Overview

- How are LUTS and quality of life (QoL) assessed?
- Patient-centred questionnaire evaluation
- ICICI-Bladder Diary

Assessment of LUTS

What are we assessing?

Symptoms
- Frequency/severity/quantity

Impact on quality of life
- Generic health status
- Condition-specific
  - Everyday life
  - Specific aspects of life e.g. sex life

Methods of assessment

- Clinical history/schedules
  - Unstandardised
  - Unreliable
  - Underestimate impact on QoL
  - Clinician-centred

- Clinical measures/test results
  - Pad tests, urodynamic parameters
  - Objective, quantifiable
  - Clinical
Methods of self-report assessment

- **Bladder diaries**
  - Prospective record of episodes
  - Reduction in recall bias
  - Do not assess patient experience

- **Self-completion questionnaires**
  - Simple questions with fixed responses
  - Measure patient’s perception
  - Quantify symptoms and QoL impact
  - Practical, efficient, inexpensive
  - Precise (if validated!)

Why use self-report instruments

- Clinical measures and questionnaires measure different (but related) aspects of LUTS
- Valid questionnaires measure patient perspective

Robustness of self—report instruments

- **Validity** – does the questionnaire measure what it claims to measure?
  - have patients been consulted during the development stage to ensure pertinent concepts are captured?
- **Reliability** – does the questionnaire measure issues related to the concept in a consistent manner?
- **Responsiveness** – is the questionnaire sensitive to treatment outcome?

Suitability/feasibility

**Is the questionnaire suitable for its purpose and feasible to be used?**

- Comprehensiveness versus respondent burden
- Brief and easy versus over-simplification
- Detailed research versus rapid clinical evaluation
- Real time vs. recall
Guidelines for selecting instruments

- Select the instrument for the **purpose**
- Consider characteristics of the **population**
- **Acceptability** of burden on patients
- **Interpretability** – will it tell you what you want to know?
- Consider **practical** issues
- Use **recommended** questionnaires – don’t reinvent the wheel!

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- First ICI 1998 need was recognised for standardisation and consensus regarding assessment of all lower pelvic dysfunction
- ICIQ provides series of questionnaire modules that clinicians or researchers can select to their requirements
- Provide symptom and bother assessment

ICIQ self-report instruments

- All questionnaires fully validated
- Fifteen questionnaires and bladder diary available
- eICIQ currently being evaluated for psychometric robustness
- Widespread national and international use

Key ICIQ modules

- ICIQ-UI Short Form – urinary incontinence
- ICIQ-MLUTS – male LUTS
- ICIQ-FLUTS – female LUTS
- ICIQ-Bladder diary – male/female bladder events
- ICIQ-LUTSqol – QoL associated with LUTS
- ICIQ-N and ICIQ-Nqol - nocturia
- ICIQ-OAB and ICIQ-OABqol - OAB
Importance of fit for purpose

• Twiss et al, 2007. 26(1): 8-13 NUU
  Comparison of outcome measures following male perineal sling
  — 24 hour pad test
  — IPSS
  — ICIQ UI Short Form
  — PGI-I
• All parameters correlated except IPSS
  — Despite widespread use and general acceptability it was not fit for purpose

Bladder diaries

• Widely used for LUTS evaluation
• Often centre-specific instrument resulting in widespread variability of
  — Parameters
  — Format
• Little effort to standardise or validate prior to ICIQ-Bladder diary

Bladder diary nomenclature

• Micturition chart - times only of voids recorded for 24 hours
• Frequency-volume chart – volumes and times of voids for 24 hours
• Bladder diary - times and volumes of voids plus other info such as incontinence, fluid intake, pad usage

Content analysis (I)

• Bright et al 2012
• Regional diaries reviewed
• Qualitative interviews with diverse group of 27 potential respondents in clinic setting
• Clinical input from 30 multi-disciplinary HCP’s
• Four rounds of content validation
• Over 30 different parameters identified
Regional diaries

- All 16 were different
- 13 portrait, 3 landscape
- 10 single sheet, 6 booklet
- Duration 3-7 days
- Variety of parameters recorded

Content analysis (II)

- Portrait format
- Most important parameters
  - Time of void
  - Volume of void
  - Fluid intake
  - Time and amount of incontinence
- Other useful parameters
  - Bladder sensation
  - Pad use

Terminology

- Patient input essential for self-report instruments to inform terminology
  - ‘Pass urine’ preferred to ‘urinate’
  - ‘Leaks’ preferred to ‘incontinence’
  - ‘Toilet’ preferred to ‘bathroom’
  - ‘Drinks’ preferred to ‘intake’

Quantitative evaluation (I)

- Four hundred consecutive patients requested to complete four day diary
- 264 (66%) returned diary – valid tool for population
- Known theories were detected (construct validity)
  - More women than men reported incontinence
  - Increasing age of nocturic participants
Quantitative evaluation (II)

- Responses between bladder diary and symptom scores were compared (criterion validity)
  - Nocturia and incontinence most closely correlated
- 59 participants completed second four day diary (reliability)
  - Good to excellent agreement for all parameters

Quantitative evaluation (III)

- Fifteen patients undergoing SNS for DO completed pre and post-procedure diaries
  - Pilot study for responsiveness evaluation
  - Significant reductions detected:
    - 24 hour frequency
    - Daytime frequency
    - Nocturia
    - Incontinence episodes
    - Reduced bladder sensation scores

Quantitative evaluation (IV)

- Diary duration evaluated
  - 81% completed all four days
  - 94% of total four day variance explained by three day diary
  - Those reporting first episode of urgency increased with longer diary duration (98% by day 3)
  - Those reporting first episode of incontinence with longer diary duration (97% by day 3)

Final diary

- Three day diary
- Portrait
- Single A4 sheet
- Fluid intake and type
- Frequency
- Voided volume
- Time of incontinence
- Bladder sensation
- Pad use
Summary

- Complete patient assessment includes clinical and patient’s perspective
- Self-report instruments provide robust method to capture patient’s perspective
- Ensure instruments are fully validated and fit for purpose
- Use ICIQ modules where available (ICI 2013 recommendation)

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Thank you