ORIGINAL ARTICLE

Open-label, sham-controlled trial of an endoscopic duodenojejunal bypass liner for preoperative weight loss in bariatric surgery candidates

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Background: The duodenojejunal bypass liner (DJBL) (EndoBarrier Gastrointestinal Liner) is an endoscopically placed and removable intestinal liner that creates a duodenojejunal bypass resulting in weight loss and improvement in type 2 diabetes mellitus.

Objective: Weight loss before bariatric surgery to decrease perioperative complications.

Design: Prospective, randomized, sham-controlled trial.

Setting: Multicenter, tertiary care, teaching hospitals.

Patients: Twenty-one obese subjects in the DJBL arm and 26 obese subjects in the sham arm composed the intent-to-treat population.

Interventions: The subjects in the sham arm underwent an EGD and mock implantation. Both groups received identical nutritional counseling.

Main Outcome Measurements: The primary endpoint was the difference in the percentage of excess weight loss (EWL) at week 12 between the 2 groups. Secondary endpoints were the percentage of subjects achieving 10% EWL, total weight change, and device safety.

Results: Thirteen DJBL arm subjects and 24 sham arm subjects completed the 12-week study. EWL was 11.9% $\pm$ 1.4% and 2.7% $\pm$ 2.0% for the DJBL and sham arms, respectively ($P < .05$). In the DJBL arm, 62% achieved 10% or more EWL compared with 17% of the subjects in the sham arm ($P < .05$). Total weight change in the DJBL arm was -8.2 ± 1.3 kg compared with -2.1 ± 1.1 kg in the sham arm ($P < .05$). Eight DJBL subjects terminated early because of GI bleeding (n = 3), abdominal pain (n = 2), nausea and vomiting (n = 2), and an unrelated preexisting illness (n = 1). None had further clinical symptoms after DJBL explantation.

Limitations: Study personnel were not blinded. There was a lack of data on caloric intake.

Conclusions: The DJBL achieved endoscopic duodenal exclusion and promoted significant weight loss beyond a minimal sham effect in candidates for bariatric surgery. **(Clinical trial registration number: NPT00469391.)** (Gastrointest Endosc 2010;xx:xxx.)

Abbreviations: BMI, body mass index; BPD, biliopancreatic diversion; DJBL, duodenojejunal bypass liner; EWL, excess weight loss; ITT, intent-to-treat; RYGB, Roux-en-Y gastric bypass; T2DM, type 2 diabetes mellitus.

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In 2004, 66% of U.S. adults were overweight or obese, with 5% classified as morbidly obese (body mass index [BMI] ≥40 kg/m^2).[1] Overweight and obesity are risk factors for increased morbidity (eg, type 2 diabetes mellitus [T2DM]) and mortality.[2-4] Bariatric surgery produces lasting weight loss in morbidly obese patients and is effective in reversing T2DM and other comorbidities.[5,6] Amelioration of medical conditions and prevention of future medical problems are the primary reasons for pursuing bariatric surgery.[7] Current surgical options include Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion (BPD), sleeve gastrectomy, and adjustable gastric banding. Unfortunately, concerns regarding morbidity and mortality associated with these procedures have prevented their widescale adoption.[7] However, despite its inherent risks, bariatric surgery is associated with decreased mortality compared with untreated obesity[5] and represents the best treatment for this disease, achieving 50% or more excess weight loss (EWL) over the long term. Even weight reductions of approximately 9 to 13 kg are associated with a 33% decrease in mortality.[8]

Weight loss before bariatric surgery is commonly recommended to decrease perioperative complications.[9-11] Benefits include decreases in hernia recurrence, operative complications, operating times, hospital stay, and an increase in weight loss.[12] As a result, many bariatric programs now have a preoperative weight loss requirement.

Capsule Summary

What is already known on this topic

- Weight loss before bariatric surgery is commonly recommended to decrease surgical complications, operative time, and hospital stay.

