

Best in Category Prize - Neurourology

28

Jairam R¹, Drossaerts J¹, Marcelissen T¹, van Koevinge G¹, Van Kerrebroeck P¹

1. Maastricht University Medical Centre

TIME OF ONSET OF SACRAL NEUROMODULATION EFFECT IN LOWER URINARY TRACT DYSFUNCTION.

Hypothesis / aims of study

Sacral neuromodulation (SNM) is a minimally invasive and effective treatment in patients with overactive bladder syndrome (OAB) or non-obstructive urinary retention (NOR) when conservative treatment fails. A test stimulation (tined lead procedure, TLP) is performed to find out whether adequate symptom reduction is achieved. In centers worldwide the duration of this test stimulation vary considerably and it is not clear when the time of onset of the therapy effect can be expected. The experience in our clinic is that during the test stimulation period for responders it takes up to one week to achieve maximal effect, after the system is turned 'on'. However, no information concerning the so called onset and offset of effect of SNM is available in current literature. The objective of this prospective study is to evaluate the average time span within which "the onset of the effect" occurs in patients with LUTS. Knowledge about time of onset and off set, could have several practical clinical implications. Clinical experience renders clues that this time spans might be different for OAB and NOR patients. This study could lead to insight about the required length of the test stimulation period.

Study design, materials and methods

In this prospective study (ClinicalTrials.gov Identifier: NCT02040519) all OAB and NOR patients who were eligible for treatment with SNM were asked to participate. These patients filled out a voiding diary 7 days prior and after test stimulation. When no effect occurred after 7 days, another diary of 7 days was filled out. The transition point between no effect and time of onset is determined by assessing when certain complaints parameters are reduced by 50% compared to baseline per 24 hours. Onset of effect will be assessed in days. The Mann Whitney U test was used to compare the mean time to success between OAB and NOR patients.

Results

In total 45 patients, 24 NOR and 21 OAB agreed and were included. After test stimulation 29 patients (64%) were successful and received an IPG. Seven patients did not fill out the diary completely and were excluded, leaving 22 patients (10 NOR and 12 OAB) to be analysed. Mean age was 46.3 (SD 14.6). In the NOR group, 5 patients were not able to void and were fully depended on self-catheterization. In patients with OAB mean frequency before test stimulation was 11,3 and mean voided volume per void was 135cc.

Mean time to success for all patients was 3.3 days (range 1-9). There was no significant difference in mean time to success between OAB and NOR patients ($p=0.73$, Figure 1).

Interpretation of results

The effect of sacral neuromodulation in successful patients can be expected after a mean of 3.3 days of test stimulation. No differences were seen between OAB and NOR patients.

Concluding message

The results of this prospective study indicate that time of onset of sacral neuromodulation effect in both OAB and NOR patients can be expected in the first two weeks of test stimulation. This implicates that a TLP test stimulation of more than two weeks, is not necessary. Besides the patient's overall comfort and well-being, a shorter duration of the test period could reduce lead infections.

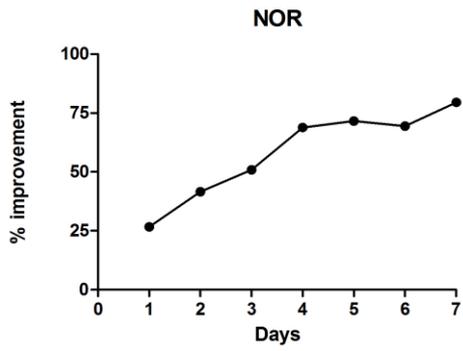
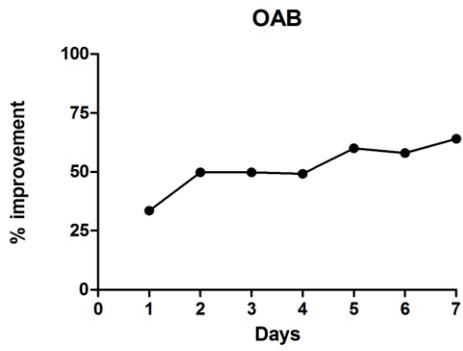


Figure 1: Mean percentage improvement during the first week after test stimulation in both OAB and NOR patients. Improvement was measured for either frequency/24h, mean voided volume/ void, leakages/24h, no. pads/24h or mean voided volume per catheterization

Disclosures

Funding: This work was supported by Medtronic **Clinical Trial:** Yes **Registration Number:** ClinicalTrials.gov Identifier: NCT02040519 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** Clinical Trial Centre Maastricht **Helsinki:** Yes **Informed Consent:** Yes