

## 50 Million Affected

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president of the AACE, prediabetes occurs in the gap between normal glucose levels and levels meeting the current criteria for diabetes. Patients whose lab values fall into that gap can be carrying a risk of complications approaching that associated with full-blown diabetes, he explained at a press briefing following the consensus conference.

In terms of numbers, the currently accepted definition for prediabetes is an impaired fasting glucose (100-125 mg/dL), an impaired glucose tolerance (a 2-hour post-glucose load of 140-199 mg/dL) or both. More than 50 million adults in the United States meet the criteria for prediabetes, according to the Centers for Disease Control and Prevention in Atlanta.

In the draft consensus document developed at the end of the 2-day conference, the group emphasized that patients considered prediabetic "should be treated for the same cardiovascular goals as diabetic patients, including blood pressure and lipid goals," Dr. Handelsman said. The consensus statement is the first to recommend that people with prediabetes make a specific effort to improve their blood pressure and cholesterol profiles, he noted.

The recommendations, which will be finalized and published later in 2008, also emphasize that signs of metabolic syndrome should prompt primary care physicians to do glucose testing and check patients for prediabetes, noted Dr. Paul Jellinger, an endocrinologist on the voluntary faculty at the University of Miami, and a mem-

ber of the writing panel. Then they can focus on reducing cardiovascular risk factors while patients are still in the prediabetes state, he said.

The recommendations emphasize intensive lifestyle management for anyone who meets the criteria for prediabetes to prevent progression to diabetes. "Nothing else matches lifestyle in reducing the complications of diabetes," noted Dr. Einhorn.

If lifestyle modification is not enough, or if someone is at increased risk for cardiovascular problems or progression to diabetes, the recommendations call for adding medications to manage blood pressure or cholesterol, in addition to glucose control medications if necessary.

The recommendations also state that "monitoring of patients with prediabetes to assess for worsening of glycemic status should include annual glucose tolerance tests and testing for microalbuminuria." In addition, fasting plasma glucose, hemoglobin A<sub>1c</sub>, and lipids should be checked twice a year. If hyperglycemia or cardiovascular risk factors are getting worse, more intense lifestyle modifications and pharmacotherapy may be needed.

One of the challenges in deciding whether to treat prediabetes is that although it is not a benign condition, it is essentially asymptomatic, said Dr. Michael Stern, an epidemiologist at the University of Texas at San Antonio.

"These people are completely well," said Dr. Stern, who spoke at the consensus conference about the challenges

of predicting disease outcomes in persons who meet criteria for prediabetes. "It needs to be demonstrated that early intervention is superior to delayed intervention."

Cost-effectiveness must be considered, too. Any treatment incurs costs, but not everyone who meets criteria for treatment will progress to poor clinical outcomes, he noted.

Data from recent studies presented at the consensus conference suggest that the beginnings of the characteristic complications of diabetes can appear in individuals who meet criteria for prediabetes. It is based on these findings that the recommendations state that persons with prediabetes should focus on reducing their risk of diabetes by taking action to improve

risk factors such as high blood pressure, high cholesterol, and excess weight, said Dr. Handelsman.

Dr. Handelsman said that he has received speaker honoraria from Amylin Lilly Alliance, AstraZeneca PLC, Bristol-Myers Squibb, Eli Lilly & Co., King Pharmaceuticals Inc., and Merck & Co. Dr. Einhorn stated that he has received speaker honoraria from Amylin Pharmaceuticals Inc. and Takeda Pharmaceuticals North America Inc. Dr. Garber stated that he has received speaker and consultant honoraria from GlaxoSmithKline, Merck & Co., and Novo Nordisk A/S. Dr. Stern stated that he had no financial conflicts to disclose, and Dr. Jellinger stated that he has received speaker honoraria from several companies including Amylin Pharmaceuticals Inc. and GlaxoSmithKline. ■

**The recommendations emphasize lifestyle management for anyone who meets the criteria for prediabetes to prevent progression to diabetes.**

## Excellent Glucose Control Enhances Obstetric Outcomes

BY MICHELE G. SULLIVAN  
Mid-Atlantic Bureau

SAN FRANCISCO — Pregnancy outcomes for women with diabetes who maintain excellent glucose control during their pregnancy are very good, and are similar to those seen in the general population, according to the results of a retrospective study.

The study, conducted by the high-risk obstetrics/endocrinology clinic at the Nebraska Medical Center, Omaha, found a low rate of diabetes-related obstetric complications among a group of 100 women who attended the clinic during their pregnancies. The clinic has used a team approach, incorporating intensive insulin and specific targets, since 1997. That approach "can result in excellent glucose control in at least half of patients, with overall maternal and fetal outcomes similar to" those in the general population, Dr. Kara Meinke Baehr said in a poster presented at the annual meeting of the Endocrine Society. The team includes perinatologists, endocrinologists, certified diabetes educators, registered dietitians, a social worker, and a translator.

