

NOVEL CHRONIC TIBIAL NEUROMODULATION (CTNM) TREATMENT OPTION FOR OAB SIGNIFICANTLY IMPROVES URGENCY (UI)/URGE INCONTINENCE (UII) AND NORMALIZES SLEEP PATTERNS

Hypothesis / aims of study

Percutaneous tibial nerve stimulation (PTNS) has been successfully used to treat symptoms of overactive bladder (OAB). PTNS currently relies on episodic stimulation of the tibial nerve once/week for 30min in an outpatient setting using an acupuncture needle and a ground

pad to create electrical stimulation. We investigated CTNM in OAB patients using this new minimal invasive chronic implantable device (StimGuard LLC).

Study design, materials and methods

In 2014, two male patients with neurogenic lower urinary tract dysfunction (nLUTD) received the first implants. Both patients suffered from refractory UI and nocturia; detrusor overactivity and detrusor sphincter dyssynergia.

In February–April 2016, sixteen additional patients received the implants through a <5mm skin incision in two institutions. Patients were asked to use the device while sleeping (max 8h). Patients were followed with bladder diary, maximum flow rate (ml/sec), post void residual (PVR) and questionnaires on a regular basis (after prior to the surgery at 7, 15, 30 and 90 days post-op). Statistics were run through Wilcoxon-test using JMP11.

Results

Implantation of the electrode was well-tolerated by all patients and performed as an outpatient procedure without perioperative complication. The initial two patients reported significant improvement of nLUTD within 48 hours. Both neurogenic patients were completely dry two months post-op; UI and nocturia disappeared (bladder diary). Both patients stopped CTNM due to the progression of their comorbidity, though a causal correlation could not be drawn. After 1.5 years the electrode of one initial patient migrated through the implantation path.

Of the second group the patient with the spina bifida was excluded related to false indication.

Overall major improvements were documented. UI-episodes, GRS, PPIUS decreased significantly. Although the number of voids did not change, the mean voided volume increased over time (70ml) and nocturia vanished. The iQoL and OABqSS improved delayed. In one patient an electrode moved (after three months) and was replaced.

Interpretation of results

CTNM might an option to increase the QoL for patients. The sign. Improvements and the option to perform the stimulation at a convenient time (like during the sleep in a subsensory way) will insure that patients continue the treatment compared to the common pTNS with treve time to the office, waiting time and the short treatment interval.

Concluding message

CTNM offers a promising treatment option using a novel chronic implantable device with an external charger. The new minimal invasive technology might revolutionize neuromodulation and offer those patients the ability to perform CTNM over several hours, even while sleeping with low or no stimulation. The implant has now been modified. A FDA study will commence shortly.

Disclosures

Funding: Stimulation devices provided by Stimguard **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** University of Salzburg **Helsinki:** Yes **Informed Consent:** Yes