

Simple, 'Low-Tech' Steps Can Avert Foot Ulcers

Look to the shoe as a source of pathology, and have patients check their foot temperature each day.

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WASHINGTON — The use of therapeutic shoes and the home monitoring of foot skin temperature by diabetic patients who are at high risk for foot ulceration are two simple, low-tech, preventive measures that could greatly reduce costs and improve patient outcomes if adopted more widely, according to Lawrence A. Lavery, D.P.M.

A foot ulcer is one of the most common precursors to the more than 100,000 diabetes-related amputations performed in the United States every year. Yet simple measures that can reduce the rate of foot ulceration are not being done, he said at the annual meeting of the American Association of Diabetes Educators.

"Prevention is a low-tech process," said Dr. Lavery of the department of surgery at Texas A&M University, Temple.

Prevention efforts should focus on patients who are at greatest risk. In a study of 1,666 diabetic patients, Dr. Lavery and his associates stratified the risk classification beyond the current system that was established by an international working group (*Diabetes Care* 2001;24:1442-7).

Over a mean follow-up of 27 months, the risk of ulceration for patients with no peripheral neuropathy or peripheral vascular disease (PVD) was 2%, whereas those with neuropathy alone had a 4.5% risk and those with neuropathy plus a foot deformity had a 3% ulceration risk. High rates of ulceration occurred in patients with a history of PVD (14% risk) and in those with a previous ulcer or a history of amputation (14% risk) (*Diabetes Care* 2008;31:154-6).

Hospitalization rates, which were 1% for patients with neuropathy alone and 2% for those with a deformity, jumped to 16% for patients with PVD, 8% for those with a history of ulceration, and 50% for those with a previous amputation. Amputation rates were relatively low: from 0% in those with no disease or neuropathy alone to 0.7%-2.2% among those with deformity, PVD, and ulcer history. But "just 20% of the patients account for 70% of the ulcers and 90% of the amputations

and hospitalizations. This tells us where to focus our educational efforts appropriately," said Dr. Lavery, coauthor of a new task force report on foot assessment from the American Diabetes Association.

For patients at risk, elimination of the shoe as a source of pathology is a simple yet underutilized measure. About 20% of foot ulcers are triggered by ill-fitting shoes, mostly among women. "The easiest thing to do is just look at their shoes," Dr. Lavery noted.

Since 1995, Medicare has covered therapeutic footwear and insoles for patients who are at risk for ulceration, but fewer than 3% of eligible patients receive the benefit. This is presumably because of a lack of awareness among providers as well as the cumbersome paperwork involved. "This is a simple, low-tech, very effective intervention that we don't do," he said.

Even when physicians are diligent about checking the feet and shoes of their diabetic patients at every office visit, the transformation from injury to ulceration occurs far too rapidly to be left to examinations at 3-month intervals. That's why it's essential for patients to check their feet at home on a daily basis.

But about 54% of patients can't see the bottoms of their feet, because of impaired vision, obesity, limited joint mobility, or a combination of those factors (*Arch. Intern. Med.* 1998;158:157-62).

"About half of patients whom we're asking to inspect their feet haven't been able to see their feet in the last several years," Dr. Lavery remarked.

Moreover, the cardinal signs of inflammation that precedes ulceration—including pain, loss of function, edema, redness, and heat—can go unnoticed, particularly

among patients who have neuropathy. Indeed, "even trained health care professionals probably cannot identify subtle precursors to ulceration," he said.

Of the five factors, heat may be the easiest to identify. In three published studies, a long-armed handheld infrared skin thermometer called TempTouch (www.temp-touch.com), manufactured by a San Antonio-based company called Diabetica Solutions Inc., reduced the risk of foot complications among high-risk diabetic patients. Dr. Lavery, who owns stock in the company and serves on its advisory board, was the lead author on two of the three studies and a coauthor on the third.

In the initial pilot study, 85 patients with either neuropathy and foot deformity, or previous history of ulceration or partial

Lavery and his associates reported (*Diabetes Care* 2004;27:2642-7).

In a second study of 225 similarly high-risk patients that used the same methods, patients in the dermal thermometry group were one-third as likely to ulcerate at 18 months as were those in the standard therapy group (12% vs. 5%), and the thermometry was associated with a longer time to ulceration (*Am. J. Med.* 2007;120:1042-6).

