

## SACRAL NEUROMODULATION IN PATIENTS WITH IDIOPATHIC OVERACTIVE BLADDER AFTER INITIAL BOTULINUM TOXIN THERAPY.

### Hypothesis / aims of study

Detrusor injection of botulinum toxin type A (BoNTA) has emerged as a treatment for patients with overactive bladder syndrome (OAB) refractory to conservative treatment. Although the treatment is regarded as effective, well tolerated and safe, up to 37% of the patients stop the treatment after the first two injections. The discontinuation is mainly due to lack of efficacy, presence of adverse events such as post voiding residual which needs clean intermittent catheterisation or the desire for a more permanent solution without the need for repeated treatments. [1]

In this study we evaluated whether patients, that were dissatisfied with BoNTA treatment can be successfully and to their satisfaction treated with sacral neuromodulation.

### Study design, materials and methods

This single center observational study included all patients with idiopathic OAB who were referred for neuromodulation therapy because they were dissatisfied with BoNTA and discontinued BoNTA due to lack of efficacy, adverse events or because they did not want a temporary treatment needing repeated injections.

All patients underwent a test stimulation with SNM. Efficacy of the test stimulation was evaluated by comparing the data of voiding diary filled out during the test stimulation to the data before the test stimulation (baseline). Primary outcome measure was improvement in leakage and success of test stimulation was defined as >50% improvement in episodes and severity of leakage. Secondary outcome measure was improvement in frequency and/or urgency and success was defined as >50% improvement in frequency and urgency. In the case of a successful test stimulation, it was subsequently followed by a definitive implant. The patients were asked for their satisfaction with the SNM therapy one year after the definitive implant at the outpatient clinic.

### Results

Twenty patients with OAB who were after BoNTA treatment were included: 17 (85%) patients had lack of efficacy during the first or subsequent treatments with BoNTA. The remaining 3 patients had been treated successfully with BoNTA, but were dissatisfied with the repeated need for injections with BoNTA treatment and desired to be screened for SNM. The mean interval between the BoNTA injection and the SNM test stimulation start was 23 months (minimum 7 months, maximum 53 months).

Fourteen patients (70%) responded successfully to test stimulation. The voiding diaries during test stimulation showed >50% decrease of episodes and severity of leakage and frequency and urgency, compared to baseline. Five of them even showed a decrease of >90% in leakage episodes.

All 14 patients underwent implantation of the internal pulse generator. One year after implantation 11 patients (79%) were satisfied with the SNM treatment.

Table 1: overview of patient data

#### *Successful test stimulation*

Patient ID	Efficacy BoNTA	Reason Discontinuation BoNTA	Implant	Leakage improvement	Satisfaction 1 year
1	no effect	no effect, retention	yes	> 50%	unsatisfied
2	no effect	no effect	yes	> 50%	satisfied
3	dry	repeating treatment	yes	> 50%	satisfied
4	no effect	no effect	yes	> 50%	satisfied
5	dry	repeating treatment	yes	> 50%	unsatisfied
6	no effect	no effect	yes	> 90%	satisfied
7	dry	repeating treatment	yes	> 90%	satisfied
8	no effect	no effect	yes	> 90%	satisfied
9	no effect	retention, pers UUI	yes	> 50%	satisfied
10	no effect	no effect	yes	> 50%	satisfied
11	no effect	no effect	yes	> 50%	satisfied
12	no effect	no effect	yes	> 90%	satisfied
13	no effect	no effect	yes	> 50%	unsatisfied
14	no effect	no effect	yes	> 90%	satisfied

#### *Unsuccessful test stimulation*

Patient ID	Efficacy BoNTA	Reason Discontinuation BoNTA	Implant	Leakage improvement
15	no effect	no effect, retention	no	< 50%
16	no effect	repeating no effect	no	< 50%
17	no effect	retention, pers UUI	no	< 50%
18	no effect	no effect	no	< 50%
19	no effect	no effect	no	< 50%
20	no effect	no effect	no	< 50%

### Interpretation of results

Success rate of test stimulation in patients after BoNTA treatment in this study was 70% (14/20). This is comparable to published data on test stimulation for SNM in patients after failure of drug and conservative treatments [2]. This suggests that

detrusor injection with BoNTA does not decrease patient's response to SNM test stimulation. Furthermore patients that fail BoNTA treatment have a similar chance of responding to SNM test stimulation as patients that receive SNM after first line drug or conservative treatment.

The one year satisfaction rate in this study 79% is comparable with the 85% reported in a study on patients receiving SNM as second line treatment immediately after drug or conservative treatment [3].

#### Concluding message

Patients that are dissatisfied with or fail BoNTA treatment can respond successfully to sacral neuromodulation. The response rate of the test stimulation is comparable to the response rate of patients that never received BoNTA. The one year satisfaction rate is comparable to patients that received SNM immediately after firstline drug or conservative treatment.

#### References

1. Dowson C. et al. Repeated botulinum toxin type a injections for refractory overactive bladder: medium-term outcomes, safety profile, and discontinuation rates. Eur Urol 2012; 61(4):834-9.
2. Marcelissen T.A. et al. Long-term results of sacral neuromodulation with the tined lead procedure. J Urol. 2010 Nov;184(5):1997-2000.
3. Leong R.K. et al. Satisfaction and patient experience with sacral neuromodulation: results of a single center sample survey. J Urol. 2011 Feb;185(2):588-92.

#### Disclosures

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