A Pilot Randomized Controlled Trial Evaluating the Effectiveness of Group vs Individual Urotherapy in Decreasing Symptoms Associated with Bladder-Bowel Dysfunction

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Purpose: We determined the feasibility of a definitive trial comparing the effectiveness of group vs individual urotherapy for children with bladder-bowel dysfunction.

Materials and Methods: Children 6 to 10 years old with bladder-bowel dysfunction were recruited during the course of 1 year. Feasibility data on screening, eligibility, recruitment and protocol compliance rates were collected. Patients with high grade hydronephrosis, vesicoureteral reflux or learning disabilities and those who had previously undergone urotherapy were excluded. Patients were randomized to 1-hour group urotherapy or 15-minute individual urotherapy. Symptoms and quality of life were measured using the Vancouver Nonneurogenic Lower Urinary Tract Dysfunction/Dysfunctional Elimination Syndrome Questionnaire and the Pediatric Incontinence Questionnaire at baseline and at 3 to 6 months of followup. Within/between group comparisons were conducted using t-tests.

Results: Of 455 screened children 79 were eligible and 60 were recruited to participate. A total of 24 patients randomized to group urotherapy and 25 randomized to individual urotherapy completed the pilot trial (6 undergoing group and 5 undergoing individual urotherapy withdrew from the study). Symptomology scores between group and individual urotherapy were not different at followup (mean $\pm$ SD 14.7 $\pm$ 7.9 vs 13.4 $\pm$ 6.3, p = 0.54, 95% CI −5.4−2.8). Quality of life scores between patients undergoing group and individual urotherapy at baseline differed (mean $\pm$ SD 21.1 $\pm$ 10.8 vs 31.0 $\pm$ 14.3, p <0.01, 95% CI 2.7−7.3) but became similar at followup (21.0 $\pm$ 14.2 vs 20.1 $\pm$ 15.3, p = 0.84, 95% CI −9.4−7.6). Within group analyses demonstrated improvement in symptomology from baseline to followup in patients undergoing group (mean $\pm$ SD 3.6 $\pm$ 7.6, p = 0.03, 95% CI 0.4−6.8) and individual urotherapy (6.0 $\pm$ 5.4, p <0.01, 95% CI 3.8−8.3). Within group quality of life analyses revealed improvement in Pediatric Incontinence Questionnaire scores from baseline to followup in patients undergoing individual urotherapy (p <0.01, 95% CI 5.0−16.9) only.

Conclusions: Urotherapy, regardless of modality, effectively improved bladder-bowel dysfunction symptoms. A definitive randomized controlled trial is feasible, considering that a high recruitment rate (76%) for this population has been established.

Key Words: child, elimination disorders, enuresis, patient education as topic, randomized controlled trial

Abbreviations and Acronyms

BBD = bladder-bowel dysfunction
GU = group urotherapy
IU = individual urotherapy
PinQ = Pediatric Incontinence Questionnaire
QoL = quality of life
RCT = randomized controlled trial
UT = urotherapy

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UROTHERAPY, or bladder retraining, is a widely accepted form of treatment for nonneurogenic lower urinary tract dysfunction and dysfunctional elimination syndrome, also called bladder-bowel dysfunction. Urotherapy combines behavior modification and constipation management.[1] Daytime urinary incontinence, a common symptom of bladder-bowel dysfunction, is observed in about 17% of school-age children.[2] Due to the relatively high prevalence of bladder-bowel dysfunction in children, various studies have examined the impact of urotherapy in pediatric populations and have shown it to be an effective treatment option.[3–9]

Alternative methods of providing urotherapy, such as in group sessions, have also been examined.[7,10] A retrospective study demonstrated a 76% success rate with UT in small groups of 2 to 5 children with BBD and urinary incontinence.[7] In another study the training of children with BBD in pairs for a half day resulted in improved bladder emptying.[10] These studies provide insight into new possibilities for UT provision in a clinical setting. In busy clinical settings it is difficult to allocate long periods to delivering individual urotherapy to patients with BBD, making group urotherapy a potential option that could have cost saving implications.[7,10]

Urinary incontinence associated with BBD is often considered a source of shame and embarrassment for the child. Not only are self-esteem, school performance and social competence negatively impacted in this clinical scenario, but the level of parenting stress is also greater than in families whose children do not have BBD.[11] Unfortunately clinicians do not often evaluate these nonclinical effects of BBD.[12] Understanding the relationship of BBD and quality of life, and how it is affected by UT, from the perspective of the child has not been studied previously.

Due to the paucity of high quality research on the various UT modalities, in this pilot randomized controlled trial we examined the feasibility and preliminary effectiveness of a 1-hour group urotherapy session compared to standard individual urotherapy in decreasing BBD symptoms, as well as their impact on quality of life of children 6 to 10 years old. Our objectives were to assess the feasibility of conducting a definitive randomized controlled trial by establishing realistic recruitment and followup rates, in addition to determining the practicality of using the Vancouver Questionnaire and PinQ to measure BBD symptoms and quality of life from the perspective of the child. We hypothesized that children who participated in group urotherapy sessions would score lower on followup on both questionnaires, ie would exhibit greater improvement of their BBD symptoms and QoL over patients undergoing individual urotherapy.

MATERIALS AND METHODS

In this randomized controlled pilot trial we used pretest and posttest questionnaires to assess the feasibility and preliminary effectiveness of GU vs IU in children with BBD. The study was approved by the research ethics board (No. 12-089).

Population

Patients 6 to 10 years old with BBD were prospectively screened and recruited from outpatient urology clinics at a tertiary pediatric hospital. We excluded patients with high grade (Society for Fetal Urology grade III or IV) hydronephrosis, vesicoureteral reflux or learning disabilities and those who had undergone UT in the preceding 12 months.

Randomization, Allocation Concealment and Blinding

Participants were allocated using 1:1, 2-6 blocked randomization tables to either a 1-hour GU session or a 15-minute IU session. Randomization sequence was generated by an independent biostatistician. A third party research associate, not involved in the trial, was responsible for randomizing each patient and reporting allocation to the trial research staff after eligibility was confirmed and informed consent obtained. Outcome assessors were blinded to treatment allocation. The results of the questionnaires were not included in the medical record and remained unknown to the clinician(s)/researcher(s).

Outcomes

BBD symptoms and QoL were evaluated in this pilot trial. BBD symptoms such as incontinence, urgency, frequency, dysuria, hesitancy, straining and constipation were measured using the Vancouver Questionnaire.[13] This questionnaire is a 14-item, 5-point Likert scale instrument revealed to be valid and reliable for children 4 to 16 years old (median 8) with BBD.

PinQ was used to measure 6 domains of QoL, ie social, self-esteem, family, body image, independence and mental health. This tool has shown high reliability under test-retest conditions in children 6 years or older.[14] Both questionnaires were completed at baseline and at followup visit by the child, under the guidance of a research assistant, with limited input from parents/guardians.

Intervention

Curriculum for the UT session included anatomy and physiology of the urinary tract system, bladder retraining, progressive relaxation and the psychosocial aspects of BBD. Pediatric urologists, urology residents and pediatric nurse practitioners provided IU as part of the standard of care within the clinic. A checklist and patient education handouts were used to ensure that the content in each IU session was consistent and similar to the GU session. One of the nurse practitioners did not provide IU to the pilot trial participants since she was responsible for conducting the GU sessions. GU sessions were held in the evening and were offered as soon as 2 or more recruits had been allocated to the GU arm of the pilot trial. Standardized timing of implementation of the intervention was determined a priori, to occur within 6 weeks of informed consent date.