466

De Gennaro M[1], Niero M[2], Capitanucci M L[1], Von Gontard A[3], Woodard M[4], Nijman R[5], Tubaro A[6], Oprandi N[2], Abrams P[7]

1. *Urodynamic Unit, Department of Nephrology and Urology, Ospedale Pediatrico Bambino Gesu',* ***2.*** *Department of Methodology, Università di Verona, Italy,* ***3.*** *Department of Paediatric Neuropsychiatry, University of Saarland, Germany,* ***4.*** *Department of Urology, Suthmead Hospital, Bristol, UK,* ***5.*** *Department of Paediatric Urology, University Hospital of Groningen, NL,* ***6.*** *Department of Urology, S. Andrea Hospital, Roma,Italy,* ***7.*** *Department of Urology, Southmead Hospital, Bristol, UK*

RELIABILITY AND VALIDITY OF ICIQ-CLUTS: THE FIRST SCREENING QUESTIONNAIRE FOR PAEDIATRIC LOWER URINARY TRACT SYMPTOMS

Hypothesis / aims of study

No validated instruments are to date available to screen lower urinary tract symptoms (LUTS) in children.Inside the International Conference on Incontinence Questionnaire (ICIQ) Committee,a screening questionnaire for paediatric LUTS (ICIQ-CLUTS) was developed simultaneously in 3 languages (English,Italian,German), involving 3 European Paediatric Centers. Methodology to construct validity and definitive validated version of ICIQ-CLUTS are presented.

Study design, materials and methods

Problems related to literacy and reliability of judgement are met developing a screener based on subjective patient's judgment. 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, ICIQ-CLUTS was designed in a version for children (ICIQ-CLUTS-C) and in a version for parents (ICIQ-CLUTS-P). The 2 versions were developed simultaneously in 3 languages (English,Italian,German) through a standard cross-cultural adaptation process.While items 1 and 2 of ICIQ-CLUTS asked for age and gender, specific items investigated:3.urinary tract infection; 4.nocturnal incontinence; 5.daytime incontinence; 6.daytime frequency;7.urgency;8.voiding postponement;9.straining to void;10.urge incontinence;11.incomplete emptying;12.bowel movements.Subjects were recruited in a consecutive order among those presenting for LUTS (case) or attending urological/paediatric outpatient clinics for different reasons (controls);post-operative controls and uncontrolled insulin dependent diabetes were excluded.ICIQ-CLUTS was administered before doctors' or nurses' visit. Children and parents completed questionnaire separately and without any help from practitioners.An identification number (IN) was assigned to ICIQ-CLUTS-C and -P before the visit.At the beginning of the visit,clinicians completed a Case Report Form (CRF) describing children medical and voiding history.CRF was numbered with the corresponding IN.Before discharge, bladder diary (BD) was explained and given to children and parents. During a second visit, BD were collected and children underwent urinalysis and flowmetry/PVR.Data from BD, urinalysis, flowmetry/PVR were reported on the CRF. Final clinician's judgement on whether the case was LUTS-positive (+) or LUTS-negative (-) and its type and severity was made based on CRF data.Diagnostic accuracy testing consisted of the search for agreement between such judgement, taken as a gold standard, and the screener. Therefore, in order to produce accuracy parameters (sensitivity and specificity), ICIQ-CLUTS-C and -P scores were processed and matched to final clinician's judgement (gold standard). Initially, acceptability and reliability of ICIQ-CLUTS-C and -P were evaluated as percentage of missing items and internal consistency (Cronbach Alpha Index ≥0.7) , respectively.Spearman's Rho was applied to test correlation between children 's and parents' answers. In order to test what items were the best predictors of LUTS+, percentage of variance of the overall score explained by each item was calculated by means of multiple step–wise regression analysis.ROC curve was calculated in order to facilitate decision about the choice of appropriate cut-point where sensitivity and specificity were optimised.Finally, sensitivity and specificity of ICIQ-CLUTS-C and -P were calculated (CI: 5-10%;level of confidence 95%).ICIQ-CLUTS was also tested in 3 age groups: 5-9,10-13,14-18 years.

