

# Total Endoscopic and Anal Irrigation Management Approach to Noncompliant Neuropathic Bladder in Children: A Good Alternative

Khalid F. Neel\*

From the College of Medicine, King Saud University, Riyadh, Saudi Arabia

**Purpose:** We prospectively evaluated the efficacy and durability of combined intradetrusor botulinum-A toxin and endoscopic treatment for vesicoureteral reflux with anal irrigation as a total endoscopic and anal irrigation management approach. This minimally invasive protocol is used to manage myelomeningocele and noncompliant bladder in children who do not respond to standard conservative therapy and have urine and stool incontinence.

**Materials and Methods:** Ten females and 3 males with a mean  $\pm$  SD age of  $5.3 \pm 2.5$  years with myelomeningocele and vesicoureteral reflux who did not respond to standard conservative treatment were prospectively included in this study. All had at least 1 year of followup. All patients received a cystoscopic intradetrusor injection of 12 U/kg (maximum 300 U) botulinum-A toxin into an infection-free bladder. Vesicoureteral reflux in a total of 20 refluxing ureters, including bilateral vesicoureteral reflux in 7 patients, showed no resolution on pretreatment voiding cystourethrogram. Thus, we administered a submucosal Deflux® injection. Since most patients were still diaper dependent due to stool incontinence, we extended management to include complete bowel rehabilitation with the new Peristeen® anal irrigation system to manage stool incontinence.

**Results:** Mean maximum bladder capacity increased significantly from  $75 \pm 35$  to  $150 \pm 45$  ml after 1 month ( $p < 0.02$ ), to  $151 \pm 48$  after 6 months ( $p < 0.002$ ) and to  $136 \pm 32$  after 1 year ( $p < 0.000$ ). Maximum detrusor pressure decreased significantly from  $58 \pm 14$  to  $36 \pm 9$  cm H<sub>2</sub>O after 1 month ( $p < 0.001$ ), to  $39 \pm 9$  after 6 months ( $p < 0.001$ ) and to  $38 \pm 6$  after 1 year ( $p = 0.000$ ). Of 20 refluxing ureters (95%) completely resolved, including 1 after attempt 2, and 1 with grade V vesicoureteral reflux remained unchanged despite 2 attempts. Seven of 8 urinary incontinent patients (87.5%) attained complete dryness between catheterizations and 1 partially improved. Ten of 13 patients achieved stool dryness with anal irrigation 1 to 2 times weekly. Three patients who were stool continent on standard enemas did not require this irrigation system.

**Conclusions:** This new total endoscopic and anal irrigation management approach is a comprehensive, minimally invasive, safe, simple, effective way to achieve most goals when treating these patients by protecting the upper tract, maintaining the bladder at safe pressure and providing a satisfactory social life with satisfactory urine and stool continence.

**Key Words:** urinary bladder, neurogenic; vesico-ureteral reflux; botulinum toxin type A; irrigation; endoscopy

## Abbreviations and Acronyms

BTX-A = botulinum-A toxin

CIC = clean intermittent catheterization

DLPP = detrusor leak point pressure

MMC = myelomeningocele

NB = neuropathic bladder

TEAM = Total Endoscopic and Anal Irrigation Management

VUR = vesicoureteral reflux

Submitted for publication June 20, 2009.  
Study received institutional review board approval.

\* Correspondence: Urology Division, Department of Surgery, College of Medicine, King Saud University POB 7805, Riyadh 11472 Kingdom of Saudi Arabia (FAX: 966-1-467-9493; e-mail: kfouda@ksu.edu.sa).

