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PRELIMINARY TESTING OF A SCREENER FOR LUTS IN PAEDIATRIC PATIENTS: THE ICIQ-S

Hypothesis / aims of study

Diagnosis of the LUTS (lower urinary tract symptoms) is far from being easy in paediatric general practice. While symptoms of this disease are often confused with any of the various kinds of urinary infections, no diagnostic test is available to that purpose. The development of the ICIQ-S, an 8 item screener for the early diagnosis of the LUTS in general paediatric practice was therefore put under way by the ICIQ group, including researchers from urologic centres based in The Netherlands, United Kingdom, United States, Germany and Italy. The screener was developed in two versions: patient (10-14 years); parent (for patients 5-14). The ICIQ-S drafted in English underwent a systematic process of cross-cultural adaptation in the languages of the participating countries, consisting of double translation, backtranslation and cognitive debriefing on a small groups of parents and children (with and without urinary problems) in order to ensure the understandability and the acceptability of the questionnaire in the different languages. This contribution is relative to a preliminary testing held in Rome (Italy) aimed at providing pilot information on the ICIQ-S functioning.

Study design, materials and methods

The complete protocol will be run on a sample of 360 patients recruited in the participating centres in consecutive order, general inclusion criteria being age 5-14 (patients) and ability to complete a questionnaire (parents); exclusion criteria, besides patients' younger or older age, will be: attending ambulatory for post-operative controls and/or uncontrolled insulin dependent diabetes. The sample size should allow to produce estimates with confidence intervals smaller than ± 5% with level of confidence 95% for an expected sensitivity/specificity 80÷90%. The protocol also foresees that on the basis of a preliminary clinician's judgement patients will be assigned to two groups as to (1) high probability of having LUTS and/or (2) high probability of not having LUTS. After parents and/or patients will complete the ICIQ-S objective measures will be collected from the clinician as comparative standards, consisting of: urine sample; volume/frequency diary (3 nights-2 days analysis); wetting; enuretic episodes; flowmetry PVR and a final clinician's judgement on whether the patient has LUTS and on its severity. ICIQ-S scores will be processed in order to provide the following: sensitivity/specificity;Youden's J; predictive value both of positive/negative result; likelihood ratio of both positive/negative results; odds-ratio; ROC curves; Kappa for measuring agreement between parent/child questionnaires.

The preliminary testing was done on 23 patients, 13 females and 10 males of age averaging 9,87 from minimum 5.8 and maximum 14 years old. All patients were assigned to group 1 (likely to have LUTS). Protocol guidelines were followed as to blindness of questionnaire completion by parents and patients while objective measures were subsequently collected by the clinician. ICIQ-S scores were calculated for both parent and patient versions. Item-score Spearman's correlations were performed in order to test internal consistency. Correlations were calculated between parent-patient versions in order to check questionnaire versions agreement, while score averages were compared with clinicians' final blind judgements for a preliminary check of the possible sensitivity of the ICIQ-S to type and severity of LUTS.

Results

Three cases were dropped because of missing values in either of the questionnaires. After clinical exams, the 45% of the Italian sample reported a normal urinary frequency (4-7 times/day) while a 50% was over this threshold (from 8 on) and only a 4,5% were below (3 or less). The 43% had enuretic episodes. The 61% had no PVR while a 26% had a PVR of 10-30% EBC and a 13% >30% EBC. The voided volume ranges from 32 to 573ml (211,2 mean).

Physician's judgement classified all patients as having LUTS (except 1), ranging on two severity levels: mild and moderate.
ICIQ-S score range virtually from 0 to 25, while in the current cases score ranged 0-6 for patients and 0-7 for parents, averaging 3.150 the former and 3.50 the latter.
Separation between patients with mild LUTS and patients with moderate LUTS were 2,948 for the ICIQ-S patients and 2.188 for ICIQ-S parents.
Spearman's rho .702 was observed between parent-patient questionnaires.
The questionnaire showed to be friendly and easy to administer and was completed quickly both by patients and parents.
Scaling tests showed that the ICIQ-S could gain consistency from dropping some of the items.

Interpretation of results
The range of minimum and maximum score is still too narrow if compared with the virtual total range of the score. The ICIQ-S should then be tested more extensively also with severe cases. Some changes in item score calibration should be attempted.
Separation between different levels of severity shows to be acceptable, though a greater sample should be tested.

Concluding message
In depth data processing is ongoing, aimed at better calibrating items. The first result showed to be encouraging.

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