ADA Guidance No Longer Bars Low-Carb Diets

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ew guidance from the American Diabetes Association gives a green light to the use of low-carbohydrate diets as a weight-control measure for patients with diabetes.

The updated guidelines for 2008 also revise recommendations on prediabetes testing, metformin use, and hypoglycemia prevention, among other topics.

The organization still does not endorse low-carbohydrate diets for weight loss or diabetes management, but it has updated the section of its guidelines that covers nutrition recommendations and interventions for diabetes to remove a specific recommendation against diets that restrict carbohydrates to less than 130 g/day. Now, for weight loss, the ADA says that either low-carbohydrate or low-fat calorie-restricted diets might be effective in the short term (up to 1 year). Previous language that recommended against low-carb diets was also removed from the 2008 update.

For patients who are on low-carbohydrate diets, the ADA now advises monitoring of lipid profiles, renal function,



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DR. STONE

and protein intake (in patients with nephropathy), as well as adjustment of glucose-lowering therapy as needed (Diabetes Care 2008;30[suppl. 1]:S61-78).

"The evidence is clear that both low-carbohydrate and low-fat calorie-restricted diets result in similar weight loss at 1 year. We're not endorsing either of these weight-loss plans over any other method of losing weight. It's important for patients to choose a plan that works for them, and that the health care team support their patients' weight loss efforts and provide appropriate monitoring of patients' health," guideline panel member and registered dietician Ann Albright, Ph.D., ADA President of Health Care and Education, said in a statement.

New data cited in the 2008 document are from the A to Z Weight Loss Study, a randomized trial that compared the Atkins, Zone, Ornish, and LEARN (Lifestyle, Exercise, Attitude, Relationships, and Nutrition) diets in a total of 311 overweight premenopausal women. At 1 year, those who followed the Atkins diet showed significantly more weight loss (-4.7 kg) than did the other three diet groups (-1.6 kg with Zone, -2.6 kg with LEARN, and -2.2 kg with Ornish). Secondary outcomes, including lipid profile, percentage of body fat, waist-hip ratio, fasting insulin and glucose levels, and blood pressure, were comparable or better with Atkins versus the other diet groups (JAMA 2007;297:969-77).

However, the ADA reiterated a point it had made in 2007: The recommended dai-

ly allowance for digestible carbohydrate is 130 g/day, based on providing adequate glucose as the required fuel for the central nervous system without reliance on glucose production from ingested protein or fat.

"Although brain fuel needs can be met on lower-carbohydrate diets, long-term metabolic effects of very low-carbohydrate diets are unclear, and such diets eliminate foods that are important sources of energy, fiber, vitamins, and minerals that are important in dietary palatability," according to the 11-member writing panel, which was cochaired by Dr. John P. Bantle of the University of Minnesota, Minneapolis, and Judith Wylie-Rosett, Ed.D., a registered dietician, who is with Albert Einstein College of Medicine, New York.

Dr. Neil J. Stone, professor of clinical medicine at Northwestern University, Chicago, is similarly cautious. "The new guideline acknowledges that based on available data, there are choices when it comes to choosing a weight loss regimen

for the short term. This is not an endorsement of lifelong marked carbohydrate restriction, and the general public as well as diabetics need to consider reasonable carbohydrate intake for nutritional balance, as [carbohydrates] can provide important sources of energy, fiber, vitamins, and minerals," he said in an interview.

But Dr. Eric C. Westman, director of the Lifestyle Medicine Clinic at Duke University, Durham, N.C., believes that low-carb diets can play an important role in diabetes



Selected safety information:

LYRICA is indicated for the management of Fibromyalgia, neuropathic pain associated with Diabetic Peripheral Neuropathy, Postherpetic Neuralgia, and as adjunctive therapy for adults with Partial Onset Seizures.

LYRICA is contraindicated in patients with known hypersensitivity to pregabalin or any of its components.

There have been postmarketing reports of angioedema in patients during initial and chronic treatment with LYRICA. Specific symptoms included swelling of the face, mouth (tongue, lips, and gums), and neck (throat and larynx). There were reports of life-threatening angioedema with respiratory compromise requiring emergency treatment. LYRICA should be discontinued immediately in patients with these symptoms.

There have been postmarketing reports of hypersensitivity in patients shortly after initiation of treatment with LYRICA. Adverse reactions included skin redness, blisters, hives, rash, dyspnea, and wheezing. LYRICA should be discontinued immediately in patients with these symptoms.

