

## PERCUTANEOUS TIBIAL NERVE STIMULATION RESULTS AFTER 5 YEARS: A CROSS-SECTIONAL STUDY

### Hypothesis / aims of study

Percutaneous tibial nerve stimulation (PTNS) is a neuromodulation treatment of the lower urinary tract with proven efficacy on overactive bladder syndrome (OAB) (1) and sparse data on different indications such as voiding dysfunction and neuropathic bladder. Study on long term results of PTNS have been performed as well, demonstrating that, with periodic stimulation sessions, its efficacy is maintained at a follow up of 12 months and longer (2). Few data are reported on long term follow up of patients treated by means of PTNS. Aim of this cross sectional study was to evaluate data of patients previously treated by means of PTNS for OAB or non obstructive voiding dysfunction (NOVD) at 5 year follow up.

### Study design, materials and methods

This is a cross sectional study performed in two centres. Patients who had been successfully treated by means of PTNS for the indication of OAB and NOVD between January 2006 and January 2008 were contacted for telephonic interview at five year follow-up. The interview was conducted five year after the date of the end of PTNS stimulation protocol with an approximation of +/- 15 days. Patients who accepted the interview were asked to answer 5 compulsory and 1 optional questions (see tab 1); one validated questionnaire (OAB-q SF for OAB patients and IPSS for NOVD patients) was sent by email and completed by the patients together with a written informed consent. Results in patients who were retreated by office based PTNS or home based tibial nerve electrostimulation were compared with those of patients who were not.

Table 1

|   |                                                                                                |      |
|---|------------------------------------------------------------------------------------------------|------|
| 1 | Would You be satisfied if Your lower urinary tract symptoms would remain unchanged?            | Y/N  |
| 2 | Have You been followed up on a regular basis?                                                  | Y/N  |
| 3 | Have You been chronically retreated by office based PTNS?                                      | Y/N  |
| 4 | Have You been chronically retreated by any kind of home based tibial nerve electrostimulation? | Y/N  |
| 5 | Have You used other treatments except PTNS?                                                    | Y/N  |
| 6 | If Yes Which treatments?                                                                       | ---- |

### Results

Thirty-seven out of 51 patients contacted (72.5%) accepted the interview. Twenty-one patients (9 M and 12 F) had been treated for OAB and 16 patients (6 M and 10 F) had been treated for NOVD. Thirty-one out of 37 patients (83.8%) answered "Yes" to question number 1 and were considered subjectively satisfied about their lower urinary tract condition. Four of the 6 unsatisfied patients were affected by OAB and remaining 2 by NOVD. Twenty-one patients (56.8%) declared to have been followed up on a regular basis (question 2); 20 patients (54%) reported to have been chronically retreated by means of office based PTNS (question 3) and 14 of them (37.8%) to have been chronically retreated by trans-cutaneous home based tibial nerve electrostimulation (question 4). It is worthy to note that 11 out of the 17 untreated patients (64.7%, 6 affected by OAB and 5 by NOVD) were still subjectively satisfied about their lower urinary tract condition. Nevertheless, the percentage of satisfied patients was 100% among treated patients versus 64.7% among untreated patients ( $p=0.005$ ). Eighteen patients (48.6%) had used treatments other than PTNS, with oral (18) and intravesical (3) drug administration being the most common answers (prevalently antimuscarinics and alpha-blockers). Mean OAB-q SF score was 23%; mean IPSS score was 9. Results are summarized in table 2.

Table 2

| <b>Question</b>                                                                                    | <b>Yes<br/>N (%)</b>                                   |
|----------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| Would You be satisfied if Your lower urinary tract symptoms would remain unchanged?                | 31 (83.8)                                              |
| Have You been followed up on a regular basis?                                                      | 21 (56.8)                                              |
| Have You been chronically retreated by office based PTNS?                                          | 20 (54)                                                |
| Have You been chronically retreated by trans-cutaneous home based tibial nerve electrostimulation? | 14 (37.8)                                              |
| Have You used other treatments except PTNS?                                                        | 18 (48.6%)                                             |
| <b>Question</b>                                                                                    | <b>Answers</b>                                         |
| If Yes Which treatments?                                                                           | Oral drugs (18)<br>Intravesical drugs (3)<br>Other (5) |
| <b>Questionnaire</b>                                                                               | <b>Score</b>                                           |
| OAB-q SF                                                                                           | 23                                                     |
| IPSS                                                                                               | 9                                                      |

### Interpretation of results

This study provides some interesting insights about the long term results of OAB or NOVD patients successfully treated by means of PTNS.

The large majority of the patients who answered our interview (83.8%) were still subjectively satisfied about their lower urinary tract condition at five year follow-up. Even if we had considered all the patients who refused to answer the interview as "failed" (as in an intention to treat analysis), subjectively satisfied patients would remain the majority (60.8%). No significant difference, in term of satisfaction, was found between OAB and NOVD patients.

The majority of patient (56.8%) had been followed regularly after the PTNS treatment and 54% of the patients had received a "chronic" stimulation (in office -54%- or at home -37.8%-). Interestingly, 64.7% of the 17 non chronically treated patients were still subjectively satisfied: this data seems in contrast with previous reports, where long term benefits seem related to a periodic retreatment of the patients (2). Nevertheless, the 6 unsatisfied patients were all in the group on untreated patients and this finding is highly significant.

It is possible that untreated patients could have found some benefits in therapies other than PTNS, with many of them treated with oral drugs.

The study presents some limitations: it is not a prospective trial; it is not controlled; several patients (14/51, 27.5%) refused to answer the interview; there is only a semi-objective quantification of the clinical condition (one questionnaire).

### Concluding message

Despite some limitations, this study shows that the large majority of the patients who responded to PTNS (83.8%) could be still subjectively satisfied at five year follow-up. The number of subjectively satisfied patients is significantly higher among patients chronically treated with PTNS (or trans-cutaneous electric tibial stimulation) than in untreated patients; nevertheless, even the majority of untreated patients can be satisfied at five year follow up, probably due to the use of ancillary treatments.

### References

1. J Urol. 2010 Nov;184(5):2001-6.
2. J Urol. 2010 Jan;183(1):234-40.

### Disclosures

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