

ORIGINAL ARTICLE

A retrospective study on female urological surgeries over the 10 years following spinal cord lesion

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Objectives: To evaluate the efficacy and safety over a 10-year period of any urological operations required by female patients with spinal cord lesions (SCLs).

Methods: Retrospective study of urological surgeries from our database performed on females with SCLs from 2001 to 2002. Surgery efficacy for neurogenic lower urinary tract dysfunctions (N-LUTDs) was evaluated by comparing 7-day voiding diaries pre- and post-surgeries, while individual investigations were done pre- and post-surgery to evaluate urological complications. Drawbacks were assessed.

Results: Thirty-eight out of 69 patients underwent one or more urological procedures. Twenty-one out of 42 patients with suprasacral lesions underwent interventions for N-LUTD. The main surgical treatment was endoscopic detrusor infiltration of botulinum-A (Botox 300 UI or Dysport 750 UI) performed 107 times on 15 subjects using aseptic intermittent catheterizations for neurogenic overactive bladder. Mean efficacy duration was 9.2 months. Six females with infrasacral lesions underwent at least one intervention for N-LUTD. Two females in each group underwent tension-free vaginal tape for stress urinary incontinence (SUI), reducing episodes per week of SUI by >90% after 5 years. The most serious urological complication was active vesico-ureteral reflux (VUR) in three patients, treated endoscopically with submucosal injection of Macroplastique. No VUR recurrence was detected during a 6-year follow-up. All bladder stones (five cases) and renal calculi (five cases) were treated with endoscopic transurethral electrohydraulic lithotripsy and extracorporeal shock-wave lithotripsy, respectively. Overall, no serious drawbacks were observed.

Conclusions: Mini-invasive surgeries were exclusively used to address urological issues in chronic SCL patients.
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Keywords: neurogenic detrusor overactivity; urinary incontinence; botulinum toxin A; sacral neuromodulation; tension-free vaginal tape; extracorporeal shock-wave lithotripsy

INTRODUCTION

Neurogenic bladder and its related problems are reported as the most frequent reasons for hospital re-admission of patients affected by chronic SCL.^{1,2}

In the last 10 years, literature has continued to report data on several new mini-invasive treatments, both for neurogenic lower urinary tract dysfunctions (N-LUTDs) and urological complications. At this time, endoscopic detrusor injections of botulinum toxin type A (BoNT-A) toxin represent the most effective minimally invasive treatment (level 1 grade A) to reduce neurogenic detrusor overactivity, as the placement of a urethral sling is currently an established procedure to treat female neurogenic stress urinary incontinence (SUI) according to the recent guidelines for N-LUTD. Moreover, bulking agents are recommended for resolving vesico-ureteral reflux (VUR).³

Objective

The aim of this study is to understand the impact of the most recent minimally invasive procedures for female urological issues 10 years post-SCL. Moreover, we evaluated patients submitted to surgeries compared with those who did not undergo surgeries, as well as examined the differences of those with suprasacral spinal cord lesions

(SS-SCLs), infrasacral SCLs (IS-SCLs) and within these two groups the females who underwent urological interventions.

MATERIALS AND METHODS

All patients admitted to our neuro-urological department provided written informed consent before each treatment and also gave permission to collect personal data for further research.

Data were collected from our neuro-urology admissions database by computerized search system typing the following keywords: 'female spinal cord lesion and urological surgeries'. Accordingly, we were able to access their demographic information, urological surgeries procedures, diagnostic investigation and voiding diaries completed at various stages: before and after each surgery. We selected females admitted to our spinal unit during the period between January 2001 and December 2002, immediately or within 8 weeks of the SCL. All urological interventions and follow-ups were performed in our neuro-urological department of the Florence Spinal Unit.

All these individuals underwent final follow-ups between June and October 2012. Our population was stratified according to anamnesis and urodynamic findings in two groups: SS-SCL and IS-SCL.

