

## IS SACRAL NEUROMODULATION STILL EFFECTIVE AFTER BOTULINE-A TOXIN INJECTIONS FOR THE TREATMENT OF NON-NEUROGENIC URINARY DYSFUNCTION -A PROSPECTIVE ONGOING STUDY-

### Hypothesis / aims of study

Sacral neuromodulation (SNM) is a proven safe and effective treatment for refractory symptoms of overactive bladder (OAB) syndrome and non-obstructive urinary retention (1). Last years many patients with OAB syndrome have been treated with botuline-A toxin (BTX) injections. First only neurogenic patients were treated but nowadays also non-neurogenic patients are submitted to this therapy (2). The use of BTX for urinary symptoms is still an off-label therapy and therefore not placed in international guidelines.

The aim of this study is to determine whether SNM is still an effective therapy after BTX treatment. A secondary goal is to discuss the treatment algorithm for OAB syndrome.

### Study design, materials and methods

In this prospective study we will include 20 patients with symptoms of OAB syndrome who were treated with BTX injections in the past and who where referred to our hospital as possible candidates for neuromodulation therapy. By this time 7 patients are included. They were all treated with 200 Units of BTX, injected into the detrusor muscle under cystoscopic guidance. In these patients all conservative treatments had failed and BTX treatment was not effective (anymore). Last BTX treatment had to be at least four months ago.

Patients with a neurogenic cause for their bladder problems were excluded. Micturition diary, full urodynamics, neurological status and urine probes were performed in all patients.

All patients were tested for SNM with a unilateral peripheral nerve evaluation (PNE) test during four days. During this test a voiding diary had to be filled out by every patient. When a moderate to good result was seen, patients were tested for a longer period (10–14 days) with a unilateral tined lead (two stage implant).

With at least 50% in symptom relieve, measured with voiding diaries, they were implanted with a permanent system. After implantation we planned systematic follow-up at six weeks, three months, six months and then once yearly. After one year all patients will be asked to fill out a voiding diary for one week.

### Results

At this time seven patients are included (two men, five women, mean age 52 years). These patients had complaints of OAB symptoms for a mean of 4.7 years at time of inclusion. Five patients had one BTX treatment and failed to respond to BTX therapy. One patient had eleven BTX treatments. Mean time between last BTX treatment and PNE test was ten months (4 -17 months).

All patients have been tested with a PNE test (mean duration 5 days, min. 4 – max. 6). Six patients (86%) had a positive reaction on the PNE test. One patient had no response during the PNE test.

Six patients are tested with a tined lead. Five patients (83%) are implanted with a definitive system, one patient had a response of less then 50% improvement and is not implanted with a definitive system. Mean follow-up time is 24 weeks (3 – 52 weeks). They all have persistent good results.

### Interpretation of results

In this limited group of patients we have a positive result for neuromodulation therapy in 83% of the patients. One patient had no response to neuromodulation therapy at all, this patient has had eleven BTX treatments in the past.

### Concluding message

With this pilot we show that SNM is still an effective treatment after BTX treatment failed. Long term effects of BTX therapy are still not known and the effect of BTX injections has proven to be only temporarily. Further research has to be done to determine where BTX injections can be placed in the treatment algorithm.

### References

1. Urology. 2000 Dec 4;56(6 Suppl 1):87-91
2. J Urol. 2006 Jul;176(1):177-85.

Fig 1. Study scheme

