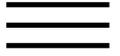


Randomized trial of percutaneous tibial nerve stimulation versus extended-release tolterodine: results from the overactive bladder innovative therapy trial.

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Voiding Dysfunction

Randomized Trial of Percutaneous Tibial Nerve Stimulation Versus Extended-Release Tolterodine: Results From the Overactive Bladder Innovative Therapy Trial

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Purpose

The Overactive Bladder Innovative Therapy trial was a randomized, multicenter, controlled study that compared the effectiveness of percutaneous tibial nerve stimulation to extended-release tolterodine. The reduction in overactive bladder symptoms along with global response assessments was evaluated.

Materials and Methods

A total of 100 adults with urinary frequency were randomized 1:1 to 12 weeks of

treatment with weekly percutaneous tibial nerve stimulation or to 4 mg daily extended-release tolterodine. Voiding diaries and an overactive bladder questionnaire were completed at baseline and at the end of therapy to compare 24-hour voiding frequency, urinary urge incontinence episodes, voids causing waking, volume voided, urgency episodes and quality of life indices. Global response assessments were completed by subjects and investigators after 12 weeks of therapy.

Results

The global response assessment demonstrated that subject assessment of overactive bladder symptoms compared to baseline was statistically significant in the percutaneous tibial nerve stimulation arm with 79.5% reporting cure or improvement compared to 54.8% of subjects on tolterodine ($p = 0.01$). Assessments by investigators were similar but did not reach statistical significance ($p = 0.05$). After 12 weeks of therapy objective measures improved similarly in both groups for reductions in urinary frequency, urge urinary incontinence episodes, urge severity and nighttime voids, as well as for improvement in voided volume. There were no serious adverse events or device malfunctions.

Conclusions

This multicenter, randomized trial demonstrates that percutaneous tibial nerve stimulation is safe with statistically significant improvements in patient assessment of overactive bladder symptoms, and with objective effectiveness comparable to that of pharmacotherapy. Percutaneous tibial nerve stimulation may be considered a clinically significant alternative therapy for overactive bladder.



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Key Words

electric stimulation therapy; tibial nerve; tolterodine; urinary bladder; overactive; urinary incontinence; urge

Abbreviations and Acronyms

FDA, Food and Drug Administration; GRA, global response assessment; OAB, overactive bladder; OAB-q, overactive bladder questionnaire; OrBIT, Overactive Bladder Innovative Therapy; PTNS, percutaneous tibial nerve stimulation; QoL, quality of life

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Study received institutional review board approval.

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