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Assessment of Pediatric Bowel and Bladder Dysfunction: a Critical Appraisal of the Literature

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Abstract

Purpose: Bowel and Bladder Dysfunction (BBD) is a clinical syndrome defined by the co-existence of constipation and lower urinary tract symptoms. Although BBD is a common condition in pediatric urology and can cause significant stress to patients/parents, clinical diagnosis of BBD has not been standardized. BBD instruments have gained popularity over the past decade to aid in diagnosis. In this review, we summarized the currently published BBD symptom questionnaires, and provide an analysis on their psychometric validation process.

Materials and Methods: We queried PubMed for articles on BBD symptom questionnaires/instruments/surveys since 2000. Two investigators (RYJ & MSK) conducted the search in duplicate. Our search was limited to English language. The included search terms were “dysfunctional elimination syndrome”, “bowel and bladder dysfunction”, “dysfunctional voiding”, “voiding dysfunction symptom score”, and “dysfunctional voiding symptom scale”. Reference lists of included studies were screened for missed studies. We also manually searched for unpublished abstracts presented at the following scientific meetings: the American Urological Association, the Society for Pediatric Urology, and the American Academy of Pediatrics Section on Urology. Exclusion criteria included articles in languages other than English, articles not related to BBD questionnaires, or articles not pertaining to pediatric patients.

Results: After initial search, a total of 54 articles were returned. Of the seven questionnaires reviewed, only one did not measure sensitivity or specificity. Almost all questionnaires showed excellent discriminative property with $AUC > 0.85$. Criterion validity was not reported in any of the questionnaires. Known-group validation was used as a common method to evaluate construct validity. Internal consistency was reported in 2 studies, and only 1 study measured questionnaire responsiveness during initial validation.

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No authors have any financial and personal relationships with other people or organizations that could inappropriately influence (bias) our work, including employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

Ethical Approval:

This protocol was reviewed by our Institutional Review Board and deemed to be exempt.

Conclusions: Although BBD is a common pediatric urology condition; a large amount of heterogeneity exists in the questionnaires' psychometric testing and validation process. To further improve the diagnosis and management of BBD in pediatric patients, there is a need for consensus on the gold standard questionnaire measure.

Introduction

Prevalence of bowel and bladder dysfunction (BBD) in pediatric urology clinics has been reported to be as high as 47%.^[1, 2] BBD is a clinical syndrome defined by the coexistence of functional constipation and lower urinary tract symptoms (LUTS).^[3, 4] Comorbid conditions associated with BBD include recurrent urinary tract infection (UTI), psychiatric & developmental disorders, and obesity^[5, 6], which can have major impacts on affected patients and their families. The diagnosis of BBD is typically based on patient history and physical exam. Secondary tests such as urodynamics and magnetic resonance imaging are often time-consuming, expensive, and must be individualized. To provide a more quantitative evaluation process, BBD symptom instruments have been created as a clinically useful tool to aid diagnosis and quantify the severity of BBD symptoms.

The instrument development methodology is very critical in the creation of a valid questionnaire. The initial step in any instrument development is identifying both a focused question and a target population. In BBD, it is important to consider whether parents, children, or both will be the respondents, as this will directly affect the language used. Second, a list of all comprehensive BBD related symptoms should be constructed. Family input should come from interviews with patients or parents affected by BBD. This is particularly important given that patients and parents are likely to emphasize different aspects of the disease as compared to the scientific literature or experts. Next, the styles of the instrument need to be decided such as single vs. multi-item scale or continuous scales (such as visual analogy scale) or categorical scale (such as Likert scale). After these factors are determined, the generated content needs to be translated into questions. In pediatrics, each question should address only one specific topic/symptom, as "double-barrel" questions should be avoided (e.g., "are you concerned or anxious about your child's bladder symptoms?" which may prompt a response about concern, anxiety or both). Lastly, in the final stage of instrument development, pre-test and field-testing are conducted.

