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Anodyne Therapy System Effective in Diabetic Neuropathy **CME**

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Complete author [affiliations and disclosures, and other CME information](#), are available at the end of this activity.

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Dec. 31, 2003 — The Anodyne Therapy System (ATS) reduces painful symptoms and improves sensation and balance in patients with diabetic peripheral neuropathy (DPN), according to the results of a randomized, double-blind trial published in the January issue of *Diabetes Care*.

"DPN has been thought to be progressive and irreversible," write David R. Leonard, MD, FACE, and colleagues from the Joslin Center for Diabetes of Morton Plant Mease Healthcare in Clearwater, Florida. "Recently, symptomatic reversal of DPN was reported after treatments with a near-infrared medical device, the ATS. However, the study was not controlled nor was the investigator blinded."

In the current study, of 27 patients with DPN, nine were insensitive at study entry to the 6.65 Semmes Weinstein monofilament (SWM) and 18 were sensitive to this filament but insensitive to the 5.07 SWM. Each lower extremity received sham or active ATS for two weeks, and then both lower extremities received active ATS for an additional two weeks.

In the 18 patients insensitive to the 5.07 SWM at baseline, the number of sites insensate after both 6 and 12 active treatments significantly decreased ($P < .02$ and $.001$, respectively). Sham treatments did not improve sensitivity to the SWM, but subsequent active ATS did ($P < .002$).

On the Michigan Neuropathy Screening Instrument (MNSI), neuropathic symptoms decreased from 4.7 to 3.1 ($P < .001$). On the 10-point visual analog scale (VAS), pain decreased from 4.2 at baseline to 3.2 after six treatments and to 2.3 after 12 treatments ($P < .03$ for both).

The proportion of subjects reporting substantial balance impairment was 90% at baseline and 17% after treatment. However, in the group of nine patients with insensitivity to the 6.65 SWM at study entry, improvements in sensation, neuropathic symptoms, and pain reduction were not significant.

Study limitations include use of the 5.07 SWM as a gross measure of sensory loss rather than use of quantitative sensory tests, inability to measure pain reduction or balance improvement for active versus sham treatment of individual limbs, lack of objective measures of balance, and no long-term data on the durability of ongoing treatment.

"ATS treatments improve sensation in the feet of subjects with DPN, improve balance, and reduce pain," the authors write. "Although there are certainly factors other than DPN that contribute to falls, the improvement in balance may offer an opportunity for fall-related risk reduction in this population despite the severity of their sensory impairment before treatment."

The Medassist Group helped fund this study and provided laboratory funds to its authors.

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Learning Objectives

Upon completion of this activity, participants will be able to:

- List the benefits of the ATS for DPN.
- Describe the appropriate frequency and nature of ATS treatment for DPN.

Clinical Context

DPN is a complication of long-term diabetes and is characterized by diminished sensation and/or pain and perceived numbness in the lower extremities. It poses a significant risk for ulcer and nontraumatic amputation, and, in the elderly, can contribute to falls due to loss of balance. Current management is aimed at prevention or delay of onset of DPN with strict glucose control, regular foot examinations, and intensive foot-care education. Secondary measures include wound prevention and customized footwear. A satisfactory pharmacologic approach for symptom and disease control in the diabetic patient with DPN has not yet been identified.

The ATS, a noninvasive medical device, was recently reported to reverse symptoms of DPN, according to a study by Kochman and colleagues in the March 2002 issue of the *Journal of the American Podiatric Medical Association*.

This is the first double-blind, randomized controlled study of the new treatment, the ATS, for improving sensation and reducing pain in diabetic patients with DPN.

Study Highlights

- 27 patients were recruited with the following eligibility criteria: type 1 or 2 diabetes and a diagnosis of DPN confirmed by testing using the 5.07 SWM with loss of sensation on at least 2 of 5 test sites on the plantar surface of both feet.
- Exclusion criteria were uncontrolled hypertension, history of back or knee surgery, active malignancy, or pregnancy.
- 18 patients (group 1) had loss of protective sensation to the 5.07 SWM only, while the remaining 9 patients (group 2) had severe DPN with additional loss of sensation to 6.65 SWM, which requires 30 times the bending force of the 5.07 SWM.
- The primary end point was observed change in sensation to the 5.07 SWM at the 5 test sites compared with baseline, measured as the number of sites sensitive to the SWM on each lower limb.
- Secondary end points were changes in response to the Michigan Neuropathy Screening Instrument (MNSI) patient questionnaire (maximum score = 11, a higher score indicating worse neuropathic symptoms) and physician examination of the foot; general pain sensation was measured by a 10-point VAS; and one yes/no question on loss of balance.
- The ATS Model 480 was supplied by the manufacturer. Treatment consisted of 1.3 J·cm² per minute of photo energy delivered by 4 diode pads to 4 areas of each foot and calf using near-infrared emission to increase arterial and venous circulation. Sham devices looked and felt identical.
- Each patient received six 40-minute treatments over 2 weeks, active treatment on one limb and sham treatment on the other limb. The limb receiving sham treatment was randomized by patient. After 2 weeks, all patients received active treatment on both limbs for 6 additional treatments over 2 more weeks.
- Patients and investigators were blinded to the treatment protocol until study conclusion.
- 5.07 SWM screening, MNSI patient questionnaire, and physician examinations were performed at entry and after 6 and 12 treatments.
- Patients were similar in age, sex, and weight. Mean age of group 1 patients was 61 years; mean age of group 2 patients was 64 years. 25 of 27 patients had type 2 diabetes.
- Analysis was by paired and unpaired Student's *t* test with statistical significance set at $P < .05$.
- Group 1: 6 active treatments reduced the number of sites insensitive to the SWM 5.07 compared with baseline and to the sham treatment foot ($P < .02$). 12 treatments resulted in further improvement of detection of the 5.07 SWM ($P < .002$

compared with baseline). The MNSI patient score was significantly reduced after 6 treatments ($P < .0001$ compared with baseline) and further improved after 12 treatments ($P < .05$ compared with baseline). However, the sham-treated foot enjoyed a similar reduction in score after 6 treatments ($P < .05$ compared with baseline).

- Group 2: No significant improvement in sensation to the 5.07 SWM or the MNSI patient score was seen after 6 or 12 treatments.
- Physician foot examination for appearance, active ulcers, ankle reflexes, and vibratory sensation did not show significant change over 6 or 12 treatments for either group 1 or group 2.
- General pain sensation was significantly improved in group 1 patients: It decreased from a VAS score of 4.2 ± 2.3 at baseline to 3.2 ± 1.9 ($P < .03$) after 6 treatments, and to 2.3 ± 1.7 ($P < .0001$) after 12 treatments compared with baseline. Responses in group 2 were more variable and differences from baseline did not reach statistical significance due to the smaller number of patients.
- In group 1, the percentage of patients answering "yes" to "feeling off-balance" decreased from 89% at baseline to 39% after 6 treatments and to 16.7% after 12 treatments. In group 2, 78% of patients reported imbalance at baseline compared with 44% after 6 treatments and 57% after 12 treatments.

Pearls for Practice

- ATS treatment for 6 or 12 sessions per study protocol improved the number of sites sensitive to the 5.07 SWM in patients with moderate but not severe DPN.
- Balance sensation was improved in patients with moderate and severe DPN, and treatment thus has the potential to reduce the risk of falls.

Instructions for Participation and Credit

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Target Audience

This article is intended for primary care physicians, endocrinologists, neurologists, and other specialists who care for patients with diabetes.

Goal

The goal of this activity is to provide the latest medical news to physicians and other healthcare professionals in order to enhance patient care.

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