STANDARD conservative treatment is effective in most but not all children with NB secondary to MMC. Anticholinergic medication and CIC are first line therapies. However, about 10% of these patients fail to respond to such treatment<sup>1</sup> and bladder reconstructive surgery seems unavoidable. Various studies suggest that urinary and fecal incontinence is one of the most stressful aspects of life in these patients, considered even more difficult than other challenges, such as impaired motor function.<sup>2</sup> Recently BTX-A proved its effectiveness as second line treatment for NB that does not respond to standard conservative treatment. These results were reproduced in children in multiple studies.<sup>3-6</sup>

VUR is present in approximately 10% to 60% of children with NB.<sup>7,8</sup> Spontaneous reflux resolution was recorded in 43% to 58% of cases with standard conservative treatment with CIC using anticholinergics and prophylactic antibiotics.<sup>9</sup> Cases that fail to improve often require major reconstructive surgery.<sup>10-12</sup>

We previously evaluated combined BTX-A and VUR endoscopic treatment, and achieved encouraging results in regard to bladder function, VUR resolution and improved urinary continence.<sup>13</sup> However, most patients remained diaper dependent due to stool incontinence. In the current study we evaluated the efficacy and durability of combined intradetrusor BTX-A and endoscopic treatment for VUR associated with the Peristeen program for anal irrigation as a 1 time, minimally invasive approach. The TEAM approach was used to manage MMC, VUR, noncompliant bladder, and urine and/or stool incontinence in children who did not respond to standard conservative therapy. We determined whether this single protocol could meet all of our treatment goals in these patients.

## MATERIALS AND METHODS

Patients with NB secondary to MMC and VUR with urine and stool incontinence who failed to respond to standard conservative treatment and who had increased intravesical pressure (greater than 40 cm H<sub>2</sub>O DLPP) or persistent incontinence were included in our study. All patients were on CIC every 3 to 4 hours, regular prophylactic antibiotics and the maximum tolerable dose of anticholinergics. However, they continued to show poorly compliant, unstable bladders with urine and/or stool incontinence.

Our TEAM approach protocol was previously described.<sup>13</sup> Briefly, patients underwent cystoscopic intradetrusor injection of 12 U/kg (maximum 300 U) BTX-A into an infection-free bladder. This treatment was combined with endoscopic VUR correction using Deflux during BTX-A therapy session 2 in the first 4 patients. The last 9 patients underwent endoscopic VUR treatment during BTX-A treatment session 1. We decided to manage VUR due to the harmful combination of high intravesical pres-

sure, CIC and VUR, which would result in recurrent pyelonephritis.

The bowel rehabilitation training program using the transanal irrigation Pristeen system was done by our urotherapist in patients with fecal incontinence who failed to achieve dryness with regular cleansing enemas after the endoscopic session. Patients were evaluated at the clinic for diaper dependency due to stool incontinence. An appointment was made with the urotherapist to give the patient a verbal and visual review of the technique and its goals. The system consists of a rectal tube that is inserted and kept in place via the rectum with a balloon. The tube is connected to a water pump to push the irrigation fluid in. The balloon keeps the tube in and prevents fluid leakage. After irrigation the balloon is deflated and the tube is removed for the desired effect of emptying the rectum and the left hemicolon. Any questions were then discussed. The urotherapist demonstrated the various parts of the system and described how to use it. A followup telephone call within 24 to 48 hours of the teaching session was needed to answer any questions and explain any difficulties or complaints after the first use.

Patients returned for followup at 1 month and were assessed by history, clinical examination and urodynamics. Voiding cystourethrogram was done 2 months after the procedure. Urodynamics were repeated every 6 months after the procedure. When urodynamic results were unavailable or urinary incontinence recurred, BTX-A injection was repeated. The group had at least 1 year of followup. Response criteria included a stable, compliant bladder with acceptable capacity given the patient age, VUR resolution, dryness between catheterizations and stool continence.

## RESULTS

Mean  $\pm$  SD maximum bladder capacity increased significantly from  $75 \pm 35$  to  $150 \pm 45$  ml after 1 month ( $p < 0.02$ ), to  $151 \pm 48$  after 6 months ( $p < 0.002$ ) and to  $136 \pm 32$  after 1 year ( $p < 0.000$ ). Maximum detrusor pressure decreased significantly from  $58 \pm 14$  to  $36 \pm 9$  cm H<sub>2</sub>O after 1 month ( $p < 0.001$ ), to  $39 \pm 9$  after 6 months ( $p < 0.001$ ) and to  $38 \pm 6$  after 1 year ( $p = 0.000$ ). Seven of 8 patients (87.5%) with urinary incontinence achieved complete dryness between CICs up to 6 months after treatment. One patient partially improved. Of 20 refluxing ureters 19 (95%) completely resolved, including 1 after attempt 2, while 1 (5%) with gastrocnemius vein reflux remained unchanged despite 2 treatment attempts.

