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ASSOCIATION BETWEEN STIMULATION PARAMETERS AT THE TIME OF IMPLANTATION OF SACRAL NERVE STIMULATOR AND EXPLANTATION AFTER SUCCESSFUL IMPLANTATION

Hypothesis / aims of study

Sacral neuromodulation is a relatively new technique indicated for the treatment of various types of lower urinary tract dysfunction. In 1997, the U.S. Food and Drug Administration approved a device, the Interstim® (Medtronic, Minneapolis, MN), for refractory urge urinary incontinence, urinary frequency and urgency, and non obstructive urinary retention. The procedure consists of two stages: a testing stage or first stage and an implantation stage or second stage. Since its introduction, several modifications have been made in the technology, with resultant changes in the surgical technique and reducing the system related complications.

Despite all modifications the failure of the implanted system and loss of efficacy without determined mechanical causes ranges between 15-30 %.

This study was sought to determine the association between stimulation parameters at the time of implantation and loss of efficacy on long term follow up.

Study design, materials and methods

Between 2002 -2007 we had 120 patients underwent sacral neuromodulation for voiding dysfunction using Interstim ®.14 patients (11.6%) were explanted due to pain (5/14) & loss of efficacy (9/14).

We retrospectively reviewed the charts of patients who explanted due to lack of efficacy, and compared their voiding (voided volume/void) and stimulation parameters (amplitude and impedance) with a group of 12 positive responders, who were well-matched for sex, age, duration of symptoms , waiting period for implant and duration of implantation. Prior to implantation, all patients were required to pass a peripheral nerve evaluation screening test that showed >50% improvement in voiding parameters over a 1-week period. A 2-tailed t-test was used to determine differences in voiding parameters and stimulation parameters between both groups (at $p<0.05$).

Results

All 9 patients who had loss of efficacy were female, mean age was (47.31±14.42 years), 6 patients (67%) were implanted for urgency/frequency symptoms, and 3 patients (33%) were implanted for urinary retention. The duration of stimulation (3.87±2.72 years), the duration of symptoms was (5.32±1.5 years), the waiting period for implant was (2.9±0.63 years).

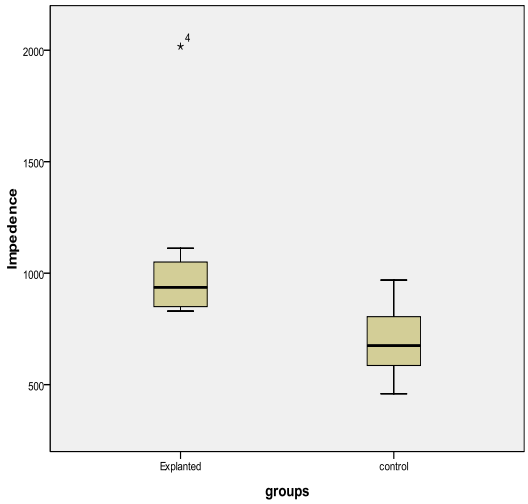
Comparison was done to 12 female patients, mean age was (4.53±1.06 years), 7 patients (58%) were implanted for urgency/frequency symptoms, and 5 patients (42%) were implanted for urinary retention. The duration of stimulation (4.53±1.06 years), the duration of symptoms was (5.24± 1.42 years), the waiting period for implant (2.6± 0.8 years).

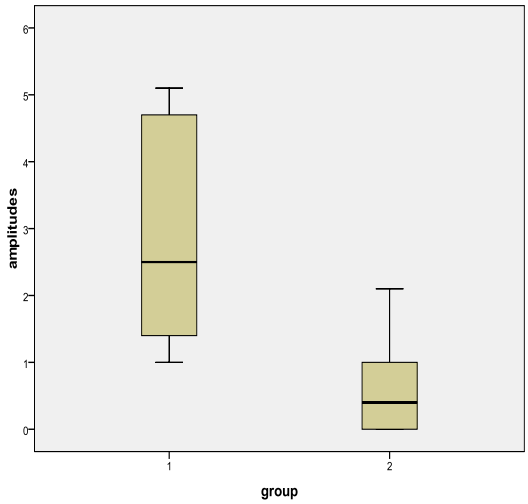
Improvement in voided volume/void in urge/frequency patients was significantly lower in explanted group due to loss of efficacy (43.6±3.2 ml) than responders group (75.2±11.37 ml) (p=0.028).

The base line amplitude levels in patients who lost the efficacy were significantly higher than control group (2.08±0.35v) Vs (1.27±0.25v) (p=0.008).

The amplitude difference between the base line and 4 years follow up was significantly higher in explanted group than responders group (3.1±1.2v)Vs (0.7±1.8v) (p=0.04).

The Impedance levels in explanted group were significantly higher than responders group (1032.4±181 Ω) Vs (590±44.6 Ω) (p=0.025).





Interpretation of results

Complications leading to explantation in our study were pain and loss off efficacy. There was no mechanical/electronic reasons (damaged, migrated electrodes or connected cables) could be identified for lack of efficacy after a period of good response.

Despite the impedance testing was within the integral part of the troubleshooting algorithm but it was significantly higher in patients who had loss off efficacy.

The amplitude measurements were significantly higher in this group of patients, either at initial stimulation or on follow up programming sessions.

The lack of efficacy and failure to maintained response despite normal impedance as reported by the surgeon might be related to the underlying disease progression, fibrosis at the electrode- tissue interface.

Concluding message

High stimulation parameters at the time of implantation contribute to loss of efficacy and explantation on the long term follow up.

Specify source of funding or grant	**Canadian Institutes of Health Research (CIHR)** **Department of Surgery, Devision of Urology, Toronto Western Hospital**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**University Health Network Reseach Ethics Board**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**