Post-Bariatric Surgery Guidelines Previewed

ACS

PAD

Not actual patients

BY JEFF EVANS

48

WASHINGTON — Adult bariatric surgery patients need to be monitored in the long-term postoperative period for nutritional deficiencies, risks to bone and joint health, and changes in obesityrelated comorbidities, according to a draft of new guidelines from the Endocrine Society.

The guidelines will focus primarily on long-term patient management, because immediate postoperative care is largely the purview of the surgeons who performed the operation, Dr. Lee M. Kaplan, a member of the seven-person task force that is writing the guidelines, said at the society's annual meeting.

Each bariatric procedure is unique in its potential nutritional complications and endocrinologic effects, so it is important to take their differential mechanisms and effects into consideration, said Dr. Kaplan, a gastroenterologist and director of the Massachusetts General Hospital Weight Center, Boston.

The American Society of Nutrition and the European Society for Endocrinology supported the formulation of the guidelines. The American Gastroenterological Association has been invited to participate.

Virtually all of the recommendations are based on expert opinion because of a lack of high-level evidence, Dr. Kaplan said.

The guidelines advise clinicians to provide appropriate long-term dietary and behavioral management and to assess whether additional surgeries would provide greater long-term benefits, such as converting a laparoscopic adjustable gastric band to a Roux-en-Y gastric bypass (RYGB), changing the length of an intestinal limb after RYGB, or adding a RYGB onto a sleeve gastrectomy.

The task force did not make specific recommendations for nutritional screening or supplement use, but advised that patients should eat 60-120 g of protein per day to prevent the loss of lean body mass. "That's particularly important for the nonbypass operations, which work in part by food restriction, and are associated with a greater lean body mass loss than the gastric bypass," he said.

The draft guidelines recommend longterm vitamin and mineral supplementation as needed, depending on the surgical procedure, and periodic monitoring for micronutrient deficiencies in the first 2-3 weeks after surgery and for macronutrient deficiencies in the first several months.

Monitoring for signs of macronutrient deficiencies, such as hypoalbuminemia (which is associated with protein malnutrition) and ketosis, is especially important for patients who have undergone biliopancreatic diversion plus duodenal switch (BPD-DS), according to the guidelines.

But micronutrient deficiencies are far more common than macronutrient deficiencies in bariatric surgery patients, Dr. Kaplan said. Deficiencies in iron, vitamin B_{12} , calcium, and vitamin D occur most often with BPD-DS and RYGB. A deficiency in vitamin B_1 (thiamine) can be induced through excessive vomiting, which occurs most often with overadjusted gastric bands. Fat-soluble vitamin deficiencies develop most often with BPD-DS, but vitamin K deficiency is known to develop in some patients with RYGB. Folic acid deficiencies are not as common as they used to be after bariatric surgery because of wide use of multivitamins with folic acid. Deficiencies in minerals such as selenium, zinc, and copper are fairly rare, he said.

The task force advised that the physician and nurse members of the patient's management team should be familiar with the management of type 1 and 2 diabetes in the postoperative period. They also recommended that lipid abnormalities should be treated according to National Cholesterol Education Program guidelines.

In addition to weight loss, clinicians should shoot for reductions in hemo-globin A_{1c} to less than 7%, fasting blood glucose to 110 mg/dL or less, and post-prandial blood glucose to 180 mg/dL or less.

Dr. Kaplan noted that a study reported at the meeting found that bariatric surgery increased the risk for fractures,

STROKE

PLAVIX—The only prescription antiplatelet with proven efficacy and a well-established safety profile in a broad range of patients

Proven protection demonstrated in:

- CAPRIE: Reduced the risk of combined end point of MI, ischemic stroke, or vascular death in recent MI, recent stroke, or established PAD*
- CURE: Reduced the risk of combined end point of MI, stroke, or CV death in UA/NSTEMI⁺
- COMMIT: Reduced the risk of all-cause mortality and combined end point of death, reinfarction, or stroke in STEMI[‡]
- CLARITY: Reduced the odds of combined end point of occluded infarct-related artery on predischarge angiography, or death or recurrent MI before angiography in STEMI[‡]

Indications

- Plavix[®] (clopidogrel bisulfate) is indicated for the reduction of atherothrombotic events as follows:
- ⁺ Use PLAVIX plus aspirin for patients with non–ST-segment elevation acute coronary syndrome (UA/non–Q-wave MI), including patients to be managed medically and those to be managed with percutaneous coronary intervention (with or without stent) or CABG, to decrease the rate of a combined end point of CV death, MI, or stroke as well as the rate of a combined end point of CV death, MI, stroke, or refractory ischemia.
- [‡] Use PLAVIX plus aspirin for patients with ST-segment elevation acute myocardial infarction to reduce the rate of death from any cause and the rate of a combined end point of death, reinfarction, or stroke. This benefit is not known to pertain to patients who receive primary angioplasty.
- * Use PLAVIX alone for patients with a history of recent ischemic stroke, recent MI, or established PAD to reduce the rate of a combined end point of new ischemic stroke (fatal or not), new MI (fatal or not), and other vascular death.

but it is unclear how the risk may differ between the various types of bariatric procedures.