Ten of 13 patients achieved stool dryness with anal irrigation administered an average of twice weekly. They discontinued diaper use since they remained dry of urine and stool. The other 3 patients were stool continent after making dietary modifications and receiving regular cleansing enemas. They did not require the transanal irrigation system. No side effects of any of these procedures were noted during this combined approach.

Each BTX-A procedure would cost around \$1,000 to \$1,500 (around \$2,000 to \$3,000 per year). The irrigation system, consisting of disposable catheters and a nondisposable pump, would cost another \$1,000 per year and Deflux would cost around \$1,000. Accordingly each TEAM procedure would cost around \$4,000 in year 1 and around \$3,000 per year thereafter. Cost would differ among countries.

## DISCUSSION

MMC is associated with varying degrees of disabling problems related to the urinary tract. Patients require a comprehensive program to manage noncompliant bladder, VUR and diaper dependency to contain urine and stool. The gold standard first line treatment includes CIC and anticholinergic medication combined with prophylactic antibiotics for VUR and cleansing enemas to manage constipation and stool incontinence. This regimen is used until resolution is achieved. Unfortunately not all children respond to this conservative protocol and some ultimately require surgical intervention, which is associated with long-term morbidity.<sup>14</sup>

We previously tested the efficacy and durability of combined BTX-A injection and endoscopic correction for VUR.<sup>13</sup> This lowered intravesical pressure and improved bladder capacity. At the same time we corrected associated reflux in 93.75% of refluxing ureters. However, despite the 83% success rate for urinary continence between CIC treatments most of our patients remained diaper dependent due to stool incontinence. Thus, we extended our protocol to include complete bowel rehabilitation with the transanal irrigation system, which provides efficient left colon emptying to offer the patient complete stool dryness for 2

to 3 days depending on dietary habits.<sup>15</sup> Ten of 13 patients required this program and became completely diaper independent. Three patients became stool continent on the classic bowel management program. Using each line of treatment we helped our patients evacuate the rectum at predictable times and gave them successful control of stool incontinence.

All patients need repeat BTX-A injection every 6 months due to recurrent incontinence and/or increasing pressure (7) or incontinence only (6). At at least 1 year of followup all except 2 patients were still in the program (see table). One of the 2 patients who needed bladder reconstruction became significantly incontinent and the family of the other patient found it difficult to continue with the program despite the favorable outcome since they did not live in the same city.

We attempted to provide these patients with complete, minimally invasive, safe, effective management to meet our treatment goals. The TEAM approach helped protect the upper tract by increasing bladder capacity and lowering intravesical pressure. The TEAM approach also helped resolve VUR and provided a socially acceptable level of urinary and stool continence. Currently the TEAM approach has saved these children from major reconstructive surgery. Extended followup is required to test the long-term effects of this protocol.

To our knowledge this is the first report to describe a simple, minimally invasive protocol that allowed us to achieve most of our treatment goals in these patients. They experienced greatly improved quality of life and this protocol has safely postponed the need for major reconstructive surgery. Our results are preliminary and our cohort included only a few patients. Furthermore,