What this study adds to our knowledge

- In a prospective 12-week study of weight loss before bariatric surgery, excess weight loss was 11.9% ± 1.4% and 2.7% ± 2.0% for 13 subjects receiving a duodenojejunal bypass liner and 24 controls, respectively.
- Eight other subjects receiving the duodenojejunal bypass liner left the study before 12 weeks because of GI bleeding (n = 3), abdominal pain (n = 2), nausea and vomiting (n = 2), and an unrelated preexisting illness (n = 1).

MECHANISMS OF WEIGHT LOSS

RYGB and BPD reroute chyme such that the duodenum and proximal jejunum are bypassed, promoting chyme delivery directly to the jejunum.[5] In an effort to treat obese patients less invasively, nonsurgical endoluminal procedures have been attempted with variable success.[13,14] Many share the ability to reduce gastric volume, thereby restricting the passage of food through the stomach into the duodenum. An alternative approach would be to duplicate the effects of the gastric bypass/BPD by diverting chyme from the proximal small intestine. The duodenojejunal bypass liner (DJBL) (EndoBarrier Gastrointestinal Liner; GI Dynamics, Inc, Lexington, Mass) is an endoscopically placed and removable intestinal liner developed to achieve this goal. The DJBL is a 60-cm, impermeable, fluoropolymer liner (Fig. 1) anchored in the proximal duodenum that prevents chyme from coming in contact with the proximal intestine, similar to RYGB but without gastric restriction. Bile and pancreatic secretions pass along the outer wall of the liner and mix with the chyme exiting distal to the liner in the jejunum.

Previous published studies demonstrated the impact of the DJBL on weight reduction in morbidly obese subjects.[15-17] In a 12-week, open-label study the DJBL was associated with a mean weight reduction of 10.2 kg in the 10 subjects completing the entire treatment (mean EWL 24%).[16] Additionally, 3 of 4 subjects with T2DM at baseline had normalization of blood glucose concentrations within 24 hours of DJBL implantation. Another 12-week study in subjects randomized to DJBL plus a low-calorie diet (n = 25) or diet alone (n = 14) yielded a 22% mean EWL (10.3 kg) in the DJBL arm and 5% mean EWL (2.6 kg) in the control arm.[17] All 3 T2DM subjects in the DJBL arm had improved glycemic control after 1 week.

The study reported here is significant because it is one of the few prospective randomized trials with an implantable device that was sham controlled and the first U.S. trial of the DJBL.

MATERIALS AND METHODS

Study population

This 12-week, open-label, randomized trial investigated the use of the DJBL versus a sham upper endoscopy for weight loss before bariatric surgery. It was conducted from May 2007 to November 2008 at 4 sites in the United States in accordance with Good Clinical Practice and in compliance with each institution's Investigational Review Board.

Subjects were people 18 years of age or older and 55 years of age or younger in whom nonsurgical weight loss treatments failed. The baseline BMI was 40 kg/m^2 or more and 60 kg/m^2 or less or 35 kg/m^2 or more for those with comorbidities. Women were postmenopausal, surgically sterile, or taking oral contraceptives. Subjects were excluded if they were using weight-loss medications or appetite suppressants or had a history of GI tract abnormalities. All subjects discontinued taking nonsteroidal anti-inflammatory drugs, corticosteroids, and drugs affecting GI motility.

Study design and endpoints

The study design is shown in Figure 2. After the 2-week follow-up visit, subjects were cleared for bariatric surgery.

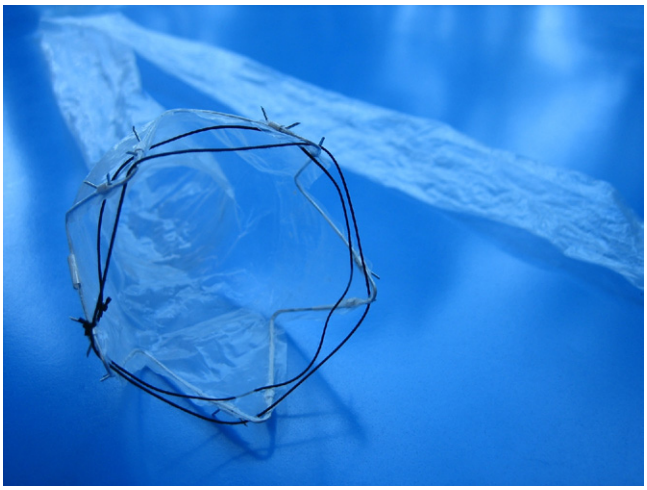

Figure 1. The duodenojejunal bypass liner.