Statistical analysis

All tests used for data analysis were performed assuming a maximum α error of 5% ($P < 0.05$).

Table 1 The characteristics of the patients at first discharge post-spinal cord lesion

	Suprasacral spinal cord lesions	Infrasacral spinal cord lesions
Total female patients	42	27
Mean duration time (in days) of the first recovery (range)	94 (34–132)	74 (20–105)
Tetraplegics	13	—
Mean age at the time of inclusion of the study (range years)	36.5 (22–64)	39.2 (24–67)
<i>Etiology of spinal cord lesions</i>		
Traumatic	31	20
Myelitis	8	6
Vascular	2	1
Others	1	0
<i>ASIA/AIS classification</i>		
Number patients (A); (B); (C); (D)	20 (A); 9 (B); 8 (C); 5 (D)	13 (A); 5 (B); 5 (C); 4 (D)
<i>Bladder management</i>		
Aseptic intermittent catheterizations	30 ^b	15
Mixed voiding ^a	2	6
Spontaneous voiding	9	5
Indwelling urethral catheter	1	1
<i>Urological history pre-SCL</i>		
Urological interventions	One patient treated with ESWL for renal calculi	One patient submitted to ESWL for renal calculi
Other neurological diseases	One epileptic	One epileptic
Patients with diabetes mellitus	2	1
Patients with blood hypertension	2	1

Abbreviations: ASIA/AIS, American Spinal Injury Association (ASIA) Impairment Scale (AIS); ESWL, extracorporeal shock-wave lithotripsy; SCL, spinal cord lesion.

^aMixed voiding = patients used daily AIC and assisted bladder emptying using Valsalva maneuver or reflex voiding as well.

^bTwelve patients were tetraplegics using self-aseptic intermittent catheterizations (AICs).

As for each intra-group, descriptive analyses were presented as a percentage and mean to compare those females submitted to surgeries with those not. Chi-square test was used comparing the SS and IS groups, considering the number of patients submitted to surgeries for N-LUTD, urological complications and different urological operations, respectively.

RESULTS

Patient population

A total of 77 females with SCL occurring between January 2001 and December 2002 were admitted to our spinal unit within 8 weeks of the SCL.

Overall, eight subjects were excluded: four were lost after the initial discharge, two died during the follow-up period (although not from urological diseases) and two opted not to come to the final visit.

Overall, 69 patients were selected.

SS-SCL group

Forty-two patients were included. The main characteristics of this group are shown in Table 1. Overall, 27 patients (64.2%) in this group

Table 2 The characteristics of patients at the final follow-up between those submitted to surgeries and those not for each intra group

Patients submitted to urological surgeries	Suprasacral spinal cord lesions		Infrasacral spinal cord lesions	
	Surgeries	No surgeries	Surgeries	No surgeries
Total patients	27	15	11	16
Mean age at the end of the study (range)	45.9 (36–73)	46.4 (32–69)	49.6 (39–68)	49.1 (34–76)
<i>ASIA/AIS scale</i>				
A	15	3	3	8
B	7	4	2	4
C	4	4	5	1
D	1	4	1	3
<i>Etiology of spinal cord lesion</i>				
Traumatic	21	10	9	11
Myelitis	4	4	2	4
Vascular	1	1	0	1
Others	1	0	0	0
<i>Bladder management</i>				
Aseptic intermittent catheterization	21	5	6	8
Spontaneous voiding	5	7	2	5
Mixed voiding	0	2	3	3
Indwelling urethral catheter	1	1	0	0
	<i>Suprasacral spinal cord lesion</i>	<i>Infrasacral spinal cord lesion</i>	<i>Statistical test χ^2 (P)</i>	
Total patients	42	27	NA	
Patients submitted to surgeries for N-LUTD	21	6	(0.040)	
Patients submitted to surgeries for urological complications	9	5	(0.989)	
Patients submitted to more than one different surgery	9	4	(0.711)	

Abbreviations: ASIA/AIS, American Spinal Injury Association Impairment Scale; NA, not applicable; N-LUTD, neurogenic lower urinary tract dysfunctions. Statistical analysis between the two groups is shown in this table.

were submitted to one or more urological procedures (see Table 2, Figures 1 and 2).