*Bladder capacity and DCPP at 1, 6 and 12 months*

Pt No.	Baseline		1 Mo		6 Mos		1 Yr	
	Max Bladder Capacity (ml)	DLPP (cm H <sub>2</sub> O)	Bladder Capacity	DLPP	Bladder Capacity	DLPP	Bladder Capacity	DLPP
1	120	56	140	35	145	50	150	40
2	30	65	135	40	190	40	174	42
3	33	61	50	38	46	50	65	40
4	80	76	116	60	100	29	110	40
5	50	36	180	20	185	23	177	22
6	50	81	240	45	230	45	140	48
7	50	40	160	40	210	57	150	46
8	125	43	175	32	150	40	160	37
9	138	45	150	30	140	31	160	40
10	60	75	120	35	100	38	110	30
11	70	54	140	30	140	35	130	39
12	80	60	150	35	140	40	100	40
13	100	70	200	30	170	35	150	38

they still require detailed, regular followup. A study in a larger number of cases and longer followup is needed to validate this new protocol. The main limitation is the need for hospitalization every 6 months since the procedure is done in children under general anesthesia and the protocol may be time-consuming for patients who do not live in the same city.

## CONCLUSIONS

This new TEAM approach is a comprehensive, minimally invasive, simple, safe, effective way to achieve most treatment goals associated with this high risk patient group. The TEAM approach protects the upper tract, keeps the bladder at safe pressure and offers patients a satisfactory social life consistent with urine and stool continence.

## REFERENCES

1. Skobejko-Wlodarska L, Strulak K, Nachulewicz P et al: Bladder autoaugmentation in myelodysplastic children. *Br J Urol* 1998; **81**: 114.
2. Lie HR, Lagergren J, Rasmussen F et al: Bowel and bladder control of children with myelomeningocele: a Nordic study. *Dev Med Child Neurol* 1991; **33**: 1053.
3. Schurch B, Stohrer M, Kramer G et al: Botulinum-A toxin for treating detrusor hyperreflexia in spinal cord injured patients: a new alternative to anticholinergic drugs? Preliminary results. *J Urol* 2000; **164**: 692.
4. Schulte-Baukloh H, Michael T, Schobert J et al: Efficacy of botulinum-A toxin in children with detrusor hyperreflexia due to myelomeningocele: preliminary results. *Urology* 2002; **59**: 325.
5. Riccabona M, Koen M, Schnidler M et al: Botulinum-A toxin injection into the detrusor: a safe alternative in the treatment of children with myelomeningocele with detrusor hyperreflexia. *J Urol* 2004; **171**: 845.
6. Neel KF, Soliman S, Salem M et al: Botulinum-A toxin: solo treatment for neuropathic noncompliant bladder. *J Urol* 2007; **178**: 2594.
7. Agarwal SK, Khoury AE, Abramson RP et al: Outcome analysis of vesicoureteral reflux in children with myelodysplasia. *J Urol* 1997; **157**: 980.
8. Cohen RA, Rushton HG, Belman AB et al: Renal scarring and vesicoureteral reflux in children with myelodysplasia. *J Urol* 1990; **144**: 541.
9. Engle JD, Palmer LS, Cheng EY et al: Surgical versus endoscopic correction of vesicoureteral reflux in children with neurogenic bladder dysfunction. *J Urol* 1997; **157**: 2291.
10. Morioka A, Miyano T, Ando K et al: Management of vesicoureteral reflux secondary to neurogenic bladder. *Pediatr Surg Int* 1998; **13**: 584.
11. Lopez Pereira P, Martinez Urrutia MJ, Lobato Romera R et al: Should we treat vesicoureteral reflux in patients who simultaneously undergo bladder augmentation for neurogenic bladder. *J Urol* 2001; **165**: 2259.
12. Granta C, Buffa P, Rovasenda E et al: Treatment of vesicoureteric reflux in children with neurogenic bladder: a comparison of surgical and endoscopic correction. *J Pediatr Surg* 1999; **34**: 1836.
13. Neel KF, Salem M and Soliman S: Total endoscopic management (TEM approach) of children with non compliant neuropathic bladder: a preliminary report. *J Pediatr Urol* 2008; **4**: 124.
14. Gros DA, Dodson JL, Lopatin UA et al: Decreased linear growth associated with intestinal bladder augmentation in children with bladder exstrophy. *J Urol* 2000; **164**: 917.
15. Del Popolo G, Mosiello G, Pilati C et al: Treatment of neurogenic bowel dysfunction using transanal irrigation: a multicenter Italian study. *Spinal Cord* 2008; **46**: 517.