

IS BILATERAL SACRAL NERVE STIMULATION EFFECTIVE IN PATIENTS WITH UNILATERAL THERAPY FAILURE?

Hypothesis / aims of study

To evaluate if bilateral sacral nerve stimulation is an effective method for restoring treatment efficacy in patients with failure of unilateral sacral neuromodulation (SNM) treatment.

Study design, materials and methods

Prospective pilot study. Patients with failure of SNM treatment after implantation of an implantable neurostimulator were included. Percutaneous nerve evaluation (PNE) with an electrode in the contralateral foramen was conducted, and the effect of contra- and bilateral stimulation was evaluated using a randomized cross-over model. Patients filled out a three-day voiding diary before PNE (baseline) and during contra- and bilateral stimulation. Clinical success was defined as >50% improvement in at least one of the relevant voiding diary parameters compared to baseline.

Results

Fifteen patients were included in this study, and underwent a contra- and bilateral test stimulation with PNE. In three patients lead migration was suspected and therefore these patients were not included in the analysis. Of the 12 remaining patients, four showed a successful response to PNE. Three of these patients were eventually implanted with a contralateral lead. After 12 months treatment, two of the three patients had a successful outcome.

Statistical analysis comparing contralateral with bilateral stimulation, showed a significant difference in the number of voids/day ($p=0.02$) and the number of pads/day ($p=0.03$), but not in voided volume ($p=0.79$) or the number of leakages/day (0.15) (fig. 1).

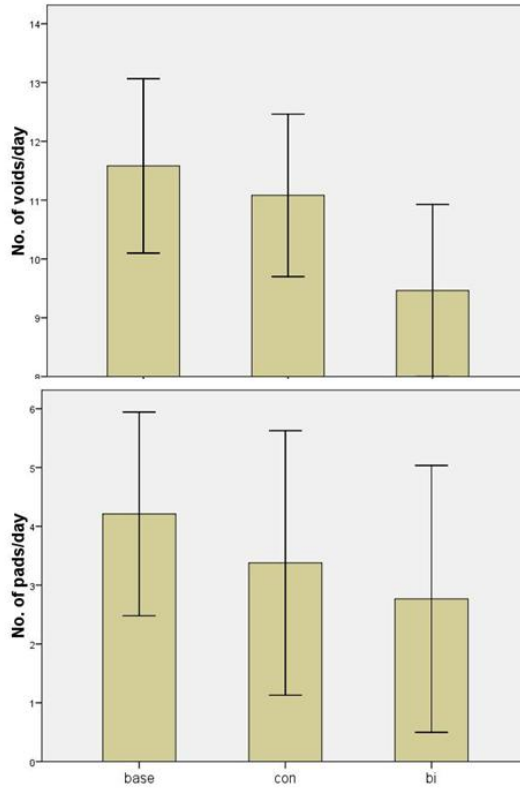
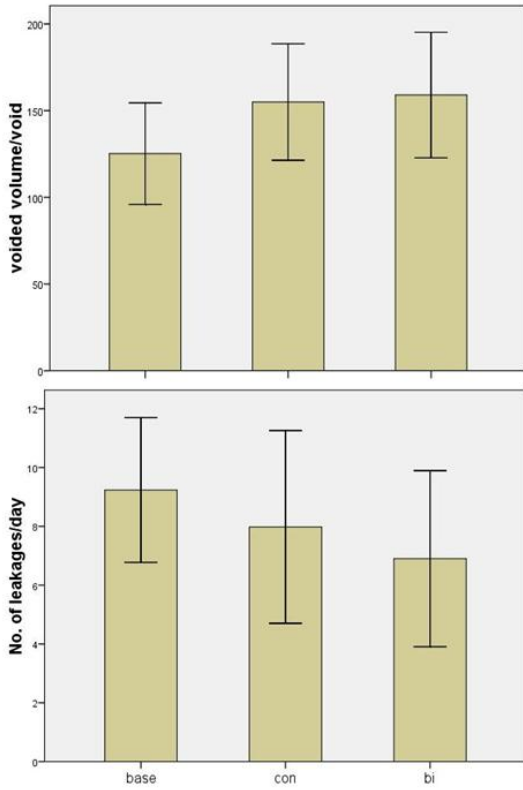
Interpretation of results

In this pilot study, a selected group of patients appear to benefit from bilateral stimulation after failure of unilateral S3 stimulation. Furthermore, it might be suggested that bilateral stimulation induces a more profound response than stimulation of a contralateral lead alone.

Concluding message

According to these preliminary data, test stimulation with a contralateral lead might be considered, although further investigation is necessary to determine the feasibility and cost-effectiveness of this treatment.

Figure 1. Mean values of key voiding diary data at baseline (*base*), with contralateral stimulation (*con*) and with bilateral stimulation (*bi*) (95% CI). Volumes are presented in ml.



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
Is this a Randomised Controlled Trial (RCT)?	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 of the Maastricht University Medical Centre
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes