

Type 2 Diabetes Algorithm Treats to HbA_{1c} Goals

BY MIRIAM E. TUCKER

A new one-page treatment algorithm for type 2 diabetes from the American Association of Clinical Endocrinologists is aimed at assisting physicians in choosing appropriate therapy from among all the approved classes of glucose-lowering medications.

The algorithm stratifies treatment by the patient's hemoglobin A_{1c} level, with separate treatment pathways for those with levels of 6.5%-7.5%, 7.6%-9.0%, and greater than 9.0% (Endocrine Practice 2009;15:541-59).

In general, patients with HbA_{1c} values of 7.5% or lower can start with monotherapy, with metformin considered the "cornerstone" but with three other drug classes included as alternatives. Patients with levels of 7.6%-9.0% typically require dual therapy. The algorithm advises insulin for patients with values higher than 9% who already are receiving other treatments or who are drug-naïve and symptomatic. For patients with values higher than 9% who are drug-naïve but asymptomatic, dual or triple combination therapies can be used.

"This is an authoritative, up-to-date, practical, and simple algorithm which should provide meaningful guidance to physicians as they make their therapeutic decisions," said Dr. Helena W. Rodbard, cochair of the consensus panel that developed the algorithm, which is officially a publication of both AACE and its educational branch, the American College of Endocrinology (ACE).

"It's an easily-readable clinical point-of-care tool designed to assist endocrinologists, primary care physicians, and others involved in the care of patients with type 2 diabetes," said Dr. Paul S. Jellinger, panel cochair who, like Dr. Rodbard, is a former president of both AACE and ACE.

Both Dr. Jellinger and Dr. Rodbard emphasized that this algorithm—written by a panel of 14 practicing endocrinologists—very accurately represents the way a majority of experienced endocrinologists approach the treatment of type 2 diabetes.

In contrast to a recently-revised algorithm from the American Diabetes Association and the European Association for the Study of Diabetes (Diabetes Care 2009;32:193-203), the AACE/ACE algorithm fully incorporates all classes of drugs approved to treat type 2 diabetes



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DR. RODBARD

and places less emphasis on their cost.

"Most previous algorithms placed an undue emphasis on the cost of medications. Drugs can be expensive, but the cost of medications is only about 11% of the total cost of care of the population with diabetes. We need to consider the total cost of care, which is overwhelmingly driven by the cost of complications," said Dr. Rodbard, an endocrinologist in Rockville, Md.

Dr. Jellinger said, "We placed a big emphasis on safety, particularly in terms of hypoglycemia. We included GLP-1 mimetics, DPP4 inhibitors and TZDs, along with metformin, since those classes have no potential for hypoglycemia. At the same time, we have down-graded the use of sulfonylureas due to their increased risk for hypoglycemia. By avoiding hypoglycemia, you avoid hospital-

izations which are far more expensive than the medicine."

But Dr. David M. Nathan, chair of the ADA/EASD consensus panel, said he doesn't believe it makes sense to include the additional agents as alternatives to metformin for first-line therapy or to list so many drug classes at every level. "The ADA/EASD guidelines were specifically formulated to help busy nonspecialists make informed choices from the large number of treatments that have become available in the last decade. With that in mind, the ADA/EASD consensus committee tried to narrow the choices, based on effectiveness, safety, tolerability/acceptability, and cost."

"AACE has taken a different tack and included all approved medications. Their more complex algorithm offers more choices but, in our opinion, doesn't help the busy clinician make the best choices," said Dr. Nathan, professor of medicine at Harvard University and director of the diabetes center at Massachusetts General Hospital, Boston.

He added, "The TZD, DPP-4, and AGI they recommend are manifold more expensive than metformin, have far less clinical experience than with metformin, are no safer—and probably less safe for TZD—and have the same frequency or far more side-effects."

Accompanying the AACE algorithm is a text document that explains the rationale for each of the treatment options along with the algorithm's underlying principles, which include the following: ▶ Lifestyle—dietary and exercise—modifications are essential for all patients with diabetes, but delaying pharmacotherapy to allow for lifestyle modifications to take effect is likely to be inadequate. Counseling regarding lifestyle should be initiated along with diabetes self-management education and medications.

▶ Achieving a hemoglobin A_{1c} of 6.5% is the primary goal, but this goal must be individualized based on factors such as comorbid conditions, hypoglycemia history/unawareness, and limited life expectancy.