DJBL subjects who underwent a bariatric procedure while the clinical trial was still active had information collected on their surgical procedure and any complications possibly related to the DJBL. Sham-treated subjects were unblinded at the 12-week visit and exited the study.

Weight loss counseling was given at baseline. The counseling was the same irrespective of the subject's treatment assignment and was conducted by each center's nutritionists. No additional dietary counseling was given. All subjects received a liquid diet for 1 week post-implantation/sham endoscopy and were then switched to a regular diet. Recommended caloric intake after week 1 was a maximum of 1200 calories per day for women and 1500 calories per day for men.

The primary endpoint was the difference in the percentage of EWL from baseline at week 12 between both groups. Secondary endpoints were the percentage of subjects achieving 10% EWL, a change in total body weight, and safety.

Device implantation and explantation

The DJBL implantation and explantation were previously described.[15-17] Subjects in either group were instructed that general anesthesia or conscious sedation would be used as determined by the treating physician. This information was included in the informed consent. Subjects underwent general anesthesia for implantation and removal of the device. Sham subjects underwent conscious sedation during which an EGD and a mock procedure were performed to ensure that the subjects were blinded. No follow-up personnel were blinded. All subjects received a proton pump inhibitor the evening before implantation and were advised to continue taking one throughout the study. On the day of implantation in subjects with T2DM, the dose of sulfonylureas was decreased by 50%.

Statistical analysis

Subjects were assigned to a treatment arm based on a computer-generated randomization schedule prepared by the sponsor. The randomization was balanced by using randomly permuted blocks and stratified by clinical site. The intent-to-treat (ITT) population was defined as all subjects who were randomized to a treatment arm and underwent either DJBL implantation or a sham procedure. The completer population was defined as all ITT subjects who completed 12 weeks on-study. The safety population was defined as all randomized subjects. Data were pooled across study sites and are presented as mean ± standard error of the mean unless otherwise indicated. Analyses were performed by using SAS Version 9.2 software or later (SAS, Cary, NC). Excess weight was calculated based on ideal body weights listed in the 1983 Metropolitan Life tables.

RESULTS

Study population

Sixty-nine subjects were screened, with 58 meeting all inclusion and no exclusion criteria (Fig. 3). Two subjects withdrew before randomization at their request. Twenty-seven subjects were randomized to the DJBL arm and 29 to the sham arm. Two subjects initially randomized to the DJBL arm were removed before implantation at their request. In the sham arm, 2 subjects were discontinued at their request, and a third was lost to follow-up. Therefore, 25 subjects randomized to the DJBL arm underwent implantation; 26 subjects randomized to the sham arm underwent EGD followed by standard-of-care diet therapy.

Of the 25 subjects who underwent DJBL implantation, it was successful in 21 of them. The DJBL could not be implanted in 3 subjects because of a short duodenal bulb. In 1 subject, a combination of subject anatomy and investigator inexperience interfered with placement. Of the 21 successful DJBL implantation subjects, 8 discontinued trial participation before 12 weeks. In the sham arm, 2 subjects discontinued after their EGD: 1 at the subject's request and 1 because of pregnancy at her week 8 visit. This subject was not pregnant at enrollment.

Subjects in the ITT population (21 DBJL, 26 sham) were morbidly obese, predominantly white, middle aged, and female, with the expected obesity-related comorbidities (Table 1).

