

Category No.

14

Ref. No.

289

Abstract Reproduction Form B-1

Author(s):

P.Bertapelle[†], F.Cappellano^{*}, M.Spinelli^{*}, F.Catanzaro^{*}, R.Carone[†], A.Zanollo^{*},
R. Vallone[^], E. Cruciani[^], G.Giardello[°], F.de Seta[°] on behalf of GINS group

Double Spacing

Institution
City
Country^{*} Multimedica, S.S. Giovanni, [†]CTO-CRF-MA, Torino, ^{*} Osp. Fomaroli, Magenta,
[^]Osp. Fatebenefratelli, Roma [°] Medtronic Italia, Italy

Double Spacing

Title (type in
CAPITAL
LETTERS)**SACRAL NEUROMODULATION: RESULTS OF A PROSPECTIVE STUDY
ON 39 IMPLANTED PATIENTS.**

Aim of the Study: Sacral Neuromodulation is a safe and effective therapy to regain bladder control in a large variety of lower urinary tract dysfunctions. However, long term results have been described in literature with a wide range of opinions.

The aim of our study is to harmonize selection criteria, diagnosis, surgical technique and follow-up of patients in a multicenter study in order to demonstrate the exact long term results of the procedure.

Materials and Methods: From May 1998 to March 1999, 39 patients (10 males, 29 females) affected by lower urinary tract dysfunctions or pelvic pain were implanted with a permanent device for sacral neuromodulation and recruited in a multicenter prospective study. The patients were affected by:

Diagnosis	N	%
Detrusor instability	15	38,46%
Voiding disorder	13	33,33%
Hyperreflexia	5	12,82%
Pelvic pain	4	10,26%
Urgency-frequency	2	5,13%

Objective parameters before surgery at 1 month, 3 months and 6 months follow-up studies, collected in a common data collecting form, were the following: urinary frequency, incontinence episodes and number of pads per day, mean voiding volume, mean post voiding residual urine and number of intermittent catheterism. Moreover a pain analogue scale (Scott) was used to evaluate pelvic pain. Parameters concerning quality of life, psychometric test and stimulation parameters was also collected.

Results: The following tables show the results of our study where * means $p < 0.05$ vs baseline, at each follow-up p is calculated with a paired t-test.

Detrusor instability (N=15)	Baseline	1 month after implant (N=10)	3 months after implant (N=11)	6 months after implant (N=5)
Voiding/day	15.88±6.13	6.59±1.4*	6.6±2.1*	6.1±3.2
Leak episodes	5.25±2.9	0.38±0.74*	1.05±1.38*	0*
Pads	5.62±2.2	0.31±0.70*	0.65±0.7*	0*
Voided volume (cc)	97.5±31.9	223.7±96.9*	188.3±75.6*	271.6±25.6

Abstract Reproduction Form B-2

Author(s): **P. Bertapelle⁺, F. Cappellano^{*}, M. Spinelli^{*}, F. Catanzaro^{*}, R. Carone⁺, A. Zanollo[§], G. Giardiello^o, F. de Seta^o on behalf of GINS group**

Retention (N=13)	Baseline	3 months after implant (N=9)	3 months after implant (N=9)	6 months after implant (N=9)
Voiding/day	2,78±4.58	5,4±5	5,25±1.33	5,25±0.64
Voided volume (cc)	55,56±101,4	284,28±35*	287,5±100	246,25±41.5*
Residual volume (cc)	267,08±209.8	42,5±46.2	0*	0
Catheterism/day	4,09±1.5	0,38±0.45*	0,33±0.5*	0,5±1

Hyperreflexia (N=5)	Baseline	3 months after implant (N=3)
Voiding/day	10.75±9.9	6.25±0.35
Leak episodes	6.1±15.1	0.5±0.7*
Pads	5.16±0.7	1±0.5*
Voided volume (cc)	137.5±149.3	250±50
Residual volume (cc)	143.3±90	50±50
Catheterism/day	2±2.8	1±0.5

Pelvic pain (N=4)	Baseline	1 month after implant (N=3)	3 months after implant (N=3)
Pelvic pain (visual analogue scale)	9.25±0.9	1±1.4*	2±2.8

QoL results

N=19	QOL-I score	bladder capacity (cc)	Incont episodes	Urinary freq.	α pads/day
baseline	30.22	109.23	6.10	15.28	5.80
3 months	79.66*	188.33	1.06	6.05	0.72
6 months	90.34*	225.00	1.0	6.13	0.50

	Detrusor instability			Retention		
	f (Hz)	amplitude (V)	pulse width (µsec)	f (Hz)	amplitude (V)	pulse width (µsec)
1 month	21.50±9.81	1.45±0.67	225.00±42.43	15.20±7.45	1.76±1.17	213.00±9.49
3 months	22.00±10.2	1.78±0.63	210.00±00	16.40±8.91	2.05±1.12	210.00±0.00
6 months	22.75±11.8	2.03±0.79	240.00±60.00	13.67±3.83	1.76±0.79	215.00±12.25

Pshycometric test vs results of SNM

MMPI-2 results	Implants results (pts)		
	Positive	Intermediate	Negative
0	8	1	0
1	4	1	0
2	1	0	4

Conclusions: Our prospective study is still continuing. Preliminary results show how sacral neuromodulation must be considered an effective therapy in well selected patients. One patients was explanted due to infection.

The definition of valid parameters of regulation for each dysfunction still need to be found, and this will be our goal for the future.