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PILOT STUDY OF SUBJECT CONTROLLED PERCUTANEOUS DORSAL GENITAL NERVE STIMULATION FOR THE TREATMENT OF IDIOPATHIC URGENCY INCONTINENCE.

Hypothesis / aims of study
To evaluate the effect of subject controlled, percutaneous, dorsal genital nerve (DGN) stimulation on non-neurogenic urgency incontinence during a one week home use setting.

Study design, materials and methods
Patients with OAB underwent a one week period of subject controlled percutaneous DGN electrical stimulation. DGN stimulation was provided by a percutaneous electrode placed near the DGN. Prior to the placement of the electrode, subjects underwent a few hours test-stimulation of the DGN using self-adhesive electrodes (Axelgaard manufacturing Co., Fallbrocok, CA) connected to a handheld battery powered stimulator (Odstock O2CHS, Salisbury, Wiltshire, UK). They stimulated for 30 s as soon as they felt the need to pass urine. If during stimulation the urgency was suppressed or diminished an electrode (Medtronic inc, Minneapolis, USA) was placed percutaneously. The electrode was connected to an external stimulator (Medtronic inc, Model 3057, Minneapolis, USA) which was set to square pulses at a pulse rate of 20Hz and a pulse width of 300 µs. The subjects were sent home for one week of stimulation with the amplitude set at the highest level that could be tolerated without discomfort.
A bladder diary, 24-hour padtest and a urgency severity score (PPIUS) was kept 3 days prior to and during the test period except for the day of implantation (day 1) and explantation, (day 7). The bladder diary included liquid intake, volume of passed urine, number and severity score of the incontinence episodes (IE) 1= few drops, 2= dash, 3= a lot, soaks pad/diaper or outer clothing. Subjects included were > 18 years old with OAB wet. Exclusion criteria included neurological diseases, primarily stress-incontinence and diabetics with peripheral nerve involvement. Patients on anticholinergic medication had a wash-out period of 2 weeks.

Results
Six subjects (4 males 2 females) were enrolled. The average age was 53 years (range 23-72). All experienced a positive effect during stimulation with the self-adhesive electrodes and had an electrode implanted. The lead placement procedure under local anesthesia was well tolerated by all subjects and the time of placement was 5–15 min. All experienced a difference in sensation of the stimulation in standing and sitting position. Five of the 6 subjects completed the week of home stimulation. In one subjects the electrode dislocated by an accidental pull at the lead. He didn't feel the stimulation anymore so the lead was removed. At the end of the week the sensation threshold amplitude did not change significantly but 3/5 participants mentioned that during the week the location of sensation moved slightly whereafter the stimulation became less effective on their symptoms (the sensation was moved from the glans penis until mid-penile level or from the clitoris to one side of the clitoris). Four of the five subjects completed the bladder diary. Three completed the padtest and all filled out the daily PPIUS and the subjective improvement score.
Bladder diary: All subjects reported heavy leaks at baseline, all of them reported at least a 80% reduction in heavy leaks with stimulation during the whole week with home stimulation. Overall incontinence score (sum of IE experienced multiplied by severity) was improved during the week with home stimulation in all the subjects; 23% in one subject, 50% in one subject, 79% in one subjects and 90% in one subject. It was significantly improved at day 2 (p=0,043) and day 3 (p=0,043) ie, the first two days of home stimulation. Day 4-6 it was improved not-significantly (Wilcoxon Signed Ranks Test). The mean voided volume did not change significantly between the voided volume before the stimulation and during the stimulation.
With padtesting all subjects perceived decreased urine loss in one subject with 27%, in one subject with 28% and in one subject with 77%. PPIUS score showed improvement in all subjects.
Subjective improvement was 68% ± 23% (range 30-90%). After the testperiod five out of six answered positively on the possibility of a future definite implant.
Complications: in 3 subjects we saw a minimal bruising at the implantation side and in one patient the implantation side was a little red and itchy.

Interpretation of results
In this small pilot study we noticed an overall improvement of idiopathic urgency incontinence in all subjects during a week period of home use. The heavy urgency incontinence episodes decreased >80% during this week. The implantation of the electrode is easy and well tolerated by the patients.

Concluding message
This study shows that DGN stimulation is feasible and has a positive effect on urgency incontinence over a week period of home use. Lead migration causing a slightly different location of sensation was observed but still a positive effect on OAB wet was seen with at least 80% reduction in heavy leaks. The subjects were satisfied with this type of stimulation and the effect on their urgency incontinence.

References
1. None

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