Diabetes Patients Voice Need for Coping Skills

BY CHRISTINE KILGORE
Contributing Writer

WASHINGTON — A significant number of patients with diabetes say they need help coping with the disease, but too few have such psychological needs addressed during initial diabetes education sessions, Mark Peyrot, Ph.D., reported at the annual scientific sessions of the American Diabetes Association.

"Most of patients' basic care needs are addressed [in diabetes self-management training]," said Dr. Peyrot of the department of medicine at Johns Hopkins University, Baltimore. "But very little of their psychosocial needs are being addressed."

Dr. Peyrot reported that 44% percent of 178 patients in this study, which was based at the University of Pittsburgh Medical Center, chose "healthy coping" as one of the areas in which they wanted help.

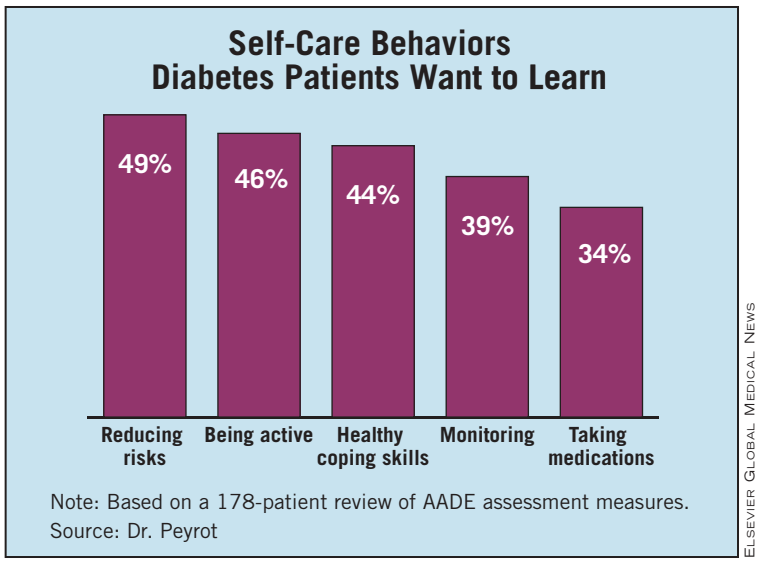
The patients were asked to review the American Association of Diabetes Educators' seven "self-care behaviors"—used in AADE's patient assessment and outcomes evaluation tools—and choose areas in which they wanted to set goals and learn skills. Patients could choose as many behaviors as they wished. The interest in "healthy coping" was unexpectedly similar to the interest expressed in "reducing risks" (49%), "being active" (46%), and "problem-solving" (41%).

Dr. Peyrot said that he expected interest in coping would be more modest. On the other hand, some areas—such as "monitoring" (chosen by 39%) and "taking medications" (chosen by 34%)—were rated "lower than what we'd expect," he said.

Diabetes educators' responses to patients' needs varied widely. In 94% of initial visits, educators addressed monitoring issues, for instance, and in 88% and 87% of initial visits they addressed exercise and eating, respectively. Medications were addressed in 75% of visits, problem-solving in 44%, and risk reduction in 56%, said Dr. Peyrot, who is also director of the center for social and community research at Loyola College, Baltimore.

Although almost half of patients expressed psychological needs, coping was addressed in only 18% of patients' initial visits, he said. "To a large extent, there was a standardized package being delivered to patients."

Patients in the study were seen at four University of Pittsburgh Medical Center diabetes self-management training programs. ■



Risk Management Program for Diabetes Drug Marks First Year

BY ELIZABETH MECHCATIE
Senior Writer

ROCKVILLE, MD. — Need proof that postmarketing risk management programs can work?

From March 1, 2005, through March 17, 2006, the year after the diabetes drug pramlintide became available in the United States, there were 10 reports of medically assisted severe hypoglycemia (MASH) in patients treated with the drug, Dr. Gary L. Bloomgren said at a meeting sponsored by the International Society for Pharmacoepidemiology.

This is a rate of 0.06 events per 1,000 units or vials of pramlintide dispensed, all occurring in type 1 patients within the first month of treatment, which "fits very clearly" with what was observed in the preapproval clinical program, noted Dr. Bloomgren, executive director of global safety, Amylin Pharmaceuticals Inc., San Diego.

The phase II and III controlled trials were blinded and allowed patients to make only minimal changes to their diets, a circumstance that may have contributed to higher rates of insulin-induced hypoglycemia, Dr. Bloomgren said. During the first 3 months of the trials, the incidence of MASH was 3% among those on placebo and insulin vs. about 7% among those on pramlintide and insulin in placebo-controlled studies in which insulin was not reduced.

The cumulative MASH reports during the year after approval were estimated as 3 cases per 1,000 patient-years of use among type 1 diabetics. He compared this with 100 MASH cases per 1,000 patient-years among those on pramlintide and insulin during the first 3 months of use in the open-label clinical practice study (in which the insulin dose was reduced during initiation), and 40 MASH events per 1,000 patient-years over the subsequent 3-6 months of treatment.

