Self-Monitoring Falls Short in Type 2 Diabetes

BY PATRICE WENDLING
Chicago Bureau

CHICAGO — Self-monitoring of blood glucose did not significantly improve hemoglobin A_{1c} levels in a trial of patients with type 2 diabetes not receiving insulin.

"Although patients with type 1 and insulin-treated type 2 diabetes benefit from self-monitoring, this trial does not provide convincing evidence of benefit in non–insulin-treated type 2 diabetes," lead researcher Dr. Andrew J. Farmer said at the annual scientific sessions of the American Diabetes Association. His team conducted the trial, known as DiGEM (Diabetes Glycaemic Education and Monitoring).

Health costs and quality of life data have yet to be presented from the three-arm, randomized, parallel group trial of 453 patients managed in U.K. general practices with diet and oral hypoglycemic agents alone.

"In the meantime, the results do not support recommendations for routine self-monitoring of blood glucose in reasonably well-controlled patients with type 2 diabetes," said Dr. Farmer, division of public health, University of Oxford (England).

The trial had an 80% power at a 5% level of significance to detect the primary outcome—a change in hemoglobin A_{1c} of 0.5 percentage points—among three groups. Patients were randomized to a control group with no blood glucose monitors and 3 monthly hemoglobin A_{1c} measurements; a less intensive self-monitoring group with the results interpreted by a nurse practitioner in addition to usual care; and a more intensive self-monitoring group that was given the usual care plus training in interpreting and applying the results in relation to diet, physical exercise and medication regimens. Patients in the more intensive group had more latitude regarding when they could test their glucose, and averaged six to seven tests per week. Those in the less intensive group were told to use their meters before meals and averaged five to six tests per week, Dr. Farmer explained.

There were 152 in the control group, 150 in the less intensive self-monitoring group, and 151 in the more intensive self-monitoring group. At admission, the average duration of diabetes was 3 years, and the mean HbA_{1c} was 7.5%. Overall, 67.5%-73% of patients in each of the groups had had no prior experience with self monitoring.

At 12 months, the mean HbA_{1c} value was 0.14 percentage points lower in the less intensive self-monitoring group than in the control group, and 0.17 percentage points lower in the more intensive self-monitoring group than in the control group. The differences between groups were not statistically significant.

Among secondary outcomes, there were no significant differences between groups in blood pressure control. Surprisingly, there was a significant difference between groups in change from baseline of total cholesterol, with a decrease of 0.14 mmol/L in the control group, 5.2 mmol/L in the less intensive group, and 5.4 mmol/L in the more intensive group.

Hypoglycemia was reported by patients in all three arms of the trial, with the number of reports significantly higher in the self-monitoring groups than in the control group. This finding may be attributable to increased awareness of low blood glucose more than a true biochemical difference arising from the use of the monitor, Dr. Farmer said.

Over the 12 months of the trial, between one-third and one-half of patients stopped using their monitors. In all, 57 patients (13%) were lost to follow-up.

Dr. Farmer speculated that for many patients, the small day-to-day improvement in glucose results may have been obscured by the measurement variation from day to day, and may have contributed to the reason some people gave up. "It's well recognized that, in some people, when the readings don't vary—or seem uninterpretable—[there is] a loss of motivation," he said.

Interpretation of the DiGEM data will be hotly debated, in part because of the financial implications of self-monitoring on health care agencies and insurers. The study moves the field ahead, but leaves some questions unanswered, Dr. Bernard Zinman, director of diabetes care at Mount Sinai Hospital, Toronto, said in an interview.

"This study proves definitively that self-monitoring of blood glucose does not seem to have an impact on changing an individual's lifestyle . . . and therefore [on improving] control," Dr. Zinman said. But he added that it didn't address the question of whether, "if you give patients instructions on how to modify their oral hypoglycemia or give their physicians the opportunity to modify [it], self-monitoring of blood glucose may be very valuable in this population." ■

Fewer Kinds of Drugs Used to Treat Diabetic Peripheral Neuropathy Pain in Older Patients

BY KERRI WACHTER
Senior Writer

WASHINGTON — Older patients with pain resulting from diabetic peripheral neuropathy are more likely to be treated with fewer categories of pain medications than are younger patients, according to a poster presented at the annual meeting of the American Pain Society.