Currently, there are seven published instruments designed to evaluate for the presence of BBD symptoms.^[7–13] Significant differences exist among these questionnaires, such as whether they are designed for a patient vs. parent respondent, their inclusion of bowel symptoms, phrasing/scoring, and the level of methodological rigor (i.e. validation) that went into their development. This variation and lack of "gold standard" can potentially limit the clinical and research application and utility of the tools.

The purpose of this review is to describe the existing BBD instruments in terms of their validation methods and clinical applications when appropriate.

Materials and Methods

Search Strategy

We searched MEDLINE, Embase, and Pubmed for English language studies indexed from 2000 to 2017 performed in patients 18 years or younger with BBD, including any gray literature. The included search terms were “dysfunctional elimination syndrome”, “bowel and bladder dysfunction”, “dysfunctional voiding”, “voiding dysfunction symptom score”, and “dysfunctional voiding symptom scale”. These terms were then restricted to articles retrieved under a second search for the exploded search terms “pediatric” or “child” or “children”. Reference lists of included studies were screened for missed studies. We also manually searched for unpublished abstracts presented at the following scientific meetings: the American Urological Association, the Society for Pediatric Urology, and the American Academy of Pediatrics Section on Urology.

Selection Criteria

All retrieved articles underwent a preliminary review. Only full text articles published in English were included. No article was excluded based on method of analysis, level of evidence, definition of success, perceived quality or susceptibility to bias. Level of evidence was assessed in accordance with the Centre for Evidence-Based Medicine guidelines as a surrogate marker of quality, and conflicts of interest were noted. In cases of ambiguity or where study reporting made evaluation difficult we attempted to err on the side of inclusiveness.

BBD instruments

We found seven published BBD instruments. We will discuss each of the instruments in detail in order of publication.

Dysfunctional voiding scoring system (DVSS)

In 2000, Farhat et al. published the first BBD-specific questionnaire. The DVSS is a 10-item instrument modeled after the international prostate symptom score (IPSS). The first 9 items define urinary and bowel symptoms and are targeted for patients aged 3–10 years. Question 10 examines the child’s domestic stress in the preceding month and is targeted for parents. Items 1–9 are scored on a 3-point Likert scale, and item 10 is binary. The total possible score is 30. A score at or above 6 for females (sensitivity 92%, specificity 87%) and 9 for males (sensitivity 80%, specificity 91%) indicates presence of BBD.^[10] The questionnaire has a reported AUC of 0.91 and 0.69 for females and males, respectively.

DVSS was the first instrument to aid in the diagnosis of BBD.^[7] Despite the high sensitivity and specificity of the score to predict BBD, a potential limitation persists with how the items were generated. DVSS items were amended from items in the adult IPSS. Although BBD and benign prostatic hyperplasia (BPH) produce some similar voiding symptoms, the underlying pathophysiology and population effected are different. This reduces the face validity of the DVSS. Furthermore, the omission of stool soiling as a symptom is significant and reduces the content validity.^[7]

Construct validity was assessed in the creation of the DVSS via known-group validation and showed good discrimination between controls and BBD patients. Because DVSS was the first published BBD instrument, its criterion validity was difficult to assess due to the lack of a “gold standard” instrument. Reliability measures (test-retest and responsiveness) were reported in two later studies.^[14, 15] Internal consistency has not been examined.

Since its development, the DVSS has been used to: investigate the relationship between constipation, LUTS, and nocturnal enuresis;^[16] the association between BBD and results of the child behavior check list;^[17] monitor improvement and resolution of VUR;^[18] survey of voiding dysfunction in attention-deficit/hyperactive disorder;^[19] predict uroflow;^[20] and was used in the randomized intervention for children with vesicoureteral reflux trial to quantify BBD.^[21]

Pediatric daytime urinary incontinence questionnaire (PDUIQ)

Sureshkumar et al. developed their 16-item pediatric urinary incontinence survey in 2001. Items address demographics, presence and severity of urinary symptoms, and family/UTI history. Questions were generated using a literature search and expert opinion, no patient/family input. Survey's target audience was the parents. The question items are in binary format, and focused on a more qualitative description of BBD as no specific scoring method was constructed. The instrument has been translated into five languages, and has good test-retest reliability with a mean correlation of 0.7.^[12]

