



# The impact of a bladder training video versus standard urotherapy on quality of life of children with bladder and bowel dysfunction: A randomized controlled trial

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## Keywords

Urotherapy; Quality of life; Bladder bowel dysfunction; Children; Incontinence; Randomized controlled trial

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## Summary

### Introduction

Bladder and bowel dysfunction (BBD) can negatively impact the quality of life (QoL) of children. Urotherapy is an accepted treatment option for BBD; however, literature that examines the impact of management options on QoL in this population is scarce.

### Objective

To determine whether a bladder training video (BTV) is non-inferior to standard urotherapy (SU) in improving QoL in children with BBD.

### Methods

Children aged 5–10 years and who scored  $\geq 11$  on the Vancouver Non-Neurogenic Lower Urinary Tract Dysfunction/Dysfunctional Elimination Syndrome Questionnaire (NLUTD/DES) were recruited from a pediatric tertiary care center. Children were excluded with known vesicoureteral reflux; spinal dysraphism; learning disabilities; recent urotherapy; and primary nocturnal enuresis. Quality of life was evaluated using the Pediatric Incontinence Quality-of-Life questionnaire (PinQ). Questionnaires were administered at the baseline and 3-month follow-up clinic visits. Following centralized electronic blocked randomization schemes to guarantee allocation concealment, patients were assigned to receive SU or BTV during their regular clinic visits. An intention-to-treat protocol was followed. Between-group

baseline and follow-up QoL scores were compared using paired and unpaired *t*-tests, and linear regression analysis.

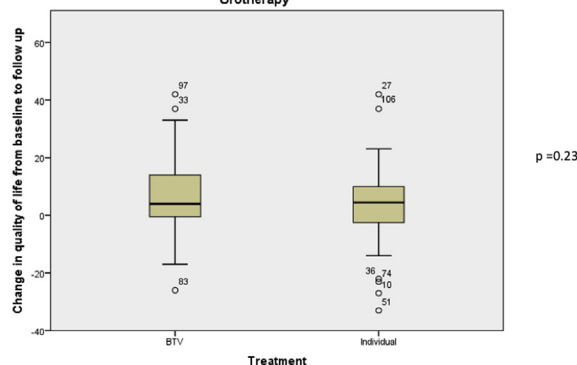
### Results

Of the 539 BBD patients who were screened, 173 (32%) were eligible, and 150 (87%) were randomized. Of these, 143 (96%) completed the study, five (3%) were lost to follow-up, and two (1%) withdrew. In total, 140/143 (97%) completed the QoL questionnaire at baseline and follow-up. Mean follow-up time was  $3.5 \pm 1.1$  months for BTV patients and  $3.7 \pm 1.6$  months for SU. At baseline, BTV and SU patients had a mean QoL score of  $26.6 \pm 13$  and  $23.8 \pm 12$ , respectively ( $P = 0.17$ ). Between-group mean change in PinQ scores from baseline was not statistically significant (BTV:  $6.25 \pm 12.5$  vs SU:  $3.75 \pm 12.2$ ;  $P = 0.23$ ; Summary Fig.). Significant predictors of positive change in QoL were: higher symptomatology score, with a correlation coefficient of 0.5 (95% CI: 0.2–0.9;  $P = 0.003$ ), and worse baseline QoL score, with a correlation coefficient of 0.5 (95% CI: 0.4–0.7;  $P < 0.001$ ). Overall, most patients had improved symptomatology and QoL scores.

### Conclusion

Significant and similar QoL changes from baseline to follow-up were observed in both the BTV and SU groups, suggesting that BTV was non-inferior to SU in improving QoL in children with BBD. Quality of life assessment should be considered when evaluating interventions for BBD, as it appears to be an important clinical outcome with which to determine urotherapy success.

Mean Change in Quality of Life from Baseline to Follow Up: BTV vs. Standard Urotherapy



Summary Figure Box plots of change in quality of life by treatment modality.

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## Introduction

Bladder and bowel dysfunction (BBD) is one of the most common conditions seen in pediatric urology outpatient clinics, accounting for >40% of referrals [1,2]. Bladder and bowel dysfunction represents a heterogeneous condition encompassing both lower urinary tract and bowel disturbances [3], triggering symptoms that can negatively affect a child's quality of life (QoL) [4–9]. While standard urotherapy (SU) is considered to be the primary treatment for BBD, the downside of this intervention is that it often requires repeated and lengthy clinic visits [3,10]. Standard urotherapy primarily consists of educational strategies provided to families, and includes information regarding normal lower urinary tract function, instruction on bladder training and healthy bladder and bowel habits, documentation of symptoms with diaries, and support and encouragement [3]. However, there is a clear need for alternative management options, which should be evaluated against this benchmark, that employ meaningful clinical outcomes.

