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Title: LONG-TERM FOLLOW UP AFTER SACRAL NEUROSTIMULATION (SNS): SINGLE CENTER EXPERIENCE

Aim of Study:

At the LUMC, Leiden, patients with symptoms of urge incontinence, urgency/frequency and voiding difficulty (incomplete and complete retention) were included in a prospective study evaluating the outcome of sacral neurostimulation on both urodynamics and clinical efficacy.

Patients and Methods:

Patients with micturition symptoms refractory to physical and medical therapy were implanted with a neurostimulator (Medtronic Inc., Minneapolis) after responding with an improvement of more than 50% in their main symptoms to Test Stimulation. This study was part of a large multicenter study (Medtronic MDT-103). Urodynamic evaluation was performed at baseline and at 6 months post implant. It included simple uroflowmetry with residual determination and water cystometry with a detrusor pressure/flow study. A micturition diary was filled in at baseline and at every follow-up visit in order to document voiding dysfunction and it's possible changes after the implant. Cystometry was performed with the MMS UD 2000 and a Gaeltec CTU/2E/L-4 12F catheter with 3 urethral sensors and 1 bladder sensor. Follow up visits were performed at 1, 3 and 6 months and subsequently yearly post implant.

Results:

22 Patients, 21 females and 1 male, were implanted. 15 Patients suffered from refractory urge incontinence (UI), 5 from urgency/frequency (U/F) and 2 from voiding difficulty (VD) due to chronic, non-obstructive urinary retention requiring intermittent selfcatheterisation. Mean follow-up time was 40.4 months (SD 14.9 months). Mean age was 45.7 years (range 31-58) and mean duration of symptoms was 8.5 years. 12 UI patients had their 3 year follow-up, one was considered as late failure and 2 patients had previously been explanted. These patients were also included in the analysis. Patients with UI showed statistically significant improvement in their symptom reduction. The number of incontinence episodes decreased from 12.2 to 4.6 per 24 hours ($p=0.002$) and the number of pads from 7.9 to 2.8 per day ($p=0.002$). 5 Patients (33%) were completely dry and additional 27% had more than 50% improvement since baseline. Urodynamic data, available for 11 UI patients at 6 months post implant showed an increase of mean first sensation of fullness from 78 to 241 ml ($p=0.0008$) corresponding with 30% and 72% of bladder capacity respectively. In the 5 patients with urgency/frequency, the treatment was regarded as a failure in 2. 24 Months follow-up was available for 3 patients. Number of voids per 24 hours reduced from 25 to 19 ($p=0.09$, including the data of 2 failures), the voided volume per void increased from 91 ml to 143 ml

(p=0.15). The mean first sensation of fullness increased from 141 ml to 232 ml (p=0.35) and maximum bladder capacity increased from 223 ml to 318 ml at urodynamic evaluation 6 months post implant. 18 Months follow-up was available for the 2 VD patients. 1 Patient was able to void without catheterisation, while the other one had less than 50% improvement in reduction of the residual volume. Since the implant, 4 of the 22 patients (2 UI, 1 UF and 1 VD) underwent device explant due to pain at the neurostimulation site and swollen abdomen. 1 Patient has the inactive neurostimulator still in situ and must be regarded as failure. The data of all these patients were included in the efficacy analysis (intention-to-treat analysis).

Conclusion:

Sacral neurostimulation is an effective treatment modality that offers sustained clinical benefit on the long term in the majority of selected patients with refractory UI, UF and VD who have failed prior treatments.