Weight loss

In the completer population at week 12 (13 DJBL, 24 sham), EWL was 11.9% ± 1.4% in the DJBL arm (95% CI, 9.0%-14.9%) and 2.7% ± 2.0% in the sham arm (95% CI, −1.4% to 6.7%; $P < .001$ between arms) (Fig. 4). In the DJBL arm, 62% achieved at least 10% EWL (n = 8) at 12 weeks compared with 17% in the sham arm (n = 4; $P = .01$). Although all subjects in the DJBL arm lost weight, 5

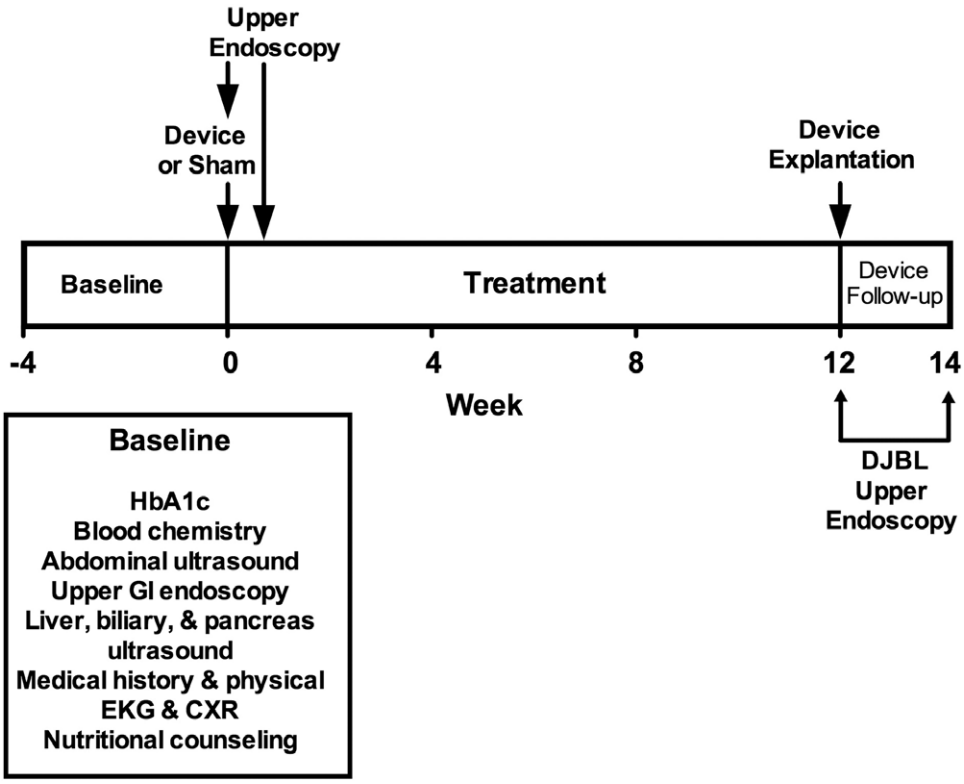

Figure 2. Study design. Subjects received nutritional counseling at baseline. Body weight was recorded at each visit. CXR, chest x-ray; EKG, electrocardiogram; HbA1c, glycosylated hemoglobin.