Results

A total of 345 questionnaires (5-9 yrs:176; 10-14 yrs:132;14-18 yrs:38) were completed. Final clinician's judgement identified 147 children as LUTS- and the remaining 198 as LUTS+ (23 overactive bladder, 55 dysfunctional voiding, 14 mixed dysfunction, 33 monosymptomatic and 73 non-monosymptomatic enuresis).Severity of LUTS was mild in 23%, moderate in 53% and severe in 24 % of children. Percentage of missing items was low in ICIQ-CLUTS-C (5-9yrs:2.69%;10-13 yrs:0.77%;14-18yrs:1.94%;total:1.67%) and in ICIQ-CLUTS-P (5-9yrs:1.66%; 10-13 yrs:2.05%;14-18 yrs:3.24%;total:2.10%).Items relevantly missed by children and parents were items 6 (5-9 yrs:7.69%), 8 (5-9 yrs:4.81%), 12 (5-9 yrs:4.81%; 14-18 yrs: 5.56%) and items 6 (14-18yrs:5,88%), 9 (5-9 yrs:4.57%;10-13 yrs:7.52%; 14-18 yrs:8.82%), 10 (14-18 yrs:5.88%), respectively. Data on Cronbach alpha, Spearman's Rho and analysis of variance are shown in table 1, 2, 3, respectively. ROC diagrams, sensitivity and specificity are reported in figure 1.

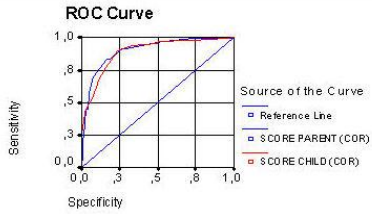
Table 1: Internal consistency (Cronbach alpha) of ICIQ-CLUTS

	Children				**Parents**			
	5-9 yrs	**10-13 yrs**	**14-18 yrs**	**Total**	**5-9 yrs**	**10-13 yrs**	**14-18 yrs**	**Total**
Alpha	**0,67**	0,70	0,76	0,71	**0,64**	0,69	**0,65**	0,69

Table 2: Correlation between children's and parents' answers

	Spearman's Rho			
Items	**5-9 yrs**	**10-13 yrs**	**14-18 yrs**	**Total**
3	0,266	0,391	0,363	0,363
4	**0,875**	**0,870**	**0,999**	**0,999**
5	**0,612**	**0,684**	**1,000**	**1,000**
6	0,404	0,448	**0,737**	**0,737**
7	0,400	0,385	**0,654**	**0,654**
8	0,484	0,481	**0,646**	**0,646**
9	0,362	0,555	0,397	0,397
10	**0,587**	**0,648**	**0,806**	**0,806**
11	0,534	0,362	**0,711**	0,711
12	0,407	0,546	**0,630**	**0,630**

Figure 1: Sensitivity and Specificity of ICIQ-CLUTS evaluated, respectively, in children's and parents' versions.



ICIQ-CLUTS	SENSITIVITY	SPECIFICITY
• Children	89%	76%
• Parents	91%	73.5%

Table 3: Analysis of Variance

	Pratt's Importance (Beta coefficient*Zero)	
Items	**Children**	**Parents**
3	0,068	0,070
4	**0,133**	**0,158**
5	**0,115**	**0,166**
6	0,059	0,050
7	**0,140**	**0,139**
8	**0,107**	**0,111**
9	0,096	0,056
10	0,087	**0,122**
11	**0,122**	**0,108**
12	0,072	0,021

Interpretation of results

Percentage of missing items and internal consistency confirms acceptability and reliability of ICIQ-CLUTS-C and –P, respectively. Worst results on both percentage of missing items and Cronbach alpha reported by children aged 5-9 years and by parents of children aged 14-18 years can be explained with the problems related to literacy and with the poor awareness of parents on voiding habits of older children.High degree of correlation (>50%) between children and parents answers was found for items investigating incontinence (4,5,10).Degree of correlation was very high for several items in age groups 14-18 years. These data are difficult to explain.Since a remarkable number of items was missed by parents of older children, we can speculate that parents chose to not answere doubtful items:consequently, the remaining answered items did correlate well with those of children.Items best predictors of LUTS+ were those investigating incontinence (4,5,10), urgency (7),voiding postponement (8) and incomplete emptying (11).Sensitivity and specificity confirm accuracy of ICIQ-CLUTS-C.

Concluding message

Data on acceptability, reliability and accuracy confirm ICIQ-CLUTS as a valid tool to screen LUTS in general paediatric population. Problems related to literacy were found in younger children. Therefore, children's versions of ICIQ-CLUTS is recommended only in children older than 9 years of age. ICIQ-CLUTS might be used to reconfigurate prevalence of LUTS in children, which was previously evaluated without validated instruments.

Specify source of funding or grant	**NONE**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Ethics Committee of Children's Hospital Bambino Gesu', Rome**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**