IS-SCL group

Twenty-seven patients were included (see Table 1).

Overall, 11 females (40.7%) in this group were submitted to one or more urological surgeries (see Table 2 and Figure 3).

Surgeries for N-LUTD

The description of the surgeries for N-LUTD is reported, taking into account the urodynamic patterns at baseline. Overall, 143 hospitalizations were needed, 129 (89.8%) of which were in day-hospital and the other 14 required 2 days of hospitalizations because of side effects (see Table 3).

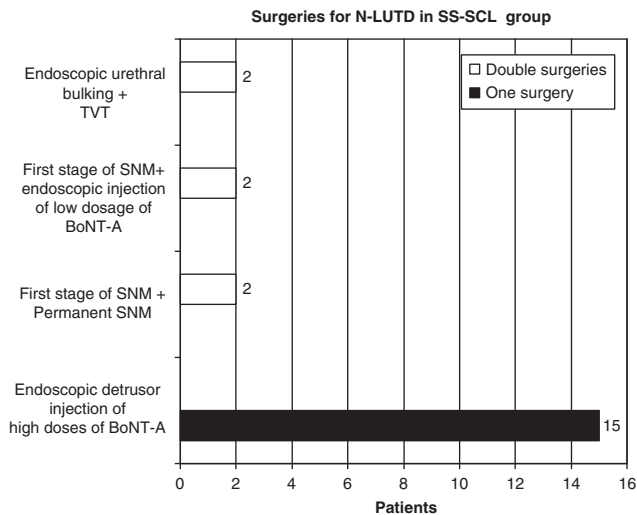


Figure 1 Surgeries performed for N-LUTDs in SS-SCL group.

Neurogenic overactive bladder with severe voiding dysfunction

Fifteen females, 3 of them tetraplegics, affected by SS-SCL with neurogenic overactive bladder (NOB) performing aseptic intermittent catheterizations (AICs) for urine retention, and 4 who were intolerant to antimuscarinics underwent intradetrusor endoscopic injections of high dosages of BoNT-A. Twelve patients had A scale and 3 B according to the American Spinal Injury Association (ASIA) Impairment Scale (AIS).⁴

Primary efficacy end point was changed from baseline in the number of weekly urinary incontinence because of neurogenic detrusor overactivity. During follow-ups, the decision to re-inject was based mainly on a 7-day bladder diary. To qualify for repeat treatment at least one daily episode of urinary incontinence was required. Urodynamic parameters taken into account were maximum detrusor pressure > 40 cm H₂O, and maximum cystometric capacity < 300 ml.

Mean efficacy was 9.2 months (range 3 to 17 months) considering the duration of clinical efficacy and the time between last injection and the rescheduling for re-injection.

Before the first treatment of BoNT-A, three patients presented VUR, two of whom had bilateral VUR, despite the fact that all were on high doses of antimuscarinics and had an indwelling catheter for at least 2 months before surgery. Three ureters had grade III and two ureters had grade IV reflux according to the International Grading System documented by videourodynamics.⁵ At 1–2 months following BoNT-A, all patients returned to blood normal creatinine level (0.6–1.2 mg dl⁻¹) and videourodynamics documented maximum detrusor pressure under 40 cm/H₂O with 5 ureters with grade 2 VUR.

