

LONG TERM RESULTS OF SACRAL NEUROMODULATION TREATMENT WITH TINED LEAD PLACEMENT

Hypothesis / aims of study

The efficacy of sacral neuromodulation with tined lead implantation has been demonstrated in short-term analysis. We analysed the outcome of tined lead implantation with long term follow up.

Study design, materials and methods

In total, 49 patients (39 with refractory overactive bladder symptoms and 10 with urinary retention) were implanted with the tined lead under local anaesthesia. The mean follow-up after implantation was 59.5 (range 43-77) months. All patients were asked to complete voiding diaries at their last follow up; these were compared with the baseline diaries. Subjective outcome was evaluated by using a questionnaire.

Results

Ten patients had a one-stage and 39 a two-stage implant; of the latter group, 31 (80%) had a positive response and eight (21%) did not. Of the 41 patients that received the definitive implant, 13 were lost to follow-up, hence 28 were included for long-term follow-up. The data of 18 patients have been analysed in this abstract. At the last follow-up, 86% of the patients had a >50% improvement in at least one of the diary variables and 14% did not reach this level of amelioration. The changes in voiding parameters are presented in table 1. All but one patient reported a subjective improvement of their symptoms compared to baseline. When patients were asked to compare the effectiveness at last follow-up with the effectiveness short after implantation, 32% of the patients reported improvement, 52% reported no change, and 16% reported deterioration. 74% of the patients were very satisfied with the current treatment and 22% were moderately satisfied. Only one of the patients claimed to be dissatisfied. This patient had a decrease in response very early after implantation. Seven patients had an adverse event; in five of these patients repositioning of the IPG was performed due to pain. In two patients the lead was replaced because it was damaged after minor trauma.

Interpretation of results

Our data show that the objective parameters on the voiding diary show a clinically relevant improvement in the long-term. Subjective improvement and patient satisfaction are also very good in the long-term.

Concluding message

Sacral neuromodulation with tined lead placement is a safe, reliable and durable treatment for patients with refractory overactive bladder symptoms or urinary retention. The lead anchoring method seems sufficient for fixing the electrode permanently.

Table 1. Results of voiding parameter analysis for 18 patients.

	Baseline	Follow-up	Difference
OAB	Mean (SD)	Mean (SD)	
voided volume/void (ml)	155.1 (54.1)	175.3 (57.9)	+13%
number of voids/day	12.0 (6.8)	8.5 (2.6)	-29%
number of leakages	6.2 (6.9)	1.8 (2.2)	-71%
Urinary Retention			
voided volume/void (ml)	93.0 (44.5)	305.1 (93.1)	+228%
number of cath/day	3.1 (0.9)	0.4 (0.6)	-87%

Specify source of funding or grant

1. WAMU Foundation (Partners: Novartis, Medtronic, GlaxoSmithKline, Coloplast, AstraZeneca, Astellas, Abbot)
2. Unrestricted educational grant by Medtronic

Is this a clinical trial?

Yes

Is this study registered in a public clinical trials registry?

No

What were the subjects in the study?

HUMAN

Was this study approved by an ethics committee?

Yes

Specify Name of Ethics Committee

Medical Ethical Committee Maastricht University Hospital / University of Maastricht

Was the Declaration of Helsinki followed?

Yes

Was informed consent obtained from the patients?

Yes