

PERIPHERAL NERVE EVALUATION VS. FIRST STAGE TINED LEAD IN A MS PATIENT POPULATION

Hypothesis / aims of study

In sacral nerve stimulation no clear predictive factors for success have been identified until now. Therefore the need for test stimulation prior to implanting the pacemaker still exists. For years this test stimulation has been done by means of peripheral nerve evaluation (PNE), with success rates around 40% in a non-neurogenic patient population [1]. No large series of neurogenic patients have been tested, but results suggest even lower PNE success rates in a neurogenic patient population. However, since the introduction of the tined lead procedure, there is a possibility to repeat and/or prolong the test phase with the permanent, quadripolar lead. In this study we have compared the effects of a test first stage tined lead procedure versus PNE, this in order to determine whether tined lead testing is more efficacious than PNE testing.

Study design, materials and methods

In our studies to determine the efficacy of sacral nerve stimulation in a multiple sclerosis (MS) patient population, we offered a selected population PNE testing during one week. Proper placement of the lead was verified by means of sacral x-ray investigation, directly after placing the lead as well as one week later. Independent of the outcome of the PNE test, patients underwent a first stage tined lead procedure 4 to 8 weeks later. This procedure was done under local anaesthesia with x-ray control. Neurological status was evaluated by history taking, physical examination and determination of the extended disability status scale (EDSS) prior to both test stimulations. 72-hour bladder diaries were completed at baseline and at day 5,6 and 7 of the test stimulations. The primary endpoints were number of voids daily and volume voided per void for the urgency/frequency patients. Number of leaking episodes, severity of leakage (four point scale: 0= none, 1=little, 2=moderate, 3=heavy) and number of pads used per day were the endpoints for the urge urinary incontinence patients. For retention patients the following endpoints were determined: number of catheterizations, total catheterized volume and total voided volume per day. A reduction of the main complaint of 50% or more was determined as success.

Results

Between July 2003 and February 2005, fourteen MS patients (5 male, 9 female) entered the study. Average age 51 years (range 37-71), mean MS duration 12.2 years (range 2.5-25), with a mean EDSS score of 3.5 (range 3.0-5.5). The neurological status remained stable between the two episodes of testing. Twelve patients had an urodynamically proven neurogenic overactive bladder, with complaints of urgency/frequency and/or urge urinary incontinence. Two patients suffered from retention, with an urodynamically hypocontractile detrusor. Out of these fourteen patients only one patient (7%) had conclusive test results (>50% improvement on the main complaint), four (29%) had inconclusive test results and the other nine patients (64%) didn't show any improvement during the PNE test phase. Testing by means of first stage tined lead procedure was successful in nine patients (64%), inconclusive in one patient (7%) and a failure in four patients (29%). We prolonged the test with one week in the patient with the inconclusive test results during tined lead testing. Voiding diary then showed a more than 50% improvement in ten patients. All these patients received an implantable pulse generator (IPG). We await the long term results.

Interpretation of results

Our results show, for the first time, a higher efficacy of tined lead testing compared to PNE in a MS patient population. Presumably due to better lead placement and fixation and the possibility to adjust the activated contact points after lead placement, the test results are superior to the results of PNE testing.

Concluding message

Especially while treating neurological patients, in whom we more often see a diminished efficacy of PNE, it can be considered to refrain from PNE testing.

1. Predictive factors for sacral neuromodulation in chronic lower urinary tract dysfunction. Urology: 60:598-602, 2002