Neurogenic overactive bladder

Treatment: sacral neuromodulation. Four women with incomplete SS-SCL (three had AIS C and one had AIS D), affected by NOB with spontaneous voiding and post-voiding residual < 50 ml were treated with percutaneous first stage of sacral neuromodulation (SNM) on the monolateral S3 sacral root (Medtronic Inc., Minneapolis, MN, USA) as a second-line treatment because antimuscarinics failed.⁶ All reported at baseline in their 7-day voiding diary a mean of minimum two episodes per day of urge incontinence (range 2–4). Comparing diaries at baseline with those before the end of first stage of SNM, two

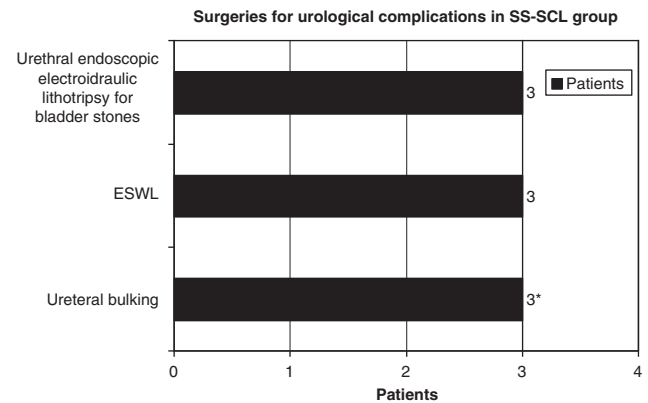


Figure 2 Surgeries for urological complication in SS-SCL group carried out. ESWL, extracorporeal shock-wave lithotripsy; 3*, these patients were submitted to endoscopic high doses of BoNT-A as well.

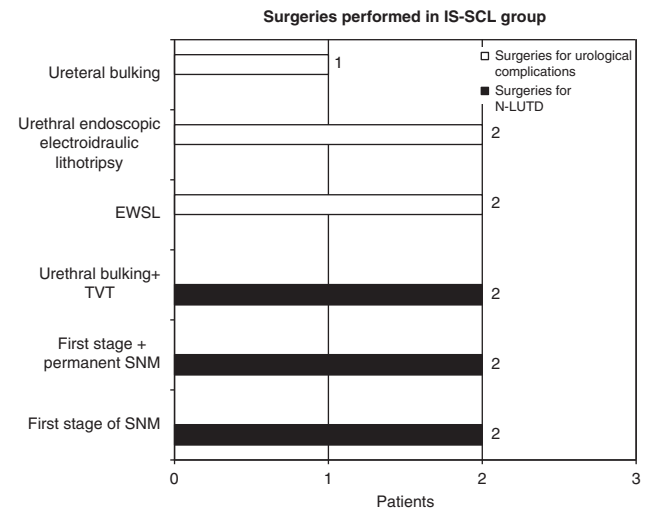


Figure 3 Surgeries in IS-SCL group carried out. ESWL, extracorporeal shock-wave lithotripsy.

females turned into responders in that a concomitant reduction of at least 50% of urge incontinence per day and pads used per day was documented compared with baseline. Subsequently, these patients were submitted to permanent SNM and continued to respond up to the final visit with a follow-up of 87 and 95 months respectively. Through urodynamics, the two patients increased their maximum cystometric capacity, shifting from 230 to 250 ml at baseline to > 400 ml in the follow-ups post-permanent SNM, respectively. Moreover, P det Max decreased from 70 to 75 cm H₂O at baseline to pressure < 40 cm H₂O in the follow-ups post-surgery, respectively.

Treatment: endoscopic detrusor injections of low doses of BoNT-A. In all follow-ups after endoscopic BoNT-A injections, the two patients voluntarily emptied a minimum of 3/4 of their bladder capacity with no need for AIC (see Table 3).

The decision to follow-up with re-injection was based on the same criteria utilized for high doses of BoNT-A. Mean efficacy was 11.6 months (range 6 to 17 months) considering the duration of clinical efficacy and the time between the injection and the moment of rescheduling for reinjection.

