



Sacral neuromodulation in congenital lumbo-sacral and traumatic spinal cord defects with neurogenic lower urinary tract symptoms: a single-center experience in children and adolescents

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Abstract

Purpose This study evaluated sacral neuromodulation's effectiveness for managing refractory neuropathic lower urinary tract dysfunction in children and adolescents.

Methods Twenty-five children and adolescents underwent peripheral nerve evaluation test phase of sacral neuromodulation at our center. Thirteen (seven boys and six girls) cases suffered from neuropathic lower urinary tract dysfunction refractory to the maximum medical treatment. The test was done with temporary wire in all patients. Patients with more than 50% improvement in symptoms were chosen for the second stage of implantation of quadripolar tined lead and implantable pulse generator. Bowel transit symptoms were recorded before and after the surgery.

Results Eight patients (61.53%; five boys and three girls) had positive responses to the peripheral nerve evaluation test phase. They underwent implantation of permanent quadripolar tined lead and implantable pulse generator. The etiologies were lumbosacral myelomeningocele, occult spina bifida, partial sacral agenesis and incomplete spinal cord injury. Positive clinical response (> 50% improvement in symptoms) was achieved in seven (85%) at a mean follow-up of 14.25 months. Three patients became capable to stop clean intermittent catheterization ($P=0.125$). The 24-h pad test decreased from 484 to 78 g from before to after the surgery ($P=0.043$).

Conclusion This clinical study on a small sample size of children and adolescents demonstrates positive results in short-term follow-up. However, as the procedure is still not approved officially, multicenter studies with more patients can prove the safety and efficacy of sacral neuromodulation in long term among this special group of patients.

Keywords Child · Urinary incontinence · Electric stimulation therapy · Congenital abnormalities · Neuropathic

Introduction

There are different etiologies for neurogenic bladder dysfunction in children; they may vary from congenital anomalies such as myelomeningoceles, occult spina bifida, partial and complete sacrum agenesis to sacro-coccygeal tumors or spinal cord trauma. The first-line approach is a non-invasive medical treatment. The invasive options are reserved for non-responding intractable cases [1].

Sacral neuromodulation was first approved in the United States in 1997 for the treatment of urinary urge incontinence in adults. So far, there has been a gradual increase in the indications [2]. There are some reports regarding the effectiveness of sacral neuromodulation in the treatment of lower urinary tract dysfunction (LUTD), fecal incontinence or defecation problems of children [3]. However, there are few reports on the treatment of neurogenic LUTD (NLUTD) in children [1, 4, 5].

This report describes our clinical results of applying sacral neuromodulation for the treatment of NLUTD in children and adolescents. The NLUTD was caused by lumbosacral congenital anomalies and incomplete spinal cord trauma in all cases.

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Materials and methods

The medical records of all patients who underwent sacral neuromodulation in our center were reviewed between July 2012 and May 2018. Those who were 18 years old or younger were included in the study. Their main complaint was of lower urinary tract symptoms, secondary to neurological disorders. The symptoms were caused by congenital malformations of the spinal cord (myelomeningoceles, tethered cord, partial sacral agenesis, occult spina bifida) or incomplete spinal cord injury. Each had remained symptomatic despite maximum medical management including: timed voiding, behavioral modification, fluid management, biofeedback, multiple pharmacologic treatments, intravesical botulinum toxin A injection, posterior tibia nerve stimulation, and clean intermittent catheterization (CIC). The minimum interval between the spinal cord trauma or the last surgical intervention on spinal cord and the sacral neuromodulation was 12 months (after a spinal shock period, return of tendon reflexes below the level of the trauma and also bulbo-cavernous reflex takes some time).