The PDUIQ was evaluated only for its test-retest reliability. Although it demonstrated good test-retest reliability, other reliability and validity testing was not completed. Content validity is limited by the lack of constipation-related items. Discriminate validity was not evaluated which impairs the clinical utility of the instrument. Internal consistency and survey responsiveness have not been evaluated. It is worth noting that these authors developed a modified version of the PDUIQ in 2006 that focused more broadly on measuring risk factors for UTI and urinary incontinence. This modified version has excellent psychometric validation.^[22]

In clinical practice, the PDUIQ has been used to evaluate pediatric voiding habits in Finland.^[23]

Dysfunctional voiding and incontinence scoring system (DVISS)

Akbal et al. published the DVISS in 2005. The DVISS is a 13-item instrument that includes 1 QOL question. The first 5 questions are scored using an ordinal scale with the remainder in binary format. Question items were generated based on the International Reflux Study in Children. Parents are the target audience. The children aged 4–10 years in the questionnaire development. The DVISS scores are based on the estimated odds ratio (OR) for each question between cases and controls. For example, a score of 1 is given if the item's OR is between 2 and 10, and a score of 5 is given if the OR is greater than 50. The total score can range from 0 to 35 with a cutoff score of 8.5 having 90% sensitivity and specificity at detecting BBD.^[8]

The DVISS has good content validity but is incomplete, as it does not include the full spectrum of BBD symptoms by not evaluating the frequency or severity of constipation.^[7] In addition, it does not evaluate encopresis. Criterion validity has not been evaluated. Construct validity has not been evaluated. Reliability tests were not completed. The majority of questions are in binary format, and thus the discriminative property of each individual item is reduced.

DVISS has been used to evaluate the efficacy of biofeedback for treatment of dysfunctional voiding^[24] and to study the prevalence of daytime urinary incontinence in Turkish primary school children.^[25] One study found that DVISS did not correlate well with bladder diaries in children with nocturnal enuresis.^[26]

Questionnaire for Dysfunctional Elimination Syndrome (QDES)

In 2007, Tukgoz et al. developed a BBD instrument aimed to expand the literature in this field. The QDES is a 35-item instrument. Beyond BBD symptoms there are questions regarding UTI frequency, school performance, and stressful events. It is unclear how the individual items were developed. The instrument is divided into two parts: 21 multiple-choice questions to be completed by the child (mean age 8 years), and 14 Likert-scale questions designed for parents. Eight of the questions in the first part are also included in the second to evaluate the child's question comprehension. Construct validity was assessed through known-group validation (81 cases and 102 controls). A more concise, 15-question form of the instrument has also been published, with an AUC >0.6. The cutoff score for positive BBD is 4.5 for males (AUC=0.91; sensitivity 93%; specificity 78%) and 7.5 for females (AUC=0.95; sensitivity 87%; specificity 94%) in the concise version. The QDES displays discriminative ability.

The QDES lacks reliability testing and criterion validity.^[13] To our knowledge, the QDES has currently not been utilized in any published clinical studies.

Incontinence Symptom Index-Pediatric (ISIP)

In 2007, Nelson et al. developed a dysfunctional voiding instrument using robust methodology and psychometrics for older children. The ISIP includes 11 Likert-type items that probe stress, urge, insensate, and nocturnal urinary incontinence symptoms. It also includes questions regarding absorbent pad use. Items were modified from the Incontinence Symptom Index for Women by experts. The intended target population is children 11 years and older. For the validation process, two groups of children aged 11–17 years completed the survey. Construct validity was evaluated via known-group validation, and test-retest reliability was also assessed. The instrument has a mean score of 9.3 for those with BBD and 0.7 for healthy controls with a Cronbach's alpha of 0.84. In addition, the instrument has very good convergent validity of 0.81.^[11]

ISIP was a major step forward in BBD instrument development. The methodology is rigorous, and the validation process included both content and construct validity. ISIP is also the first instrument to evaluate both convergent and discriminant validity. Furthermore, reliability evaluation includes both test-retest and internal consistency.