Table 3 The surgeries for neurogenic lower urinary tract dysfunction for both groups

Patients	Treatments	Description of the surgeries	Side effects
15	Endoscopic detrusor injection of high doses of BoNT-A	Endoscopic detrusor infiltration in 20 different sites trigone sparing diluted with 20 ml of 0.9 NaCl was performed 88 times using Botox 300 UI (Botox, Allergan, Irvine, CA, USA) and 19 times using Dysport 750 UI (Ipsen, Boston, MA, USA). Range of treatments (4–11)	One patient with hyposthenia after the Botox 300 that disappeared 2 weeks post-injection Four ^a patients with hematuria with Botox 300 Two ^a patients with hematuria with Dysport 750 UI Two ^a patients with fever with Botox 300
8	First stage of SNM (Medtronic Inc.)	The percutaneous first stage of SNM (Medtronic Inc.) lasted a minimum of 4 weeks on the monolateral S3 sacral root	—
4	Permanent SNM	The permanent implantable pulse generator was implanted in the soft tissue of the patient's buttock	One ^a patient with hematoma One patient with bowel disturbances One patient with pain/spasticity in the leg
4	Urethral bulking	Endoscopic peri-urethral injection of Macroplastique 1 cm distal to the bladder neck at three or four points 'around the clock' under cystoscopic control were performed. Macroplastique dosages varied from 5 to 7 ml	One ^a patient with fever
4	Tension-free vaginal tape	Tension-free vaginal tape is a synthetic mesh tape placed beneath the middle of the urethra through a vaginal approach	One ^a patient with fever
2	Endoscopic detrusor injection of low doses of BoNT-A	Same methods reported above using Botox 100 UI 10 times (Botox) and 2 times Dysport 250 UI (Ipsen)	Two ^a patients with fever with Botox

Abbreviations: BoNT-A, botulinum toxin type A; SNM, sacral neuromodulation; UI, urinary incontinence.
^aPatients required 2 days of hospitalizations.

Stress urinary incontinence

Treatment: bulking agent. Four females, two with SS-SCL (one AIS A and one AIS B) and two with IS-SCL (one AIS A and one AIS C) affected by SUI were treated with urethral bulking (see Figures 1 and 3) because of SUI > 14 per week evaluated through the 7-day voiding diary pre-surgery⁷ (see Table 3). Two females with SS-SCL were on antimuscarinics. Three patients had chronic urinary retention and required AIC before surgery, while one female with IS-SCL emptied her bladder spontaneously using valsalva maneuver. Videourodynamics at baseline showed SUI at a bladder volume of 200 ml with valsalva leak point pressure < 60 cm H₂O. During cystometry, no NOB was detected. Only one patient with SS-SCL did not improve after first injection. A decrease in > 50% of SUI episodes compared with baseline was documented in three out of four females (75%) only up to 6 months following treatment. A second treatment was performed on all patients between 6 and 12 months following the first because they returned to similar baselines. Comparable clinical results were noted with the second injection.

Tension-free vaginal tape (TVT) procedure. All four patients (two with SS-SCL and two with IS-SCL), previously treated with bulking agents, underwent the TVT procedure, when SUI occurred again after a second sphincter injection.^{8,9} The only patient with IS-SCL who previously emptied her bladder spontaneously started AIC regimen after TVT surgery.

A reduction of around 90% in SUI compared with baseline was maintained up to the final follow-up at around 6 years. In particular, two patients with IS-SCL recovered continence and were fully dry for a follow-up of 5 and 7 years, respectively.

Detrusor acontractility or underactivity

Four females with incomplete IS-SCL (three AIS C and one AIS D) suffering from neurogenic non-obstructive urinary retention, two of whom with complete urinary retention and two incomplete urinary

retention using three catheterization per day for high residual urine around 300 ml reported in their 7-day voiding diary, underwent first stage of SNM because all were unresponsive to oral alpha-blockers.⁵

Two females received permanent SNM implants because a concomitant reduction of at least 50% of their residual urine ml⁻¹ and number of catheterizations per day was detected until the final follow-up of 6 and 7 years, respectively; evaluation occurred through the comparison of their 7-day voiding diaries before first stage of SNM with those at the end of first stage. Urodynamics documented the presence of bladder sensation and a bladder contractility index of > 100 in the emptying phase compared with baselines in the follow-ups after surgery.¹⁰

Surgeries for urological complications

Overall, 14 patients underwent interventions to remedy urological complications (see Figures 2 and 3).