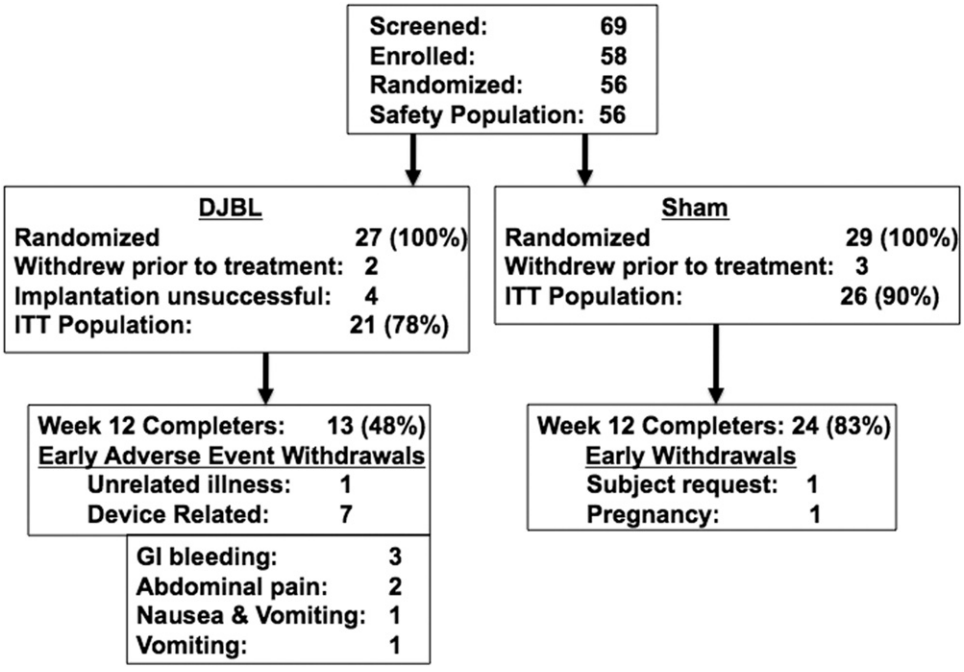

Figure 3. Subject flow chart and disposition.

did not achieve 10% EWL (9.8%, 9.7%, 8.5%, 5.6%, and 3.1% EWL, respectively).

Total body weight change at week 12 in the DJBL arm was −8.2 ± 1.3 kg (95% CI, −10.9 kg to −5.5 kg) compared with −2.0 ± 1.1 kg in the sham arm (95% CI, −4.4 kg to 0.3 kg; $P = .002$ between arms). These data corresponded to a 5.8% ± 0.7% decrease in the DJBL arm (95% CI, −7.4% to −4.2%) and a 1.5% ± 0.9%

TABLE 1. Baseline demographics and subject characteristics in the intent-to-treat population

	All (n = 47)	DJBL (n = 21)	Sham (n = 26)	*P* value*
Age (y)	44 ± 9	45 ± 7	43 ± 10	>.05
Sex (% female)	81	71	89	—
Ethnicity (%): white/Hispanic or Latino/other	77/9/15	86/5/10	69/12/19	—
BMI (kg/m^2)	46 ± 6	46 ± 5	46 ± 6	>.05
Body weight (kg)	131 ± 21	131 ± 21	130 ± 21	>.05
Comorbidities (%)				
Hypertension	49	57	42	
Dyslipidemia	32	43	23	
Heart disease	9	10	8	
Type 2 diabetes mellitus	55	67	46	

BMI, Body mass index; *DJBL*, duodenojejunal bypass liner.
*Comparison of duodenojejunal bypass liner and sham groups (mean ± standard deviation).

