872

Bianchi D¹, Petta F¹, Parisi I A², D'Amico A², Iacovelli V¹, Topazio L¹, Finazzi Agrò E¹

1. Department of Experimental Medicine and Surgery, Tor Vergata University and Unit for Functional Urology, Policlinico Tor Vergata University Hospital, Rome, Italy, **2.** Neurourology Unit, Fondazione Santa Lucia Rehabilitation Hospital, Rome, Italy

REAL-LIFE DATA ON THE LONG-TERM FOLLOW-UP OF PATIENTS TREATED BY PERCUTANEOUS TIBIAL NERVE STIMULATION (PTNS)

Hypothesis / aims of study

Percutaneous tibial nerve stimulation (PTNS) is a neuromodulation technique proposed for lower urinary tract dysfunctions (LUTD); evidence of efficacy is present in particular for overactive bladder syndrome (OAB) (1). However, there are sparse data about PTNS as a treatment for other conditions, such as voiding dysfunction and neurogenic LUTD. Although some long-term results of PTNS have been published (2,3), showing that —if periodic stimulation sessions are provided to the patient—improvement are maintained in OAB patients up to three years, there is need for more information on long-term follow-up of patients treated by PTNS. The aim of this cross-sectional study is to evaluate the "real life" data of patients successfully treated with PTNS for OAB or non-obstructive voiding dysfunction (NOVD) at a seven-year follow-up.

Study design, materials and methods

This cross-sectional study was performed in two centres. Patients who were successfully treated with PTNS for OAB or NOVD between February 2008 and January 2009 were contacted for a telephonic interview at a follow-up of seven years. The interview was conducted seven years after the end of their PTNS stimulation protocol (± two months) by a physician who had not met the patients during the PTNS treatment. Patients who agreed to the interview were asked to complete the Global Response Assessment (GRA) consisting of the seven point scale centred at zero (no change): markedly worse (-1); moderately worse (-2); slightly worse (-3); no change (0); slightly improved (+1); moderately improved (+2); and markedly improved (+3). Patients had to compare their present condition with the situation before PTNS. Patients in the OAB category completed the OAB q SF, and NOVD patients were evaluated using the International Prostate Symptom Score – voiding questions (v-IPSS, questions 1,3,5,6 of IPSS). Results of both questionnaires were compared with those obtained seven years before, before the initial PTNS treatment. Details about further treatment were recorded.

Results

Seventeen patients were identified using our database. Sixteen agreed to the interview, and the remaining patient was unreachable and therefore considered as lost at follow-up.

Eight patients were classified into the OAB group (all females), and eight were classified into the NOVD group (six females, two males). Seven of the eight patients in the OAB group gave positive responses to the GRA, while the remaining patient gave negative responses.

Four patients (three female, one male) of the eight patients in the NOVD group gave positive responses to GRA, while the other four patients (three females, one male) gave negative responses.

Two patients in the OAB group underwent further periodic PTNS treatments in combination with antimuscarinic drugs, and one patient in the NOVD group was chronically retreated with transcutaneous home-based tibial nerve electrostimulation. Two other patients were taking antimuscarinic drugs. The remaining patients reported no further treatments.

Overall, a good level of satisfaction was reached by 87.5% of the patients in the OAB group (mean GRA, 2.42) and 50% of the patients in the NOVD group (mean GRA, 2.00). The results are summarized in Table 1.

Questionnaire	After PTNS	At 7 year Follow-up	Р
Mean GRA	-	2.27 (SD ± 0.90)	
OAB-q SF	22.85 (SD ±9.94)	20.71 (SD ±10.96)	0,67
v-IPSS after PTNS	7.14 (SD ± 2.6)	9 (SD ± 3.7)	0,21

SD= standard deviation; OABq: results expressed in % (100%: worst possible condition, 0%: no OAB); v-IPSS: data on a 0 to 20 scale.

Interpretation of results

This study provides some interesting insights about the long-term results of PTNS for OAB and NOVD patients. This is the first study, to our knowledge, showing "real life" data of PTNS treated patients seven years after the initial treatment. Excluding the only patient lost at follow-up, the majority of patients considered themselves still improved regarding their lower urinary tract condition at the seven-year follow-up. In terms of improvement, the OAB patients showed better results (87.5% considered themselves improved vs. 50% in the NOVD group).

It is worthy to note that only 3 patients (2 in the OAB, 1 in the NOVD group) underwent further periodic tibial nerve stimulations: this finding seems to contradict previous data showing the necessity of periodic maintenance stimulation sessions to maintain the results. On the other hand, two patients in the OAB group were assuming antimuscarinic drugs at seven year follow-up. Overall, 4 out of 8 patients in the OAB group were still receiving a therapy after seven years, in comparison to one out of 8 in the NOVD group. This finding should be kept in mind when considering the lower percentage of improved patients in the NOVD group. Neither OABq nor v-IPSS results changed significantly at seven year follow-up in comparison to the end of PTNS treatment. The study presents several limitations: it is neither prospective nor controlled, there is only a semi-objective quantification of the clinical condition (one questionnaire for each group, in combination with GRA), and the sample size is small.

Concluding message

Despite some limitations, this study shows that the majority of patients who responded to PTNS considered themselves still improved at a seven-year follow-up. There were more improved patients in the OAB group compared to the NOVD group. Larger studies are needed to investigate this subject in the future, but this small study presents the advantage to show data coming from the "real life".

References

- Finazzi Agrò E, Petta F, Sciobica F, Pasqualetti P, Musco S, Bove P. Percutaneous tibial nerve stimulation effects on detrusor overactivity incontinence are not due to a placebo effect: a randomized, double-blind, placebo controlled trial. J Urol. 2010 Nov;184(5):2001-6.
- 2. Peters KM, Carrico DJ, Wooldridge LS, Miller CJ, MacDiarmid SA. Percutaneous tibial nerve stimulation for the long-term treatment of overactive bladder: 3-year results of the STEP study. J Urol 2013 June;189(6):2194-201.
- 3. Yoong W, Shah P, Dadswell R, Green L. Sustained effectiveness of percutaneous tibial nerve stimulation for overactive bladder syndrome: 2-year follow-up of positive responders. Int Urogynecol J. 2013 May;24(5):795-9.

Disclosures

Funding: None. Clinical Trial: No Subjects: HUMAN Ethics Committee: Policlinico Tor Vergata Ethics Committee. Helsinki: Yes Informed Consent: Yes