

SACRAL NEUROMODULATION FOR REFRACTORY URINARY URGENCY/FREQUENCY : UTILITY OF REPROGRAMMING DURING THE INITIAL TEST PHASE

Hypothesis / aims of study

The aim of the study was to assess the utility of sacral nerve stimulation's reprogramming during the initial test phase (stage 1) in refractory urinary urgency/frequency (UF) and urge incontinence. During stage 1, stimulation's parameters are adjusted to provide the best improvement in voiding dysfunction. We evaluated stage 1 results with different parameters of reprogramming to better select candidates for neurostimulation.

Study design, materials and methods

We prospectively evaluated 30 consecutive patients (26 women, 4 men) (mean age 61.3±13.1 years) implanted by a single surgeon between June 2008 and November 2010. Etiologies were 30 UF (idiopathic (26), radiation cystitis (2), interstitial cystitis (2)). Pre-operative assessment included clinical examination, voiding diaries, urodynamics, cystoscopy, MHU-score, and kidney ultra-sound. During stage 1, the device was systematically programmed at 5Hz, 15Hz, 40Hz and a Test-Off, with a bipolar lead configuration, pulse width 210MHz and electrode evaluation. Effectiveness was based on voiding diaries and the permanent implantation was decided if improvement >50%. Mean follow-up was 15±7.7 months.

Results

The overall implantation rate was 70% (21/30). Mean test period was 25.6±7.9 days with an average of 5.8±2.7 medical consultations. Among the UF permanent implanted patients, daily and nocturnal voids decreased respectively by 36.1% and 63.6%, mean voiding volume increased by 21.2%, number of leakage episodes decreased by 76.8%, pads per day decreased by 80% and MHU-score decreased by 65.4%. Of the 21 permanent implanted patients, stage 1 was successful for 19 (90.5%) at 15Hz, 10 (47.6%) at 5Hz, 15 (71.4%) at 40Hz; Test-Off was always positive. Optimal frequency was 15Hz, 5Hz, 40Hz for respectively 15 (71.4%), 4 (19%) and 2 (9.6%) patients. One patient (4.8%) was only improved with 40Hz and was permanently implanted at this frequency with stable results at 6 months. One patient (4.8%) was only improved with 5Hz and was permanently implanted at this frequency (follow-up 1 month). During stage 1, complications occurred in 3 patients (10%) : acute urinary retention (1), regional pain (1) and infection requiring electrode removal (1) with new implantation 3 months later. Long term revision surgery was 4.8% (1/21 patients : infection with material removal).

Interpretation of results

Although 10-20Hz are the frequencies usually used during stage 1 to evaluate the efficiency of sacral neuromodulation, only few data is available about frequencies programming. This study shows that, even if stage 1 was successful for 90.5% of patients at 15Hz, 28.6% of patients were permanently implanted at frequencies different from the 10-20Hz usually used and that 9.6% of patients could benefit of sacral neuromodulation although the neuromodulation's test was not successful at 15Hz during stage 1.

Concluding message

In 10-20Hz non responders during initial test phase, 5Hz and 40Hz should also be tested. In our experience, modifying frequencies during this phase improves neuromodulation outcomes in 28.6% of patients and better select 9.6% of patients but needs high physician availability.

Specify source of funding or grant	none
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	No
This study did not require ethics committee approval because	pre-operative inform consent form
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes