Journal of Pediatric Urology (2014) 10, 899—905

Journal of Pediatric urology

Effect of Botox injection at the bladder neck in boys with bladder dysfunction after valve ablation

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Received 26 March 2013; accepted 31 December 2013
Available online 06 February 2014

KEYWORDS
Bladder neck;
Botox;
Bladder dysfunction;
Posterior urethral valves;
Valve bladder

Abstract *Objective:* After posterior urethral valve ablation, some boys are still have a hostile bladder. We conducted a prospective randomized study to determine if Botox injection at the bladder neck will help improve vesical dysfunction in this subgroup of boys or not.
Patients and methods: Twenty boys with history of posterior urethral valve ablation and severe bladder dysfunction with a mean age of 16 months were studied. Cases were further randomized into two groups. Group I (study group) had endoscopic injection of a single dose of 100 IU of Botox into the hypertrophied bladder neck at 3, 6, and 9 o'clock. Group II (control group) patients with the same parameters had urethroscopy to exclude residual valves. Both groups had the standard conservative treatment. Cases were followed after 6 months of initiating the management protocol. This includes laboratory studies (urine culture and sensitivity, blood urea nitrogen, serum creatinine), ultrasound of the urinary tract. Voiding cysto-urethrogram and urodynamic study (pressure flow study).
Results: There was no statistical difference in both groups regarding rate of urinary tract infection, improvement of hydronephrosis, resolution of vesico-ureteral reflux, creatinine level at the start or at the end of the study. Urodynamic parameters revealed an increase in cystometric capacity in both groups at the end of the study but without statistical difference. The mean voiding pressure reduced significantly in both groups but without statistical difference.
Conclusions: Temporarily abolishing the effect of bladder neck by Botox injection does not seem to improve the outcome of those boys who had a severe voiding dysfunction after valve ablation.

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http://dx.doi.org/10.1016/j.jpurol.2013.12.023

Introduction

Posterior urethral valves (PUVs) are a common cause of lower urinary tract obstruction in male infants and the most common congenital cause of bilateral renal obstruction [1,2] Although primary endoscopic valve ablation is effective in resolving the anatomical obstruction, the sequelae in the bladder and kidneys might remain (and sometimes worsen) after valve ablation in a subgroup of these boys during childhood and through adolescence. The prognosis of these children is quite poor. In long-term follow-up, at least one-third of such children have a poor outcome with respect to renal function [3]. On the other hand, bladder function continues to be an important factor in the long-term outcome of these boys. Proper evaluation and management is crucial in maintaining vesical and kidney function [4]. Proactive treatment of vesical dysfunction is a cornerstone in the management of these boys. Conservative treatment options include double or triple voids, suppressive therapy, anticholinergics, Clean Intermittent Self Catheterization (CISC), and an overnight indwelling catheter as described by Koff [5]. Some authors performed simultaneous Bladder Neck Incision (BNI) and valve ablation as a primary treatment of PUV and they reported better outcome but they did not report the risks of incontinence or retrograde ejaculation in those children [6]. Botox is a reversible toxin that can produce transient relaxation to the bladder neck musculature without risking the permanent long-term effect on bladder neck function.

Materials and methods

Twenty children with severe bladder dysfunction and unfavorable clinical course after primary valve ablation were included. Approval from our hospital ethical committee and informed consent from the parents was obtained. All available scientific information regarding the use of Botox as an off-shelf material to this young age was explained to the parents.

The age of the children ranged between 6 months and 3 years, with a mean age of 16 months. Regarding previous surgical intervention, all children had primary valve ablation at an age between 1 month and 24 months (mean 9 months). All the patients were on anticholinergic therapy and Clean Intermittent Catheterization (CIC) and none of them were on alpha-blockers (to better study the bladder neck effect without medication modification). The dose of anticholinergics is determined by the child's body weight, and the frequency of CIC is determined from his urodynamic study. Any child with a history of urinary diversion (vesicostomy or ureterostomy) was excluded from the study.

All boys were subjected to the following at the start and at the end of the study (6 months).

- Measurement of weight and height, complete blood count (CBC), serum creatinine level, blood urea nitrogen, urine analysis, urine culture and sensitivity.
- Ultrasonography of the kidneys and urinary tract.
- Voiding cysto-urethrogram (VCUG) where the Mitchell bladder score and vesico-ureteral reflux (VUR) were recorded. Bladder scores [7] were calculated at the beginning and at the end of the study.
- Urodynamic study in the form of filling cystometry and pressure flow studies was performed without anesthesia using a 6F double-lumen catheter inserted per urethra. Video-urodynamics was not performed. The residual volume was considered significant if it was more than 15% of the expected bladder capacity.

Then patients were blindly randomized into two groups as follows:

- The first group (study group) included 10 children with severe bladder dysfunction who underwent cysto-urethroscopy and simultaneous injection of 100 IU of Botox (Allergan, Irvine, CA, USA) into the hypertrophied bladder neck at 3, 6, 9 o'clock position and follow up.
- The second group (control group) included 10 matched children who underwent diagnostic cysto-urethroscopy to exclude the presence of residual valves and follow-up.

All our children in both groups were found to have bladder neck hypertrophy on cystoscopy. A collar could always be demonstrated at the internal meatus with the examining cystoscope, the eyepiece being depressed as the tip of the cystoscope reaches the meatus.

Statistical analysis

Data were fed to the computer using Predictive Analytics Software (PASW Statistics 18). Qualitative data were described using number and percent. Association between categorical variables was tested using the χ^2 test. When more than 20% of the cells had an expected count less than 5, correction for χ^2 was conducted using the Fisher exact test or Monte Carlo correction. Quantitative data were described using median, minimum and maximum as well as mean and standard deviation. Significance test results are quoted as two-tailed probabilities. Significance of the obtained results was judged at the 5% level.

Results

Frequency of UTI

There was no statistical difference between the two groups as shown in Table 1.

Table 1 Frequency of upper UTI among the two studied groups at the beginning and at the end of the study.

Culture proven UTI	Study group		Control		*p*
	No.	%	No.	%	
At the start					
No UTI	4	40.0	6	60.0	0.605
UTI	6	60.0	4	40.0	
At the end					
No UTI	5	50.0	8	80.0	0.542
UTI	5	50.0	2	20.0	