Management Crunch Forecast in Type 1 Adults

BY BRUCE JANCIN

FROM A CONFERENCE ON MANAGEMENT OF DIABETES IN YOUTH

KEYSTONE, COLO. — The number of adults with type 1 diabetes is quietly and steadily climbing—and the American health care system is utterly unprepared to handle their needs.

So asserts Dr. Irl B. Hirsch, professor of medicine and holder of the Diabetes Treatment and Teaching Chair at the University of Washington, Seattle.

"The folks at [the Centers for Medicare and Medicaid Services] are not ready for the impact of type 1 diabetes in the Medicare age group over the next 10 years. I'll say it publicly: They are clueless," Dr. Hirsch said at the conference, sponsored by the University of Colorado at Denver and the Children's Diabetes Foundation at Denver.

Adult type 1 diabetes poses huge public health issues, in part because of physician workforce constraints. This is a disease that will of necessity be managed primarily by nonendocrinologists, he said.

The projected number of internal medicine–trained clinical endocrinologists is nowhere close to meeting the growing demand for management of type 1 diabetes in adults. Primary care physicians have neither the skill set nor time to provide state-of-the-art diabetes management. Few geriatricians are trained in type 1 diabetes. So the task, by default, will fall upon the shoulders of the midlevel providers—nurse practitioners, physician assistants, diabetes educators, and registered dieticians, he predicted. And he's just fine with that.

"The DCCT [Diabetes Control and Complications Trial] was done by midlevel practitioners. That's how we run our clinic, too," he said. "The midlevels are going to be in charge, there's no doubt in my mind. And this will work."

The incidence of type 1 diabetes is doubling roughly every 2 decades in developed nations. The rising population of U.S. adults with type 1 diabetes has two sources: a steady increase in patients with new-onset type 1 disease arising in their 30s, 40s, and beyond, and improved longevity of patients with childhood-onset type 1 diabetes.

"In our clinic, the biggest surprise for our internal medicine residents and our endocrine fellows is how many of our patients are diagnosed after the age of 20," said Dr. Hirsch.

"We [don't] really understand the epidemiology and demographics of type 1 diabetes in adults. … But now with the better treatments, having patients live for 50 years with type 1 diabetes is routine. It's not a big deal anymore," he said.

A large new research grant from the Leona M. and Harry B. Helmsley Charitable Trust is going to provide badly needed data on type 1 diabetes in adults. "We're in the midst of planning a very large registry of patients called the Type 1 Diabetes Exchange, where we hope eventually to have data on 100,000 individuals," said Dr. Hirsch.

With regard to new-onset type 1 diabetes in adults, Dr. Hirsch highlighted a well-documented Italian study that demonstrated the incidence in Northern Italians aged 30-49 years was similar to that in 15- to 30-year-olds. Among males there were twin peaks in incidence: one at age 10-14, and a second at age 45-49. The trend in females was similar except that the second peak wasn't as high as the first (Diabetes Care 2005;28:2613-9).

Dr. Hirsch said that by a very conservative estimate there are 1.1 million American adults with type 1 diabetes of either the classic type or latent autoimmune diabetes of adults (LADA), a group whose absolute need for exogenous insulin is somewhere between that of classic childhood-onset type 1 diabetes and adult type 2 disease. By a recent estimate, LADA accounts for 2%-12% of all cases of diabetes (J. Clin. Endocrinol. Metab. 2009;94:4635-44).

He does not include in his tally of adults with type 1 diabetes the very large group with what is often called "type 1.5"

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A rise in adult type 1 diabetes presents a substantial public health challenge.

disease: that is, phenotypic type 2 disease with autoantibody positivity. Type 1.5 diabetes is roughly two- to threefold more common than classic childhood-onset type 1 diabetes, but there is not as yet agreement on how to classify it. He excludes them from the type 1 diabetes category because type 1.5 patients have major problems with obesity and metabolic syndrome, which are not issues in managing type 1 disease or LADA.

The forecast is that in the year 2019 there will be roughly 3,200 internal medicine–trained adult endocrinologists. Assuming that close to half of them are not seeing any new patients because they are fully booked, or are not taking new diabetic patients because the reimbursement is paltry compared with the effort required in state-of-the-art disease management, or due to pressing research or administrative responsibilities, that would work out nationwide to 636 type 1 diabetic patients per practicing endocrinologist. That's not realistic, Dr. Hirsch said.