Despite its merits, several limitations exist in the ISIP validation process. The instrument was only administered to a relatively small group of respondents during field-testing, 19 respondents per group. Perhaps more importantly, the ISIP's item selection is more specific to urinary incontinence in older children, and thus may not be suitable for younger age groups. In addition, it is not designed to evaluate the full range of BBD symptoms, as it does not include any bowel-related questions, which weakens its content validity. Regarding reliability testing, responsiveness is not assessed.

Cutoff scores and sensitivity/specificity were not initially reported. In 2010, De Gennaro et al. further evaluated the psychometric properties of ISIP and found excellent discriminative ability between children (sensitivity 89%; specificity 76%; AUC 0.89) and parents (sensitivity 91%; specificity 73.5%; AUC 0.9).^[27] Recently Olesen et al. used the ISIP to investigate the relationship between urinary continence and QOL in pediatric spina bifida patients.^[28]

Vancouver Symptom Score (VSS)

In 2009, Afshar et al. developed the VSS, a 13-item instrument using a combination of literature review, expert opinions, and family interviews. Similar to the ISIP, the developmental methodology is rigorous, but the VSS is more specific to BBD patients than ISIP. The instrument is targeted for patient completion in those aged 9 years or older; for younger children, parents answer instead. Each question is scored on a 5 point Likert scale (range 0 to 4) with score of 0 indicating no complaints and a score of 4 indicating maximum symptoms. All questions have the same weight. A cutoff score of 11 out of 52 has a sensitivity and specificity of 80% and 91%, respectively, at identifying BBD.^[7]

Face validity is assessed in a pretest group of 7 patients with voiding dysfunction. The VSS has good content validity as question generation was derived from expert opinion, patient interview, and literature review. Like other published BBD instruments, criterion validity is not evaluated due to the lack of gold standard BBD diagnostic criteria. Similar to ISIP, construct validity is evaluated via known-group association with the instrument administered to both a control and case group. Test-retest reliability is validated through instrument administration 1-week apart. Internal consistency is reported to be 0.445 indicating the heterogeneity of BBD. Although the VSS has good test-retest reliability with a correlation coefficient of 0.845, responsiveness was not assessed during the initial validation process.

Since its publication, physicians' experience with VSS utility in the clinical setting have been described.^[29] A Dutch version of the VSS has been validated by Hoen et al. using appropriate linguistic translation methodology. They found that the translated VSS showed good discriminative ability, moderate internal consistency, and moderate test-retest reliability. A score of 9 and 11 were set as cutoff scores for parent and patients, respectively.^[30] The VSS has been applied in clinical setting for evaluation of effectiveness of Miralax for pediatric urge symptoms, identification of BBD in children with normal renal anatomy and recurrent UTI, to evaluate the efficacy of bladder training video,^[31] and identification of LUTS in patients with Pompe disease.^[32–34]

Concise Lower Urinary Tract Dysfunction Symptom Scale in Children

In 2016, Ebiloglu et al. published a simplified version of the DVISS in order to provide a shorter instrument that is easier to understand by patients and parents.^[9] Using factor analysis, questions 1, 3, 8, and 10 on the DVISS were found to be correlated with a BBD diagnosis when compared to controls. The selected 4 questions had a high reported predictability with an AUC = 0.86. Questions 1, 3, and 10 have high sensitivity, while question 8 has a high specificity than the other questions in DVISS.^[9]

However, a key methodological limitation is the lack of comparison between the simplified scale and the original DVISS. Although the simplified instrument can detect a difference between patients with known BBD and healthy controls, it does not necessarily support whether the simplified version has better diagnostic utility than the original version. Furthermore, test-retest reliability and responsiveness were not included in their validation process.

