Small Diabetic Foot Burns Can Cause Big Problems

BY PATRICE WENDLING Chicago Bureau

CHICAGO — Patients with diabetes have an increased risk for foot burns and once a burn occurs, the morbidity and mortality are quite high, Dr. David Greenhalgh said at the annual meeting of the American Diabetes Association.

A patient might sustain a foot burn without being aware of the injury because of impaired sensation in the feet. In sensitive feet, lead to prolonged exposure and deeper burns. Walking on hot surfaces, soaking in hot water, and even car heaters can cause foot burns.

“You don’t feel the pain after soaking your feet for a half hour, and that leads to the problem,” he said. “This is a duration-of-contact problem.”

The neurovascular changes associated with diabetes also lead to impaired wound burn healing. Impaired healing leads to higher graft loss and an increased risk of amputation, said Dr. Greenhalgh, professor and chief of burn surgery, University of California Davis Medical Center, Sacramento.

Dr. Greenhalgh described his own experiences treating small foot burn cases, including a patient with insensitive feet who had been admitted for walking on hot asphalt, which resulted in transmetatarsal and below-knee amputations.

Another patient with insensitive feet returned home from a walk over hot rocks at a river bed to discover blood oozing from his feet. After lengthy treatment, four of the patient’s toes were amputated.

“This is not only a disease that leaves a scar, but a disease that won’t heal,” he said. These are high-risk patients and once you have a wound, it can lead to a cascade of events.

“Once minute you’ve got a patient with ulcers between the toes, the next you’re sticking a hemostat up their pus out of their plantar, and then you’re doing a below-the-knee amputation,” said Dr. Greenhalgh.

He reported on a chart review of 27 patients, mean age 52 years, with diabetes who sustained foot burns from January 2000 to December 2005. Of these, 22 (81%) had burns resulting from insensitive feet.

In 16 patients, including 15 with insensitive burns, the patients were not aware of their feet having been injured, he said.

Burns were caused by soaking feet in hot water (77), putting feet near a heater or a radiator (6), walking on a hot surface (2), having contact with a heating pad (1), and being exposed to other sources (11).

Most foot burns that occur in diabetes patients are the result of insensitive feet.

No major hypoglycemia occurred in either group, and mild hypoglycemia was seen only in patients taking concurrent sulfonylureas. Injection-site bruising was more common in the twice-daily group than in the once-weekly group (10% vs. 5%). Nausea was less frequent in the once-weekly group (20% vs. 35% for the twice-daily group), but was predominantly mild and transient. And although the patients reporting nausea did lose more weight, those without nausea also experienced weight loss, Dr. Drucker noted.

American Diabetes Association president John Buse presented the 52-week data in a special ‘Late-Breaking Clinical Studies’ session. Following the 30-week study, a total of 120 patients from the once-weekly group continued on that formulation for another 22 weeks, while 121 who had been on the twice-daily version switched to the once-weekly formulation for the next 22 weeks.

Improvements in glycemic control were sustained in the group that stayed on once-weekly exenatide sustaining a 4.1-kg loss from baseline, while those who switched had a mean weight loss of 4.5 kg. Both groups also had clinically significant reductions in both systolic blood pressure (5.7 mm Hg in the once-weekly group and 4.0 mm Hg among those who switched) and diastolic blood pressure (2.2 and 2.1 mm Hg, respectively). Improvements in serum lipid profiles were similar in the two groups at 52 weeks, Dr. Buse said.

Rates of reported nausea were similar at 52 weeks, and lower than they had been at 30 weeks (7.0% for the once-weekly group and 7.7% among those who switched). Injection-site pruritus was reported by 6.8% of the once-weekly group at 52 weeks, compared with 4.6% of the switchers. Again, no severe hypoglycemia occurred and mild hypoglycemia occurred among only the patients also taking sulfonylureas, he reported.

On the annual scientific sessions of the American Diabetes Association, which funded the study.

A statement issued by the three companies, which funded the study.

Breaking Clinical Studies” session.

The proportion of patients in the entire cohort achieving an HbA1c of less than or equal to 7% was 77%, while 49% reached an HbA1c of 6.5% or below and 25% dropped to 6% or lower. Improvements in HbA1c were significantly greater among the patients in both formulation groups who had baseline values of 9% or higher, Dr. Drucker reported.

Fasting plasma glucose levels also dropped to a greater degree in the once-weekly group, by 42 mg/dL, compared with 25 mg/dL for the twice-daily patients. Despite the improved glycemic control, weight loss occurred in both groups, with an average loss of 3.6 kg for patients taking the once-weekly formulation and 3.7 kg for patients taking the twice-daily formulation—not significantly different. Reductions in total cholesterol, triglycerides, and systolic and diastolic blood pressure were also seen and were predominantly due to the weight loss, he said.

No major hypoglycemia occurred in either group, and mild hypoglycemia was seen only in patients taking concurrent sulfonylureas. Injection-site bruising was more common in the twice-daily group than in the once-weekly group (10% vs. 5%). Nausea was less frequent in the once-weekly group (20% vs. 35% for the twice-daily group), but was predominantly mild and transient. And although the patients reporting nausea did lose more weight, those without nausea also experienced weight loss, Dr. Drucker noted.

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BY MIRIAM E. TUCKER Senior Writer

SAN FRANCISCO — An investigational once-weekly formulation of exenatide resulted in superior improvements in glycemic control, compared with the current twice-daily version, and elicited sustained glycemic control and weight loss at 1 year in patients with type 2 diabetes.

The phase III data were presented in two separate sessions at the annual scientific sessions of the American Diabetes Association.

Known commercially as Byetta, the twice-daily injectable incretin mimetic is marketed by Amylin Pharmaceuticals Inc., Eli Lilly & Co., and Alkermes Inc.

An application for approval of the long-acting release formulation was filed with the Food and Drug Administration in the first quarter of 2008, according to a statement issued by the three companies, which funded the study.

Dr. Daniel J. Drucker, professor of medicine and director of the Banting and Best Diabetes Centre at the University of Toronto, presented the 30-week data from an open-label study in which 293 patients with type 2 diabetes were randomized to receive either the twice-daily formulation (10 mcg twice a day) or the once-weekly version (2 mg/wk). At baseline, about 15% of the patients were drug-naive, while the rest were being treated with one or more oral glucose-lowering agents.

They had a mean hemoglobin A1c (HbA1c) of 8.3%, fasting plasma glucose (FPG) of 169 mg/dL, body mass index (BMI) of 35 kg/m2, and diabetes duration of 7 years.

Withdrawals prior to 30 weeks were not significantly different between the groups: 13.5% of the 147 patients in the once-weekly formulation, vs. 11.6% of the 147 patients in the twice-daily group. At 30 weeks, the mean HbA1c had dropped by 1.9 percentage points in the once-weekly group, compared with 1.5% in the twice-daily group.

The proportion of patients in the entire cohort achieving an HbA1c of less than or equal to 7% was 77%, while 49% reached an HbA1c of 6.5% or below and 25% dropped to 6% or lower. Improvements in HbA1c were significantly greater among the patients in both formulation groups who had baseline values of 9% or higher, Dr. Drucker reported.

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