

PNE VS 1ST STAGE TINED LEAD: WHICH ONE IS A BETTER SCREENING TEST FOR SACRAL NEUROMODULATION?

Hypothesis / aims of study

Sacral neuromodulation (SNM) is a well established therapy for urgency, urge-incontinence and non-obstructive urinary retention (1). In order to achieve optimal results accurate screening method is essential. Actually there are two different tests that can be used, the "classical" Percutaneous Nerve Evaluation (PNE) test and the 1st stage tined-lead test (2).

The main goal of this research is to compare the efficacy of these two tests as screening methods for SNM.

Study design, materials and methods

In this prospective observational study, all patients with symptoms of urgency, urge-incontinence or non obstructive retention, refractory to conservative therapy, screened with both PNE and TLP, between July 2002 and September 2007, were included. The responses to the PNE test and 1st stage tined lead test were assessed for each patient. More than 50% improvement in two of the relevant urinary symptoms measured by bladder diaries was considered a positive response. The number of patients with a positive response to the PNE test was compared to the number after the 1st stage tined lead test. As 1st stage tined lead testing is usually performed for a longer duration than PNE testing, a correction was also performed by using only data of the first three days. To detect a 20% difference between both tests we would need about 50 persons (paired t-test), with an alpha of 0,05 and a 1-beta (power) of 75%.

Results

In total, the data of 54 patients were included (43 female and 11 male). The mean age was 55.6 (34-76). 2 had urgency, 42 urge incontinence and 10 non-obstructive urinary retention.

Out of the 54 patients, 28 (52%) had a positive reaction with the PNE test and 38 (70%) had a positive reaction with 1st stage tined lead test (mean 6.6 days). When the length of the test period with tined lead was corrected to the first three days, a positive reaction was seen in 37 (69%) out of 54 patients. A paired sample t-test was conducted, which showed a significant difference ($p=0.001$). At a median follow-up of 22.8 months (0-61), therapy failed in only 1 patient of the 38, due to pain at IPG site requiring explant. This results in a 97% long term success rate in this group.

Interpretation of results

More people reacted positively to TLP compared to PNE, which means a significant amount of people (18%) would be missed if PNE were used as the only screening method. The duration of the tined lead test does not seem to have any influence on the efficacy of the screening test.

Concluding message

The 1st stage tined lead test is a more effective tool for sacral neuromodulation screening compared to PNE test.

References

1. European urology, 2001. 39(1): p. 101-6.
2. World J Urol. 2005 Jul;23(3):225-9

Specify source of funding or grant	WAMU (through an unrestricted education grant of Medtronic)
Is this a clinical trial?	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 azM/UM
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes