

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 Burn Association.

A patient might sustain a foot burn without being aware of the injury because of impaired sensation in the feet. Insensate 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 might also lead to impaired burn wound healing. Impaired healing leads to higher graft loss and an increased risk of amputation, said Dr. Greenhalgh, professor and chief of burn surgery, Uni-

versity of California Davis Medical Center, Sacramento.

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

Another patient with insensate 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."

"One minute you've got a patient with ulcers between the toes, the next you're sticking a hemostat up their foot draining 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 pa-



COURTESY DR. DAVID GREENHALGH

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

tients, mean age 52 years, with diabetes who sustained foot burns from January 2000 to December 2005. Of these, 22 (81%) had burns resulting from insensate feet. In 16 patients, including 15 with insensate burns, the patients were not aware of their feet having been injured, he said.

Burns were caused by soaking feet in hot water (7), 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 (93%) of the patients were male, 16 were taking insulin, and 6 were diagnosed as having insulin-dependent diabetes.

Mean burn size was 4.7% of total body surface area (range 0.5%-15%), and 69% were full-thickness burns. Despite the small burn size, the mean length of hospital stay was 10 days (range 1-25) and 11 days for the insensate burns.

Skin grafting was required in 14 patients (52%). Five patients needed to be grafted at least once, and one patient required four grafting procedures. Six patients required readmission, and three patients underwent amputations. There were 16 complications, with 11 episodes of infections, mostly cellulitis. Three patients died.

"All diabetic patients should be taught about the risk of foot burns," Dr. Greenhalgh concluded. "All patients with loss of sensation should never be exposed to heated water, heating pads, or heaters, or walk outside with bare feet." ■

Once-Weekly Exenatide Helps Glycemic Control, Weight Loss

BY MIRIAM E. TUCKER
Senior Writer

SAN FRANCISCO — An investigational once-weekly formulation of exenatide resulted in superior improvements in glucose control at 30 weeks, 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 295 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-naïve, while the rest were being treated with one or more oral glucose-lowering agents. They had a

mean hemoglobin A_{1c} (HbA_{1c}) 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 148 patients with the once-weekly formulation, vs. 11.6% of the 147 patients in the twice-daily group. At 30 weeks, the mean HbA_{1c} 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 HbA_{1c} of less than or equal to 7% was 77%, while 49% reached an HbA_{1c} of 6.5% or below and 25% dropped to 6% or lower. Improvements in HbA_{1c} 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 the 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 (26% 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 (mean 2.0-percentage point drop from baseline in HbA_{1c} and FPG reduction of 47 mg/dL), while further improvements from baseline occurred among those who switched to the long-acting formulation (2.0% and 43 mg/dL). The mean HbA_{1c} in both groups at 52 weeks was 6.6%, said Dr. Buse, professor of medicine, director of the Diabetes Care Center, and chief of the division of endocrinology at the University of

North Carolina at Chapel Hill.

Again, the results were far more dramatic among the patients who started with worse glycemic control. Among those with a baseline HbA_{1c} of 9% or above, the group that took the once-weekly formulation for the entire 52 weeks had dropped by 2.8 percentage points, and those who switched formulations dropped by 2.6. In contrast, those drops were just 1.3% and 1.2%, respectively, among those with baseline HbA_{1c} levels less than 9%.

Weight loss was similar in both groups at 52 weeks, with 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 reduc-

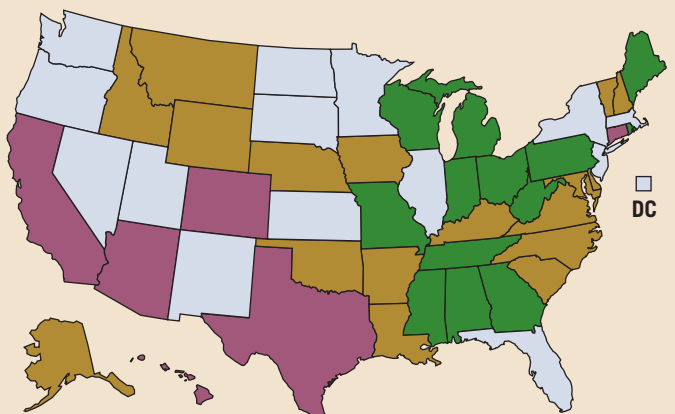
tions in both systolic blood pressure (5.7 mm Hg in the once-weekly group and 4.0 mm Hg among those who switched) and diastolic blood pressure (2.2 and 2.1 mm Hg, respectively). Improvements in serum lipid profiles were similar in the two groups at 52 weeks, Dr. Buse said.

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 0.8% 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. ■

DATA WATCH

Prevalence of Arthritis Among Adults With Diabetes

43%-46% 47%-52% 53%-56% 57%-62%



Note: Based on 2005 and 2007 data for 773,684 adults.
Source: Centers for Disease Control and Prevention