insertion, none had migration of the balloon, obstructions, or the need for surgery. The most common adverse events were mild to moderate gastrointestinal symptoms that occurred within the first 30 days and resolved quickly after the procedure. Symptoms during adjustment to the device can be treated with fluids, reassurance, and prescription medication.

Fifteen percent of the balloons had to be retrieved because of ulcers or intolerance. Given an interim analysis showing more removals in shorter patients, the researchers began to use smaller fill volumes (750 cc) for shorter patients, and this lowered intolerance by 60%. The researchers also modified the tip of the device owing to concerns that it was causing damage to the incisural wall. This change reduced the ulcer rate to 10.3%.

Dr Ponce noted some possible future uses for the Duo system. These included sequential use to increase weight loss, use in combination with medication for weight loss, and use in adolescents needing a reversible approach. Furthermore, it can assist with weight loss before surgery for patients who are not surgical candidates owing to the risks associated with a high body mass index (≥ 40).

Continuous Infusion of Local Anesthetic Provides No Benefits in Laparoscopic Sleeve Gastrectomy

Written by Lynne Lederman

Reducing the use of opioid narcotics in bariatric surgery could lead to less morbidity, shorter hospital stays, more comfortable recovery, and lower costs. In nonbariatric, open surgical procedures, continuous infusion of local anesthetic via catheters reduced narcotic usage, pain scores, time to ambulation, and length of stay (LOS) [Beaussier M et al. *Anesthesiology*. 2007; Baig MK et al. *J Am Coll Surg*. 2006]. However, intraoperative infusion of local anesthetics through continuous infusion catheters (CICs) has not been shown to be as effective in bariatric procedures [Iyer CP et al. *Surg Ober Relat Dis*. 2010; Rosen MJ et al. *Surg Endosc*. 2009; Sherwinter DA et al. *Obes Surg*. 2008]. Because there had been no study of laparoscopic sleeve gastrectomy involving local anesthesia delivered via CICs, a prospective double-blind study in patients undergoing sleeve gastrectomy was conducted. The single-institution study results were reported by Elaine M. Cleveland, MD, William Beaumont Army Medical Center, El Paso, Texas, USA.

The goal of this study was to determine if CICs were effective in reducing narcotic usage and would be cost-effective. Patients aged > 18 years were eligible if they had a body mass index (BMI) > 40 kg/m^2 or a BMI > 35 kg/m^2 in the presence of comorbidities. Exclusion criteria included revision surgery, single-port surgery, or allergy to local anesthetic. Study end points included total narcotic usage measured in morphine equivalents, antiemetic usage, patient-controlled analgesia (PCA) attempts, pain scores, LOS, and adverse events.

Patients (n = 82) were randomly assigned to ropivacaine (n = 39) or normal saline (placebo; n = 43) by a pharmacist flipping a coin. The pharmacist filled the pain pumps, which were distributed to the operating room. After access to the abdomen was gained, 2 catheters were placed in the preperitoneal space, 1 on each side of abdomen. Each catheter was primed with 5 mL of 1% lidocaine at start of surgery, and an additional 10 mL of lidocaine was administered at the completion of surgery. A pain pump was attached to the catheters in the operating room. The initial flow rate of 7 mL/h was reduced to 4 mL/h on the morning of postoperative day (POD) 1.

On the day of surgery, patients received PCA and intravenous antiemetic medications as needed. On POD 1, patients transitioned to oral fluids, oral narcotics, and oral antiemetics; they were discharged when they could walk and tolerate > 90 mL of oral fluid and when their pain and nausea were controlled by oral medications.

A 1-sided *t* test was used to compare end points. The demographics of the 2 treatment groups were equivalent. More than 90% of patients were women, with an average age of 35 years and an average BMI of 42.5 kg/m^2. There were no significant differences between groups in total narcotic usage, PCA attempts, antiemetic usage, or hospital stay.

There were no statistically significant differences in postoperative pain scores between the 2 groups at any time point. Adverse events were minimal, with no hypoxia or ileus in either group.

This study had several limitations, including its being conducted at a single institution among patients who may not represent the national bariatric population. CICs provide no benefit regarding narcotic usage, pain scores, PCA attempts, antiemetic usage, or LOS for patients undergoing laparoscopic sleeve gastrectomy.