BBD instruments: comparisons in the literature

There have been multiple direct comparisons between these instruments. Schneider et al. compared how well the DVSS, DVISS, and ISIP correlate with physician's clinical impression of BBD symptom severity (very mild, mild, moderate, and severe). The three questionnaires were given to a total of 71 subjects with LUTS. They found that all three instruments significantly correlated with physician's clinical impression of LUTS. DVSS had better correlation with physician clinical impression in younger children while the DVISS had better correlation with physician impression in parents. ISIP had the strongest correlation with physician clinical impression in older children.^[35]

In a similar study, Goknar et al. compared how well the ISIP and DVISS correlated with physician's impression of children with LUTS. They found that the DVISS had the best AUC (0.93–0.98) for LUTS compared to the children (0.87–0.91) and parental (0.84–0.88) versions of the ISIP. In addition, the DVISS had the best internal consistency with Cronbach's alpha = 0.81 compared to children ($\alpha=0.72$) and parental ($\alpha=0.74$) versions of the ISIP. However, this study was limited by 2 different clinician assessments of LUTS.^[36]

Altan et al. also compared the diagnostic utility among DVSS, DVISS, and ISIP. They found that DVISS had the highest diagnostic accuracy (89%) while the DVSS had the lowest (76%) compared to physician assessment of BBD. All three instruments appropriately demonstrated a change in score with responsiveness to treatment.^[37]

Future Directions for Instrument Development

Over the past decade, there has been a tremendous amount of interest and improvement in instrument development for BBD. Given BBD's symptom complexity, it is not surprising that significant heterogeneity exists among the published BBD instruments. None of the published questionnaires have carried out complete validity and reliability assessments, though several have been relatively well-vetted. This underlines the labor-intensiveness and difficulty of complete psychometric testing.

Based on our review, a few points are worth highlighting. None of the questionnaires tested criterion validity. This is not necessarily a limitation of the individual instruments, but rather a limitation imposed by the lack of a “gold standard” questionnaire for BBD. This finding underscores the need for the pediatric urology community to come to a consensus on a “gold standard” instrument for BBD similar to the IPSS used for BPH/LUTS in adults.

Second, only DVSS formally assessed reliability beyond test-retest measures; specifically only DVSS formally assessed instrument responsiveness. While this may be due to a lack of standardized treatment algorithms for BBD, this lack makes it difficult to evaluate any changes in a given patient’s clinical status. Furthermore, only 2 of the 7 instruments underwent assessments of internal consistency.

Furthermore, it is not only important to quantify BBD symptoms, but also to consider BBD symptoms’ bother and impact on patients’ QOL. Patients may have high scores and thus be diagnosed with BBD, but they may not be bothered by their symptoms. The importance of a “bother score” has been demonstrated, notably including the IPSS. Prior studies have found that a visual analog scale may be a reasonable approach to measure BBD symptom bother.^[38] Currently, there are two published QOL surveys on pediatric voiding dysfunction, one focused on enuresis and the other focused on bladder dysfunction.^[39–41] QOL related questions would be an important addition to BBD literature in the future.

In addition, the symptom of constipation is not adequately assessed in any of the instruments/surveys. For example, none of the instruments addressed encopresis, which can significantly impact patient/family’s quality of life. To improve future BBD symptom score development, expertise from pediatric GI literature is warranted such as the utilization of the Bristol stool chart or ROME constipation scale.

Finally, during instrument development, it is important to consider whether parents, children or both will be the respondents on the final instrument, as this will directly affect the language used. Questions targeted to elicit the presence of certain symptoms may be vexing for one audience versus another; thus it is crucial to define the target audience *a priori*. For example, older children may be able to better quantify their BBD symptoms and thus potentially improve the content validity of a questionnaire. Parental input is another important factor to consider. For example, certain BBD related symptoms may be quantified as “severe” by parents but have minimal effect on children. These factors can certainly affect a questionnaire’s validity and reliability.

Our review is limited by inclusion of only articles in English as BBD related survey in other languages could be omitted. However, the overall clinical impact of this limitation is likely marginal. In addition, given the heterogeneity of the BBD survey and reported results, it is not possible to conduct a formal meta-analysis. Finally, given the lack of consensus on any one specific BBD survey, the pros/cons of each survey stated in our review represent largely expert opinions. Long-term clinical data is needed to more objectively evaluate each individual instrument.

Although there has been significant improvement in BBD questionnaire methodology, ongoing refinement of these tools utilizing fundamental psychometric principals of

validation and reliability assessment is needed to further advance their clinical and academic utility.

