ELSEVIER

Surgery for Obesity and Related Diseases 5 (2009) 435–438

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Laparoscopic adjustable gastric banding with truncal vagotomy versus laparoscopic adjustable gastric banding alone: interim results of a prospective randomized trial

Luigi Angrisani, M.D.*, Pier Paolo Cutolo, M.D., Melania Battaglini Ciciriello, M.D., Giuliana Vitolo, R.D., Francesco Persico, M.D., Michele Lorenzo, M.D., Ph.D., Paolo Scarano, M.D.

General and Laparoscopic Surgery Unit, S. Giovanni Bosco Hospital, "Federico II" Medical School, Naples, Italy

Received May 27, 2008; revised August 7, 2008; accepted August 18, 2008

Abstract

Background: In an attempt to potentiate the effect of laparoscopic gastric banding (LGB) on weight reduction and to reduce the risk of weight regain, we added laparoscopic truncal vagotomy (TV) to adjustable LGB. We report on our early interim results of a prospective 5-year randomized clinical trial comparing patients who underwent LGB plus TV (LGBTV) with a control group who underwent LGB alone.

Methods: From December 2005 to November 2006, patients were randomly allocated to LGBTV or LGB alone. In the LGBTV group, the anterior and posterior vagus trunks were isolated and resected after preparing and encircling the esophagus at the diaphragmatic crus. In both groups, an 11-cm Lap-Band System was positioned by way of the pars flaccida.

Results: A total of 50 patients were entered into the study. No mortality resulted, and no conversion to laparotomy was needed. Neither group had any intra- or postoperative complications. The mean weight, body mass index, and percentage of excess weight loss were not significantly different statistically between the 2 groups at 12 or 18 months after surgery (P = NS). At 6 months of follow-up, band adjustment was not required in 10 (50%) of 20 patients with LGBTV compared with 5 (20%) of 25 patients with LGB alone (P = .034). At 12 months, 7 (35%) of 20 LGBTV patients and 2 (8%) of 25 LGB patients still did not require band adjustment (P = .024). Conclusion: The results of our study have shown that adding TV to LGB does not cause specific morbidity or mortality compared with LGB alone. During the first postoperative year, the addition of TV to LGB decreased the number of patients requiring band adjustments. (Surg Obes Relat Dis 2009;5:435–438.)

Keywords: Vagotomy; Truncal; Gastric banding; Severe obesity

The role of the vagus nerve in appetite regulation has long been recognized [1]. From animal studies [2] and the clinical observations of Dragstedt and Owens [3] of reduced hunger sensations in vagotomized ulcer patients, Kral [4], in 1978, originally described truncal vagotomy (TV) for the treatment of obesity. Kral explored the possibility of affecting the nervous system regulation of appetite and delaying gastric emptying to cause weight loss. After that initial experience, Kral et al. [5] demonstrated the possibility of using TV to potentiate the weight loss of vertical banded gastroplasty.

After the initial enthusiasm occurring with the clinical introduction of laparoscopic adjustable gastric banding (LGB) in 1994 for the treatment of obesity in Europe [6], at the beginning of the 21st century, a number of centers

Presented at the 25th Annual Meeting of the American Society for Metabolic and Bariatric Surgery, June 15–20, 2008, Washington DC

*Reprint requests: Luigi Angrisani, M.D., Division of Endoscopic Surgery, Department of Surgery, S. Giovanni Bosco Hospital, Piazza Vittoria 7, Naples 80121 Italy.

E-mail: luigiangrisani@chirurgiaobesita.it

1550-7289/09/$ – see front matter
doi:10.1016/j.soard.2008.08.024

introduced laparoscopic Roux-en-Y gastric bypass in their practice to manage the increasing numbers of patients with weight regain during long-term follow-up [7–9]. In an attempt to develop a safe technique to potentiate the effect of LGB on weight reduction and to reduce the risk of weight regain, using Kral's previous clinical experience, we developed the laparoscopic technique of TV plus LGB. The present study reports on the interim results of a prospective 5-year randomized clinical trial to compare a group of patients treated using TV + LGB (LGBTV) with a control group who underwent LGB alone.

Methods

The patients were recruited from December 2005 to November 2006. The inclusion criteria were a body mass index (BMI) of $\geq$35 kg/m^2 but $<$45 kg/m^2 and age between 20 and 45 years. Patients with any history of diagnosed ulcer disease, hiatus hernia preoperatively or intraoperatively diagnosed, or cholelithiasis were excluded. A specifically designed informed consent form, approved by the hospital's institutional research review board, was signed by all enrolled patients after an explanation of the study and the risks and benefits of the procedures were given. To enter the study, patients had to be willing to accept randomization, which occurred 24 hours before surgery, while in the hospital, at which time they were informed of the operation to which they had been randomized. They were allowed to refuse, in which case they were excluded from the trial. The patients were randomly allocated into 2 groups: LGBTV or LGB alone by sealed envelope according to a randomization table.

