Evidence Table

Clinical area: **Percutaneous tibial nerve stimulation (PTNS)**
Reference: **Govier FE, Litwiller S, Nitti V et al. Percutaneous afferent neuromodulation for the refractory overactive bladder: Results of a multicenter study. *J Urol* 2001; 165: 1193-1198.**

Study Type: Case Series
Study Aim: To evaluate percutaneous tibial nerve stimulation (PTNS) for the treatment of refractive overactive bladder and/or pelvic floor dysfunction.

Outcomes
- *Primary*: Primary efficacy outcome: change in mean daytime voiding frequency from baseline to 12 weeks (end of treatment period). Primary safety outcome: composite event consisting of either moderate to severe pain, infection or device malfunction.

Design
- *Number of subjects:* N=53
- *Description of study population:* Study conducted at 5 sites in the United States. Mean age=57.4; 90% female.
- *Inclusion criteria:* At least 18 years old; documented urgency, frequency and/or pelvic floor dysfunction; mean frequency of at least 10 voids/day and/or 3/night; failed conventional therapies e.g. medication, kegel exercise, biofeedback and pelvic floor stimulation.
- *Exclusion criteria:* Active UTI, structural abnormality, urodynamically proven instability.
- *Consecutive patients?* Not specified.
- *Intervention*: Weekly 30-minute sessions of PTNS for 12 weeks using the PerQ SANS device.
- *Source of outcome data*: Patient self-report, physical examination, voiding diary.
- *Length of follow-up:* 12 weeks.

Validity
- *Was population homogenous?* No, had different indications for treatment.
- *Potential selection biases:* Individuals who dropped out may have been more likely to fail intervention.
- *Were intervention/ care/follow-up similar in each group?* Yes.
- *Did an objective observer assess outcomes?* Not for patient self-report outcomes.
- *Completeness of follow-up:* 47/53 (89%) completed the 12 week treatment period.

- **Conclusions regarding validity of methods:** Limitations are those common to all case series, lack of control or comparison group and lack of blinding. Two of the five authors reported financial relationships with the device manufacturers. The primary outcome was assessed at 12 weeks, the end of treatment, which may be too short a time frame for a valid evaluation.

Results

Note: Data on efficacy were presented in figures and were reported separately for each center. Exact numbers and composite statistics were not reported.

Primary efficacy outcome: change in mean daytime voiding frequency from baseline to 12 weeks

There was a significant reduction in mean daytime voiding frequency among patients at 4 out of the 5 study sites.

Secondary efficacy outcome, baseline to 12 weeks

There was a significant reduction in the number of mean voids per night at all study sites.

Primary safety outcome: composite event consisting of either moderate to severe pain, infection or device malfunction.

There were 3 pain events. No infections or device malfunctions were reported.

Authors' Conclusions

"Percutaneous peripheral afferent nerve stimulation offers a safe, minimally invasive and effective treatment for managing refractive overactive bladder and/or pelvic floor dysfunction."

Reviewer's Conclusions

This was a case series with no control or comparison group. In this case series, the number of daytime and nighttime voids decreased at the end of a 12 week treatment period. Since there was no comparison group, it is not know much of the improvement is due to natural history, or the placebo effect. In addition, a statistically significant decrease in number of voids is not necessarily a clinically important outcome, it depends on the initial number of voids and the extent to decrease.