The inclusion criteria were: (1) being younger than 18 years old, (2) having at least two of the following conditions: post-void residual volume greater than 50% of the functional bladder capacity, inability to void and dependence on CIC, 90 min or less continence duration (depending on absorbent pads), (3) detrusor over activity with pressure peaks more than 40 cmH₂O, (4) bladder compliance less than 15 ml/cmH₂O, (5) intact function of sacral nerves (presence of bulbo-cavernous reflex or sensation in the dermatomes of S3 or S4 roots), (6) motivation and ability of the patient and parents to maintain with voiding diary schedule, and (7) participation in the follow-up visits and evaluations.

The exclusion criteria were having: (1) major psychological disorders, 2) sacral agenesis involving more than 50% of sacrum, and 3) local risk factors for device implantation such as skin infection. All patients underwent a detailed medical history and physical examination, plain abdominal radiography, urinalysis and culture, urinary tract ultrasound imaging, measurement of residual urine, three channel urodynamic study, voiding cystourethrography, and thoraco-lumbo sacral magnetic resonance imaging.

We did radionuclide imaging to evaluate the kidney function if it had been indicated by the basic evaluation. Retrograde urethrography and cystourethroscopy were done in all male cases who were under chronic CIC to rule out anatomic urethral strictures. Urinary tract infection was treated according to anti-biogram and sensitivity results as much as possible before the surgery. All medical treatments including anti-cholinergics, baclofen,

alpha blockers, and cholinergics were discontinued for at least 14 days before the study and during the test phase. Multi-channel urodynamic studies were done before and 3 months after the procedure.

The patients maintained 72 h of frequency volume charts and 24-h pad tests before the study, plus all the days during the test phase. If there were associated fecal problems (fecal incontinence, fecal soiling, chronic constipation), it was recorded in a separate sheet by the patient or parents. Constipation was defined as a delay or difficulty in defecation for 2 or more weeks or less than three bowel movements a week that causes distress for the patients [6].

We did a test phase by inserting a temporary wire (305765SC, Medtronic, Minneapolis Inc.) percutaneously in the S3 foramen [peripheral nerve evaluation (PNE) test] under local anesthesia with intra-venous sedation. An experienced urologist did the procedure according to the technique described by Spinelli et al. [7]. We did bilateral testing to determine the side with the best result. If there was no response with S3 foramens, we tried the S4 foramen. The side with the best Bellow's anal reflex was chosen, with or without plantar flexion reflex and sensory response, if ever, with the lowest threshold of stimulation. The PNE wire was inserted unilaterally and connected directly to the external pulse generator (Brown Box, Verify 3531, Medtronic, Minneapolis, Inc). If there was a 50% reduction of incontinence episodes, 50% improvement in urinary frequency, 50% decrease in post-void residual volume, and 50% reduction of necessity for CIC, the patient was scheduled for implantation of quadripolar tined lead (3889-28, Medtronic, Inc.) and implantable pulse generator (IPG) (3058, Medtronic, Minneapolis Inc.).

In case of failure of unilateral PNE in achieving a clinical response, the patient underwent a repeated PNE test by placing the temporary wire in the contralateral foramen, if present, in a second session. The assigned duration of PNE test phase was 14 days. In cases with positive clinical response who lived in a far distance from our center and could not commute easily, the quadripolar tined lead and IPG were implanted in one stage surgical session. Otherwise, the IPG implantation was planned for a two-stage procedure. IPG was implanted in the upper buttock area.

There was a two-week interval in cases of staged IPG implantation. The procedure was performed under general anesthesia. All patients received broad-spectrum intravenous antibiotics before and following the procedure until the next 24 h. They were discharged at the first post-operative day and maintained on oral broad spectrum antibiotics for the first week after surgery. The outcome was measured by clinical evaluation of ability to void, measurement of post-void residual urine according to ultrasound imaging or CIC, and evidence of urinary incontinence episodes according to the frequency volume chart and the last 24-h

pad test. Follow-up visits were repeated at 2 weeks, 1, 3, and 6 months after the surgery. Afterward, they were repeated every six months.

