Tuning Fork Excels in Diabetic Neuropathy Dx

BY MIRIAM E. TUCKER

ATLANTA — The clanging tuning fork test is far more accurate and sensitive than is the 10-g monofilament in screening diabetes patients for peripheral neuropathy, results from two studies suggest.

In fact, relying on the monofilament alone to screen patients for diabetic peripheral neuropathy (DPN) will miss all but the most severe, advanced cases, Dr. David S. Oyer and Dr. David Saxon said at the annual meeting of the American Association of Diabetes Educators.

"The clanging tuning fork [CTF] test detects diabetic peripheral neuropathy and increased risk of ulcer earlier than the monofilament. It should be the standard test for DPN. I don't think you need the monofilament at all. The CTF should be the A_{1c} of the foot," said Dr. Oyer, an endocrinologist at Northwestern University, Chicago.

He presented data from two studies, one of which showed that the 10-g Semmes-Weinstein monofilament test was normal in more than two-thirds of patients who were found by the CTF test to have severe DPN. Yet guidelines from the American Diabetes Association—endorsed by the American Association of Clinical Endocrinologists—recommend the 10-g monofilament as the main screening tool for diabetic foot evaluation, along with a choice of one of four other tests. The 128-Hz tuning fork is among those four choices (the others are pinprick sensation, ankle reflexes, and vibration perception threshold testing), but no specific parameters are given for how to use it (Diabetes Care 2008;31:1679-85).

Dr. Saxon, an endocrinology resident at the University of Michigan, Ann Arbor, enumerated several limitations of the monofilament, including the fact that those distributed free by drug companies often are not reliable and do not always give 10 g of force. Moreover, cold monofilaments must be warmed up to work properly. After about 100 bends, monofilaments tend to "fatigue" and need to "rest" for 24 hours. Also, testing on a callus can give an inaccurate result, Dr. Saxon said.

In a previously published study, Dr. Oyer demonstrated reproducibility of the CTF in 12 patients with diabetes on whom he performed the test 10 times on the same toe for each. Scores ranged from 3.4 to 18.8 seconds, with a mean of 10.2 and standard deviation of 1.3 seconds, representing less than a 10% error.

In a second part of that study, a single reading from the right foot versus the left foot was compared in 30 randomly selected patients with diabetes. The vibration duration sensation averaged was 10.9 seconds on the right foot and 9.7 seconds on the left. The two feet will almost always be nearly the same unless the patient has sciatica, Dr. Oyer noted.

Monofilament testing was done in patients whose mean vibration duration was 8 seconds or less, and was consistently reported as normal (correctly identified and patient able to feel all eight spots touched) among the 26 patients who had vibration durations of 5 seconds or more. Only at vibration perceptions of 4 seconds or less did the monofilament testing begin to demonstrate abnormal results, but even then patients with abnormal CTF scores were missed. Of 32 patients with vibration perception of 4 seconds or less, 50% still had normal monofilament test results, including 5 of 17 (29%) with completely absent vibration sensation, Dr. Oyer and his associates reported (Endocr. Pract. 2007;13:5-10).

In a review of 81 patients with a history of diabetic foot ulcers, among those with a CTF vibration perception duration of 4 seconds or less, 10 of 32 had diabetic foot ulcers, compared with 1 ulcer in 49 patients who had a CTF score of 5 seconds or more (Endocr. Pract. 2007;13:5-10). Thus, there was a 15-fold increased relative risk for foot ulcers in patients with a CTF score of 4 seconds or less, compared with those having a vibration perception duration of 5 seconds or above, Dr. Oyer said.

In a second study, published as an abstract for the ADA's 2008 annual scientific sessions, 68% of 148 patients with CTF scores of 8 seconds or less had normal monofilament test results. In 112 patients with CTF scores indicating severe neuropathy (4 seconds or less), 68% had a normal monofilament test. And in 49 patients with CTF scores of 0 seconds, 16 (33%) still had a normal monofilament test.

A history of a diabetic foot ulcer was present in 21 patients. All had CTF scores of 4 seconds or less, while 5 (24%) had normal monofilament tests. When the CTF score was 5 seconds or more, monofilament testing was normal in 96% of patients. Thus, a CTF score of 4 seconds or less was 100% sensitive for ulcer risk, whereas the 10-g monofilament was only 76% sensitive.

The increased sensitivity of the CTF comes at the expense of specificity, however, identifying many at-risk patients who would not end up developing an ulcer if left untreated. Specificity of the CTF is just 20%, compared with 75% for the monofilament. "If you want to prevent ulcers, you have to identify everyone at risk, so you can do everything you can to prevent them, with measures such as teaching patients to use mirrors to inspect their feet, and in some cases provide custom footwear," he noted.

