

## TIBIAL NEUROMODULATION: NOVEL CHRONIC IMPLANTABLE DEVICE ACHIEVES URINARY CONTINENCE IN INITIAL CASES

### Hypothesis / aims of study

Percutaneous tibial nerve stimulation (PTNS) has been successfully used to treat symptoms of overactive bladder (OAB). It relies on episodic stimulation of the tibial nerve once a week for 30 minutes, commonly performed in an outpatient setting. A novel minimize chronic implant allows stimulation of the tibial nerve for several hours per day, which might revolutionize PTNS. We report on chronic tibial neuromodulation using this new chronic implantable device.

### Study design, materials and methods

After an initial three-month study of four patients suffering from OAB conducted in Mexico in 2013, a reduction of the urgency index was documented. In August, 2014, two males were implanted with neurogenic lower urinary tract dysfunction (nLUTD); an 82-year old patient with Parkinson's disease for 6 years and a 69-year old patient with multiple sclerosis for 16 years. Both patients suffered from refractory urgency incontinence (UI) and nocturia; detrusor overactivity (DO) and detrusor sphincter dyssynergia were demonstrated during video-urodynamics. The implantation was accomplished as live surgical procedure in local anaesthesia during the 3rd International Neuro-Urology Meeting in Zürich, Switzerland.

### Results

The implantation of the novel electrode was well-tolerated by both patients and performed as outpatient surgery. Within 48 hours the patients reported significant improvement of nLUTD. Two months after surgery, both patients are completely dry; urinary urgency and nocturia disappeared according to their bladder diary. Due to this reported implantation success, stimulation was continued only during sleep (night time). The urodynamic follow-up at 2 months follow-up documented a significant increase of maximum cystometric capacity; no DO was detected. Thus far, no implant-related adverse events were reported.

### Interpretation of results

Tibial neuromodulation using a novel chronic implantable device introduces a promising treatment option with minimal- invasive technology that is urgently needed for patients suffering from refractory OAB or even from multiple problems.

### Concluding message

The new technology offers the opportunity for the patient to perform chronic tibial neuromodulation for several hours over 24h, even while sleeping. Further follow-up data will be reported. This new device might revolutionize neuromodulation procedures.



- A) Chronic Implant next to 9F dilator
- B) Dilator inserted in LA at the tibial bone
- C) Inserted chronic implant
- D) X-Ray to verify the correct positioning, \* Microchip, \*\* 4 Electrodes
- E) External device after the stimulation positioned at the ankle

### Disclosures

**Funding:** Implantable devices provided by StimGuard **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** select patients approved **Helsinki:** Yes **Informed Consent:** Yes