In controlled studies, a higher proportion of patients treated with LYRICA reported blurred vision (7%) than did patients treated with placebo (2%), which resolved in a majority of cases with continued dosing. More frequent assessment should be considered for patients who are already routinely monitored for ocular conditions.

Reference: 1. Data on file. Pfizer Inc, New York, NY.

For more information, please visit www.pfizerpro.com/lyrica.

management. "Carbohydrates, especially sugar and starch, are the main factors in the diet that raise blood glucose. Carbohydrate-restricted diets are as effective, and sometimes even more effective, than medication therapy for type 2 diabetes.

"[With obesity], carbohydrate-restricted diets have the advantage over medication because most people then lose weight, which then improves insulin resistance. Those with type 2 diabetes who are taking medications should consult a physician trained in using the carbohydrate-restricted approach, to ensure a safe reduction and possibly elimination of medication," he said in an interview.

Other guideline revisions include:

- ▶ The addition of new tables that list screening recommendations and diagnostic cutpoints for gestational diabetes, summarize interventions and results of diabetes prevention trials, and summarize evidence for statin therapy in diabetics.
- ▶ A more explicit recommendation to consider testing for prediabetes in asymptomatic patients of any age who are overweight and have additional risk factors for diabetes.
- ▶ Metformin, in addition to lifestyle counseling, as an option in those at high risk and who are obese and aged under 60 years.
- ► Continuous glucose monitoring might

be a supplemental tool to self-monitoring of blood glucose for selected patients with type 1 diabetes, especially those with hypoglycemic unawareness.

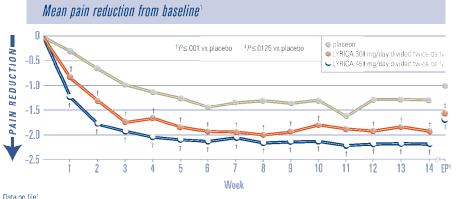
- ► More information in the hypoglycemia section about prevention and hypoglycemia unawareness, with the recommendation that patients who have hypoglycemic unawareness or episodes of severe hypoglycemia raise their glycemic targets to strictly avoid hypoglycemia for at least several weeks, with the aim of partially reversing the unawareness and reducing the risk of further episodes.
- ▶ The reduction of the number of treatment recommendations for hypertension

and blood pressure control to emphasize use of ACE inhibitors or angiotensin receptor blockers.

► Fewer recommendations in the dyslipidemia/lipid management section to emphasize the use of statins for most patients, along with new language stating that if patients don't reach specified targets on maximal tolerated statin therapy, an LDL cholesterol reduction of about 40% from baseline is an alternative goal. Triglyceride levels of less than 150 mg/dL and HDL cholesterol levels greater than 40 mg/dL in men and more than 50 mg/dL in women are desirable, though "cholesterol-targeted statin therapy remains the preferred strategy."

LYRICA

Rapid and powerful relief of chronic widespread pain^{1*}



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*Results from a 14-week, randomized, double-blind, placebo-controlled study of 745 patients to evaluate the efficacy and safety of LYRICA in Fibromyalgia. Criterion for entry into the double-blind phase was absence of a high placebo response (≥30% decrease on the pain VAS) during the 1-week run-in phase. Patients received: LYRICA 300 mg/day (150 mg twice daily), 450 mg/day (225 mg twice daily), 600 mg/day (300 mg twice daily), or placebo. The primary efficacy measure was symptomatic relief of pain associated with Fibromyalgia. ugh LYRICA was also studied at 600 mg/day, there was no evidence that this dose confers additional benefit and this dose was less well tolerated. In view of the dose dent adverse reactions, treatment with doses above 450 mo/day is not recommended.

End point (EP) mean pain score.

Sustained relief of pain in a separate 6-month durability study¹¹

Results from a 26-week, double-blind, placebo-controlled, randomized discontinuation trial of 1051 patients designed to evaluate the time to loss of therapeutic response of LYRICA in Fibromyalgia patients. The study was comprised of 4 phases: baseline, open label, 26-week double-blind treatment, and 1-week follow-up.

Selected safety information:

The most common adverse reactions occurring in ≥5% of all LYRICA-treated patients and occurring at least twice the rate of placebo during Fibromyalgia clinical trials for patients taking LYRICA vs those taking a placebo were dizziness, somnolence, weight gain, blurred vision, dry mouth, constipation, euphoric mood, peripheral edema, balance disorder, disturbance in attention, and increased appetite.



Please see adiacent brief summary of prescribing information.