Lorcaserin May Regulate Glucose Homeostasis Independent of Weight Loss

Written by Brian Hoyle

Elisa Fabbrini, MD, PhD, Washington University School of Medicine, St Louis, Missouri, USA, discussed a post hoc analysis of data from the phase 3 Behavioral Modification and Lorcaserin for Obesity and

Table 1. Baseline Characteristics of Patients Receiving Lorcaserin BID or Placebo, Mean ± SD

	Lorcaserin BID[a] (n = 256)	Placebo[a,b] (n = 252)
Age, y	53.2 ± 8.3	52.0 ± 9.3
Body mass index, kg/m²*	36.1 ± 4.5	35.8 ± 4.5
Fasting plasma glucose, mg/dL	163.3 ± 48.3	160.0 ± 41.6
HbA_{1c}, %	8.1 ± 0.83	8.1 ± 0.84
Fasting plasma insulin, μIU/mL	15.0 ± 10.0	16.2 ± 14.7
Triglycerides, mg/dL	172.1 ± 103.6	163.5 ± 87.5

Each treatment was administered in conjunction with diet and exercise. Significant reductions ($P < .001$) in body weight in the lorcaserin-treated patients were evident starting at week 4 and thereafter to week 52.

[a]N values apply to age and HbA_{1c} only (safety population). For other parameters, the MITT population is presented.

[b]The published abstract reports 253 patients randomized to placebo; the safety population presented here, however, reports the 252 treated patients in the placebo group.

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*On May 1, 2015, kg/dL was changed to kg/m².

Overweight Management in Diabetes Mellitus study [BLOOM-DM; NCT00603291], concerning the effects of the weight loss drug lorcaserin in patients with type 2 diabetes mellitus (T2DM) who are overweight or obese.

About 85% of Americans with T2DM are overweight or obese [Centers for Disease Control and Prevention. *Morb Mortal Wkly Rep.* 2004]. Sustained weight reduction of 3% to 5% is advantageous in improving glycemic control [Jensen MD et al. *Circulation.* 2014; Wing RR et al. *Diabet Care.* 2011]. Lorcaserin is a selective 5-HT_{2c} receptor agonist that acts to decrease food consumption and promote satiety, and it has been approved for weight loss in conjunction with diet and exercise.

In the 52-week BLOOM-DM trial, obese and overweight T2DM patients were randomized 1:1:1 in a double-blind manner to placebo, lorcaserin–10 mg QD, or lorcaserin–10 mg BID, in conjunction with a calorie-reduced diet and exercise. Significant reductions versus placebo were evident in HbA_{1c} and fasting plasma glucose levels in patients receiving lorcaserin BID [O'Neil PM et al. *Obesity.* 2012].

The present post hoc analysis involved patients who were randomized to either placebo or lorcaserin BID, who received ≥ 1 dose of study drug, and whose post-baseline weight was measured at least once—that is, the modified intention-to-treat population. This retrospective analysis aimed to evaluate the putative weight-loss independent effects of lorcaserin on HbA_{1c}, fasting plasma glucose, and fasting plasma insulin.

The baseline characteristics of patients treated with placebo or lorcaserin BID were comparable (Table 1).

Patients receiving lorcaserin BID displayed significant reductions ($P < .001$) in fasting plasma glucose when compared with the placebo group, beginning at week 2 and continuing through to week 52. The drop in glucose levels preceded any significant weight loss. A similar pattern of glucose reduction was also evident among a subgroup of patients who did not lose weight while on lorcaserin treatment and who were therefore considered nonresponders (defined as weight loss ≥ 5% at 12 weeks).

Reductions in HbA_{1c} were significantly greater in the lorcaserin-treated group as compared with the placebo group starting at week 12 (first measurement of HbA_{1c}) throughout week 52. A similar pattern of reduction in HbA_{1c} was evident in the nonresponder group, even though no changes in body weight occurred. Mean changes in fasting plasma insulin from baseline were not significantly different in patients treated with lorcaserin BID and placebo.

Examination of 256 patients receiving lorcaserin BID and 252 receiving placebo revealed increased treatment-related adverse events of hypoglycemia (29.3% vs 21.0%), headache (14.5% vs 7.1%), back pain (11.7% vs 7.9%), cough (8.2% vs 4.4%), and fatigue (7.4% vs 4.0%).

These post hoc observations of a significant lorcaserin-mediated reduction in fasting plasma glucose and HbA_{1c} before or in the absence of significant weight loss suggest that lorcaserin might affect glucose homeostasis, at least in part, independently from weight loss. Further prospective randomized clinical trials are needed to confirm these observations.

Liraglutide Helps Achieve Significant Weight Loss in Overweight or Obese Patients

Written by Brian Hoyle

Ken Fujioka, MD, Scripps Clinic, La Jolla, California, USA, reported results of the Effect of Liraglutide on Body Weight in Non-diabetic Obese Subjects or Overweight Subjects With Co-morbidities study [SCALE; NCT01272219], a 56-week randomized, double-blind, placebo-controlled trial demonstrating the efficacy of liraglutide in inducing and maintaining weight loss, and enhancing health-related quality of life (HRQOL), in 3751 obese or overweight patients with or without prediabetes.

The diminished QOL attributable to obesity can be improved by weight loss [Warkenten LM et al. *Obesity Res.* 2014; Ul Haq et al. *Obesity.* 2013]. Liraglutide is a long-acting glucagon-like peptide-1 agonist approved by the Food and Drug Administration for the treatment