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ABSTRACT

- Recovery of bladder and bowel function are the highest priority among para and tetraplegic patients.
- Pelvic organ autonomic disorders are among the most important factors affecting morbidity and quality of life of thoracic spinal cord injured patients
- Idealized by Brindley in 1977, sacral nerve roots stimulation by means of a neuroprosthesis implantation showed good results and became commercially available (Finetech-Brindley Bladder System®, Finetech Medical® Ltd., Welwyn Garden City, UK), with more than 2500 procedures performed worldwide, reaching 20 years of follow-up. After the procedure, most of the patients became or remained continent, had their bladder capacity increased and managed to void with low residual (less than 30mL) without the need of self-catheterization, which drastically reduced the incidence of urinary infections. Moreover, many reported electrically induced bowel movements and penile erection.[1]
- Initially described by Possover and colleagues in 2007 as a rescue procedure for patients with damaged Brindley cables,[2] the laparoscopic implantation of neuromodulation electrodes (LION procedure) was further developed and allows for selective neuromodulation of virtually any intrapelvic nerve.[3]
- Since 2014, the LION procedure became approved and available in Brazil, being considered a level 1C evidence for promoting locomotion.
- The objective of this study is to assess the urodynamic (UDS), mobility and independence outcomes of patients submitted to the LION procedure for modulation of pudendal, sciatic and femoral nerves.

METHODS

- This is a retrospective analysis of UDS outcomes of spinal cord-injured patients submitted to the LION procedure for bilateral neuromodulation of femoral, sciatic and pudendal nerves (fig 1 and 2) who completed 12 months of follow-up.
- Average operative time was 3.9 hours and one patient demanded a reoperation due to a femoral electrode displacement. One of the patients was also diagnosed with a left pudendal electrode displacement, which did not demand reoperation, since urinary and sexual outcomes were stable even with unilateral stimulation.
- All patients underwent an intensive rehabilitation protocol (3-5 sessions/week) where they were taught how to use the movements generated by nerve stimulation on their daily activities. Twelve-month data was collected while they were still under the rehabilitation protocol, which is carried out until patients are still experiencing sensible improvements on the quarterly quantitative assessments.
- All the UDS were performed by the same examiner before the LION procedure and one year after the procedure.
- The results were tabulated to compare the maximum cystometric capacity (MCC), bladder compliance (BC), volume of the first detrusor overactivity (VDO) and the use of anticholinergics.
- Primary outcome were the UDS results. Secondary outcomes were Quality of Life as Measured by the Qualiveen questionnaire, reduction in Anticholinergic use, mobility and independence status, and overall treatment satisfaction.
- Mobility was assessed qualitatively with regards to subject's ability to stand up with (dependent) aid of caregiver/orthosis and ability to take steps/walk. Independence was assessed qualitatively regarding patients ability to transfer and self-catheterize.
- All patients had signed a consent authorizing the use of their clinical data for research and educational purposes.
- Paired T test was used to compare pre and post-operative means.

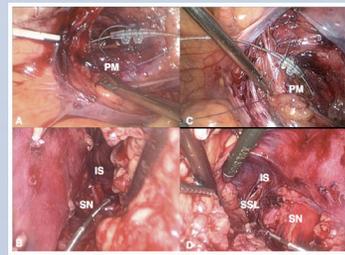


Figure: Electrodes Placement: A – left femoral nerve; B – left sciatic and pudendal nerves; C – right femoral nerve; D – right sciatic and pudendal nerves (PM – Psoas Musculo; IS – Ischial Spine; SN – Sciatic Nerve; SSL – Sacrospinous Ligament)



Figure 2: Electrodes Placement – Schematic. This diagram shows electrodes and pulse generator placement with a 16-poles device. Two four poles electrodes sit justo-neurally to the femoral nerves, whilst larger spacing electrodes would have 2 poles inserted into the Alcock's canal and 2 on the sciatic nerve at the level of the sciatic notch.

RESULTS

- Nine patients were submitted to the LION procedure from 2016 to 2017 and had their UDS results collected previously and one year after the procedure. The data results are displayed on table 1.
- We observed a statistical significant (p=0.050) increase of 103.6mL on MCC, which corresponds to a 40% increase in relation to preoperative MCC. BC and VDO showed a trend for improvement, which was not statistically significant (Table 2)
- Two out of nine patients reduced the doses or discontinued the use of anticholinergics postoperatively.
- All patients improved at least one parameter regarding mobility. All patients who were initially dependent on caregivers for CIC showed progression to totally independence or partial dependence.
- Quality of life parameters as measured by the Qualiveen questionnaire showed a trend for improvement, but these did not reach statistical significance.

Patient	Preoperative				12 months after LION procedure			
	MCC (mL)	BC (mL)	VDO (mL)	Anticholinergics (mg/day)	MCC (mL)	BC (mL)	VDO (mL)	Anticholinergics (mg/day)
1	100	15	20	10	150	20	15	5
2	120	18	25	12	180	22	18	8
3	110	16	18	11	140	19	16	6
4	130	20	22	13	160	24	20	7
5	140	22	24	14	170	26	22	9
6	150	24	26	15	190	28	24	10
7	160	26	28	16	210	30	26	11
8	170	28	30	17	230	32	28	12
9	180	30	32	18	250	34	30	13
Mean	140	20	22	14	170	24	22	8
Median	130	18	20	12	160	22	18	7
Standard Deviation	30	4	4	2	30	4	4	2

Patient	Preoperative				12 months after LION procedure			
	MCC (mL)	BC (mL)	VDO (mL)	Anticholinergics (mg/day)	MCC (mL)	BC (mL)	VDO (mL)	Anticholinergics (mg/day)
1	100	15	20	10	150	20	15	5
2	120	18	25	12	180	22	18	8
3	110	16	18	11	140	19	16	6
4	130	20	22	13	160	24	20	7
5	140	22	24	14	170	26	22	9
6	150	24	26	15	190	28	24	10
7	160	26	28	16	210	30	26	11
8	170	28	30	17	230	32	28	12
9	180	30	32	18	250	34	30	13
Mean	140	20	22	14	170	24	22	8
Median	130	18	20	12	160	22	18	7
Standard Deviation	30	4	4	2	30	4	4	2

CONCLUSIONS

- These results are comparable to the ones observed by the ones described by Possover at al[3], the idealizers of the LION procedure. No significant surgical or perioperative complications were registered, except for one reoperation due to one electrode displacement on the femoral nerve. A second patient presented with a unilateral pudendal nerve displacement, without any deterioration of urinary and sexual outcomes.
- Mobility and independence outcomes were still improving when data were collected and all reported patients are still under treatment. As per our protocol, patients undergo an intensive rehabilitation (2-3h/day; 3-5 session/week) whilst quarterly goals (individually established) are being met. When evolutions ceases, patients are transitioned to maintenance protocols. So far, no patient has been transitioned to that protocol.
- Such outcomes are extremely encouraging and suggest that neuromodulation of the lumbosacral plexus can play an important role on the rehabilitation of patients with SCI. These outcomes are being quantified on a randomized controlled trial with conclusion expected for 2020.
- The LION procedure is feasible and reproducible procedure and pudendal neuromodulation promotes a significant increase in bladder capacity, likely by improving bladder compliance and controlling DO in spinal cord injured patients, whereas sciatic and femoral stimulation can promote improvement in mobility.

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