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Appendix – Psychometric Terminology

1. Single-item instrument – a type of psychometric scale that consists of one question. These instruments are simple, fast, and provide a “bird’s eye” view of the condition of interest. (e.g. SF-1, basic quality of life scale).
2. Multi-item instrument – a type of psychometric scale that consists of more than one question. These instruments tend to be more reliable and less prone to random errors than single-item scales. (e.g. SF-36, International prostate symptom score).
3. Continuous scale – a type of psychometric scale where the scores are continuous variables. These types of scales can provide fine discrimination among individual responses. (e.g. Visual analog scale).
4. Categorical scale – a type of psychometric scale where the score is a categorical or ordinal variable. (e.g. Likert scale).
5. Validity – how well an instrument measures what it intends to measure; i.e., its accuracy.
6. Content validity – A type of validity that is defined by how well an instrument adequately addresses all facets of the problem it intends to measure.
7. Face validity – A type of validity that is defined by whether items in an instrument superficially appear to address the condition being studied. It is based on “expert opinion”, and is often being considered to have the lowest credibility of all validity measures.
8. Criterion validity – A type of validity that is defined by how well an instrument compares against the outcome of interest or a “gold standard”.
9. Concurrent validity – A type of criterion validity that refers to a comparison of the new instrument to one or more established instruments or measures at the same point in time.
10. Predictive validity – A type of criterion validity that refers to how well an instrument can predict future health states.
11. Construct validity – A type of validity that measures how well the instrument’s outcome is in line with the conceptual model of the condition being studied. This

relationship between the instrument and the conceptual model can be positive, negative, or null. If the relationship is positive, this is referred to as convergent validation. If the relationship is negative, this is referred to as discriminant validation.

12. Known-group validation – a validation method used to determine construct validity by administering the instrument to a group of subjects who are expected to score differently than the general population.
13. Reliability – A type of psychometric testing that determines the ability of an instrument to produce consistent results.
14. Test-retest reliability – a type of reliability that determines how well an instrument can give similar results when given to the same stable respondent.
15. Internal consistency – a type of reliability that determines how well individual items in an instrument are inter-related. It is typically measured using Cronbach's alpha.
16. Responsiveness – a type of reliability that determines how well an instrument can detect changes in a respondent's condition.

	Sensitivity	Specificity	AUC	Respondent	Content validity	Criterion validity	Construct validity	Test-retest	Internal consistency	Responsiveness
Farhat (2000)	80% for male; 92% for female	91% for male; 87% for female	0.91 for female; 0.69 for male	children 3–10 years; Q10 by parents	suboptimal - items based on IPSS; omission of stool soilage	Not tested	Yes; known-group validation	Yes	Not tested	Yes
Sureshkumar (2001)	Not tested	Not tested	Not tested	Parents	suboptimal - lacks constipation related questions	Not tested	Not tested	Yes	Not tested	Not tested
Akbal (2005)	90%	90%	0.96	Parents	suboptimal - incomplete bowel related questions	Not tested	Yes; known-group validation	Not tested	Not tested	Not tested
Tukgoz (2007)	93% for male; 87% for female	78% for male; 94% for female	0.91 for male; 0.95 for female	Parents and children	suboptimal - unclear how items were generated	Not tested	Yes; known-group validation	Not tested	Not tested	Not tested
Nelson (2007)	89% for child version; 91% for parent version	76% for child version; 73.5% for parent version	0.89 for child version; 0.9 for parent version	Children > 11 yrs	suboptimal - modified from symptom index for women	Not tested	Yes; known-group validation; convergent coefficient=0.81	Not tested	Yes; Cronbach=0.84	Not tested
Alshar (2009)	80%	91%	0.9	Children > 9 yrs and parents	optimal - lit. review, interview, expert opinion	Not tested	Yes; known-group validation	Yes	Yes; Cronbach=0.45	Not tested
Ehilogut (2016)	93.8% for male; 87.7% for female	78% for male; 94% for female	0.91 for male; 0.95 for female	Parents	suboptimal	Not tested	Yes; known-group validation	Not tested	Not tested	Not tested

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