

NB48 compared with NB32.

The treatment group reported significant decreases in food cravings compared with baseline, Dr. Apovian said.

Approximately half of the patients in the drug and placebo groups discontinued the study, but discontinuation rates due to adverse events were low. Nausea, the most common adverse event, was mild or moderate in most cases, "and occurred mostly in the first 4 weeks," she said.

The combination drug seemed to be well tolerated and the safety profile was consistent with previous data on the two drugs when used separately, she added.

Dr. Apovian is on the advisory board of Orexigen and has received financial support from other pharmaceutical companies, including Lilly and Amgen. Orexigen intends to submit the drug for FDA approval in the first half of 2010, according to a company statement.

Dr. Lee Kaplan of Harvard University in Cambridge, Mass., presented results of a study of lorcaserin, a selective 5HT_{2C} agonist designed to promote weight loss without the cardiovascular side effects associated with nonspecific 5HT agonists.

The randomized, double-blind, placebo-controlled phase III study enrolled

4,008 patients, aged 18-65 years, for 52 weeks. The study involved patients with a BMI of 27-45 kg/m² with and without at least one comorbid condition. The average age was 44 years, average BMI was 36 kg/m², and 80% were female. Baseline demographics were similar between the treatment and placebo groups.

Overall, the intent-to-treat analysis showed that a 5% weight loss was achieved by 47% of participants who took 10 mg lorcaserin twice daily, by 40% of those who took 10 mg lorcaserin once daily, and by 25% of those who took a placebo, said Dr. Kaplan, who is

also director of the Massachusetts General Hospital weight center.

Patients in the twice-daily, once-daily, and placebo groups who completed the study according to the protocol lost an average of 7.7 kg, 6.5 kg, and 3.9 kg, respectively. The most common adverse events were headache, fatigue, dizziness, and nausea, each of which occurred in less than 5% of patients. Lorcaserin was not associated with increased valvulopathy, said Dr. Kaplan, who has received financial support from lorcaserin's manufacturer, Arena Pharmaceuticals, among other pharmaceutical companies. ■

Be Aware Of Bariatric Complications

BOSTON — Malnutrition could send obese patients to the emergency department if they have a history of bariatric surgery, Dr. Joshua Broder said at the annual meeting of the American College of Emergency Physicians.

Dr. Broder, of Duke University in Durham, N.C., reviewed the following complications that can arise after different types of bariatric procedures:

► **Laparoscopic adjustable gastric banding.** There have been reports of mechanical problems including breakage, infection, and erosion of the band into the GI tract. Patients often are discharged on the same day or 1 day after undergoing this procedure, he noted.

Early complications include obstruction, edema from intravenous fluids, and proximal migration of the band. Late complications include obstruction and proximal band migration that may cause gastric necrosis and perforation. In cases of gastroesophageal obstruction, deflate the band as soon as possible.

► **Roux-en-Y gastric bypass.** The Roux-en-Y procedure currently is the most common surgery performed to help morbidly obese patients lose weight, Dr. Broder said. It is arguably the most effective because it bypasses a segment of the small bowel and limits the amount of food that can be eaten at a single meal. Early complications from this procedure include anastomosis, found in approximately 2%-11% of these patients.

Long-term complications include systemic nutritional deficiencies because nutrients aren't being absorbed in a section of the small bowel, Dr. Broder said. And the bypassed segment of the small bowel can become obstructed, which produces highly variable symptoms.

► **Biliopancreatic diversion.** The potential for weight loss is high with this type of surgery, but so are the metabolic risks, he noted. All the possible complications of a Roux-en-Y are much more likely, including nutritional deficiencies of fat-soluble vitamins, selenium, and zinc. Studies have shown that about 2% of these patients experience hepatic dysfunction, said Dr. Broder, who disclosed having no financial conflicts.

—Heidi Splete



Clinical Therapeutics Call for Manuscripts

Vaccines Theme Issue

Clinical Therapeutics, the world's premier peer-reviewed, rapid-publication journal, is planning a special issue focused on all relevant topics related to vaccine development, clinical evaluation, safety, tolerability, and cost-effectiveness. Well-known vaccinologist Scott A. Halperin, MD, will serve as Guest Editor of this focus issue.

We encourage submissions from all interested parties who are involved in research on vaccines. The submission deadline for this special issue is February 15, 2010, with a projected print publication date of July 2010.

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