

Background. The European Bladder Dysfunction Study (EBDS) is a multi-center prospective study, comparing treatment plans for neurologically normal children with bladder-sphincter dysfunction. In Branch I of the EBDS, children with urodynamically proven urge syndrome (detrusor overactivity during filling of the bladder) are randomly allocated to either bladder rehabilitation with biofeedback or pharmacotherapy. In Branch II, children with urodynamically proven dysfunctional voiding (pelvic floor overactivity during voiding) are randomly allocated to either standard therapy or bladder rehabilitation with biofeedback. In both Branches, all children receive standard textbook therapy, with the randomly allocated EBDS treatment plans added as interventions, on an out-patient basis.

Outcome is assessed with a clinical as well as a urodynamic score, and investigations for both scores are performed before and after the 6-month treatment period; follow up thereafter covers 1 year.

Methods. Clinical scores are obtained with a questionnaire on voiding and wetting, voiding diaries, follow-up notes, post-void residuals and the incidence of urinary tract infections.

Urodynamic studies consist of continuous registration of bladder pressure, abdominal pressure, pelvic floor electromyogram (EMG), and urine flowrate, during at least 2 cycles of filling and emptying of the bladder. The urodynamic score is derived from detrusor activity, pelvic floor activity, and cystometric bladder capacity.

Standard therapy consists of low-dose chemoprophylaxis and treatment of constipation whenever indicated, complemented with elaborately standardized sets for explanation of the bladder-sphincter dysfunction problem and for instructions how to cope with it. There are separate sets for Branch I and Branch II.

Pharmacotherapy is double blinded, either oxybutynine-HCl or placebo, 0.3 mg/kg bodyweight per day.

Standardized bladder rehabilitation with biofeedback has urine flowrate/EMG recordings displayed on-line on a personal computer as biofeedback, and consists of at least 12 sessions of 3 hours each.

Results. Since mid-1995, 216 children have been enrolled in the EBDS, 97 in Branch I, 104 in Branch II, and 15 with non-groupable bladder-sphincter dysfunction. Clinical results for the children who passed the 6-month follow-up mark are tabulated below, for Branch I and Branch II, in the categories 'cured', 'same' and 'worse'.

Clinical outcome Branch I (64 patients, 33 still in follow up)

Clinical outcome Branch II (59 patients, 45 still in follow up)

| | cured | same | worse | | cured | same | worse |
|-----------------|----------|----------|---------|----|----------|----------|--------|
| Biofeedback | 9 (39%) | 11 (48%) | 3 (13%) | 23 | 20 (59%) | 12 (35%) | 2 (6%) |
| Pharmacotherapy | 23 (56%) | 16 (39%) | 2 (5%) | 41 | 18 (72%) | 6 (24%) | 1 (4%) |
| Total at T12 | 32 (50%) | 27 (42%) | 5 (8%) | 64 | 38 (64%) | 18 (31%) | 3 (5%) |

With the χ^2 -test (Mantel-Haenszel), no statistically significant differences in outcome emerge between bladder rehabilitation and pharmacotherapy in Branch I, neither between the outcome of standard therapy and bladder rehabilitation in Branch II. This overall conclusion will not change when the patients still being followed pass their 12-months follow-up marks.

This conclusion strongly supports the hypothesis that the EBDS module for standard therapy contains the key for success. Adding pharmacotherapy or bladder rehabilitation with biofeedback does not significantly improve the outcome. With standard therapy alone, approximately 65% of neurologically normal children with bladder-sphincter dysfunction can be cured.

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12

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| ALPHA-ADRENERGIC BLOCKADE IN CHILDREN WITH VOIDING DYSFUNCTION |

Aims of Study: Inadequate bladder emptying is a common urinary dysfunction encountered in children and the therapeutic benefits of alpha blockers on lower urinary tract symptoms in adults with bladder outlet obstruction are well established. Because of the promising impact of alpha blocker therapy, the aim of this study was to investigate the potential benefits of selective alpha blocker therapy to improve bladder emptying in the pediatric population.

Methods: Twenty children with documented poor bladder emptying ranging from 3 to 15 years of age (mean 8 y.o.) were treated with the alpha-1 adrenergic receptor antagonist doxazosin. Poor bladder emptying was documented by post void residual (PVR) measurements, symptomatology, as well as by demonstration of new hydronephrosis on ultrasound. All patients were initially placed on 0.5-1.0 mg of doxazosin nightly and followed weekly or monthly with PVR measurements and ultrasonography. Maximum urinary flow rates were

also measured in those patients able to void. Two patients with neurogenic bladders were also followed with cystometrograms and leak point pressures (LPP).

Results: Sixteen of the 20 patients (80%) exhibited improved bladder symptomatology and/or emptying. Dosage of doxazosin ranged from 0.5 mg to 8 mg (mean 2.26 mg) and duration of ongoing therapy ranged from 2 weeks to 16 months (mean 3.5 mos). None of the patients exhibited untoward side effects necessitating discontinuation of treatment. Ten of the 11 patients in whom PVR was measured demonstrated a mean 84% reduction in PVR during treatment (range 35-100%). Six patients had pre- and post-treatment peak flow rates for comparison and demonstrated an average 5-fold increase in their maximum flow rate. Only one patient with a previous ureteral bladder augmentation demonstrated a persistent large PVR (6.5% reduction) despite improved flow on uroflowmetry (10-fold increase). In 5 children with a history of posterior urethral valves, new or increased hydronephrosis was seen in 3 patients (2 bilateral, 1 solitary kidney) while chronic hydronephrosis was present in the remaining 2 patients (1 solitary kidney). After alpha blocker therapy, hydronephrosis resolved in 2 patients, improved in 2 patients, and remained unchanged in 1 patient. Finally, the 2 patients with neurogenic bladders demonstrated a mean 56% decrease in their LPP with alpha-blocker therapy.

Conclusions: Selective alpha-blocker therapy seems well tolerated in children and appears effective in a variety of pediatric voiding disorders on short-term follow-up. In our early experience, patients with valve bladders appear to particularly benefit from selective alpha blocker therapy. Not only is bladder emptying improved, but hydronephrosis due to elevated bladder pressures has also substantially improved in most patients. Future investigation is necessary to determine if selective alpha blocker therapy may provide long term benefit in patients with PUV as well as other pediatric voiding dysfunctions.

13

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TRANSCUTANEOUS NEUROMODULATION IN NON-NEUROPATHIC BLADDER SPHINCTER DYSFUNCTION IN CHILDREN: PRELIMINARY RESULTS.

Aims of study

In adults, neuromodulation has found its place in the treatment of functional voiding dysfunction. Due to the invasiveness of the treatment it has until today rarely been used in children. With transcutaneous neurostimulation available this treatment modality can also be used in children.

In order to investigate the clinical effects of transcutaneous neuromodulation on detrusor overactivity in children with non-neuropathic bladder sphincter dysfunction a prospective study was conducted.

Material and methods

Between 1st May 1998 and 28 February 1999, 40 children (15 girls, 25 boys) with proven detrusor instability, underwent neuromodulation. Most children have been under anticholinergic therapy for more than 3 months. Children in whom anticholinergics had no effect, neurostimulation was used as single therapy, in those children in whom anticholinergics had partial effect, they were continued during neurostimulation.

Stimulation of 2 Hertz is applied during 2 hours every day. Surface electrodes are put at the level of the sacral root S3. In children not responding to the 2 Hertz stimulation, 80 Hertz was applied during the whole night. After one month of trial stimulation, those children who respond continue the treatment for 6 months. Every 2 months they are evaluated.