In the LGBTV group, the anterior and posterior vagus trunks were isolated after preparing and encircling the esophagus at the diaphragmatic crus. About 2 cm of nerve tissue was resected, and the specimens were sent for routine histologic examination, with no attempt to identify additional vagal fibers. For LGB, the patients were positioned in the reverse Trendelenburg lithotomy position. A closed carbon dioxide pneumoperitoneum was created, and 5 trocars (2 of 10 mm and 3 of 5 mm) were inserted. Dissection was started near the angle of His, above the greater curvature of the stomach. The lesser omentum was opened through the pars flaccida, and the fat on the posterior wall of the lesser sac was retracted to expose the right crus of the diaphragm. The Endo-Grasper Roticulator (U.S. Surgical, Tyco Healthcare, Norwalk, CT) was then passed along this retrogastric tunnel to appear on the greater curvature of the stomach at the site of the previous dissection at the angle of His. The 11-cm Lap-Band System (Inamed-Allergan, Santa Barbara-Carpinteria, CA) was passed along this pathway and closed and fixed to the stomach using 3 gastrogastric nonabsorbable stitches. The port was sutured to the left anterior rectal sheet with 5 nonabsorbable stitches. Band inflation was not performed at surgery, and office adjustment was not considered until the first postoperative month. No intraoperative or postoperative tests were done to determine the completeness of the vagotomy.

The data on mortality, conversion to an open procedure, postoperative complications leading to reoperation, hospital stay, weight, BMI, and percentage of excess weight loss, were collected. Excess weight (in kilograms) was calculated by subtracting the ideal weight (determined using the 1983 Metropolitan Life Insurance Company Height and Weight Table for a person of medium frame) from the patient's weight. Improvements in co-morbidities were analyzed. All patients were followed up in the surgeon's office every 3 months for the first year and every 6 months thereafter. Specific symptoms of vagotomy (e.g., belching, bloating, "dumping syndrome," and diarrhea) were monitored in both groups. Gallbladder ultrasonography was performed at 1 year postoperatively. Band adjustment was performed when clinically required and was individually tailored for each patient to obtain weight loss and symptoms of satiety. Satiety was defined as the patient's subjective report of fullness after eating compared with this sensation at previous visits. The band was inflated after independent evaluations by both the dietician and the surgeon. No specific questionnaire on hunger, fullness, or satiety was administered. Vomiting was considered as an absolute contraindication to band inflation. Band deflation was not performed. Data are expressed as the mean $\pm$ standard deviation, except as otherwise indicated. Statistical analysis was done by paired and group means analysis using Student's t test and Fisher's exact test. $P < .05$ was considered significant.

Results

A total of 57 patients were considered for the study. Of these patients, 7 were excluded preoperatively because of Crohn's disease, cardiomyopathy, fibromyalgia, peptic ulcer, hiatus hernia, previous cholecystectomy, or previous abdominoplasty.

The remaining 50 patients were entered into the study. No significant differences were found between the LGBTV group (n = 25, 2 men and 23 women, mean age 36.3 $\pm$ 9.1 y, range 21–42; mean BMI 38.9 $\pm$ 5.9 kg/m^2, range 35.1–43.2) and the LGB group (n = 25, 2 men and 23 women, mean age 35.9 $\pm$ 8.7 y, range 22–43; mean BMI 39.1 $\pm$ 5.1 kg/m^2, range 37–42.9) at baseline. The comorbidities present at surgery were weight-bearing arthropathy in 7, type 2 diabetes mellitus in 1, hypertension in 2, and dyslipidemia in 2.

Of the 25 patients randomly allocated to the LGBTV group, 2 were intraoperatively excluded from the study and underwent LGB. Of these 2 patients, 1 had had a preoperatively unrecognized hiatus hernia, and 1 had an enlarged caudate liver lobe. Of the remaining 48 patients eligible for a minimal follow-up of 1 year, 46 were available. One LGBTV patient was lost to follow-up 1 month after the

Table 1
Weight, BMI, and %EWL at different intervals

Group	Interval	Weight (kg)	BMI (kg/m^2)	EW (kg)	%EWL
LGBTV					
	Preoperative	102.3 ± 12.9	38 ± 4	42.2 ± 13.2	
	12 mo (20/22)	83.5 ± 12.5	30 ± 8		39.3 ± 19.8
	18 mo (15/17)	77.7 ± 23.2	29 ± 9		46.6 ± 19
LGB alone					
	Preoperative	105.2 ± 17.1	38 ± 4	44.7 ± 14.3	
	12 mo (25/25)	90.8 ± 14.8	33 ± 5		34.6 ± 26.1
	18 mo (17/17)	86.1 ± 15.8	32 ± 5		44.1 ± 27.9

BMI = body mass index; %EWL = percentage of excess weight loss; EW = excess weight; LGBTV = laparoscopic gastric banding plus laparoscopic truncal vagotomy; LGB = laparoscopic gastric banding.

operation, and another presented with lung cancer at 6 months of follow-up and was excluded from the study.