The patients were re-visited in case of a new bothering symptom or apparent surgical site complications. The outcomes were defined as: 1) positive response: more than 50% objective improvement in at least one implantation criteria, and 2) failure: less than 50% objective improvement. Secondary end points were defined as the changes in the related bowel transit symptoms and related adverse events.

The study was approved by the ethics committee of our university (IR.SBMU.UNRC.1397.16). Written informed consent was obtained from the patients and their parents. We did all the analyses with the statistical package for social sciences (SPSS) version 24 software. P value of less than 0.05 was considered significant. Descriptive statistics included mean and standard deviation for quantitative variables and frequency and percentage for qualitative variables. Wilcoxon rank sum and McNemar test were used to compare pre- and post-treatment data for quantitative and binary variables, respectively.

Results

There were 13 cases of NLUTD among 25 children and adolescents who underwent the PNE test phase of sacral neuromodulation due to refractory lower urinary tract or bowel symptoms (the remaining 12 were bladder bowel dysfunction cases). The S3 and S4 roots were detected in 11 and two patients, respectively. Eight (61.53%) patients (five boys and three girls) had more than 50% improvement in symptoms. They had a mean age of 14.12 years (10–18 years).

The etiologies were lumbosacral myelomeningocele, occult spina bifida, partial sacral agenesis and incomplete spinal cord injury in three, one, two and two patients, respectively (Table 1). Seven patients were ambulatory, and one was only able to ambulate with assistance (case no 6).

One patient had remained on colostomy drainage (from 13 years ago) at the time of PNE test phase (Table 2). Three patients were totally dependent on CIC to empty the bladder. In cases with urinary incontinence, 24-h pad test revealed a mean 484 grams of urine leakage of (100–1600 grams). Mean residual urine was 190 milliliters (120–400 mL). Serum creatinine level was higher than normal in one patient (1.8–2 mg/dL) (Table 3). A patient suffered from urethral sphincter deficiency (maximum urethral closure pressures less than 20 cm H₂O according to urethral pressure profilometry) (case no. 6, Table 1) Four patients underwent unilateral PNE in one session and four other patients repeated contralateral PNE test for the second time. The mean duration of

Table 2 Surgical history of the children who underwent IPG implantation in our study

Surgery	Number (%)
Thoraco-lumbar vertebra fracture and surgical fixation	2 (0.25)
Colostomy drainage	3 (0.375)
Meningomyelocele surgical closure	3 (0.375)
Surgical release of tethered spinal cord	1 (0.125)
Surgical repair of pylorus stenosis	1 (0.125)
Anal reconstruction	1 (0.125)
Vesicostomy	3 (0.375)
Splenectomy	1 (0.125)
Abdominal laparotomy	2 (0.25)

Table 1 Demographic data of our patients treated with permanent sacral neuromodulation

Patient No.	Age (years old)/sex	Etiology of NLUTD	Main complaint	CIC	24-h pad test before surgery	Related bowel symptoms
1	11/M	Congenital myelomeningocele	Urinary incontinence + Incomplete voiding	+	500	Fecal soiling
2	11/M	Partial sacral agenesis	Urinary retention + Enuresis	+	140	Fecal soiling
3	16/M	Incomplete spinal cord lesion (T11-12-L1 vertebra fracture)	Urinary retention + enuresis	+	0	Constipation
4	17/M	Spina bifida (L4–L5)	Urinary incontinence + Incomplete voiding	+	130	Constipation
5	14/F	Partial sacral agenesis	Urinary retention	+	0	Colostomy (fecal incontinence)
6	16/F	Congenital myelomeningocele	Urinary incontinence + enuresis	–	1600	Fecal soiling
7	18/F	Incomplete Spinal cord lesion (L1–L2 vertebra fracture)	Urinary retention	+	0	Constipation
8	10/M	Congenital myelomeningocele	Urinary retention + enuresis	+	120	Fecal soiling + constipation

