Intragastric Balloon Offers Surgical Alternate for Treatment of Obesity: The REDUCE Trial

Written by Emma Hitt Nichols, PhD

Saline-filled intragastric balloons are a possible option for patients who are not suitable candidates for bariatric surgery or do not want it. Jaime Ponce, MD, Hamilton Medical Center, Dalton, Georgia, USA, presented the results of A Prospective, Randomized Multicenter Study to Evaluate the Safety and Efficacy of the ReShape Duo Intragastric Balloon System in Obese Subjects [REDUCE; NCT01673698]. In the study, when the Duo system was used with diet modification and a regular exercise program, it showed overall improvements in obesity-related comorbidities and increased quality of life (QOL) in addition to measureable weight loss. Dr Ponce is the principal investigator of the trial.

In this multicenter double-blind study, patients (n = 326) with a body mass index of 30 to 40 kg/m^2 with ≥ 1 obesity-related comorbidity were randomized into 1 of 2 groups. For the first 24 weeks, the DUO group (n = 187) was treated with the Duo system (2 connected balloons delivered endoscopically), diet, and exercise. The DIET group (n = 139) was treated with diet and exercise alone. From weeks 24 to 48, the DUO group was treated with diet and exercise, while the DIET group had the option of exiting the study or having a Duo balloon inserted. The patients were counseled monthly and assessed for weight, adverse events, and QOL measures. The co–primary end points were as follows: (1) a > 7.5% excess weight loss (EWL) in the DUO group compared with the percentage EWL in the DIET group and (2) a > 35% response in the DUO group with ≥ 25% EWL.

The DUO group had a significantly (P = .0041) greater percentage EWL than the DIET group and a greater proportion of ≥ 25% EWL at 24 weeks (Figure 1). Additionally, the mean percentage EWL at 48 weeks was 65% of the percentage EWL when the device was removed at 24 weeks. A total of 36% of the patients maintained a ≥ 25% EWL. Of note, about 1 in 4 patients continued to lose weight after balloon retrieval.

Patients also showed significant improvements in laboratory measurements associated with comorbidities, including HbA_{1c}, lipids, and blood pressure (Table 1). In addition to reporting significantly better improvement in QOL based on 3 surveys, 64% of patients said that they would repeat the Duo treatment, and 78% said that they would recommend the procedure to a friend.

Most (99.6%) of the balloon insertions were successful, and all were retrieved successfully. However, 3 patients (1.1%) experienced serious adverse events following retrieval. These included pneumonia, a contained perforation of the cervical esophagus (successfully treated with antibiotics), and a proximal esophageal mucosal tear. Of the 264 patients who experienced balloon

Table 1. Improvements in Laboratory Values Associated With Comorbidities: DUO Group (n = 187)

		Change From Baseline			
		During Dual Balloon Therapy		After Dual Balloon Therapy	
Measure	Baseline	Wk 12	Wk 24	Wk 36	Wk 48
HbA_{1c}	5.7	**–0.1**	**–0.2**	**–0.3**	**–0.2**
Triglycerides	140.9	**–17.9**	**–15.7**	–6.7	–9.0
Cholesterol					
HDL	52.0	–0.9	1.0	**1.6**	**1.9**
LDL	121.0	–3.0	**–4.1**	**–6.8**	**–4.6**
Blood pressure					
Systolic	130.4	**–8.2**	**–8.3**	**–9.3**	**–6.6**
Diastolic	81.8	**–2.7**	**–4.3**	**–4.3**	**–4.4**
Measurements, in					
Waist	42.3		**–2.9**		**–2.2**
Hip	47.1		**–2.2**		**–1.5**

Bold values are significantly better than baseline values.

DUO, group treated with the Duo system; HDL, high-density lipoprotein; LDL, low-density lipoprotein.

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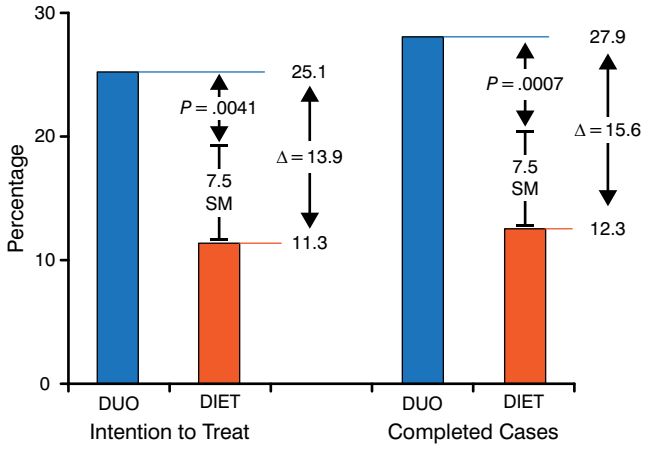
Figure 1. Primary End Point



"Percentage" indicates excess weight loss percentage. DIET, group treated with diet and exercise only; DUO, group treated with the Duo system plus diet and exercise; SM, superiority margin.

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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