No mortality occurred, no conversion to laparotomy was needed, and no intraoperative or postoperative complications developed in either group. The postoperative histologic findings confirmed the presence of nerve tissue in all the resected specimens. One LGBTV patient presented with a tube port disruption and underwent reconnection at 1 year. Her data were excluded from the analyses of weight loss, co-morbidity resolution, and band adjustments. The mean hospital stay was 2 ± 1 days for both groups. None of the 46 patients (21 LGBTV and 25 LGB) had gallstones at liver ultrasonography at 1 year postoperatively.

The data on weight, BMI, and percentage of excess weight loss are presented in Table 1. The mean weight, BMI, and percentage of excess weight loss in the LGBTV versus LGB alone groups were not significantly different statistically at 12 or 18 months after surgery by paired and group means analysis. Co-morbidity improvement/resolution was found in all patients at 1 year of follow-up, except for the single male patient with diabetes mellitus, who continued to require oral antidiabetic agents with a decrease in BMI from 38 to 30 kg/m^2. Belching, bloating, dumping, and diarrhea were not found in the LGB group but were recorded in the LGBTV group at 3, 6, 12, and 18 months (Fig. 1).

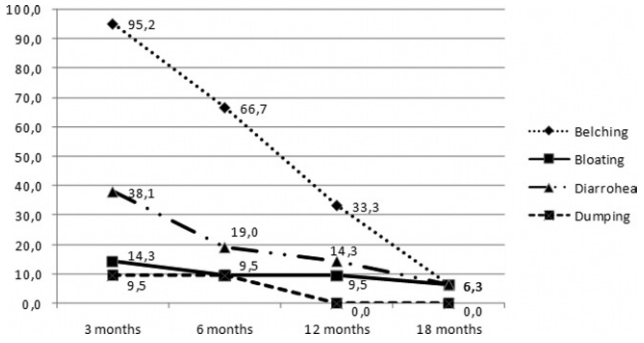

Fig. 1. Percentage of patients from LGBTV group presenting with symptoms and their evolution over time.

Band adjustment was not required in 10 (50%) of 20 patients with LGBTV compared with 5 (20%) of 25 patients with LGB at 6 months of follow-up (P = .034). At 12 months, 7 (35%) of 20 LGBTV patients and 2 (8%) of 25 LGB patients still did not require band adjustment (P = .024).

Discussion

TV was frequently performed in the past for the treatment of peptic ulcer disease, when it was generally combined with gastric drainage operations such as pyloroplasty or gastrojejunostomy. Recently, TV has been proposed for the treatment of perianastomotic peptic ulcers after gastric bypass for obesity. Other than the classic use of vagal resection to decrease acid secretion, Kral [4] was the first to report on the performance of TV in humans for the treatment of obesity. The early results of his clinical experience using the operation as a stand-alone procedure by way of laparotomy were modest, and the procedure did not gain diffusion in the bariatric surgical community. More recent data have demonstrated that in some patients the weight loss was very durable [10]. More interesting data were obtained when TV was combined with vertical banded gastroplasty, producing a statistically significant greater reduction in the BMI compared with vertical banded gastroplasty alone at ≥5 years of follow-up: 14.2 kg/m^2 versus 7.2 kg/m^2, respectively (P < .001) [5]. A similar difference has been maintained for a mean 20 years with no difference in mortality [10].

The laparoscopic and thoracoscopic techniques of TV for ulcer disease were initiated in Europe shortly after the clinical introduction of minimally invasive surgery [11,12]. Laparoscopic TV alone and laparoscopic TV in association with LGB for the treatment of obesity were only recently reported in the United States [13,14]. We independently developed the laparoscopic technique of TV plus LGB in 2005 on the basis of our substantial clinical experience with laparoscopic surgery of the gastroesophageal junction [15]. Technically, the operation appeared quite simple and uneventful. The vagotomy side effects were few and minor

and well tolerated by the patients. They had almost completely disappeared within 2 years after the procedure in the 11 patients studied to date (not shown).

The patients who underwent LGBTV required significantly fewer band adjustments and reported less "hunger" and more fullness at 6 and 12 months postoperatively. The limitations of this study included our learning curve with the laparoscopic technique of TV without an extended search for nerve fibers, the lack of intraoperative or postoperative testing of the completeness of the resection, the learning curve for the selection and treatment of those undergoing TV, the small numbers of patients, and the short follow-up period.

Conclusion

The interim results of this 5-year prospective randomized clinical study have demonstrated that adding TV to LGB does not cause specific morbidity, mortality, or debilitating or unpleasant long-lasting side effects compared with LGB alone. The small difference in weight loss in favor of the LGBTV group at 18 months and 2 years has not reached statistical significance. In the short-term, TV added to LGB significantly decreased the number of patients requiring band adjustments during the first postoperative year.

Acknowledgments

The authors wish to thank Professor John Kral for his invaluable guidance and support to start and realize the entire project.

Disclosures

The authors claim no commercial associations that might be a conflict of interest in relation to this article.

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