F female, M male, CIC clean intermittent catheterization

Table 3 The results of para-clinical evaluation of children with NLUTD who had a positive response to PNE test before IPG implantation

Para-clinical results before surgery	Number (%)
Increased level of serum Creatinin	1(0.125)
Moderate hydrouretero-nephrosis (bilateral)	2(0.25)
Moderate vesicoureteral reflux (bilateral)	2(0.25)
Increased maximum cystometric capacity (1.5 fold)	2(0.25)
Acontractile or underactive detrusor	2(0.25)
Absence of sensation	3(0.375)
Detrusor over activity	6(0.75)
Low compliance bladder (< 15 ml/cm H ₂ O)	2(0.25)

PNE test phase was 12 (10–14) days. Quadripolar tined lead and IPG were implanted in a one-stage procedure in four patients and as a two-stage procedure in four other children. Tined lead was implanted at S3 and S4 foramina in seven and one patients, respectively.

The mean of follow-up time after IPG implantation was 14.25 months (3–36 months). The mean amount of urine leakage according to the 24-h pad test changed from 484 to 78 grams ($P=0.043$). Residual urine decreased from 190 ± 90 mL to 45 ± 30 mL ($P=0.049$). Positive clinical response to IPG implantation was achieved in seven cases (85%; four cases of one stage and three cases of two-stage procedure) (Table 4).

One boy reported complete fecal control and great improvement in bowel transit. He was a case of congenital lumbosacral myelomeningocele with less than 50% response to stimulation over urinary tract symptoms by quadripolar tined lead. He gained the ability to feel the bladder sensations for the first time in his life. Although he was still dependent on CIC, he was satisfied with the result. He stopped using the absorbent pads and decided to undergo IPG implantation in a staged procedure. Urodynamic characteristics were recorded before and 3 months after the surgery (Table 5).

Among those who responded to the treatment, one patient gradually became unresponsive after 3 years. He had a history of surgically repaired congenital lumbo-sacral myelomeningocele and refused to undergo another PNE test because of economic problems. The IPG was explanted finally according to the patient's request 5 years after surgery. Another patient with myelomeningocele became unresponsive to treatment 3 months after the surgery (case no 6, Table 1). The pelvic X-ray revealed a deviation of the tined lead. Tined lead and IPG were explanted due to a pocket site infection, although there was no breakage for deviated tined lead. The appropriate antibiotics were registered according to the culture result of the infected IPG pocket site. PNE test was repeated and the unaltered re-sterilized quadripolar tined lead and IPG were re-implanted in a one-stage procedure 2 months later (Fig. 2). Three patients stopped regular daily CIC ($P=0.125$; Table 4) (cases nos. 2, 4, 5).

Table 4 Clinical results of patients treated by sacral neuromodulation for treatment of lower urinary tract dysfunction

Patient no.	Etiology of NLUTD	Follow-up (months)	24-h pad test before surgery (g)	24-h pad test after surgery (g)	CIC before surgery	CIC after surgery	Clinical response	Improvement in associated bowel symptoms
1	M.M	72	400	200	+	+	< 50%	+
2	PSA	21	140	60	+	–	> 90%	+
3	ISCI	19	0	0	+	+	> 50%	+
4	SB	11	100	–0	+	–	> 90%	+
5	PSA	10	0	0	+	–	> 90%	– (Colostomy drainage)
6	M.M	6	1600	120	–	–	> 50%	+
7	ISCI	8	0	0	+	–	> 90%	–
8	M.M	3	180	10	+	+	< 50%	+

NLUTD Neurogenic lower urinary tract dysfunction, M.M myelomeningocele, PSA partial sacral agenesis, ISCI incomplete sacral cord injury, SB spina bifida, CIC clean intermittent catheterization

Table 5 Urodynamic characteristics before and 3 months after sacral neuromodulation