Dr. Bloomgren attributed what he described as a "safe start" to the drug's use in the United States to the risk management program in place when it was approved. The plan, which included warnings in the label about the risk of severe hypoglycemia and limited drug promotion to diabetes specialists, is the reason the drug is on the market today, he said.

Pramlintide, which is marketed by Amylin under the trade name Symlin, is a synthetic analogue of human amylin, a naturally occurring neuroendocrine hormone that is secreted with insulin by pancreatic B cells and is also deficient in diabetes. It was approved in March 2005 for use at mealtimes as an adjunct to insulin in patients with type 1 or 2 diabetes who have not achieved their desired glucose control despite optimal insulin therapy.

The risk management program was instituted to manage the risk of severe insulin-induced hypoglycemia, which had been identified as a serious safety issue associated with the drug. Overall, the risk-benefit assessment favored approval, given the glycemic control evidenced by HbA_{1c} and postprandial glucose values.

MASH is defined as hypoglycemia requiring treatment with a glucagon injection or IV glucose, hospitalization or an emergency department visit, or paramedic assistance. This was distinguished from mild to moderate hypoglycemia and patient-ascertained severe hypoglycemia.

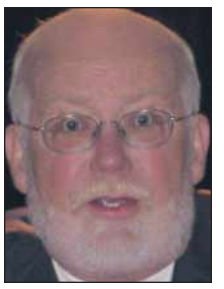
Factors that were identified before approval as increasing the risk of insulin-induced hypoglycemia included being a type 1 diabetic, having had recent episodes of hypoglycemia and/or a history of hypoglycemia unawareness, and not reducing mealtime insulin before starting pramlintide. Carefully selecting candidates for pramlintide was emphasized as "critical" to the safe and effective use of the drug, Dr. Bloomgren said. ■

Intensive Tx Benefits Poorly Controlled Type 2 Diabetes

BY MICHELE G. SULLIVAN
Mid-Atlantic Bureau

BOSTON — Intensive treatment with multiple oral hypoglycemics and insulin can bring glucose and blood pressure levels within acceptable values in patients with poorly controlled type 2 diabetes, Dr. William Duckworth said at the annual meeting of the Endocrine Society.

Interim results of the 7-year Veterans Administration Diabetes Trial (VADT) also show that intensive therapy improved lipid levels and stabilized ophthalmic microvascular disease, said Dr. Duckworth, VADT's lead investigator and the director of diabetes research at the Carl T. Hayden Veterans Affairs Medical Center, Phoenix.



'Surprisingly, the amount of insulin needed actually decreased from baseline in both groups.'

DR. DUCKWORTH

VADT will assess the impact of long-term intensive glucose control on cardiovascular and microvascular disease in 1,792 older patients who had poorly controlled type 2 diabetes at study entry and were randomized to standard or intensive therapy. At baseline, the patients' mean age was 60 years and mean duration of diabetes was 11.5 years. Mean hemoglobin A_{1c} level was 9.4%, mean body mass index was 30 kg/m^2, and 46% had a history of cardiovascular disease.

Both groups began therapy with metformin (for obese patients) or glimepiride (for lean patients). If their daily glucose goals were unmet, rosiglitazone was added, followed by insulin if necessary to achieve the goal. The major difference between the groups was the HbA_{1c} target: For the intensive treatment group, the target is 6% or less; for the standard treatment group, it is 8%-9%.

Within 1 year, the mean HbA_{1c} level fell to 7% in the intensive therapy group and to 8.5% in the standard therapy group. By year 4, the level in the intensive therapy group had decreased to 6.75%, but it remained steady in the standard therapy group. Also by year 4, almost all of the patients were on combination oral therapy, and the percentage on insulin had risen from 50% to 80%. The mean insulin dosage was 50 units/day in the intensive treatment group and 40 units/day in the standard treatment group.

"Surprisingly, the amount of insulin needed actually decreased from baseline in both groups, and it isn't all that much compared to what we usually think of as necessary in a group like this," Dr. Duckworth said.

Blood pressure improved significantly by year 4 in both groups, he said, decreasing from a mean of 131/77 mm Hg to 125/70 mm Hg. Lipid profiles also improved in both groups: Triglycerides declined from 161 mg/dL to 143 mg/dL, LDL cholesterol was reduced from 104 mg/dL to 89 mg/dL, and HDL cholesterol rose from 34 mg/dL to 38 mg/dL. Albumin/creatinine levels did not significantly change from their mean baseline value of 70 mg/g.

Based on routine exams, retinopathy "hasn't gone away, but it certainly hasn't gotten any worse," Dr. Duckworth said.

The trial is being supported by GlaxoSmithKline, Sanofi-Aventis, Novo Nordisk, and Roche Diagnostics as well as the Veterans Administration. ■