96

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Title: TWO-STAGE NEUROMODULATION TECHNIQUE FOR CHRONIC VOIDING DYSFUNCTIONS: LONG TERM FOLLOW-UP RESULTS.

Aims of the study

Sacral neuromodulation is an established treatment for patients with chronic urinary dysfunctions. Janknegt et.al. [1] reported on the two-stage implant technique and its short term results in 10 patients. Prior to the two stage technique was used, these patients had a positive acute percutaneous nerve evaluation (PNE) test, but were technical failures in the sub-chronic part. In the first stage of this procedure only the permanent electrode was implanted and connected to a temporary external stimulator. Patients were screened for a longer period of time ranging from 7-25 days, as compared to the standard PNE procedure (3-4 days). If an improvement of more than 50% in the main symptoms was obtained, the patient was a candidate for the second stage; an implantation of the Implantable Pulse Generator (IPG). Long-term results in standard sacral neuromodulation procedures are well documented and the reported success rate is approximately 60-70%. We investigated the long-term results of patients who underwent the two-stage sacral neuromodulation.

Methods

We reviewed all patients who underwent a two-stage implant in our department. All patients had signed an informed consent and were asked to fill out voiding diaries. A questionnaire was filled in to measure subjective effects of the therapy. Only one patient had urinary retention and urge-incontinence (UI), both factors were analyzed for their improvement. Long-term voiding diary results are compared with baseline diary results and statistically analyzed using Wilcoxon paired test.

Results

Between 1991 and 1998, 15 patients were implanted using the two-stage technique. One patient died due to unrelated causes before undergoing the second stage, two patients were explanted leaving analyzable data of 12 patients. The average age was 53 years (44-66), average follow-up time is 4,8 years (29-90 months). Six patients were diagnosed with urge incontinence and six with urinary non-obstructive idiopathic retention. Voiding diary results of these 12 patients showed significant improvement in all main diary parameters. The number of leaking episodes reduced from 9.4 to 2.5 ($p=0.07$) and the number of pad used from 4.7 to 0.8 ($p=0.03$). Average volume voided per void for these UI patients was increased from 83 ml to 323 ml ($p=0.03$) and maximum voided volume from 285 ml to 628 ml.

In retention patients catheterized volume per catheterization decreased from 303 ml to only 83 ml ($p=0.04$) and only 2 patients required an average of 2 catheterisations per 24 hrs. Total percentage of daily voided volume increased from 32% to 91% while total percentage of daily catheterized volume decreased from 68% to only 9% and this stayed unchanged during the 4,8 year follow-up.

Subjective results collected from the questionnaires demonstrated the patients perception of improvement and satisfaction with the therapy at 91% (range 50-100%) as compared to baseline.

Conclusion

The long-term results of patients who underwent a two-stage implant demonstrate a clinically and statistically significant improvement as compared to baseline. This is different to what has been reported in the standard neuromodulation technique, where the success is reduced in the 6-18 months follow-up. Probably this is due to longer sub-chronic test phase as compared to the normal test-procedure and to the immediate use of the permanent lead.

If for various reasons a temporary PNE-test is not optimal for some patients (lead migration, longer testing time needed), the two-stage technique can offer a good alternative with the same or higher success rate at long term follow-up. If the two-stage technique was not offered to these 12 patients, they would not have been presented for neuromodulation treatment at all.

Reference

1. Improving neuromodulation technique for refractory voiding dysfunctions: two stage implant. Urology 1997;49:358-362

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