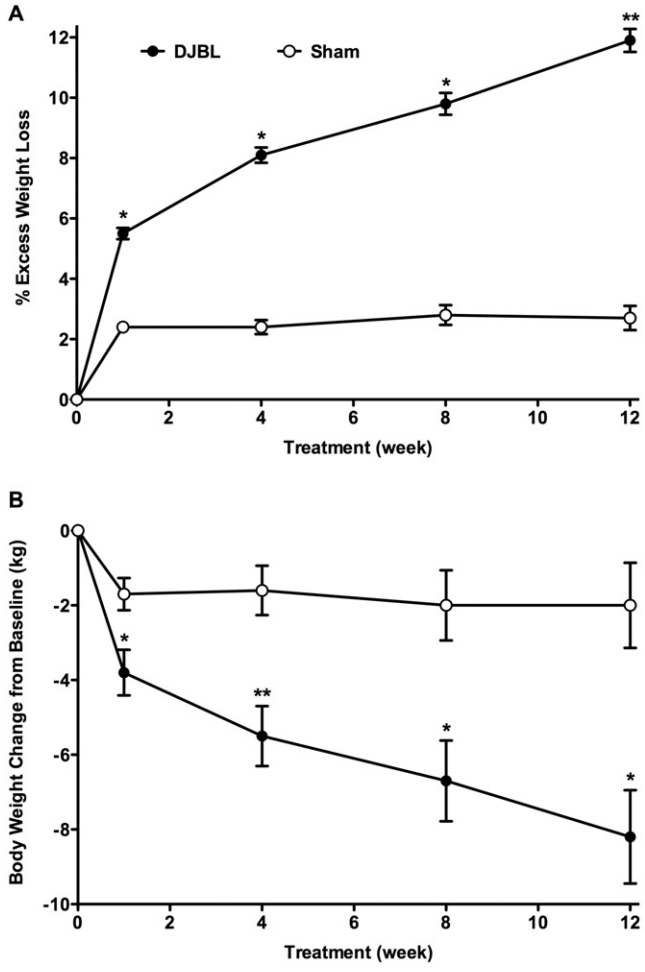

Figure 4. Body weight change from baseline in the 12-week completer population. **A,** Percentage of EWL. **B,** Total body weight. DJBL, 13 subjects; sham, 24 subjects. Mean ± standard error the mean. *$P \leq .01$ and **$P \leq .001$ between treatment arms.

decrease in the sham arm (95% CI, −3.3% to 0.3%; $P = .002$ between arms). All subjects in the DJBL arm lost weight. In contrast, 6 subjects gained weight in the sham arm.

Safety and tolerability

The majority of adverse events were mild or moderate (Table 2). There were no signs or symptoms of biliary obstruction, pancreatic duct obstruction, or obstruction or migration of the device in any subject. There were no clinically significant abnormal blood values observed during the study, with the exception of the 3 subjects who presented with a decrease in hemoglobin and hematocrit associated with GI bleeding.

Seven subjects had the DJBL explanted early because of a device-related adverse event. One additional subject was withdrawn from the study because of breast carcinoma. Three of these subjects discontinued early because of GI bleeding. Two of these incidents were classified as severe adverse events related to the device. All 3 subjects presented with hematemesis at 11, 25, and 43 days postimplantation. The devices were removed endoscopically with no subsequent sequelae in 2 subjects. In 1 subject, the source of bleeding was identified and successfully treated with sclerotherapy and endoscopic clips. Two of these subjects required transfusions.

Four DJBL subjects discontinued early because of abdominal pain, nausea, and/or vomiting on days 3, 9, 30, and 36. All removed devices appeared normal, and there was no evidence of gastritis, esophagitis, or ulcerations. These symptoms resolved without further treatment or clinical sequelae.

Of the 21 DJBL subjects, 12 underwent a bariatric surgical procedure (9 RYGB, 3 adjustable gastric bands) while the clinical trial was active. Their procedures were suc-

TABLE 2. Device-related adverse events with ≥1% frequency in the device group (N = 27)

Adverse event with the DJBL	% (n)
Upper abdominal pain	13.0 (14)
Procedural nausea	9.3 (10)
Nausea	5.6 (6)
Procedural vomiting	5.6 (6)
Vomiting	3.7 (4)
Constipation	2.8 (3)
GI bleeding	2.7 (3)
Hematemesis	2.7 (3)
Abdominal pain	1.9 (2)
Dyspepsia	1.9 (2)
Anemia	1.9 (2)
Pyrexia	1.9 (2)

DJBL, Duodenojejunal bypass liner.
Device-related adverse events are definitely or possibly related to the device. Percentages are based on the total number of adverse events (n = 108) in the duodenojejunal bypass liner group.

cessfully completed without complications related to the DJBL.

DISCUSSION

This 12-week trial evaluated the safety and weight loss efficacy of the DJBL as adjunctive therapy before bariatric surgery. Subjects who tolerated the DJBL experienced significantly greater weight loss than sham subjects, even though both groups received the same preoperative nutritional counseling.

