

IS THE METHOD OF SCREENING IN SACRAL NEUROMODULATION A PROGNOSTIC FACTOR FOR LONG-TERM SUCCESS?

Hypothesis / aims of study

To evaluate if there is a difference in long-term outcome of sacral neuromodulation (SNM) between patients screened with the percutaneous nerve evaluation (PNE) and first stage tined lead procedure (TLP). Furthermore, we wanted to evaluate the outcome in patients who only responded to screening with TLP after failure of initial PNE.

Study design, materials and methods

We evaluated all patients screened for eligibility to receive SNM treatment since the introduction of the tined lead technique in our centre in 2002. Patients with overactive bladder and chronic non-obstructive urinary retention were included. All patients were initially screened with PNE, unless they were at high risk for lead migration (these patients were directly screened with TLP). Patients who showed a negative response to PNE were additionally screened with TLP. Patients were implanted after showing a successful response to PNE or TLP. In May 2009, all implanted patients were asked to keep a voiding diary to record the effect of SNM on urinary symptoms. Success was defined as more than 50% improvement in at least one of the relevant voiding diary parameters compared to baseline. Logistic regression analysis was used to evaluate differences in long-term outcome for the separate screening methods.

Results

In total, 92 patients were screened for SNM. Of the 76 patients who were screened with PNE, 35 (46%) met the criteria for permanent implantation, whereas 11 of the 16 patients (69%) who underwent direct screening with TLP had permanent stimulators placed. Of the 41 patients who failed PNE and subsequently underwent screening with TLP, 18 (44%) were implanted with an INS after showing a successful response (fig. 1). The mean follow-up at the time of voiding diary analysis was 53 months (range 35-77 months). The long-term success rate for the different screening methods, with direct comparison of groups is illustrated in figure 2. Statistical analysis showed no difference between type of screening and long-term success ($p=0.94$).

Interpretation of results

According to these results, the method of test stimulation does not have an influence on long-term outcome. Patients who only responded to screening with TLP after failure of PNE had no significantly lower chance of success compared to patient who were directly screened with PNE or TLP.

Concluding message

Although the first stage TLP is a more reliable screening tool than PNE, the long-term success rate appears to be independent of the screening method. Furthermore, patients who initially failed PNE but responded to prolonged screening with TLP, are in the long-term at least as successful as patients who directly responded to PNE or TLP.

Fig 1. Overview of all patients screened for SNM treatment. Note that 16 patients were immediately screened with TLP without a prior PNE test, due to increased risk of lead migration. In total, sixty-four patients showed a positive response to screening and received an INS.

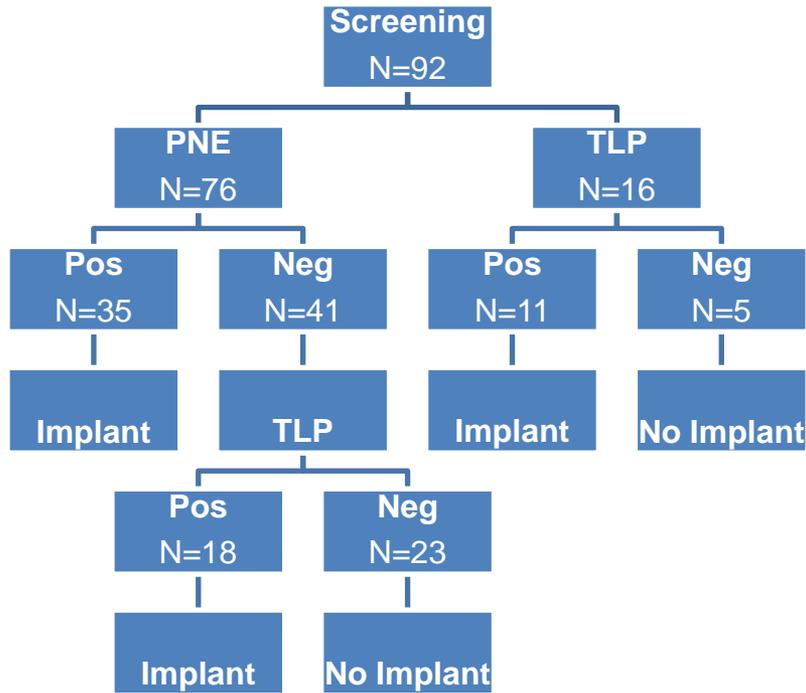
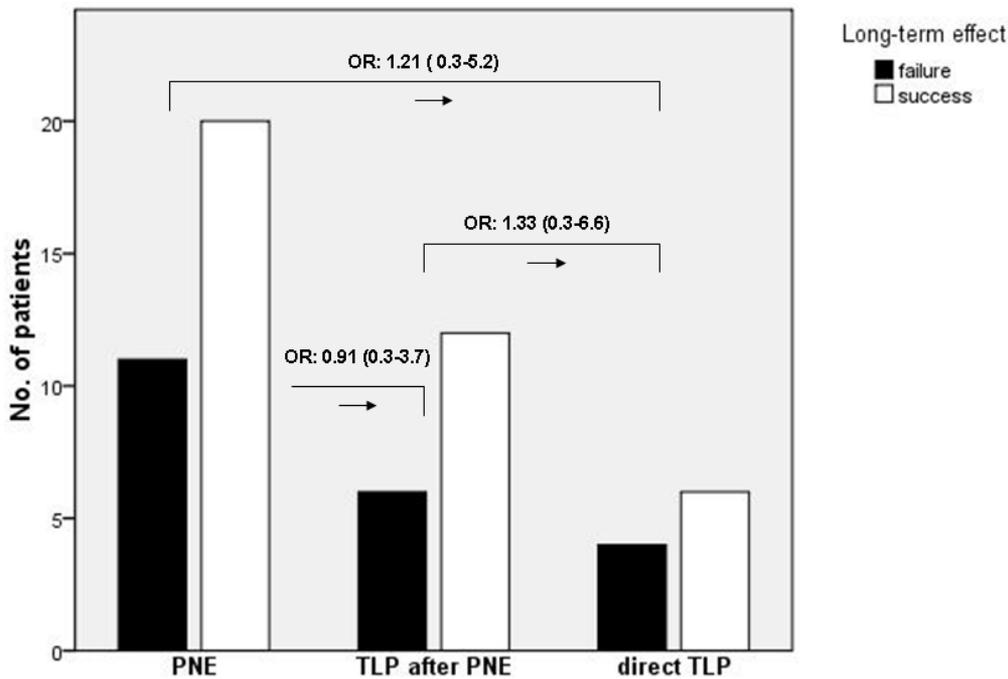


Fig 2. Long-term success for all patients divided into three subgroups: patients who showed a positive response to PNE (*PNE*), patients who showed a positive response to TLP after failure of PNE (*TLP after PNE*) and patients who showed a positive response to direct screening with TLP (*direct TLP*). Odds ratios (OR) are shown for success, with 95% confidence intervals between brackets.



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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, Maastricht University Medical Centre
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes

