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NEUROPHYSIOLOGICAL EVIDENCE MAY PREDICT THE OUTCOME IN SACRAL NEUROMODULATION

Aims of Study

Chronic stimulation of the sacral nerves has now become one of the most accepted stimulation therapies in treating functional Lower Urinary Tract Symptoms (LUTS) which are refractory to conservative treatment. Despite the existence of a large amount of literature on Sacral neuromodulation (SNM), which shows a fairly high percentage of significant improvements in clinical outcomes (2, 3), there are few experimental studies related to SNM stimulus parameters and/or neurophysiological monitoring. Aim of study was to evaluate the specific action of SNM on the primary sensory cortical area, the Somatosensory Evoke Potentials (SEPs) of the Pudendal and Posterior Tibial nerves were evaluated in patients implanted with a monolateral permanent quadripolar electrode.

Methods

Twenty-four female patients (23.76%) (Tab 1) with a normal neurological profile exhibiting no history or diagnoses of nervous system pathologies, previous sacral or pelvic injuries or diabetes mellitus and classified as idiopathic, and had proved refractory to both pharmacological treatment and/or temporary methods of electromodulation (PTNES, IVES;PFS) underwent SNM. The results of SNM were evaluated in relation to symptoms evolution, micturition diary, QoL questionnaire, pain VAS, uroflow and residual urine. All patients gave their written consent to the study

Twenty-four patients underwent the $\int_{1}^{5^{t}}$ stage of monolateral sacral nerve implant (SPI). The lead is implanted percutaneously (10) in S3 foramen using local anaesthesia (14 with fascial fixation and 10 with the new tined lead (11)) and connected to an external screener.

Three patterns of SEPs were evaluated: before implant (baseline, T0), 1 month after the 1st stage with stimulation set at 21 Hz (T1) and again with pulse rate of 40 Hz (T2). The pulse width of 210μ sec and the intensity adjusted to a subjective sensory non-nociceptive threshold were kept unchanged.

<u>Results</u>

Based on clinical outcome after SNM, patients were divided into 2 groups: group A consisting of 16 patients (66.6 %) with a satisfactory result (improvement of more than 50% in main symptoms: residual volume in retention, number of incontinence episodes in urge-incontinence, number of voiding and voided volume in urgency-frequency) during the 1st stage with the result remaining stable at 6 months follow up and goup B consisting of 8 patients (33.3 %) who did not undergo the 2^{d} stage of SPI because of an unsatisfactory result (improvement of less than 50% in main symptoms).

In Group A the decrease of the sensory threshold is statistically significant and is related to pulse rate independently as to whether the lead implant site is ipsilateral or contralateral to the stimulus.

In all patients SNM produced a significant decrease of Pudendal SEP P40 latency between T0, T1 and T2, and between T2 and T1, at both ipsilateral and contralateral implant sites

In group B we observed a significant decrease only of the left Pudendal P40 latency in T1 vs T2. In 5 patients with urinary retention in group B, the Pudendal SEPs did not show any alteration to the afferent pathway fom the Pudendal nerve to the cortical area and the P40 latency in T0 was within normal values. Although 2 patients with urinary incontinence and 1 patient with urgency/frequency showed a decrease in the P40 latency in T1 and T2, this is not statistically significant compared with T0.

Conclusions

Our study confirms previous observations that SNM acts by means of the afferent pathway at the cortical site level and sheds light on the so-called idiopathic LUTS. The action of SNM on the afferent pathway from the sacral area to the somatosensory cortex is specific and neurophysiological evaluation, by means of Pudendal SEPs, provides evidence to this effect. The simplicity of this method, the fact that it is standardised and repeatable makes this tool

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easy to use as a guide in setting SNM parameters and selecting ideal candidates for implant. The evidence indicating that the effects of SNM on the cortical area are the same whether lead implant is at the ipsilateral or the contralateral SEPs measurement site, provides material for discussion regarding the possible advantages of bilateral implant.