"This is an area where we're going to have substantial additions to the final guidelines," Dr. Kaplan said.

Patients undergoing bypass operations should have calcium, phosphorus, and alkaline phosphatase levels measured every 6 months and dual energy x-ray absorptiometry scans annually.

The task force also suggested routine postoperative calcium and vitamin D supplementation.

For patients with frequent preopera-

tive episodes of gout, the task force recommended prophylactic therapy because of an increased risk for disease flares in the postoperative period.

Postoperative constipation occurs much more often than does diarrhea in bariatric surgery patients, Dr. Kaplan said, so the guidelines recommend a low-quantity fluid diet in the immediate postoperative period with a gradual progression of food consistency over time.

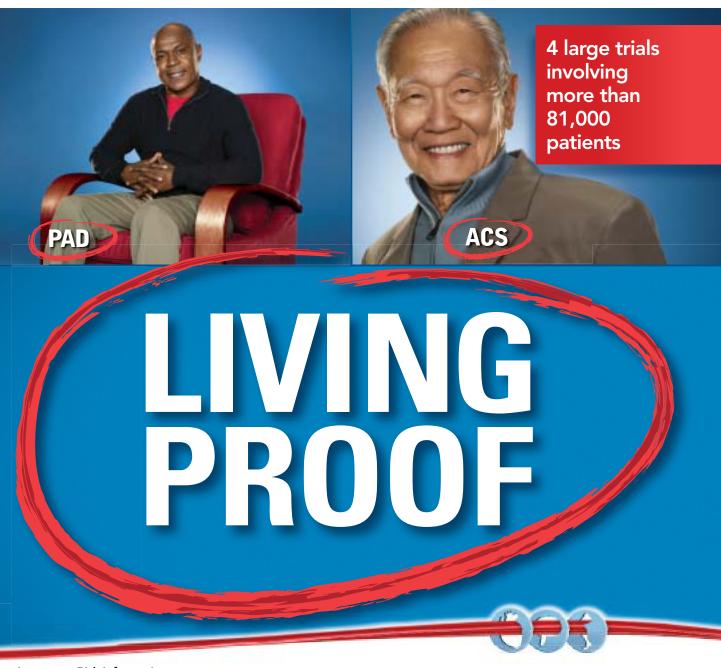
The guidelines also advise periodic monitoring of liver enzymes because some patients have increases in liver enzyme levels despite the improvement of fatty liver disease in most patients. Postoperative hypoglycemia, which may occur through stimulation of pancreatic beta-cell function, needs to be carefully monitored as well.

The panelists did not reach a consensus on the relative importance of factors that contribute to weight regain, including physiologic factors, surgical failure (breakdown of anastomoses or suture lines or device failure), and noncompliance.

One audience member noted that the draft guidelines lack any mention of kidney stones, which are common in gastric bypass patients, and should be monitored with urine oxalate levels. Other audience members called for sections in the guidelines on dosing medications in bariatric surgery patients, such as GLP-1 medications and thyroxine in patients with hypothyroidism.

49

Dr. Kaplan serves as the principal investigator for studies with Merck & Co., Johnson & Johnson, and GI Dynamics; as an advisory group member for Merck & Co., Johnson & Johnson, Stryker Development, and C.R. Bard; and as a scientific board member for Gelesis and GI Dynamics.



Important Risk Information

PLAVIX is contraindicated in patients with active pathologic bleeding such as peptic ulcer or intracranial hemorrhage. PLAVIX should be used with caution in patients who may be at risk of increased bleeding from trauma, surgery, or coadministration with NSAIDs or warfarin. (See CONTRAINDICATIONS and PRECAUTIONS.[§])

The rates of major and minor bleeding were higher in patients treated with PLAVIX plus aspirin compared with placebo plus aspirin in clinical trials. (See ADVERSE REACTIONS.[§])

Due to an expected reduction in drug levels and clinical efficacy, concomitant use of drugs that inhibit CYP2C19 (eg, omeprazole) should be discouraged. (See PRECAUTIONS.[§])

As part of the worldwide postmarketing experience with PLAVIX, there have been cases of reported thrombotic thrombocytopenic purpura (TTP), some with fatal outcome. TTP has been reported rarely following use of PLAVIX, sometimes after a short exposure (<2 weeks). TTP is a serious condition that can be fatal and requires urgent treatment including

plasmapheresis (plasma exchange). (See WARNINGS.[§]) Based on literature, patients with genetically reduced CYP2C19 function have diminished antiplatelet responses and generally exhibit higher CV event rates following MI.

(See PRECAUTIONS.§)

In clinical trials, the most common clinically important side effects were pruritus, purpura, diarrhea, and rash; infrequent events included intracranial hemorrhage (0.4%) and severe neutropenia (0.05%). (See ADVERSE REACTIONS.[§])

[§]Please See Brief Summary of Full Prescribing Information on Adjacent Page.



© 2009, Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership

Sanofi aventis www US.CLO.09.06.010/June 2009 sanofi-aventis U.S. LLC

www.plavix.com Bristol-Myers Squibb 09 264US09AB19703-06-09 Printed in USA