▶ Effectiveness of therapy must be evaluated frequently, typically every 2-3 months.

▶ Rapid-acting insulin analogs are a better, superior alternative to "regular human insulin." Similarly, long-acting synthetic analogs glargine and insulin detemir yield better reproducibility and consistency as basal insulins than does NPH, which is not recommended.

▶ The algorithm should conform as nearly as possible to consensus of expert endocrinologists who manage patients with type 2 diabetes, and should provide specific guidance to physicians with prioritization and rationale for the selection of any particular regimen.

Dr. Rodbard has received consultant honoraria from Abbott Laboratories, AstraZeneca Pharmaceuticals LP, Biondi Inc., GlaxoSmithKline, MannKind Corp., Merck & Co., Novo Nordisk Inc., Sanofi-Aventis U.S., and Takeda Pharmaceuticals America Inc. She also receives speaker honoraria and/or research grant support from some of those companies, as well as from Amylin Pharmaceuticals, Bristol-Myers Squibb, Eli Lilly, and MacroGenics Inc.

Dr. Jellinger has received speaker honoraria from Amylin, Lilly, Merck, Novo Nordisk, Sanofi-Aventis, and Takeda, and consultant honoraria from Daiichi Sankyo Inc., MannKind, and Tethys Bioscience.

Dr. Nathan has received a research grant for investigator-initiated research support from Sanofi-Aventis and support for educational programs from GlaxoSmithKline. ■

Group Visits Offer Alternative for Diabetes Treatment

BY MARY ELLEN SCHNEIDER

BOSTON — Struggling to help your diabetic patients stay in control?

The answer may be to get those patients together for a group visit, said Dr. Edward Shahady, medical director of the Diabetes Master Clinician Program at the Florida Academy of Family Physicians Foundation in Jacksonville.

During a traditional one-on-one office visit, physicians generally assess the patient and give out instructions. But diabetes is a self-management disease that requires patients to change their behavior, something that isn't likely to happen based solely on advice received during an office visit, Dr. Shahady said at the annual meeting of the American Academy of Family Physicians.

The evidence for this is in the national statistics on diabetes: Less than half of diabetic patients in the U.S. achieve recommended hemoglobin A_{1c} goals, and only about a third reach their LDL cholesterol and blood pressure goals. "Just the simple office visit is not working," he said.

Dr. Shahady and his colleagues at the Florida Academy of Family Physicians Foundation have developed a model for group visits that has improved satisfaction

among diabetic patients, while allowing physicians to get paid for seeing complex patients.

Under the model, group visits can occur every month to every 3 months with the same group of patients. The group visit may replace some of the routine diabetes visits and last about two-and-a-half hours. During the first hour, a nurse or medical assistant takes vital signs, helps patients complete questionnaires and other forms, and provides individual "report cards" with hemoglobin A_{1c} levels and other clinical values. The nurse then gets the conversation started on the visit topic, which may be on some aspect of nutrition, exercise, foot care, or lipids.

The nurse also fields questions, for which Dr. Shahady recommends that practices use a "parking lot" sheet to keep questions unrelated to diabetes from taking up time in the group discussion. Putting unrelated questions on the sheet lets patients know that their questions are important, but that the group visit is for discussing their diabetes, he said. The physician can get to those questions at the end of the session or address them later during individual office visits.

During the second hour, a physician, nurse practitioner or physician assistant joins the group to reinforce the curriculum point for the day. Leave extra time at the be-

ginning and end of the group visit for checking in, filling out paperwork, and writing prescriptions, he advised.

While each visit has a set topic, the idea is not for the visits to be lectures. Instead, patients should drive the conversation. This group dynamic can have a huge impact. If one patient admits to having difficulty finding time to exercise, other members may have valuable suggestions about how they fit exercise into their schedules. "Patients like to share solutions with each other," he said. This interaction is much more effective than getting the suggestions from the physician, Dr. Shahady said.

Ideally, groups should be kept to about 10 patients. Most of the group members should be patients whose diabetes is not well controlled, since they will benefit the most. But it's also valuable to include a couple of patients who are in good control, since they may be offer advice to other group members.

If properly documented, most group visits will qualify for billing with a 99214 code, Dr. Shahady said. It's not necessary to conduct a physical exam to use the 99213 or 99214 codes for established patients. Clinicians need only collect vital signs, provided that they have already satisfied the history and level of complexity requirements. The ICD-9 code should reflect the level of control, the type of diabetes, and any complications. ■