Population Screens for Type 2 Diabetes Do Not Cut Mortality Rates

San Francisco — A population-based screening program for type 2 diabetes that included all-cause, cardiovascular, or cancer-related mortality over a 5-year period, according to a large randomized controlled trial presented at the annual scientific sessions of the American Diabetes Association.

Moreover, screened patients offered intensive diabetes treatment did not benefit in terms of mortality than did screened patients offered routine diabetes treatment, said Dr. Justin Basile Echouffo-Tcheugui of the University of Cambridge (England).

The results call into question the value of large-scale screening for type 2 diabetes and of intensive diabetes management. And they conflict with mathematical models that predicted such screening would result in a 26%-40% reduction in diabetes-specific mortality, he said.

The 79,085 people who participated in the study were at 32 primary care practices in England. Using data from medical records, researchers calculated patients’ Cambridge Risk Score (CRS), which reflects an individual’s risk of developing diabetes. Of the original cohort, 19,481 people with a CRS score above 0.17 were included in the study. According to an earlier study, using a CRS score of 0.17 as a cut-off point results in a 70% sensitivity and a 64% specificity in identifying patients at high risk of type 2 diabetes (Diabetes Care 2002;25:984-8).

In five of the practices, having a total of 4,137 high-risk patients, no further screening was done. These practices constituted the control group. In the remaining 27 practices, patients were offered stepwise screening for type 2 diabetes.

In the first step, patients were tested for capillary blood glucose and hemoglobin A1c. Those with suspicious results went to the second step: capillary fasting blood glucose. Those with suspicious results from that test underwent a glucose tolerance test for a definitive diagnosis of diabetes.

In 13 practices, with 7,462 high-risk patients, those with diabetes were offered pramlintide without prandial insulin, and without weight gain. By week 24, a baseline average HbA1c level of 8.3% in each group had decreased by 0.9% in the pramlintide group and by 1.1% with rapid-acting insulin. In the pramlintide group, 45% of patients reached an HbA1c level of less than 7%, and 29% reached levels below 6.5%, compared with 15% and 23%, respectively, in the intensively managing insulin group. The differences were not statistically significant in the intent-to-treat analyses. After 6 months, patients in the rapid-acting insulin group gained 0.8 kg, compared with 0.3 kg in the pramlintide group. Hypoglycemia was seen in 55% of the rapid-acting insulin group and 82% of the routine care insulin group. Nausea affected 21% of pramlintide patients and none in the prandial insulin group. Two patients stopped pramlintide because of nausea.

Dr. Riddell also has been an adviser and consultant and has received research support from Eli Lilly & Co., Novo Nordisk Inc., and Sanofi-Aventis, which also make insulin and oral glucose control agents.

HbA1c Levels May Help Predict Post-Arthroplasty Complications

San Francisco — Complications after total knee or hip arthroplasty in patients with diabetes treated within significantly more common in those with higher hemoglobin A1c (HbA1c) levels, a retrospective study of 119 patients found.

The overall rate of medical and surgical complications was more than 50% in patients with an HbA1c level below 7%, and less than 40% in those with an HbA1c level below 7%, researchers reported. American Diabetes Association recommendations set a treatment goal of an HbA1c level below 7%. Patients who significantly elevated HbA1c levels should have their glycemic control better optimized prior to undergoing total hip [or knee] arthroplasty, as well as in the perioperative period, Dr. Yussef C. Blum said during a poster session at the annual meeting of the American Academy of Orthopaedic Surgeons.

In a review of inpatient and outpatient charts of total knee or hip arthroplasty performed by a single surgeon at one institution from 2000 to 2007, Dr. Blum, of Montefiore Medical Center, New York, and his associates found 199 patients whose HbA1c level had been measured in the year before surgery or within 3 months after the surgery. Those with conditions other than diabetes that led to an immunsuppressed state, such as HIV or rheumatoid arthritis, were excluded.

Patients did not have to have a diagnosis of diabetes to be included—just an HbA1c measurement—because up to a third of people with diabetes do not have a formal diagnosis, they reported. In all, 73% of the patients underwent total knee arthroplasty and 27% total hip arthroplasty. Their mean age was 68 years. The cohort was 76% men, 34% white, 34% black, 23% Hispanic, and 9% other races or ethnicities. The mean body mass index was 34 kg/m², and their mean HbA1c level was 6.6% (range 4.9%-12.3%).

A multivariate analysis looking at associations between HbA1c levels and outcomes reported showed that higher HbA1c levels were significantly associated with a higher risk for any complications, and surgical site and wound complications after surgery.

Only four surgical site infections occurred—too few to determine a specific association between HbA1c levels and wound infection—but “it is notable that three of four infections occurred in patients with an HbA1c [above] level 7.5%,” Dr. Blum said, adding that although too few complications occurred to show a specific association with HbA1c levels, an association might be seen in a larger study.

The current study found no association between HbA1c level and the risk of non-surgical-site infections, urinary retention, or discharge after surgery into an inpatient facility. Overall, 43% of the patients developed medical or surgical complications.

Future studies with [more] patients may help determine a cut-off HbA1c level above which total hip [or knee] arthroplasty can be considered too high risk,” Dr. Blum said. A 2003 review by other investigators of 296 diabetic patients undergoing non-cardiac surgeries found that those with an HbA1c level above 7% had a statistically significant increased risk for postoperative complications. But there have been few studies to date on the results of total knee arthroplasty in diabetes patients, and even fewer studies on the results of total hip arthroplasty in diabetes patients, he noted. Some report a risk of 1%-7% for deep infection in diabetes patients after total knee arthroplasty, and overall wound complication rates of 1%-12%. A 1983 study of outcomes after total hip arthroplasty in diabetes patients reported superficial infections in 10% of the patients and deep infections in 7%.

Pramlintide Equals Meal Insulin, Curbs Side Effects

San Francisco — Adding an injection of pramlintide at mealtime to basal insulin therapy worked as well as meal-time rapid-acting insulin to control postprandial glucose levels, but caused less weight gain and hypoglycemia, a study of 112 patients with type 2 diabetes found.

The randomized, open-label, 6-month trial showed that 30% of patients in the pramlintide group and 11% of patients in the rapid-acting insulin group achieved the primary composite end point of a hemoglobin A1c (HbA1c) level of 7% or lower, no increase in body weight, and no severe hypoglycemia. The difference was significant, Dr. Matthew Riddle of the Oregon Health and Science University, Portland, reported at the annual scientific sessions of the American Diabetes Association.

In response to a question, Dr. Riddle said that three of four infections occurred in patients with an HbA1c level above 7.5%.

Dr. Riddle also has been an adviser and consultant and has received research support from Eli Lilly & Co., Novo Nordisk Inc., and Sanofi-Aventis, which also make insulin and oral glucose control agents.