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NEUROMODULATION; CLINICAL EXPERIENCES WITH THE NEW MINIMAL INVASIVE APPROACH.

Aims of Study

This pilot study was carried out to evaluate the feasibility and short term clinical results of the new procedure for neuromodulation as proposed by Spinelli et al.

Methods

Nine patients with urgency/frequency, urge -incontinence or urinary retention underwent a staged test procedure using the Tined Lead. In a minimal invasive procedure a tined quadripolar lead (Model 3889, Medtronic) was placed percutaneously in either left or right S3 foramen under local anesthesia. This allowed for patient's sensory and motor responses testing during the lead placement. The four sets of tines on the lead enable fixation without suturing. Thereafter the lead is brought to a gluteal incision and tunneled to the contralateral side. Using an extension cable the lead is connected at the contralateral exit point to an external stimulator (model 3625, Medtronic). The time of testing ranged between one to two weeks. During this test period, patients used a voiding diary and record their urinary behavior. This data were compared to the baseline voiding diary. Patients with more than 50% improvement in their primary voiding parameters during the first stage-screening period were implanted with a definitive implantable pulse generator (IPG). The IPG was connected to the same tined lead with the new extension cable. This part of the procedure also takes place under local anesthesia. After the implant, patients were followed on regular intervals.

Results

1 Patient with urgency/frequency, 5 patients with urge incontinence and 3 patients with urinary retention were implanted with a tined lead. In the UI and UF group, 5 out of 6 (83%) patients were eligible for definitive implantation, while in the retention group 2 (66%) patients met the criteria and had a definitive implant. There were no differences in clinical outcomes between test and implant results. Implanted patients were followed for 4 ± 2,3 months.
During follow-up one patient (urgency) switched her stimulator off due to abdominal complaints. Investigation for the cause of the complaints is going on. All other patients have lasting ≥ 50% improvement of their urinary complaints.
No lead migrations were observed. The implantation of the tined lead is more complex than the PNE procedure because of the use of X-ray, need for surgical facility employment and it takes more time. In our experience with the first 9 patients, the average procedure time was one hour. The implantation of the IPG as the second stage procedure is done in 15 minutes and is very simple compared to implantation according to the classical procedure. In the non-responding patients the lead could be easily removed under local anesthesia. Removal of the lead and the extension takes about 10 minutes.

Conclusions

The new minimal invasive approach of neuromodulation gives good preliminary clinical results. 78 % of the tested patients were eligible for the neurostimulator implantation. The relative amount of of positively screened patients is higher than already reported with PNE, suggesting that testing with the tined lead is a better screening method. Further study with larger amounts of patients is needed to confirm this finding. Lead migration did not occur and therefore the lead anchoring method seems sufficient for fixation of the electrode at least on the short term.
Long-term follow-up data on the tined lead performance and possible migration are not yet available. We are currently doing a evaluation and hope to report on these data in future publications.
The use of local anesthesia enables us to place the definitive electrode on guidance of the sensory response of the patient, additional to the motor response guidance in the classical implantation. The new minimal invasive method of neuromodulation is safe and simple and is

a promising innovation in neuromodulation technique despite the higher costs of material and the need for more facilities.

References

1. Spinelli, M., Gerber, M., Arduini, A. et al.: Improving neuromodulation technique: preliminary results of minimally invasive implant with tined lead. *Neurourology and Urodynamics*, 21: 388, 2002