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FIVE-YEAR FOLLOW-UP OF SACRAL NERVE NEUROMODULATION IN 60 WOMEN WITH IDIOPATHIC REFRACTORY URGE INCONTINENCE

Hypothesis / aims of study

Sacral nerve neuromodulation (SNS) for the treatment of voiding dysfunction refractory to conservative therapy was introduced about two decades ago. Reports on the long-term follow-up in large homogeneous groups of patients are however still scarce. This abstract reports on the 5-year follow-up of 60 women implanted because of idiopathic urge incontinence refractory to pharmacologic therapy.

Study design, materials and methods

Patients qualified for implantation if they responded positively to a 3 to 5-day test stimulation (PNE), that is, with a more than 50% decrease in the number of incontinence episodes and pads used per day. Implants were placed by open surgery. During follow-up, the stimulation amplitude was adjusted to achieve an optimal result, while the pulse frequency and width were kept at 10 Hz and 210 µsec, respectively. The use of anticholinergics was allowed. Evaluation consisted of the completion of 3-day voiding-incontinence diaries on a 3 to 6-monthly basis. Derived from these diaries were: the number of incontinence episodes and pads used per day, the daily voiding frequency and the average voided volume per void. In case of missing parameter values, the last available value was carried forward to prevent over-representation of responders at the longer follow-up marks. At each follow-up mark, the patients were classified as a success or a failure as follows: a) Complete success: at least 90% improvement in the number of incontinence episodes and pads used per day, b) Partial success: at least 50% improvement in these two parameters, c) Failure: a less than 50% improvement in at least one of these two parameters or conversion to an other therapy (including explantation of the IPG, botulinum toxin injections, urinary diversion and anti stress incontinence surgery, but not including anticholinergics).Results are shown as the median value and interquartile (25th to 75th percentile) range. The paired t test was used to assess within-patient differences.

Results

The 60 women, aged 48 (41 – 54) years, were implanted between 1990 and 2004. The pre-operative cystometrogram demonstrated detrusor overactivity in 57 of them. Table 1 shows the diary parameters at baseline and at a selection of follow-up marks (because of space limitation) using the last observation carried forward procedure. The changes with respect to baseline were all statistically significant (all p's <= 0.001). This was also true for the follow-up data not shown. Results were not essentially different when using the data of the really available diaries (numbers displayed in Table 1).

Table 1. Voiding diary results in 60 women with urge incontinence using the last observation carried forward procedure.

	incontinence episodes	pads	frequency	voided volume (ml)	# diaries
baseline	8.85 (6.10 – 10.83)	5.85 (4.85 – 9.10)	11.80 (9.15 – 15.38)	122 (91 – 178)	60
1 month	1.00 (0.00 – 3.23)	1.30 (0.00 – 2.83)	8.30 (7.08 – 10.00)	196 (137 – 239)	47
6 months	2.00 (0.30 – 4.23)	1.50 (0.00 – 3.53)	8.45 (7.00 – 10.00)	189 (136 – 212)	53
12 months	1.85 (0.30 – 4.53)	1.80 (0.00 – 3.00)	8.35 (7.00 – 9.30)	195 (143 – 222)	50
30 months	3.00 (1.00 – 6.05)	2.70 (0.48 – 4.23)	9.00 (7.33 – 10.65)	171 (121 – 220)	42
60 months	3.15 (0.78 – 6.30)	3.00 (0.00 – 5.30)	8.85 (7.63 – 11.00)	170 (107 – 211)	31

In spite of these good results, the number of patients who classified as a success gradually decreased to 25 (42%) after 5 years (Figure). The success rate at this follow-up mark was 62% using a less strict definition of success: an at least 50% (partial success) or 90% (complete success) improvement in the number of incontinence episodes *or* (instead of *and*) pads used per day. Table 2 shows the state of the patients after 5 years. SNS was still used by at least 45 (75%) women; the exact number is unknown due to the patients who were lost to follow-up. Three patients post-operatively underwent surgery for stress urinary incontinence. This condition was diagnosed before implantation in one of them, but the urge incontinence was considered more important. Five patients (8%) underwent invasive surgery (bladder augmentation or urinary diversion) for their overactive bladder symptoms and two intradetrusor injections of botulinum toxin.

