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CHRONIC PUDENDAL NERVE NEUROMODULATION USING AN IMPLANTABLE MINI-STIMULATOR IN WOMEN WITH IDIOPATHIC REFRACTORY DETRUSOR OVERACTIVITY INCONTINENCE

Hypothesis / aims of study

Detrusor overactivity incontinence is a condition refractory to multiple treatment options in many patients. Chronic pudendal nerve neuromodulation with a novel technique called bion® therapy (Advanced Bionics Corporation, Valencia CA, USA) might be a valuable addition to the physician's therapeutic arsenal. This abstract summarizes the 6-month results of a pilot study on idiopathic female patients in whom other treatments failed.

Study design, materials and methods

The bion is a self-contained, battery-powered, telemetrically programmable, current-controlled mini-neurostimulator (size 27 x 3.3 mm, weight 0.7 g) with an integrated electrode. It can be implanted at its target location, adjacent to the pudendal nerve at Alcock's Canal, with a specially developed tool kit after making a 3-4 mm skin incision 1.5 cm medial to the ischial tuberosity. Vaginal palpation of the ischial spine, X-ray screening and electrodiagnosis are used for guidance. The default stimulation parameters are: frequency 20 Hz, pulse width 200 microseconds, duty cycle 4.92 seconds on / 4.92 seconds off. The amplitude is adjusted to the patient's sensations and can be changed by the patient with a remote control. The bion's battery can be recharged while the patient sits on a specially developed chair pad for about 15 minutes. Recharging needs to be done regularly, preferentially daily.
Trial subjects qualified for implantation of a bion after a positive percutaneous screening test (PST). Such a test includes the performance of a cystometrogram without and with percutaneous pudendal nerve stimulation. A PST is considered positive if stimulation results in a more than 50% increase in the bladder volume at the first involuntary detrusor contraction or the maximum cystometric capacity. The test is repeated at the contralateral side in case of a negative result.

Five-day voiding-incontinence diaries were the main tool for the evaluation of therapy. The amounts of urine voided, the occurrence of urinary incontinence, the amounts of urine lost (subjectively graded as small (1 point), moderate (2 points) or large (3 points)) and the number of pads used were recorded. A leakage severity index was calculated by multiplying the average grade of a leak by the number of leaks per day. The Wilcoxon signed-ranks test was used for statistical analysis.
The pilot study was approved by the institutional ethical committee and all patients gave their informed consent.

Results

A PST was performed in 14 women with idiopathic urodynamically demonstrated detrusor overactivity incontinence who had failed drug treatment, pelvic floor physiotherapy and various forms of neuromodulation, including anal and vaginal plug stimulation (AVPS), posterior tibial nerve stimulation (PTNS) and sacral nerve neuromodulation (percutaneous nerve evaluation (PNE) as well as definitive implant (SNS)). Five (36%) women (1 to 5 in

Patient	Age (yrs)	Suspensions	Previous treatment
1	44	Sling	tolterodine, oxybutynin, trial medication, SNS, 3 PNE's (a)
2	48	-	tolterodine, oxybutynin, physiotherapy, AVPS, PTNS, PNE
3	32	-	tolterodine, oxybutynin
4	56	3x	tolterodine, oxybutynin, flavoxate, physiotherapy, 2 PNE's (b)
5	67	-	tolterodine, oxybutynin, PNE
6	73	-	oxybutynin, flavoxate, trial medication, physiotherapy, AVPS, PNE

(a) The sling procedure was performed between the explant procedure of the SNS pulse generator and 3 renewed PNE's
(b) The second PNE was positive, but the patient preferred to participate in the pilot study

Table I) responded positively to the PST (this PST was positive on the side of the failed PNE in patient 2) and received a bion. A sixth patient failed the PST, but had a significant carry-over effect: she was completely dry for the next four days. Because she also failed a PNE, she received a bion as well. The implant procedures in the six patients took 15, 25, 119, 123, 67 and 38 minutes, respectively.
The results from the voiding-incontinence diaries in the first 5 implanted patients after 6 months compared with baseline are summarized in Table II. Patient 6 had a 3-month follow-

	incontinence episodes		pads		leakage index	severity	voided volume (ml)	
Patient	baseline	6 mo	baseline	6 mo	baseline	6 mo	baseline	6 mo
1	9.6	5.4	8.2	5.4	16.2	8.6	102	121
2	4.6	1.2	2.0	1.4	5.6	2.0	134	128
3	8.2	4.3	8.2	5.3	13.4	6.0	107	191
4	5.8	0.6	2.8	0.6	8.8	0.6	188	192
5	6.2	2.8	6.0	2.8	11.6	6.2	164	139
Mean	6.9	2.9	5.4	3.1	11.1	4.7	139	154
6	2.6	0.2*	2.8	1.2*	3.8	0.4*	145	209*

* Value at 3 months of follow-up

up at the time of writing and was not included in the statistical analysis. On average, no statistically significant change was found in the voided volume per micturition, but the number of incontinence episodes per day, the number of pads used per day and the leakage severity index had decreased significantly. There were no severe side effects.

Interpretation of results
A statistically significant and clinically relevant reduction of detrusor overactivity incontinence was obtained in 6 implanted patients in whom established therapies had failed. Bion therapy is relatively simple and minimally invasive. It is well tolerated by the patient.

Concluding message
Chronic pudendal nerve neuromodulation by bion therapy may considerably reduce the degree of detrusor overactivity incontinence in severely refractory cases. The fact that clinically relevant results were obtained in 5 of 6 patients who failed sacral nerve neuromodulation indicates that pudendal nerve neuromodulation may be a more effective approach in patients with idiopathic detrusor overactivity incontinence.

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