**Evidence Table**

Clinical area: Percutaneous tibial nerve stimulation (PTNS)  

**Study Type:** Case Series  
**Study Aim:** To evaluate urodynamic changes after percutaneous tibial nerve stimulation (PTNS) for the treatment of overactive bladder syndrome.

**Outcomes**  
- **Primary:** Reduction in number of urinary leakage episodes of 50% or more per 24 hours.  
- **Secondary:** At least 50% reduction in leakage severity; subjective success: patient request for continuation of therapy.

**Design**  
- **Number of subjects:** N=90.  
- **Description of study population:** Study conducted in the Netherlands and Italy between November, 1999 and August, 2001. 67 females/ 23 males; median age= 51 years (range 19-82 years). Median duration of symptoms= 4.5 years.  
- **Inclusion criteria:** Diagnosis of overactive bladder syndrome, which was included as urgency, frequency and/or urge incontinence. International definitions were used for urgency and urge incontinence. Frequency was defined as ≥8 voids per 24 hours.  
- **Exclusion criteria:** Stress incontinence (excluded through urodynamic studies).  
- **Consecutive patients?** Yes.  
- **Intervention:** 12 sessions of PTNS. The authors reported using a low voltage stimulator by Cystomedix. This is likely the Urgent PC, since Cystomedix was bought by Uroplasty.  
- **Source of outcome data:** Urodynamic sessions at baseline and end of treatment; patient self-report.  
- **Length of follow-up:** End of 12 sessions.

**Validity**  
- **Was population homogenous?** Had different types of urinary incontinence.  
- **Potential selection biases:** Individuals who dropped out or did not complete voiding charts may have been more likely to fail intervention.  
- **Were intervention/ care/follow-up similar in each group?** Yes.  
- **Did an objective observer assess outcomes?** Included objective urodynamic investigations. There were also subjective outcomes.  
- **Completeness of follow-up:** Voiding charts were available for 78 patients (87%). Urodynamic data at baseline and follow-up were available for 46 patients (51%).  
- **Conclusions regarding validity of methods:** Limitations are those common to all case series, lack of control or comparison group and lack of blinding. Urodynamic follow-up data needed to assess the primary outcome were missing for about half of the patients. In
addition, follow-up occurred at the end of treatment, there was no long-term follow-up. No financial conflicts of interest were reported.

**Results**

Of the 90 patients enrolled, frequency/volume charts were available for 80 patients (89%). 60/80 (75% of those with charts available) had urine leakage at least once a day at baseline. 73/80 (91%) had increased frequency at baseline.

Specific data on the primary outcome, reduction in number of urinary leakage episodes of 50% or more per 24 hours, were not clearly reported. The authors claim a 56% rate of success in the primary outcome.

**Incontinence episodes at least once daily**

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<th>Baseline</th>
<th>Follow-up</th>
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<tr>
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<td>60/80 (75%)</td>
<td>35/80 (44%)</td>
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**Voiding frequency ≥8 times a day**

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<td>73/80 (91%)</td>
<td>20/80 (25%)</td>
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**Authors’ Conclusions**

“PTNS sessions could not eliminate DI (*detrusor instabilities*) but resulted in increased bladder capacity and delayed onset of DI to such an extent that the patients experienced a clinically relevant decrease in leakage episodes, severity of incontinence and voiding frequency.”

**Reviewer’s Conclusions**

This was a case series with no control or comparison group, and there was incomplete follow-up at the end of treatment, all of which can introduce bias. The proportion of patients with daily incontinence at the end of treatment (among those with available data) decreased from 75% to 44% after 12 treatment sessions, and the proportion of patients with voiding frequency decreased from 91% to 25%. Since there was no comparison group, it is not know much of the improvement is due to natural history, or the placebo effect. There were no long-term follow-up data.