In the third study, 173 high-risk patients with a history of foot wound and sensory neuropathy with a loss of protective sensation were randomized to one of three groups. Standard therapy consisted of lower-extremity evaluation by a physician every 8 weeks; education focusing on foot complications and self-care practices; therapeutic insoles and footwear; and advice to the patients to inspect their feet every day and to contact the study nurse if they identified any areas of concern (*Diabetes Care* 2007;30:14-20).

A second group had the standard therapy plus a structured foot exam, in which they were trained to use a mirror twice a day to inspect the bottom of their feet for redness, discoloration, swelling, and warmth by palpation and to log the results. Patients in a third group received standard therapy and were instructed to use the digital infrared thermometer twice daily and to record the temperatures.

At 15 months, the ulceration rate was essentially identical in the standard and structured foot exam groups (29% and 30%, respectively). In contrast, only 8.5% of the group that used the thermometer developed a foot ulcer, a fourfold reduction in risk. Not surprisingly, the patients in the thermometer group who did develop ulcers were less compliant in using the device: Overall, 80% of them recorded temperature values at least 50% of the recommended time, compared with 92% of those who didn't develop ulcers, Dr. Lavery and his associates reported.

The number of patients needed to treat to prevent one foot ulceration with the thermometer is just 4, compared with 30 to prevent microproteinuria with an ACE inhibitor, and 260 to prevent pneumonia with the pneumococcal vaccine.

Use of the thermometer is "inexpensive, practical, and something patients can do," Dr. Lavery said. ■



Lawrence A. Lavery, D.P.M., checks the temperature of a patient's foot using a dermal thermometer device.

foot amputation, were randomized to standard therapy—including therapeutic footwear, diabetic foot education, and regular foot evaluation by a podiatrist—or to "enhanced" therapy, which included the standard measures plus twice-daily use of the dermal thermometer device at six sites on each foot. Patients were instructed to contact a study nurse and to minimize walking if they detected a temperature difference of more than 4° F. in the corresponding sites of the two feet.

At 6 months, there were nine foot complications, including seven ulcers and two Charcot's fractures, among the 44 patients in the standard therapy group (20%), compared with just one ulcer (2%) in the 41 patients who used the thermometer, Dr.

Foot Protocol

Assessment from page 1

Neurologic assessment for loss of protective sensation (LOPS) should include the use of a 10-g monofilament test, with the device placed at specific points on the bottom of the foot while the patient's eyes are closed, as well as one of these additional tests:

- ▶ Vibration using a 128-Hz tuning fork.
- ▶ Pinprick sensation.
- ▶ Ankle reflexes.
- ▶ Vibration perception threshold testing.

Vascular assessment using ankle brachial pressure index testing should be performed to determine the presence of peripheral arterial disease (PAD) in two groups of patients: those who are symptomatic (claudication, rest pain, or nonhealing ulcer) and those who have absent pos-

terior tibial or dorsalis pedis pulses (*Diabetes Care* 2008;31:1679-85).

Patients assessed using the protocol should be assigned to a foot risk category from 0 to 3, with 0 being no LOPS, no PAD, and no deformity, 1 being LOPS with or without deformity, 2 being PAD with or without LOPS, and 3 being a history of ulcer or amputation.

Subsequent therapy and follow-up care should be provided according to the category assigned: Primary care monitoring is appropriate for risk categories 0 and 1, and specialist care is indicated for risk categories 2 and 3.

Foot examinations "are not done regularly on patients with diabetes," noted Dr. Richard Hellman, one of

the study authors and immediate past president of the American Association of Clinical Endocrinologists.

The task force report describes in detail how a foot examination can be used in a busy practice setting to identify the foot at high risk for ulceration, Dr. Hellman, an endocrinologist at the University of Missouri-Kansas City, said in an interview.

To ensure coordinated care of the diabetic foot, specialists, and primary care physicians need to work together, not in separate "silos of care," with the specialist brought in early on to focus on prevention, Dr. Hellman said. "The expert may see things that the primary care person either doesn't know or doesn't have the time to ferret out." ■



DR. HELLMAN