

## MENTAL HEALTH AS A PROGNOSTIC FACTOR FOR SUCCESSFUL NEUROMODULATION THERAPY

### Hypothesis / aims of study

In Sacral Neurostimulation (SNS) the results of percutaneous nerve evaluation prior to definitive implantation is the main prognostic factor for success. The same goes for Percutaneous Tibial Nerve Stimulation (PTNS): through test stimulations it is investigated whether chronic treatment or, in the future, implantation of a subcutaneous stimulation device is justified. In our study we tried to identify prognostic patient characteristics to improve patient selection for neuromodulation therapy.

### Study design, materials and methods

After ethical committee approval PTNS was applied to 132 patients in 8 study centers. PTNS therapy consisted of 12 weekly sessions of 30 minutes each. There were 51 men and 81 women, the mean age was 53 years (range: 21-82 years). 83 patients were treated for overactive bladder, 16 for non-obstructive urinary retention and 33 for chronic pelvic pain. All patients had to fill out micturition or pain diaries, as well as quality of life questionnaires at study entry and at completion of treatment at 12 weeks. PTNS was considered an objective success in case of a  $\geq 50\%$  improvement of symptoms. Subjective success was defined as the request of patients to continue chronic treatment to maintain the obtained response. Patient characteristics were evaluated for their prognostic value for successful outcome of neuromodulation therapy with use of logistic regression (Odds ratio, 95% Confidence Interval, (OR (95% CI))).

### Results

Objective success was seen in 32.6% of all patients, subjective success in 51.5%. Sex, age, weight, Body Mass Index, indication for PTNS, duration of complaints, number and kind of treatments used before, PTNS study center and stimulation parameters all proved not to be of prognostic value.

However, a low total score ( $\leq 50$  out of a maximum of 100 points) at baseline in the Short Form 36 (SF-36) questionnaire, a questionnaire addressing general quality of life, proved to be predictive for negative outcome (OR 0.444 (95% CI: 0.198-0.996),  $p=0.04$  for objective success and OR 0.424 (CI: 0.203-0.887),  $p=0.02$  for subjective success). When evaluating the SF-36 Physical and Mental Component Summaries (PCS and MCS), patients with a low MCS ( $\leq 30$  out of a maximum of 50 points) were most likely to fail neuromodulation therapy: OR 0.123 (95% CI: 0.273-0.552),  $p=0.006$  for objective success.

### Interpretation of results

Most basic parameters do not seem to influence the outcome of neuromodulation therapy. This is in concordance with the scarce literature on this subject. It proves, amongst other things that old patients and patients with a long history of complaints should not be ruled out for therapy and that the tibial nerve even in patients with a high Body Mass Index can well be reached for stimulation. Stimulation intensity most likely is not of prognostic value as high intensity parameters seem to indicate less well positioning of the stimulation needle more than actual higher stimulation of the nerve itself. Although other studies suggested otherwise, the indication for therapy proved not to be a prognostic factor, most probably because of the relatively small number of patients within the non-obstructive urinary retention and chronic pelvic pain groups.

Our study indicates what is already felt by urologists working in this field: those patients that mentally suffer the most from their complaints are less susceptible to successful outcome of

treatment. Whether bad mental health is caused by the complaints or part of the origin remains unanswered, but measured with the SF-36 Mental Component Summary it may be a useful tool to narrow patient selection criteria for neuromodulation therapy.

Concluding message

Bad mental health is a negative predictive factor for success of percutaneous tibial nerve stimulation. As the same was suggested in an earlier study on sacral neurostimulation (1), the SF-36 Mental Component Summary might be used as a tool for better patient selection in neuromodulation therapy.

(1) Quality of life of patients with lower urinary tract dysfunction after treatment with sacral neuromodulation (abstract 95). *Neurourology and Urodynamics* 1997; 16:483-484.