The present paper reports on the secondary outcome of quality of life (QoL) as part of the bladder training video (BTV) trial, which sought to evaluate an animated BTV compared to standard individual urotherapy (SU) [11]. In the first paper, it was concluded that BTV was not inferior to SU in reducing bladder/bowel symptoms in children aged 5–10 years, and such an educational tool may be an alternative modality to deliver conservative-based urotherapy consistent with the International Children's Continence Society terminology [3,11].

Measurement of quality of life (QoL) provides a holistic assessment from the child's perspective of the impact that BBD has on their daily life [12,13]. Quality of life is recognized as an important health outcome measure in clinical practice and pediatric studies [7,14–17]. In addition to having a negative effect on self-esteem, family and peer relationships, BBD has been shown to be a source of shame and embarrassment for children [5,9]. Despite the recognized need to measure QoL in children with BBD, this variable is not routinely captured. A survey of pediatric continence experts found that 94% of respondents identified a need for routine QoL assessments in children with BBD; however, this was carried out less than one quarter of the time [15]. Indeed, one of the main reasons to devote resources and time to address BBD is to improve QoL and minimize adverse impacts on self-esteem and family life. When a change to SU modality is considered, it is proposed that QoL be considered as an important outcome measure to ensure that the newly proposed modality is comparable to the established norm.

It is believed that the value of an animated educational video on the QoL of children with BBD has not been previously studied. This represents an interesting, novel and theoretically cost-effective intervention for BBD management. Therefore, as part of the BTV trial, the impact of a 7-min animated BTV versus SU on QoL was evaluated in school-aged children with BBD. The hypothesis was that BTV would be similar in improving QoL compared to SU, and that an improved quality of life score would correlate with a lower BBD symptomatology score.

## Methods

### Design

This study was conducted as a post-hoc analysis of a secondary outcome in the setting of a non-inferiority randomized trial. The study design and methods have been previously reported in detail [11] and the trial was registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (#NCT01915004). The primary outcome of the trial was to determine the non-inferiority of BTV in improving symptomatology scores. Changes in QoL were measured as a secondary outcome. The present paper is an extension of the BTV trial [11], and focuses on the impact on QoL.

### Setting, population, and inclusion/exclusion criteria

After receiving institutional Research Ethics Board approval, a non-inferiority RCT was conducted at the tertiary care center. All children aged between 5 and 10 years and referred to the pediatric urology clinic between August 2014 and November 2015 for symptoms consistent with BBD (i.e. urinary incontinence, recurrent UTI, frequency and urgency, constipation, and other lower urinary tract symptoms) were screened ( $n = 539$ ). Children younger than this age range, patients who scored  $\leq 11$  on the Vancouver Non-Neurogenic Lower Urinary Tract Dysfunction/Dysfunctional Elimination Syndrome Questionnaire (NLUTD/DES) [2], those with primary monosymptomatic nocturnal enuresis, VUR, high-grade Society of Fetal Urology (SFU) (III/IV) hydronephrosis [18], underlying neuropathic bladder dysfunction, a diagnosed learning disability, and those who had received urotherapy in the past 6 months were excluded ( $n = 366$ ). Of the remaining 173 eligible patients, 150 were enrolled into the study. The main reasons for declining to participate in the study were lack of interest in being part of a research study and concern that participation would make the clinic visit too long ( $n = 23$ ) (Fig. 1).

### Randomization, allocation concealment, and blinding

Participants were randomized with an equal (1:1) chance of allocation to BTV ( $n = 75$ ) or SU ( $n = 75$ ). The trial biostatistician developed a computer-generated randomization scheme with random blocks of four, six and eight children to ensure that groups were balanced for baseline characteristics. REDCap (Research Electronic Data Capture) web-based application was used to ensure allocation concealment (<https://catalyst.harvard.edu/services/redcap/>). Due to differences in the intervention, participants and their parents, pediatric urologists, nursing personnel, and research assistants were not blinded to the intervention; however, the study's biostatistician and outcome adjudicators were.

Although clinicians were aware of treatment allocation, results of the QoL questionnaire were not included in the

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