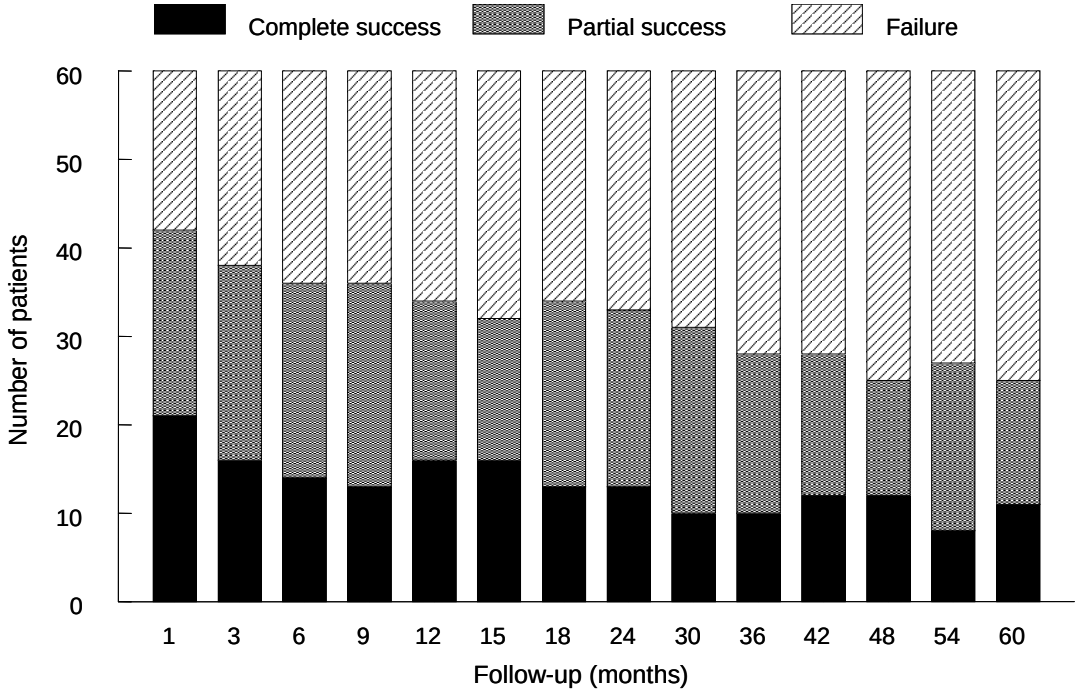

Table 2. State of 60 women with urge incontinence 5 years after implantation of an IPG.

On active SNS	43
On active SNS, undergone anti stress incontinence surgery	2
IPG turned off, left in situ	1
Explantation of IPG	1
Explantation of IPG, undergone anti stress incontinence surgery	1
Ileocystoplasty, IPG turned off	1
Suprapubic catheter, IPG turned off	1
Urinary diversion (Bricker anastomosis)	3
Urinary diversion (Bricker anastomosis) and cystectomy	1
Botulinum toxin type A	2
Withdrawn from follow-up	4

Interpretation of results

The voiding-incontinence diary results after 5 years of SNS demonstrated a statistically significant improvement with respect to baseline in our group of 60 urge incontinent women. On an individual level, however, the success rate had dropped to 42 or 62% dependent on the definition of success. At least 75% of the patients still used SNS. A bladder augmentation or urinary diversion was undergone by 8%. Botulinum toxin was however not available at the 5-year follow-up mark in most patients, so that it may be assumed that this rate will be lower in future patient groups.

Concluding message

The success rate of SNS dropped to 42 to 62% after 5 years in a group of 60 women with idiopathic urge incontinence. At least 75% of the patients still used SNS at this follow-up mark.

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Medical Ethics Committee METC, Erasmus MC**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**