Dr. Meinke Baehr of the Nebraska Medical Center and her colleagues reviewed the records of 100 women whose pregnancies were managed at the clinic from 1997 to 2006. Fetal outcomes were compared with the Nebraska 2004 Vital Statistics report.

The mean age at enrollment in the clinic was 29 years; the mean prepregnancy body mass index was 32 kg/m<sup>2</sup>. Most of the women (54%) were white; 21% were Hispanic, 18% were black, and the rest were other races or ethnicities.

More than a third of the women (36%) had type 1 diabetes; 26% had type 2 dia-

betes; 26% had gestational diabetes managed with insulin; and 12% had gestational diabetes managed by diet.

Women with types 1 and 2 diabetes significantly improved their blood glucose levels during the second and third trimesters of their pregnancies. At 8 weeks, only 25% had a hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) value of less than 7%. That number rose to 80% by week 16 and to 90% by week 24; it then dropped back to 80% by week 32.

By the second half of pregnancy, about half of the cohort was meeting the goal of an HbA<sub>1c</sub> value of 6% or less, a significant improvement from the first trimester.

Maternal complications during pregnancy included retinopathy (6%), proteinuria (38%), and pre-eclampsia (17%). There were 104 hospitalizations, more than half of which were for glucose control. One woman was admitted 10 times.

Insulin regimens were used in 115 of the 127 pregnancies (90%). At the time of delivery, 43% were taking four injections per day; 2% were taking one insulin injection per day; 22% were taking two injections per day; and 3% were taking three injections per day. In all, 20% were using an insulin pump.

There were 127 pregnancies among these women over the study period, including 121 live births with two sets of twins. Most of the deliveries (71%) were by cesarean section; the rest were vaginal.

The mean gestational age was 37 weeks. Apgar scores were good, with a mean of 7.4 at 1 minute and 8.5 at 5 minutes. The mean birth weight was 3,479 grams; 28% of the infants were macrosomic. Overall, 35% of the infants required a stay in the neonatal intensive care unit (mean length of stay, 16 days). ■

## Nephropathy a Predictor of Poor Diabetic Foot Outcomes

BY MARK S. LESNEY  
Senior Editor

An initially successful healing rate in patients who were hospitalized with diabetic foot ulcers did not lead to comparable long-term outcomes in a prospective study of 94 consecutive patients.

The presence of nephropathy was found to be an important predictor of poorer outcomes, whereas age was an independent predictor of global therapeutic success (GTS), according to a report presented in *Diabetes Care*.

Of 94 consecutive diabetic patients hospitalized for diabetic foot ulcers between January 1998 and December 2000, 89 (63 men) were successfully followed up for an average of nearly 80 months. The mean age of the patients was nearly 64 years.

Researchers calculated the rates of primary healing, new ulcers, amputations, mortality, and disability, and evaluated the GTS of foot care management (defined as primary healing without recurrence or disability at the end of follow-up). To their knowledge, this was the first time that disability and dependency, which were measured using Katz's index of activities of daily living, were considered as end points of a prospective diabetic foot study, according to Dr. Edouard Ghanassia and colleagues from the Centre Hospitalier Universitaire Montpellier (France).

Primary healing without major amputation occurred in 69 patients (nearly 78%). Amputations were performed in 39 patients (44%), with 30 minor and 9 major amputations; of the minor am-

putations, 24 occurred in the primary healing group. Ulcers recurred in nearly 61% of patients. Ultimately, 46 patients (nearly 52%) died, including 23 from cardiovascular events.

At the end of the follow-up period, 25 patients (28%) were dependent and 40 patients (nearly 45%) had achieved GTS.

Using multivariate analysis, the researchers found that smoking and renal impairment were independent predictors of healing failure; an age older than 70 years was the only independent predictor of GTS. There were no independent predictors of disability.

Insulin treatment prior to admission was the only predictor of ulcer recurrence, and diabetic nephropathy was the only independent predictor of first amputation. The only independent predictors of cardiovascular mortality were insulin therapy before admittance and renal impairment.

Diabetic nephropathy was also seen to be an important marker of other factors in long-term prognosis, with impaired renal function being an independent predictor of healing failure and all-cause mortality; in conjunction with albuminuria, it was associated with amputations. With use of univariate analysis, popliteal stenosis (diagnosed by Doppler ultrasound) was found to be an independent predictor of amputation, "confirming that vascular involvement in diabetic patients with foot ulcers is particularly important," the authors stated (*Diabetes Care* 2008;31:1288-92).

One limitation of the study, according to the authors, was that interview follow-up was conducted by telephone rather than in person. ■