Comprehensive Care a Burden, Some Diabetics Say

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any patients with diabetes might prefer to have some risk of minor complications from the condition than to live life saddled with the rigors of comprehensive diabetes management, according to a survey conducted by researchers at the University of Chicago.

In their 1-hour, face-to-face survey interviews with 701 patients with diabetes, investigators found that patients certainly preferred life with treatment to life with complications, Dr. Elbert S. Huang, of the section of general internal medicine at the University of Chicago, and his colleagues reported. But they also found that patients perceived comprehensive diabetes care as having many negative impacts on quality of life—impacts that they rated as about equal to a number of intermediate complications (Diabetes Care 2007;30:1-6).

The researchers described comprehensive care to the study subjects as management that entailed cholesterol-lowering drugs, aspirin, intensive blood pressure control (perhaps with more than one agent), intensive glucose control (perhaps with insulin and oral agents, and close monitoring), and diet and exercise.

The study was conducted, said Dr.

Symlin Pens to Be Available for Select Patients

The glucose-lowering drug pramlintide will now be available in pens, but not for patients not using premeal bolus insulin.

Last month the Food and Drug Administration said Amylin could begin marketing the SymlinPen 60 and the SymlinPen 120 pen-injector devices for administering pramlintide injection, currently sold in vials. The pens are expected to be available by December 2007, the firm said.

Dosing had been an issue with the vials due to confusion with insulin syringes, which are not marked in microgram units. But the SymlinPen 60 delivers fixed doses of 15, 30, 45, or 60 mcg; the SymlinPen 120 delivers only 60- and 120-mcg doses.

The agency also issued a "Not Approvable" letter for those using only basal insulin without concurrent mealtime (bolus) insulin. Supporting data included results from a 16-week, double-blind, placebo-controlled study of 212 patients with type 2 diabetes who used glargine (basal) insulin with or without oral antidiabetic agents, but who did not use premeal insulin (Diabetes Care 2007 Aug. 13 [Epub ahead of print]). In those completing the study, hemoglobin A_{1c} reductions from baseline were greater in the 87 on pramlintide (7.8%, from 8.5%), compared with the 91 on placebo (8.1%, from 8.5%), said Dr. Matthew Riddle, of Oregon Health and Science University, Portland, and associates. An FDA spokeswoman said the agency does not discuss its nonapprovable actions.

-Miriam E. Tucker

Huang, because although numerous studies have shown that intensive diabetes control reduces complications and much effort and money is expended to encourage intensive management, at least 20% of patients continue to have poor glycemic control, 33% have suboptimal blood pressure, and 40% have high cholesterol. The survey may give some insight into why patients with diabetes so often do not meet recommended treatment targets, he added.

The study used a quantitative scale to

rate patient preferences, or "utilities," so answers about treatments and complications could be compared.

The patients ranked intensive control and comprehensive control significantly lower than conventional control. And, the mean rating for comprehensive care was not statistically different from the ratings for angina, diabetic neuropathy, and diabetic nephropathy. The mean rating for intensive therapy, which was demanding but not quite as taxing as comprehensive care,

was similar to that of diabetic neuropathy.

Despite those overall findings, Dr. Huang noted that there was much variation in the way the patients answered the questions. The majority actually rated life with treatments as being close to perfect health, and only 18% rated life with treatments as being a significant burden on quality of life.

The heterogeneity of responses indicates that doctors need to talk to their patients in the clinic and share decision making when making treatment plans, he said.

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Patients and caregivers should be informed that impulse control disorders/compulsive behaviors may occur while taking medicines, including pramipexole, to treat Parkinson's disease and RLS.

Please see accompanying Brief Summary of Prescribing Information.

*Results of a 12-week, placebo-controlled, randomized, double-blind, fixed-dose-treatment trial to assess the efficacy and safety of MIRAPEX vs placebo in the treatment of moderate to severe primary RLS.

Responders defined as patients with symptoms rated as "much improved" or "very much improved," as measured on the CGI-I.

Reference: 1. Data on file, Boehringer Ingelheim Pharmaceuticals, Inc.



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