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LONG TERM RESULTS OF SACRAL NERVE STIMULATION FOR LOWER URINARY TRACT SYMPTOMS: A SINGLE CENTER STUDY

Hypothesis / aims of study

Since 1990 neuromodulation for refractory complaints of urge incontinence, urgency-frequency and urinary retention by sacral nerve stimulation has been applied. Initially patients were implanted according to the protocol of a multicenter study initiated by Medtronic in order to achieve FDA approval (MDT-103). Few data on long term follow-up are available. In this study we analyse the results of patient treatment in a single center with long-term treatment experience.

Study design, materials and methods

This is a retrospective transversal study. The surgery logs covering the period between October 1990 until December 2002 were examined of patients either receiving a new definitive neuromodulation system or having revision surgery.
The following data were recorded: name, sex, date of birth, complaints, date of implantation, date of last check-up, result of neuromodulation at the last check-up, number of adverse events, number of surgical corrections of possible adverse events and, when applicable, if the adverse events had successfully been addressed. Patients were included in the analysis if they had a follow-up of more than 12 months.
To make statistical analysis feasable the complaints were divided into an 'urge' category and 'retention' category. For the same reason and because in many charts the result at the last follow-up visit was written down in terms of 'good' or 'insufficient' results have been categorized accordingly.
The criteria for a good result were: complete and lasting disappearance of symptoms or satisfactory symptom relief for the patient.
An insufficient result was noted when patients were not satisfied, when symptoms recurred or in the case of an unresolved adverse event. When a patient was explanted an insufficient result was recorded. If a IPG was reprogrammed at the last visit, a good result was assumed. This is based on our policy that patients are instructed to report when the symptoms do not improve or worsen after reprogramming.
The data were analyzed using SPSS 11.5 for Windows (SPSS inc., USA)

Results

Between 10/90 and 12/02 157 patients received a new implant or had a revision.
The group consisted of 28 male (17,8%) and 129 female patients (82,2%). The reason for implantation was urge symptoms in 111 (70,3%) and retention in 46 (29,1%). All patients had successful screening using the Percutaneous Nerve Evaluation with a temporary lead or a two-stage procedure. Mean age at the time of implantation was 47,5 (±10,0) years, range between 21 and 72 years. Follow-up ranged between 13 and 154 months after implant and the mean follow-up period was 64,0 (± 38,3) months. The mean follow-up for patients who were implanted for urgency symptoms was 65,0 months (±39,8) and for patients with urinary retention 62,7 months (±34,9).
At the time of their last follow-up 97 (60,8%) patients had a good result and 61 (38,6%) patients had insufficient results, 64 (57,6%) patients with urgency and 33 (71,7%) patients with retention had good results. 47 (42,4%) patients with urgency and 13 (28,3%) with retention had insufficient results. Logistic regression analysis of date of implantation, sex of the patient, the type of complaints, follow-up time, the number of adverse events and whether the adverse events had been resolved at last follow-up showed a significant correlation between result and adverse events being resolved. The correlation coefficient was 0.882 (p=0,000)
Analysis of our data shows a statistically significant difference in the percentages of a good result between the patients implanted in 1990-1994 and 1995-2003. Good results were achieved in patients implanted before 1995 in 52,0%, while 66,3% of the patients implanted

after 1995 had a good result (p=0,003). The mean follow-up of the patients implanted before 1995 was 98,7 (± 39,6) months and the mean follow-up of the patients implanted after 1995 was 47,8 (±24,5) months.
In the group of 157 patients 118 experienced at least one adverse event. In total 138 surgical procedures have been performed to correct adverse events. 84 patients did not have surgery for their adverse events. All patients with more than 2 adverse events had at least one surgical correction. When implanted before 1995, 88,0% of the patients had an adverse event. Of the patients implanted after 1995 only 68,2% of the patients had an adverse event. A group of 31 patients (13,3%) was explanted. Indications for explant were either loss of efficacy or a serious adverse event. Of the patients implanted before 1995 28,0% were explanted, while 6,5% of the patients implanted after 1995 were explanted.

Concluding message

Sacral neuromodulation produces prolonged benefit in a therapy resistant group of patients. The difference in results before and after 1995 suggests a considerable learning curve in the selection, the implantation and follow-up of patients with neuromodulation. Other contributing factors are the implementation of new surgical techniques and the new technical developments as the external patient programmer and new implant hardware.

References

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