	Before surgery	After surgery	P value
Maximum cystometric capacity (mL)	250 ± 90	330 ± 90	0.07
Compliance (mL/cm H ₂ O)	12 ± 4	20 ± 3	0.06
Detrusor overactivity (numbers)	20 ± 5	8 ± 1	0.05
Residue (mL)	190 ± 90	45 ± 30	0.049

Six patients reported improvement in bowel transit. One patient who is still on colostomy drainage at the time of writing this report will do colostomy closure surgery soon. Both adverse events (deviation of tined lead and IPG pocket site infection), as well as late failure of device occurred in two cases of congenital myelomeningocele.

Urodynamic study 3 months after the surgery showed a decrease in numbers and magnitude of detrusor over activity, while there was the least change in the maximum cystometric capacity. Figures 1 and 2 show changes of late filling phase of urodynamic study as well as free uroflowmetry in a studied patient.

Discussion

The prevalence of NLUTD depends on the type and duration of neurological defects, which may affect from half to all patients involved with neurological diseases [8]. The main goal of NLUTD management is restoring continence, avoiding high intra-detrusor pressure, and regular and complete bladder emptying [9].

Sacral neuromodulation was first described by Tanagho and Schmidt for treating non-neurogenic bladder dysfunctions [10]. The exact mechanism of action of neuromodulation in humans is not clear. Few studies propose the effect on afferent sensory nerve fibers through the S3 root mainly (or S4) and modulation of continence and voiding in the central nervous system [11, 12]. The role of cortico-subcortical structures has been emphasized in functional brain imaging studies [13].

Sacral neuromodulation was gradually used for the treatment of NLUTD in selected patients. However, its efficacy in NLUTD is an off-label indication, still not approved officially, including by the United States' Food and Drug Administration (FDA) [14]. In adults, sacral neuromodulation has been assessed in patients with incomplete spinal cord injury and concomitant NLUTD. Lombardi et al. reported 38% success rate in 37 cases at a median follow-up of more than 3 years [15]. Kessler et al. described the efficacy of sacral neuromodulation in 256 patients with NLUTD. The pooled success rate for permanent sacral neuromodulation was 92% with a 99% probability that the success rate was more than 75% [16].

Groen et al. reported their 15-year experience with sacral neuromodulation in children with lower urinary tract symptoms. They included 18 cases of dysfunctional elimination syndrome, neurogenic bladder, bladder over-activity and Fowler syndrome. 16 cases underwent S3 sacral modulation and two cases underwent pudendal stimulation from the beginning. Finally, five out of 16 underwent a revision by pudendal stimulation. They reported initial full and partial responses in 50% and 28%

of cases, respectively. At the end of study, the rates of full and partial responses were 40% and 33%, respectively. The high dislocation and re-operation rate was attributed to the effect of skeletal growth and more active movement in children. The experience with myelomeningocele as a cause of NLUTD was disappointing in their study because all three cases failed [17].

Guys et al. evaluated the clinical results of sacral neuromodulation in 42 children with NLUTD enrolled in investigation and control groups. Their mean of age was 11.9 years old. The etiologies were from spina bifida, to partial sacral agenesis, trauma, tumor, neonatal cerebral palsy, meningoencephalitis and uro-facial syndrome. In the investigation group, the IPG was implanted in the anterior abdominal wall in eight children and upper buttock in 13 children, respectively. Total disappearance of urinary leakage was observed in one child out of 21 children in one group, although he still required CIC to empty the bladder. They concluded that the clinical result with sacral neuromodulation was poor in this group of children [1].

Tanagho treated six children with voiding dysfunction using an implantable sacral device. He reported resolution of incontinence in four of them [18]. Humphreys et al. did sacral neuromodulation to treat dysfunctional elimination syndrome in 23 children. Their mean of follow-up was 13.3 months. They reported 16% and 68% complete and partial responses for urinary incontinence. Among the patients with urinary retention, 60% had improved. 33% of those who were dependent on CIC did not need to use it anymore. They concluded that a longer follow-up period was needed [19].

