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Objective versus subjective outcome measures of biofeedback: What really matters?

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Abstract *Objective:* Clinical epidemiologic studies suggest that once established, voiding dysfunction can become a lifelong condition if not treated correctly early on in life. Biofeedback is one component of a voiding retraining program to help children with voiding dysfunction. Our goal was to compare objective non-invasive urodynamic data obtained during office biofeedback sessions with patient reported voiding symptom scores.
Methods: Charts of 55 children referred in 2010 for pelvic floor muscle biofeedback therapy for urinary incontinence were retrospectively reviewed. Patients with any anatomic diagnoses were excluded. Forty-seven (86%) females and eight males (14%) with a mean age of 8.2 years made up the cohort. Uroflow curves, voided volumes, and post-void residuals were recorded at each visit and served as objective data. Volumes were normalized as a percentage of expected bladder capacity according to age. The patient reported symptom score and patient reported outcome (improved, no change or worse) served as subjective measures of intervention.
Results: The primary referral diagnoses were day and night wetting in 37 (67%) and daytime incontinence in 18 (33%) children. A history of urinary tract infection (UTI) was noted in 32 (64%) patients, and 25% were maintained on antibiotic prophylaxis during the study period. Twenty-nine percent were maintained on anticholinergic medication. Patients attended an average of 2.5 biofeedback sessions. Voided volumes and post void residual volumes were unchanged, 50% of the abnormal uroflow curves normalized over the course of treatment ($p < 0.05$). Patient reported symptom score decreased from 12.8 ± 5.6 to 8.0 ± 6.5 ($p < 0.002$) over an average follow-up time of 276 days reflecting fewer daytime voiding symptoms. There was no significant change in the patient symptom score component for the nighttime wetting. Patient-reported outcomes at the final session of biofeedback were rated an improved in 26 (47%), no change in 15 (27%), worse in three (5%) patients, and not rated in 11 patients (21%).
Conclusions: Pelvic floor muscle biofeedback is associated with patient-reported improvement in symptoms, reduction in voiding symptom score, and normalization of uroflow curves, but

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these improvements are not correlated with objective parameters of voided volumes and post-void residual urine obtained during office visits for biofeedback. It is important to identify the most relevant outcome measures for BFB, as insurance coverage for medical interventions that cannot offer outcomes analysis that demonstrates a benefit for the patient will eventually be eliminated.

Introduction

Voiding dysfunction and urinary incontinence are among the most common conditions for which children are referred to a pediatric urologist. Clinical evaluation and treatment of these patients consumes a great deal of time and resources, and requires commitment and considerable effort for a parent to bring the child to the clinic for frequent visits. Epidemiologic studies [1] and experimental evidence from mouse models of voiding dysfunction [2] suggest that, once established, voiding dysfunction can become a lifelong condition if not treated early in life. It is therefore important to identify optimal clinical management and outcome measures for this condition to allow for the best allocation of office and healthcare system resources.

Pelvic floor muscle training through biofeedback (BFB) is one component of a voiding retraining program aimed at helping children with voiding dysfunction when pelvic floor overactivity is the underlying cause [3]. BFB, along with focused nurse teaching involving body awareness and voiding education, is a non-invasive, interactive modality aimed at retraining the child's awareness of pelvic floor activity during the voiding cycle, with the goal of sustaining pelvic floor relaxation during voiding. There is wide variation in BFB protocol including the recommended number and timing interval of sessions associated with successful outcomes. Objective outcome measures of BFB include urine flow rate curves, post-void residual (PVR) urine, maximum voided volumes and pelvic floor electromyogram (EMG) tracings. Recent studies have called into question the best outcome measures for this modality. While subjectively continence may be achieved following BFB, objective improvements in uroflow parameters and PVR have not always been reported after BFB sessions [4].

Patient-reported symptoms and outcomes are intended to complement clinical and physiologic assessments and are fast becoming incorporated into patient-centered models of care. Patient-reported outcomes may be the quintessential measure when a condition lacks a more apparent outcome measure. A validated pediatric voiding symptom score tool may be used to assess lower urinary tract symptoms [5–7] at baseline and throughout treatment so that subjective changes in symptoms can be measured. Identifying the best outcome measure for an intervention is critical to determining its value for both patients and payers.

In an effort to understand how objective and subjective outcome measures of BFB compared in patients in our practice setting, a cohort of pediatric patients with voiding dysfunction and urinary incontinence who underwent BFB training was reviewed. Our goal was to compare objective non-invasive urodynamic data obtained during office BFB sessions with a parent-completed voiding symptom score and parental impression of outcomes.

Materials and methods

Patients

Charts of children referred for BFB for urinary incontinence associated with dysfunctional voiding between January and December 2010 were retrospectively reviewed. Patients with neuropathic bladder or anatomical pathology were excluded from this review, as were patients who did not complete a voiding symptoms score. The charts of 55 children enrolled in the CHOP IRB-approved urology registry were included in this review. All data were collectively reviewed by the authors but entered and maintained in a RedCap database by the study coordinator; from this a de-identified data set was then used for statistical analysis.

All patients underwent evaluation including history, physical examination, uroflow and PVR measurements. Each patient and/or parent completed a Pediatric Lower Urinary Symptom (PLUS) score at the initial visit and at each treatment visit. The presence of UTIs was noted. The diagnosis of dysfunctional voiding was based on symptoms and demonstration of abnormal or notched uroflow pattern and/or significant PVR urine. When present, constipation was treated before starting BFB. All patients were initially treated with conservative therapy including bowel management, body education, instruction in proper hydration and timed voiding. If compliance with these measures failed to improve symptoms or abnormal flow parameters, patients were referred for BFB. Patients with recurrent UTIs were generally referred for BFB after their second clinic visit if their PLUS score failed to drop with conservative measures. Select patients were started on anticholinergic therapy and those with recurrent UTIs were offered antibiotic prophylaxis.

Pediatric lower urinary symptom score

Originally published at the Dysfunctional Voiding and Incontinence Symptom Score [7], this 14-item measure is a validated survey of empirically derived symptoms of voiding dysfunction. This self-assessment instrument completed by the parent and/or child, measures the frequency and severity of day and night wetting and the presence or