Vesico-ureteral reflux. Overall, four females using AIC as bladder management had VUR, two of whom had bilateral VUR. Three out of four females had SS-SCL and two presented bilateral VUR. Only one patient (AIS A) affected by IS-SCL was treated for monolateral VUR. Videourodynamics showed that all six ureters had grade II reflux according to the International Grading System and maximum detrusor pressure < 40 cm H₂O.⁵ The six ureters were treated through endoscopically submucosal injections of Macroplastique. Macroplastique with dosage variable (0.7–1.5 ml) was injected submucosally under each ureteric orifice to convert the opening to a slit-like shape.^{11,12}

One-month post-treatment, new videourodynamics showed that all VUR had disappeared. Only one patient with SS-SCL was retreated with Macroplastique for recurrence of monolateral VUR (grade II) 1-year after the first treatment. Subsequently, no recurrence was detected in a follow-up of 5–7 years.

Table 4 Results in the two groups with stones in the urinary tract

	Suprasacral spinal cord lesions	Infracsacral spinal cord lesions
<i>Bladder calculi</i>		
Total patients	3	2
Number of patients according to their ASIA/AIS class (A–D)	2 (A); 1(B)	1 (A); 1 (B)
Number of patients according to their bladder management	Two aseptic intermittent catheterizations One indwelling catheter	Two aseptic intermittent catheterizations
Range size of the stones	0.9–2.3 cm.	1.2–2.1 cm
Main results	In one patient, indwelling catheter recurrence was observed after about 2 years. All patients were free from bladder stones in the final follow-up of 2, 3 and 6 years	In one patient, recurrence was documented after about 2 years. All patients were free from bladder stones in the final follow-up of 2 and 8 years
<i>Kidney calculi</i>		
Total patients	3	2
Range size of the calculi	0.9–1.6 cm	1–1.7 cm
The lithotripters used	Storz, Tuttlingen, Germany: Germany company Model: Wolf Piezolith 3000 piezoelectric or SLX-F2 ^a	
Number of patients according to their ASIA/AIS class (A–D)	2 B; 1 C	1 B; 1 C
Number of patients according to their bladder management	Two aseptic intermittent catheterizations One spontaneous voiding	One mixed voiding One spontaneous voiding
Main results	In one patient, recurrence was observed after about 4 years. All patients were stone free up to the final control with a follow-up of 2, 3 and 4 years, respectively	In one patient, recurrence was noted after about 3 years. All patients were stone free up to the final control with a follow-up of 1 and 7 years, respectively

Abbreviations: ASIA/AIS, American Spinal Injury Association (ASIA) Impairment Scale (AIS); ESWL, extracorporeal shock-wave lithotripsy.

ASIA/AIS was used to classify patients according to injury severity.

^aSLX-F2 = this lithotripter was used in the two patients with kidney stones recurrence.

Bladder stones. Five females, three with SS-SCL and two with IS-SCL, had bladder stones treated with urethral electrohydraulic lithotripsy (see Table 4).

Kidney stones. Extracorporeal shock-wave lithotripsy was used on five patients.

The treatment was reserved evaluating both clinical symptoms such as recurrent symptomatic urinary tract infection, abdominal pain and hematuria, as well as several imaging modalities such as abdominal ultrasound for detecting hydronephrosis and Uro-TC to gain information about the stone (size, location and radiodensity). The extracorporeal shock-wave lithotripsy was always performed at day-hospital (see Table 4).

