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. Bolomyitis4, B. Somanii5, J. Philip4, F. Wood1

1 School of Medicine, Cardiff University, 2 Department of Urology, University Hospital of Wales, 3St. James’s University Hospital, 4North Bristol Hospital, 5Southampton 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 (40 patients) 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): 7
- Individual domain item assessments: Item characteristic curves and DIF analyses
- Tests of unidimensionality for domains: By equating t tests

Phase 3a: Conduct validity assessments

- USIQoL Physical Health:SF12/EuroQoL usual activities (0.6-0.85, p<0.01)
- USIQoL Psychological health : HADS/EuroQoL (0.75, p<0.001)
- USIQoL Sexual health: SF12/EuroQoL usual activities (0.6-0.85, p<0.01)

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.