Approaching the manpower issue from another angle, Dr. Hirsch said his recent informal, nonscientific survey of adult endocrinologists in St. Louis, Seattle, Los Angeles, and Chicago suggests type 1 diabetes typically accounted for 20% of their patient load. Again, that doesn't come close to meeting demand. "No matter how one does the math, type 1 diabetes in adults will by necessity be cared for by the primary care physicians."

But that's not realistic, either, the way primary care medicine is practiced at present, he quickly added. "In current internal medicine residency training, we put little or no emphasis on insulin therapy in general, let alone type 1 diabetes. And current primary care systems lack an infrastructure for insulin therapy, let alone pumps, sensors, and the like," according to Dr. Hirsch.

And then there are the brutal time constraints imposed on primary care practice, he continued, citing a recent survey of 2,500 family physicians which showed that patients with well-controlled diabetes were on average allocated just two 10-minute office visits per year for their chronic disease.

Dr. Hirsch declared having no financial conflicts regarding his presentation. ■

Rapid-Acting Insulin Curbed Hypoglycemia, Weight Gain

BY MIRIAM E. TUCKER

FROM THE ANNUAL SCIENTIFIC SESSIONS OF THE AMERICAN DIABETES ASSOCIATION

VITALS

Major Finding: At 6 months, mean reduction in hemoglobin A_{1c} was similar between patients taking VIAject and those taking regular human insulin before meals but hypoglycemic event rates were significantly reduced with VIAject (0.33 vs. 0.66 events/month) and weight gain was significantly less with VIAject (0.46 vs. 1.35 kg).

Data Source: Open-label, multicenter, randomized phase III trial of 471 patients with type 2 diabetes

Disclosures: Biodel Corp. funded the study. Dr. Rodbard serves on the company's advisory board and has received research support from it. She also has consultant, speaker, and/or research grant support relationships with other companies that make diabetes-related products.

ORLANDO — An investigational rapid-acting human insulin formulation provided similar glucose control to regular human insulin but with a twofold reduction in hypoglycemia and significantly less weight gain in a 6-month, multicenter, open-label study of 471 patients with type 2 diabetes.

The insulin formulation, called VIAject, is absorbed more rapidly after subcutaneous injection than either insulin lispro or regular human insulin. Findings from Biodel Corp.'s phase III study of VIAject were presented by Dr. Helena Rodbard, an endocrinologist in private practice in Rockville, Md., and a past president of the American College of Endocrinology and the American Association of Clinical Endocrinologists.

The subjects had a mean age of 56 years, slightly more than half were male, and the mean body mass index was 33 kg/m^2. At baseline, they had a mean hemoglobin A_{1c} value of 8%. They were randomized to either preprandial VIAject or human regular insulin in combination with previously prescribed insulin glargine, metformin, and/or thiazolidinedione therapy. Because of the difference in action time, regular human insulin was injected 30-40 minutes before meals, while VIAject was given immediately before eating.

At 6 months, the mean reduction in hemoglobin A_{1c} was similar in the two groups, with the VIAject group dropping by 0.56 percentage points and the regular human insulin group by 0.70 points. But nonsevere hypoglycemic event rates were significantly reduced in the patients taking VIAject, at just 0.33 events/month, compared with 0.66 events/month with regular human insulin, Dr. Rodbard reported.

Patients taking VIAject also gained significantly less weight, an average of 0.46 kg vs. 1.35 kg with regular human insulin.

Insulin antibody levels and other laboratory tests monitoring safety were similar for both groups. Injection site pain or irritation was greater with VIAject, but this declined during the course of the study. Moreover, the proposed U-100 pH-neutral commercial formulation of VIAject is associated with less injection site discomfort than the U-25 pH 4 version used in this study, she pointed out.

Biodel is seeking Food and Drug Administration clearance to market VIAject based on two pivotal 6-month phase III clinical trials in patients with type 1 and type 2 diabetes, as well as results from long-term, 18-month safety extension trials for patients who completed the two pivotal phase III clinical trials. The Prescription Drug User Fee Act action date for Biodel's new drug application is expected to be Oct. 30, 2010, the company said in a statement. ■