Anesthesia. No general anesthesia was ever used for any of the interventions.

Statistical analysis

In comparing the characteristics of patients submitted to surgeries with those not undergoing surgeries, we noted that AIS A represented a higher risk factor in the SS-SCL group, documented in 15 out of 18 females (83.3%), while the higher risk factor for the IS-SCL group was AIS C, evident in 5 out of 6 females (83.3%) (see Table 2).

A significant statistical difference was reached between the two groups regarding the number of patients submitted to surgeries for N-LUTD (see Table 2).

DISCUSSION

Over this 10-year period, 55.1% of females with SCL required urological surgeries. This confirms data in literature reporting that urological issues represent frequent causes of re-hospitalization for chronic SCL patients.^{1,2}

The inclusion of a large patient pool in the SS-SCL group mainly with AIS A needing high doses of BoNT-A to treat NOB explains why those with AIS A have an elevated risk for undergoing urological surgeries. Endoscopic detrusor infiltration of high doses of BoNT-A is the most frequent urologic surgery performed and this fact justifies the significant statistical difference found in the number of patients undergoing N-LUTD surgeries in the SS-SCLs compared with IS-SCL group.

Concerning the duration/efficacy of detrusor infiltration, our findings are similar to other studies, taking into account the doses and types of BoNT-A used.^{13–16}

To reach a notable improvement in voiding symptoms, two different procedures were utilized during the follow-ups of patients with incomplete SCL and NOB who were able to void spontaneously and were unresponsive to various antimuscarinics.

All patients started with the first stage of SNM because it is a minimally invasive surgery with the possibility of long-lasting voiding improvement compared with endoscopic detrusor infiltration of low dosage of BoNT-A, and to avoid the risk of increasing the post-voiding residual urine ml⁻¹ and having to start AIC as well.^{3,17,18}

However, the repetitive use of endoscopic detrusor injections of low dosages of BoNT-A never required the use of AIC to increase the post-voiding residual urine ml⁻¹ on the two patients who did not respond to first stage of SNM.

Concerning patients with incomplete SCL suffering from neurogenic non-obstructive urinary retention, SNM is, even at this time, the only available mini-surgery option in case conservative treatments failing which explains why a higher percentage of the IS-SCL group with AIS C incurred urological interventions during follow-ups.

Regarding females submitted to different surgeries during the 10-year follow-up, an interesting and favorable commonality for both groups is the dramatic clinical improvement over the medium-long term of SUI with TVT surgery, after the partial and short-time clinical benefits with peri-urethral injections of Macroplastique. This result confirms previous positive findings in literature; therefore, TVT surgery should be part of the neuro-urologist's surgical armamentarium.^{8,9}

It was worth saying that at the time of patient inclusion in the studies, literature had not reported any data concerning, for example, the efficacy/safety of repetitive use of BoNT-A on SCL patients for NOB who were unresponsive to antimuscarinics or the use of SNM on subjects with SCL suffering from N-LUTD.

It was not always easy to give patients comprehensive information regarding the chosen treatment. Over the course of a 10-year period, we were able to increase our knowledge of the efficacy/safety of the surgeries used.

All urological complications, as well as LUTD, for both groups, were resolved through mini-invasive surgeries exclusively.

Although it was impossible to draw general efficacy and safety conclusions for urological operations based on the few patients included (range 2–15 patients), the fact that we used mini-invasive treatments exclusively for all urological issues represented relevant data. The only case where major surgery was indicated was for patients submitted to repetitive BoNT-A. The alternative option was ileocystoplasty augmentation, but none of them were willing to undergo more invasive surgery.^{19,20}

One more encouraging result of our study is that overall side effects correlated to surgeries were documented in few patients, and drawbacks were slight and transient.

Finally, the surgeries were almost always performed at day-hospital, and so this study seems to indicate that neuro-urological departments should be organized to provide predominantly day-hospital surgery.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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