59

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TESTING ACCURACY OF THE ICIQ-LUTS-C: A NEW INSTRUMENT TO SCREEN LOWER URINARY TRACT SYMPTOMS IN CHILDREN

Hypothesis / aims of study

Lower urinary tract dysfunction occurs in at least 5 % of the paediatric population. Children with lower urinary tract symptoms (LUTS) need to be diagnosed, quantification and monitoring of LUTS over time. Scores developed for adults are not suitable for use in children. A study to design a high-validation level instrument to screen LUTS in children is still under way, within the project of the International Conference on Incontinence Questionnaire (ICIQ) Committee. The study, which involves three European Centres, aims to preliminarily test accuracy of the ICIQ screener for LUTS in children (ICIQ-LUTSC).

Study design, materials and methods

Developing a screener based on subjective patient's judgment meets problems related to literacy and reliability of judgement. Possible solutions were either to design an instrument for children starting from the age of literacy and/or to rely on proxy judgement, namely carer's observations. Therefore, the ICIQ-LUTSC was designed in two versions: one for children (ICIQ-LUTSC-C) and another one for their parents (ICIQ-LUTSC-P). The two versions were developed simultaneously in 3 languages (English, Italian and German) through a standard cross-cultural adaptation process including double forward translation, backtranslation and cognitive debriefing. While items 1 and 2 of the instrument asked for age and gender of the respondent, specific ICIQ-LUTSC items investigated: 3. urinary tract infection; 4. nocturnal enuresis; 5. urinary incontinence; 6. daytime frequency; 7. urgency; 8. voiding postponement; 9. straining to void; 10. urge incontinence; 11. feeling of incomplete emptying; 12. bowel movements. While a total number of 360 cases test was statistically planned, a preliminary accuracy study on 136 children and their parents was undertaken. Fifty-two female and 84 male patients, averaged 9.3 (SD: 2.7) years, were recruited in a consecutive order among those attending urological or paediatric outpatient clinics, main inclusion criteria being age 5-18 years and exclusion criteria post-operative controls and uncontrolled insulin dependent diabetes. ICIQ-LUTSC was administered before doctors' or nurses' visit. Children and parents completed questionnaire separately and without any help from practitioners, in order to avoid interference and biases. The anonymous questionnaires were closed into an envelope and an identification number (IN) was assigned before the visit. At the beginning of the visit, clinicians completed a Case Report Form (CRF) describing children medical history that focused on LUTS. CRF was numbered with the corresponding IN. Before discharge, bladder diary (2-day, 3 night) was explained and given to children and parents. During a second visit, bladder diary (BD) were collected and children underwent urinalysis and flowmetry/PVR. Data from objective measures (BD, urinalysis, flowmetry/PVR) were reported on the CRF. Final clinician's judgement, based on CRF data, on whether the case was LUTS-positive (+) or LUTS-negative (-) and its severity (mild, moderate and severe) was made. Diagnostic accuracy testing consisted in the search for agreement between such judgement, taken as a gold standard, and the screener. Therefore, ICIQ-LUTSC-C and ICIQ-LUTSC-P scores was processed and matched to final clinician's judgement (taken as gold standard) in order to produce accuracy parameters, mainly sensitivity (SEN) and specificity (SPE). Initially, acceptability by the respondents of the two ICIQ-LUTSC versions was evaluated as percentage of missing items. Internal consistency was tested through Cronbach Alpha Index (threshold for acceptability > 0.7) and analysis of items distribution was performed to check the capability of each of the items to discriminate between LUTS + and LUTS -. In order to test what items were the best predictors of LUTS+ the percentage of variance of the overall score explained by each item was calculated by means of multiple step –wise regression analysis. Best performing items combination was selected by also checking score distribution cut-point where SEN and SPE were optimised. ROC curve was calculated in order to facilitate decision about the choice of appropriate cut-point. Finally, SEN and SPE of ICIQ-LUTSC-C and ICIQ-LUTSC-P were calculated (confidence interval 5-10%; level of confidence 95%). Data were also analysed by comparing performances of the screener on three groups of age, separately: 5-9 (n=82), 10-13 (n=44), 14-18 (n=10) years.