Lippmann et al. reported a successful use of sacral neuromodulation in a 12-year-old child with cerebral palsy and neurogenic bladder dysfunction. The patient went on a bilateral test phase with quadripolar tined lead. In the second stage, placement of the right S4 lead was retained. There was a dramatic improvement in life quality with rare leakage at times after a 16-month follow-up [5].

Mason et al. evaluated sacral neuromodulation in the treatment of 30 children with refractory bowel symptoms. Medians of age and follow-up were 8.3 year and 14.8 months, respectively. Their patients reported a significant improvement in life quality and symptom scores. Those with episodes of detrusor over-activity on urodynamic study before surgery had significantly greater improvement in symptoms. Lower body mass index was a risk factor for neuro-stimulator breakage [20].

Fuchs et al. did sacral neuromodulation in 63 children. Their means of age and follow-up were 11.5 years and 1.9 years, respectively. They divided them into two groups of primarily bowel symptoms (49%) and primarily bladder symptoms (51%). They concluded that children with primarily bladder symptoms may have higher rate of lead complications for unclear reasons. However, they did not give

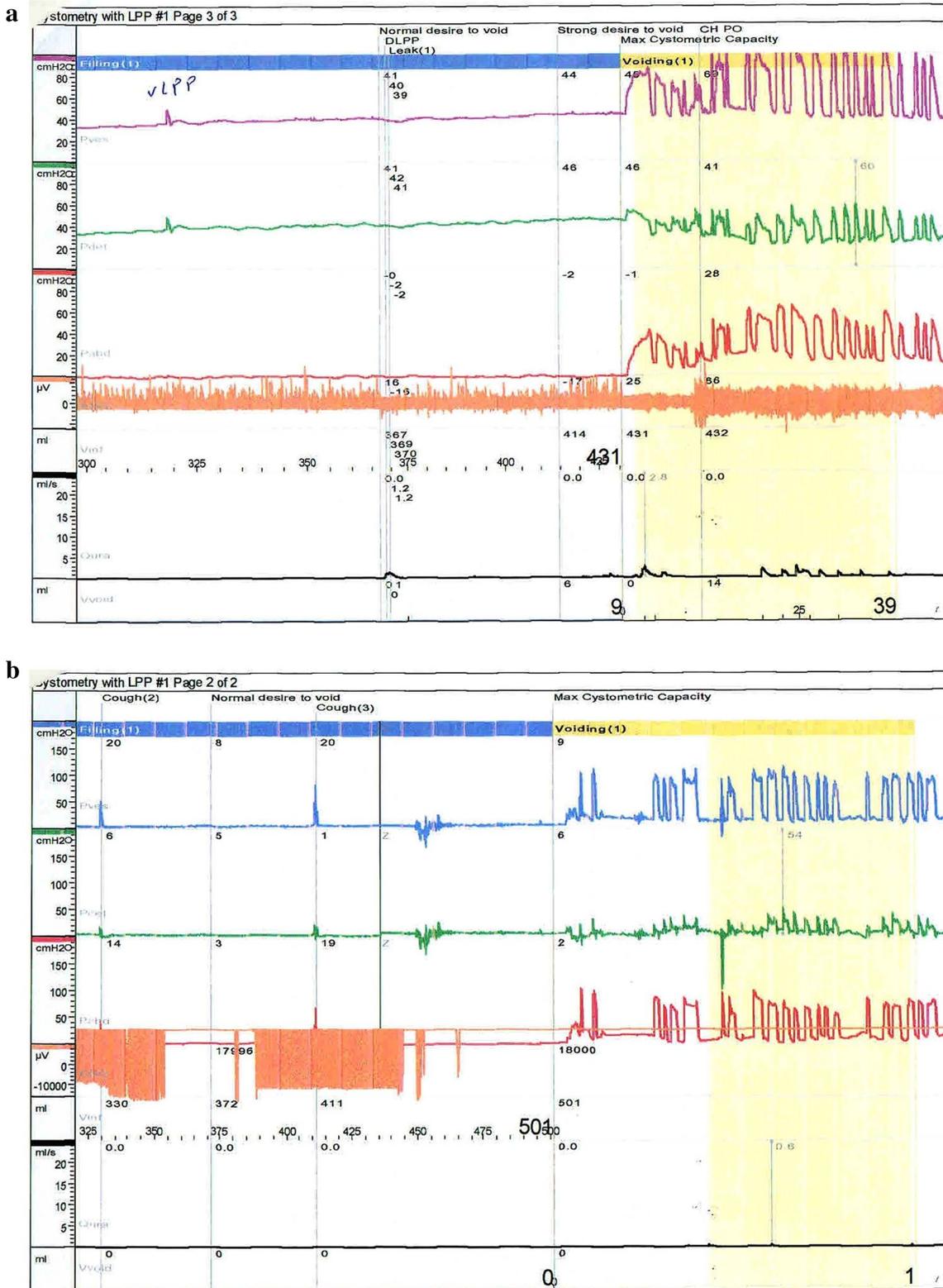
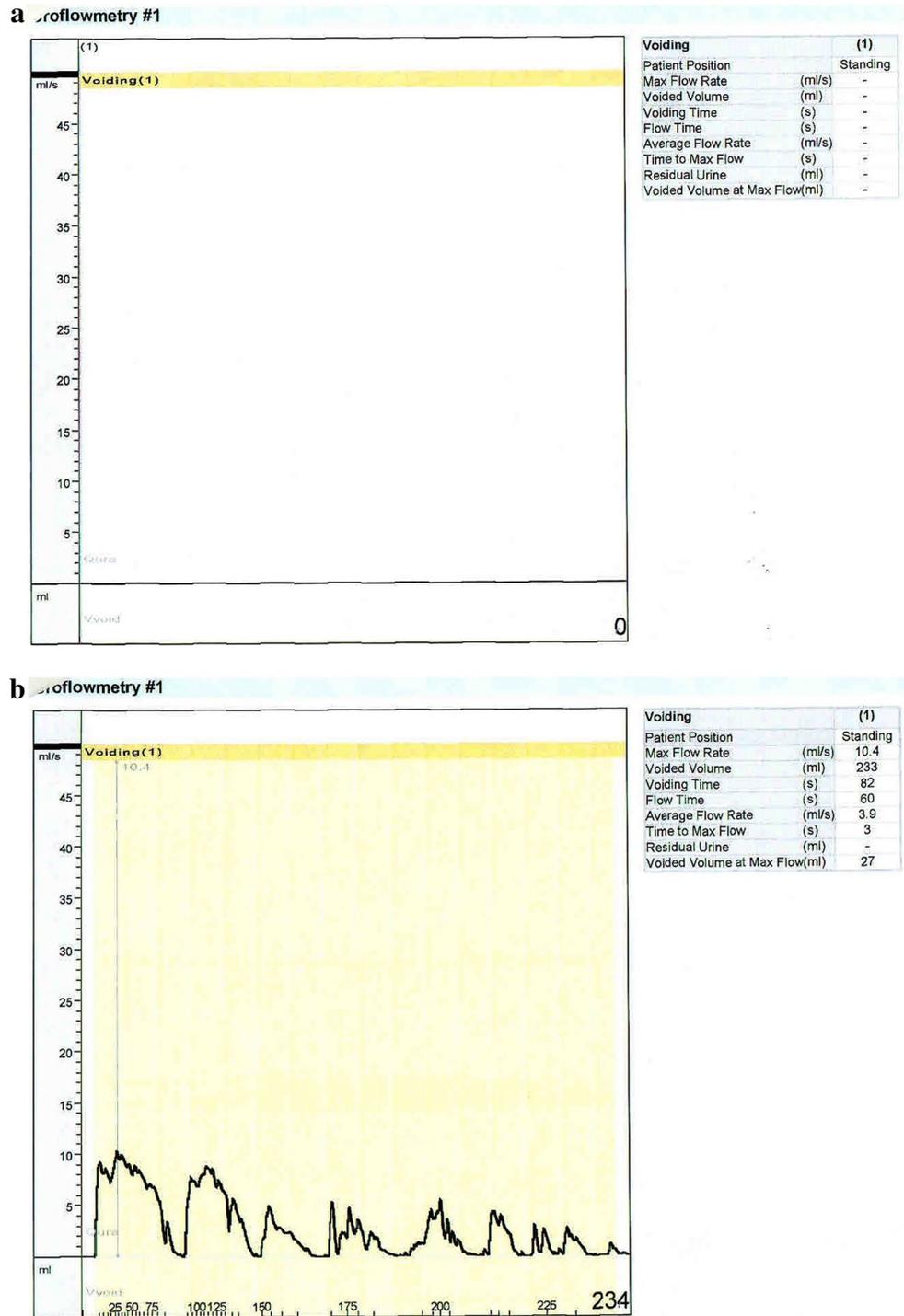