Roughly half (51%) of patients aged 65 years or older with diabetic peripheral neuropathy (DPN) were prescribed only one category of drugs on average to treat their pain each year, compared with 40% of those younger than age 65 years, wrote Stephen Able, Ph.D., a researcher at Eli Lilly & Co., and his colleagues. Lilly makes Cymbalta (duloxetine), which has Food and Drug Administration approval for the treatment of pain associated with DPN.

The researchers used pharmacy data from the Department of Veterans Affairs' National Pharmacy Benefits Management Program as well as VA administrative data, including inpatient and outpatient files from Oct. 1, 2001, through Sept. 20, 2004. Patients were included if they had a diagnosis of diabetes (based on ICD codes) or a pharmacy claim for a diabetic medication. Patients also had to have a diagnosis of neuropathy and an outpatient prescription drug claim for medication recommended for the management of pain.

Patients were excluded if they had a diagnosis of schizophrenia, bipolar disorder, psychosis, depression, or anxiety.

In particular, the researchers looked at the numbers of different pain-related medication categories used to treat patients with DPN annually and the percentage of patients with DPN using medications from each category. Categories included anticonvulsants, antidepressants, short- and long-acting narcotics, and nonnarcotic analgesics.

In fiscal years 2002, 2003, and 2004, the analysis included 52,947 patients, 54,924 patients, and 58,145 patients, respectively.

Patients 65 years of age and older were less likely to receive a prescription for more than one category of medications. On average, 30% of those 65 years of age and older had prescriptions for two categories of pain medication each year, compared with 32% of those younger than 65 years. Additionally, 13% of those aged 65 and older had prescriptions for three categories of medication, compared with 19% of those younger than 65.

The researchers hypothesized that the differences in prescribing patterns between the age cohorts may reflect different strategies for managing pain in older patients with DPN as a result of greater concerns about drug tolerability in this age group; differences in the manifestations of pain associated with DPN as the condition progresses; and/or changes in patient perception of pain as they age.

Overall, nonnarcotic analgesics (COX-2 inhibitors, NSAIDs, and others) were the most commonly prescribed category of pain-related medications in this population—70% or more in each of the study years.

However, the use of long-acting narcotics (tramadol, oxycodone, and others) doubled during the study period, up from 7% overall in fiscal year 2002 to 14% overall in fiscal year 2004. The use of anticonvulsants (gabapentin and others) increased steadily in both age groups with time, although more so for the younger cohort. ■

Characteristics of VA Diabetic Population

	2002 (n = 52,947)	2003 (n = 54,924)	2004 (n = 58,145)
At least 65 years old	64%	62%	60%
With diabetic peripheral neuropathy	18%	21%	23%
DPN patients on pain medication	76%	74%	74%

Source: Dr. Able

Screening for Kidney Disease Vital in Diabetes

ORLANDO — Every patient with type 1 or type 2 diabetes should be screened annually for the presence of diabetic kidney disease, according to comprehensive guidelines developed by the National Kidney Foundation as part of its Kidney Disease Outcomes Quality Initiative.

The clinical practice guidelines offer "simple, clear messages about managing risk factors not only for kidney disease but also for cardiovascular disease," Dr. Katherine R. Tuttle said at a meeting sponsored by the National Kidney Foundation.

The working group that drafted the guidelines included representatives of the American College of Physicians, the American Diabetes Association, and the American Heart Association, as well as the NKF. An estimated 21 million people in the United States have diabetes and over half of them have kidney damage. The incidence of diabetic kidney disease is expected to double by the year 2030.

The guidelines recommend measurements of urinary albumin-to-creatinine ratio in a spot urine sample, and measurement of serum creatinine to estimate the glomerular filtration rate.

"We recommended a spot urine sample rather than 24-hour urine collection so that this [measurement] can actually be done in an internist's or other primary care provider's office. Plus, it's cheap," said Dr. Tuttle, medical and scientific director of research at Providence Medical Research Center, Spokane, Wash.

—Fran Lowry

The guidelines are available online at www.kdoqi.org.