There is a growing acceptance among clinicians that preoperative weight loss is beneficial for those undergoing bariatric surgery.[9-12,18-20] The 1998 National Institutes of Health Obesity Consensus Panel called for aggressive treatment of obese individuals including the use of diet, exercise, behavioral modification, pharmacotherapy, and bariatric surgery.[12] In addition to these recommendations, the panel proposed that obese patients attempt to lose 10% of their body weight over 6 months before undergoing bariatric surgery. More recently, Still et al[9] reported that morbidly obese candidates for bariatric surgery who were able to achieve 5% to 10% EWL before surgery had shorter hospital stays. In addition, individuals with the greatest EWL before surgery reached their goal EWL more quickly than those with low EWL or weight gain before surgery. Subjects with 10% preoperative EWL were more than twice as likely to achieve 70% EWL postoperatively than those with 0% to 5% preoperative EWL.

Liu et al[10] found less intraoperative blood loss, fewer observations of enlarged livers during surgery, and fewer surgical complications in preoperative weight losers. Huerta et al[18] observed that an 8% weight decrease was associated with shorter operating time. Alami et al[19] reported that patients who achieved 10% EWL preoperatively had shorter operating times and enhanced postoperative weight loss. Alvarado et al[11] found that a 1% preoperative weight loss correlated with a 1.8% increase in postoperative EWL at 1 year. Also, a preoperative weight loss greater than 5% was correlated with shorter operating times. Alger-Mayer et al[20] found significant positive correlations between the magnitudes of preoperative and 3- or 4-year postoperative weight reductions. Solomon et al[21] reported preoperative subjects who lost at least 5% excess body weight had improved long-term postoperative weight loss compared with subjects with no weight loss or with weight gain.

Bariatric surgery candidates are often unable to lose sufficient body weight, even with dietary counseling or pharmacotherapy. Given this context, the significant differences in weight loss between the DJBL and sham arms represent a new option for achieving meaningful preoperative weight loss. The facts that both study arms included subjects highly motivated to lose weight and that the trial was sham controlled demonstrate the efficacy of the device, eliminating many confounding variables. All DJBL subjects lost weight, compared with weight gain in 6 of 24 sham subjects, providing further evidence of the limitations of standard-of-care diet therapy alone. In addition, 62% of DJBL subjects achieved 10% EWL compared with 17% of sham subjects, again highlighting the ability of the DJBL to help obese individuals lose weight over 12 weeks.

Of the 25 subjects who underwent an attempted DJBL implantation, the DJBL was successfully implanted in 21. Not surprising for an exploratory clinical trial, there were a number of technical challenges during the implantation procedure that could be expected to decrease with more experience. There seems to be a procedural learning curve of 5 to 7 procedures, which may have affected procedural success rates or subsequent complications. In addition, the DJBL could not be implanted in those with duodenal bulbs less than 25 mm in length because of size limitations.

The majority of DJBL-related adverse events were mild or moderate in the implantation subjects. Many of the adverse events occurring within the first 2 weeks likely reflect adaptation to the DJBL. Episodes of GI distress occurring more than 2 weeks post-implantation may be diet related and in most instances did not prompt any action or treatment.

Mild bleeding is an expected adverse event associated with the anchoring of the device. There were 3 episodes of bleeding in implanted DJBL subjects. The duodenal submucosa is quite vascular, and animal studies have demonstrated that the anchor embeds in the submucosa; there-

fore, one might expect that vessel disruption is a possibility. In humans, bleeding has been reported with the use of GI stents.[22,23] Improvements in anchor designs and patient management are under evaluation in clinical trials to decrease the potential for GI bleeding. Overall, adverse events were similar to those observed during previous DJBL studies.[16,17]

The magnitude of the 12-week weight loss observed in this sham-controlled U.S. study was lower than previously observed in a diet-controlled Chilean study[17] (12% vs 22% EWL, respectively). A number of factors could account for this difference including cultural and dietary differences, differences in subject counseling and support, lower BMI (mean 42 kg/m^2 vs 46 kg/m^2) for the U.S. population, and the fact that this was the first sham-controlled DJBL trial.

CONCLUSIONS

The DJBL can be safely implanted and explanted endoscopically and maintained for 12 weeks. Importantly, the DJBL achieved significant preoperative weight loss compared with standard counseling in candidates for bariatric surgery. These data support further clinical research with the DJBL in obese subjects.

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