Fig. 1 Late filling phase of a patient **a** before and **b** after sacral neuromodulation showing the increase in compliance and capacity after surgery

Fig. 2 Free uroflowmetry in the same patient **a** before and **b** after sacral neuromodulation



more details regarding the demographic data and the precise etiology of the bladder or bowel symptoms [21].

Scheepens and Keppene considered the neurologic origins of urinary incontinence (including congenital malformations) as unfavorable predictors of clinical response to sacral neuromodulation. There are concerns regarding the IPG longevity and tined lead migration in growing children [22]. Right now, the safety and effectiveness of sacral

neuromodulation in children with neurogenic diseases or those younger than 16 years old has not been approved by the United States’ FDA and the clinical response does not always correlate with the changes in urodynamic parameters. Sacral neuromodulation seems investigational in this special group of patients [23].

In our patients, we dealt with the extreme cases of neuropathic bladders in children and adolescents. 61.53%

responded to the PNE test phase. Four out of eight patients had been scheduled to undergo augmentation cystoplasty, but they had refused it. Four patients stopped using CIC during the follow-up after surgery ($P=0.125$). The mean amount of 24-h urine leakage decreased from 484 g before the surgery to 78 g after the surgery ($P=0.043$).

Three patients who had left school and were studying at home regained their confidence and returned to school and social life. The early and late failure of the device and its adverse events (deviation of the tined lead and IPG pocket site infection in one patient) all occurred in cases of congenital myelomeningoceles. This can be attributed to the effect of skeletal growth, and more physical movement at this age. Also, six out of eight patients reported improvement in their bowel transit in terms of chronic constipation or fecal soiling.

There were some limitations in our study which should be addressed. They included low number of enrolled cases, heterogeneous etiology of NLUTD, including both pre- and post-pubertal age groups, and having a short follow-up period. However, the results added to our knowledge regarding the treatment of extreme cases of NLUTD in children and adolescents.

Conclusion

Our study evaluated the clinical effects of sacral neuromodulation in a small sample size of children with NLUTD. Although the results are promising in a short-term follow-up, the procedure is still not approved officially. Multicenter trials with more homogenous patients and longer follow-up will clarify the efficacy of this procedure in this special group of patients.

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Authors contribution One author has done the data collection, data analysis and writing of the manuscript.

Compliance with ethical standards

Conflict of Interest The authors declare that they have no conflict of interest.

Research involving human participants and/or animals This article does not contain any studies with animals.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocol was approved by the ethics committee of our university.

Informed consent Written informed consent was obtained from the patients and their parents.

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