But Dr. Andrew J.M. Boulton, chair of the ADA's Foot Care Interest Group, said he believes that it's too soon to replace the monofilament with the CTF as a first-line screening test for diabetic neuropathy. The CTF results are "very interesting, and I think that this is certainly a useful addition to the monofilaments," he said in an interview, adding that they are consistent with last year's recommendation of using monofilaments together with one other of four tests.

Dr. Boulton, who divides his time between the Manchester (England) Diabetes Centre and the division of endocrinology, diabetes, and metabolism at the University of Miami, noted that data from prospective studies also support the monofilaments. In one review of six such studies, the increased risk of ulceration ranged from an odds ratio of 2.2 to 9.99, and the relative risk of amputation was 2.9 with an abnormal monofilament test (J. Fam. Pract. 2000;49[11 suppl]:S17-29).

"What is needed with this test is a prospective study. … This new tuning fork test may well be useful but before it can replace the monofilament—if it is to at all—good longitudinal studies must be done to show its predictive value," said Dr. Boulton, who has received honoraria/consulting fees from Pfizer and Eli Lilly & Co.

Dr. Oyer and Dr. Saxon are conducting two ongoing trials with the CTF test. One is seeking to establish vibration perception ranges for nondiabetic people aged 40 and older. The other is looking at whether Metanx, a widely-used vitamin therapy for diabetic neuropathy, improves the CTF score, he said in an interview.

Dr. Oyer and Dr. Saxon stated they had no conflicts of interest to disclose. ■

Using the CTF Method

Although the method takes some practice, the clanging tuning fork test is simple and reliable, Dr. Saxon said, using these steps:

- ► Using a standard C-128 tuning fork, strike the tuning fork against the palm with an upstroke, just hard enough to make the ends clang together. If there is no metallic "clang," try hitting harder. But if there is an extra-loud "clang," dampen it and try again more lightly.
- ► Hold the tuning fork with only two fingers. "Pretend you're at a bar holding a dart," Dr. Saxon said. Don't rest your hand against the tines because contact will shorten the vibration time.
- ► When using the CTF on patients for the first time, it's a good idea to demonstrate on one of their hands to make sure they understand the difference between vibration and pressure by checking if they recognize when the vibration stops.
- ► For the actual test on the foot, immediately after striking, the tuning fork is placed on the dorsal toe just proximal to the nail, and the seconds counted until the patient says "now," signifying the point at which he or she begins to doubt that the vibration is perceptible.
- ► The test is repeated on the other foot, and the score from both toes is averaged.

Incidence of Diabetes-Related ESRD Declining Overall

BY DOUG BRUNK

NEW ORLEANS — The overall U.S. incidence of end-stage renal disease among people with diabetes decreased steadily between 1997 and 2006.

Yet diabetes-related end-stage renal disease (ESRD-DM) continues to disproportionately affect non-Hispanic blacks and Hispanics, compared with non-Hispanic whites.

The findings were presented in a poster at the annual scientific sessions of the American Diabetes Association.

"The declining ESRD-DM incidence in the population with diabetes is likely due in part to a reduction in prevalence of ESRD risk factors, improved treatment and care, and other factors," said Nilka Ríos Burrows, an epidemiologist with the Division of Diabetes Translation at the Centers for Disease Control and Prevention, Atlanta, and her colleagues. "Continued efforts are needed to sustain and improve these encouraging trends, particularly among older and among minority populations."

She and her associates analyzed data from the United States Renal Data System to examine racial- and ethnic-specific trends in the incidence of ESRD-DM among patients who began therapy for the disease between 1997 and 2006. They also studied data from the National Health Interview Survey and the Census 2000 to estimate the United States population with diabetes in calculating the incidence of ESRD-DM as well as the age-adjusted incidence.

The number of patients who began treatment for ESRD-DM increased nearly threefold, from 17,727 in 1997 to 48,215 in 2006. During the same period, the overall age-adjusted incidence of ESRD-DM decreased 28%.

The decline in the age-adjusted incidence between 1997 and 2006 was significant (37%) among non-Hispanic whites and among non-Hispanic blacks (18%). Among Hispanics, the decline in the age-adjusted incidence was 17%.

However, in 2006 alone, the incidence of ESRD-DM was 1.8 times higher among Hispanics and 2.3 times higher among non-Hispanic blacks, compared with non-Hispanic whites.

Study limitations include the fact that the data analyzed were for patients receiving treatment as reported to the Centers for Medicare and Medicaid Services, and that changes in factors other than "true" disease incidence could affect trends, the researchers said, adding that they were unable to stratify risk of developing ESRD-DM by duration of diabetes.

Ms. Burrows had no conflicts of interest to disclose. ■