Results

According to objective measures, 34 children were detected as LUTS- and 102 as LUTS+, severity of LUTS being mild in 19%, moderate in 49% and severe in 32 % of children. Internal consistency was acceptable (Cronbach Alpha >0.7) for ICIQ-LUTSC-P and for ICIQ-LUTSC-C in the age group 14-18 years, only. A relevant percentage of missing items was found in ICIQ-LUTSC-C completed by children aged 5-9 years, thus suggesting a low rate of acceptability in questionnaire completion (Tab.1). By contrast item 9 (straining to void) was the only one relevantly missed by parents respect to the average missing rate of ICIQ-LUTSC-P (table 1). Analysis of items distribution did not show difference among LUTS+ and LUTS- as to item 3 and 12 by triggering so discussion about keeping or dropping then in the definitive version of the instrument. As to variance explained, the best predictors of LUTS+ were items 7 (40,7%), 9 (16,78%), 5 (13,52%), 4 (9,97%) of ICIQ-LUTSC-C and items 10 (52,97%), 7 (18,71%), 4 (9,52%), 8 (8,77%) of ICIQ-LUTSC-P. Scores 10-12 were suggested as optimal cut points by the ROC diagrams in the various sub-groups, by giving place to SEN and SPE reported in table 2.

Table 1: Analysis of missing items in the overall Questionnaire and age groups

% of Missing Items	5-9 years		10-13 years		14-18 years		Total	
	children	parents	Children	Parents	Children	Parents	Children	Parents
3	34,1	3,7	2,3	2,3	10	20	22,1	4,4
4	36,6	2,4	0	0	10	20	22,8	2,9
5	37,8	2,4	0	0	10	20	23,5	2,9
6	42,7	2,4	4,5	6,8	10	30	27,9	5,9
7	39	2,4	0	4,5	10	20	24,3	4,4
8	40,2	3,7	0	2,3	10	20	25	4,4
9	35,4	**8,5**	0	**20,5**	10	**40**	22,1	**14,7**
10	34,1	2,4	0	2,3	10	30	21,3	4,4
11	37,8	2,4	0	4,5	10	20	23,5	4,4
12	39	6,1	4,5	4,5	20	20	26,5	6,6
Mean	**38,2**	**3,5**	**1,3**	**4,9**	**10,8**	**24,2**	**24,3**	**5,5**

Table 2: Sensitivity and specificity in the overall questionnaires and in age groups

ICIQ-LUTSC	SENSITIVITY (%)	SPECIFICITY (%)
Children	**87,5**	**68,0**
• 5-9 years	74,5	66,7
• 10-13 years	75,0	66,7
• 14-18 years	83,0	85,7
Parents	**80,6**	**78,8**
• 5-9 years	83,3	64,3
• 10-13 years	71,4	93,3
• 14-18 years	Not evaluable*	Not evaluable*

* little number of respondent parents

Interpretation of results

ICIQ-LUTSC acceptability, SEN and SPE were better in parents and in children aged 10-13 years than those reported from children aged 5-9 and 14-18 years. The worst results reported from younger children can be explained with the problems related to literacy; therefore, younger children should be excluded. The low number of patients aged 14-18 years does not allow definitive interpretations. Even if some items (3, 12 and 9) should undergo appropriate reformulation, best items predictors of LUTS in parent's and children's version of ICIQ-LUTSC have been identified. The best predictors items of children are not the same of parents; this observation not only underlines a different symptoms perception between children and parents but also confirms the need of two differentiated screener versions.

Concluding message

Results of the ICIQ-LUTSC pre-test are encouraging. Parent's ICIQ-LUTSC version seems to be able to screen LUTS with an acceptable degree of accuracy at least when patients are lass than 13 years. It is presumable that the final test of ICIQ-LUTSC confirms accuracy of the children's version, with the exclusion however of younger children. The development of a short version (3-4 items) of the ICIQ-LUTSC should be considered in the future, which might be possible, identifying the best combination of predictors items.

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