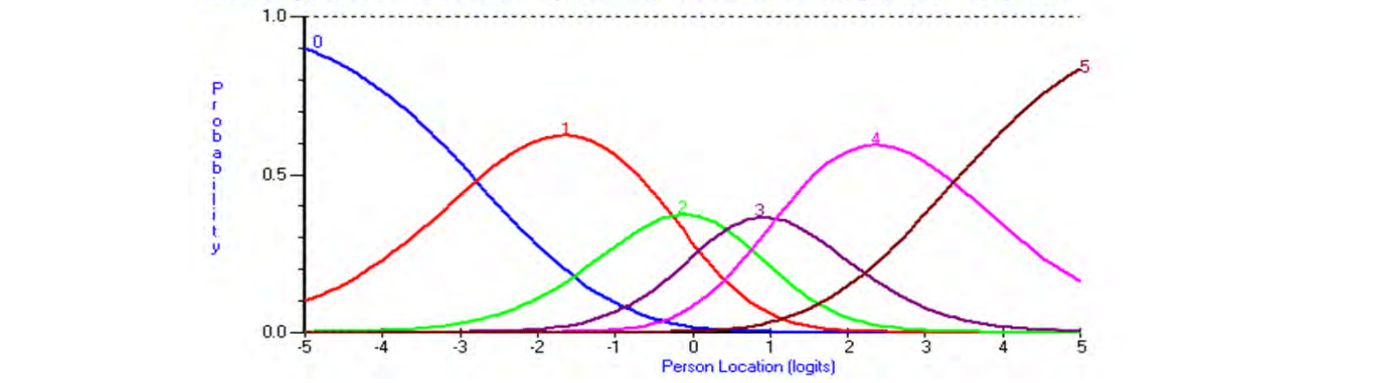
RESULTS

- Phase 1-2:** Stone disease and treatments have significant QoL impact
- Thematic analysis - Many domains affected
 - Construct map: USIQoL: Initial draft of 56 + 4 intervention specific questions
 - 7 Domains covered: Pain, Physical health, Psychological health, Sex, Social health and dependence, Work and career, Travel and leisure
 - Outcome space: Guttman scaling
 - Cognitive debrief : minor refinements
 - Expert review: Satisfactory coverage
- Phase 3:**
- Age: 52 yr. (range 18-92) - Sex: M (65%) : F (35%)
 - Site: Kidney (68%) : Ureter (32%)
 - Symptoms: Sympt (62%) : Min/Asympt (38%)
 - Previous stones: Yes (60%) : No (40%)

Internal Construct : Rasch analysis (Polytomous ext response category format)

Factors evaluated for the selection of items for the final draft:

- Item person interaction (item fit) – mean near 0 and std. dev. <2
- Power of test of fit and reliability indices ≥ 0.7
- Fit residuals: ≤ 2.5
- Person Item threshold distributions (e.g. graph below):
- Individual domain item assessments: Item characteristic curves and DIF analyses

- Tests of unidimensionality for domains: By equating t tests

- The new USIQoL measure is refined from 60 items to 20 items with good fit.
 - It has five sections covering domains of
 - Pain - Physical health - Work
 - Psychological Health - Social health
 - It has two formats (disease and intervention specific)
 - The scoring involves domain scores, derived from each item, converted to 0 to 100, based on the logit points.
 - Validated to cover all index stone patient categories as well as medical and surgical interventions.
- External validity:**
- Good item reliability and correlations with existing measures and using correlation coefficients
 - USIQoL Pain : EuroQoL /SF12 pain (0.6 – 0.8, p<0.01)
 - USIQoL Psychological health : HADS/EuroQoL (0.75, p<0.001)
 - USIQoL Physical Health: SF12/EuroQoL usual activities (0.6-0.85, p<0.01)

Urinary Stones and Intervention Quality of Life Measure (USI-QoL)

We are interested in knowing how your quality of life is affected by your **current urinary stone problems**. Please answer the following questions in order by ticking the appropriate boxes. If you feel a question is not applicable to you, please tick the 'N/A' column.

Hospital number: _____ Date of birth: _____ Today's date: _____

Please think about your current stone problems:

Pain:	No pain (1)	Mild (2)	Moderate (3)	Severe (3)	Unbearable (4)	N/A (0)
Q1. Since your current stone problems began and due to your stone(s), on average, how bad is your pain:						
Since your current stone problems began and due to your stone(s), how much do you suffer with	Not at all (1)	A little (2)	Quite a bit (3)	Very much (3)	A lot (4)	N/A (0)
Q2. Mild to moderate pain?						
Q3. Severe to unbearable pain?						

CONCLUSIONS

- Urinary calculi and their treatments have variable, but significant impact on HRQoL that influence treatment decisions
- The new USIQoL is a comprehensive valid PROM, developed using rigorous standards in measurement studies [internal construct (Rasch analysis) and external validity assessments].
- USIQoL will be undergoing application, field testing, revision and expected to serve as a standard PROM to evaluate impact of stone disease and treatments

Contact Information

Email: hrishijoshi@hotmail.com

