

Superior Weight Loss With Patient-Driven, Fluoroscopically Guided Band Adjustment Following Laparoscopic Adjustable Gastric Banding

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ABSTRACT

Background: Laparoscopic adjustable gastric banding has led to variable weight loss results in the United States. We believe a patient-driven, fluoroscopically guided method of band adjustments results in the most successful weight loss.

Methods: Between November 2001 and October 2003, 248 patients underwent laparoscopic adjustable gastric banding. Patients underwent band adjustments when consuming solid food, not sensing satiety, and not experiencing regular weight loss. Adjustments were done under fluoroscopic guidance. Data were collected at the time of adjustments and through periodic telephone interviews.

Results: Weight loss data are available for 141 patients with a minimum of 6-month follow-up. Patients were divided into 3 groups by length of follow-up: 6 to 12 months, 12 to 18 months, and 18 to 23 months. Mean preoperative weight and body mass index for all 141 patients were 144.4 kg (range, 92.3 to 214.1) and 50.9 kg/m² (range, 35.6 to 73.8), respectively. Following a mean of 4.1 (range, 0–10) adjustments, percentage excess weight loss was 35.3% (range, -2.1 to 81.0), 44.4% (range, 13.6 to 98.9), and 52.1% (range, 13.3 to 80.1) for the 6 to 12, 12 to 18, and 18 to 23 month follow-up periods, respectively.

Conclusions: Our data suggest that patient-driven band adjustment results in superior weight loss. Additionally, fluoroscopic guidance may optimize the result of each adjustment and minimize the incidence of adjustment-related complications.

Key Words: Laparoscopic adjustable gastric banding, Band adjustment, Fluoroscopy.

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INTRODUCTION

Although much discussion has centered around the appropriate technique for performing laparoscopic adjustable gastric banding (LAGB) and has led to modifications to reduce postoperative complications, less information is available regarding the ideal method for postoperative management of the band. Optimal weight loss following LAGB is highly dependent on follow-up band adjustments. A variety of methods have been reported for band adjustment protocols. They range from regularly scheduled adjustments with predetermined volumes of saline, to patient-driven fluoroscopically guided adjustments.^{1–6} Timing between adjustments ranges from a few weeks to several months.³ We propose that patient-driven, fluoroscopically guided band adjustment performed during cine-esophagography obtains optimal restriction while reducing the incidence of overtightening. This likely results in less postadjustment dysphagia and esophageal and pouch dilation. Fluoroscopy is also likely to eliminate injury to the subcutaneous reservoir during band adjustments.

METHODS

Between November 2001 and October 2003, 248 patients underwent LAGB at Loyola University Medical Center. All procedures were performed using the pars lucida technique. The 10-cm Lap-Band device (Inamed, Santa Barbara, CA) was implanted in all patients. The bands were left unfilled at the end of the procedure. Patients were discharged on a liquid diet, which was slowly advanced over the following 4 weeks to 6 weeks. Patients were seen for band adjustments on an as needed basis with a minimum 6-week interval from the date of surgery. Criteria for adjustment were based on the patient consuming solid food, not sensing satiety, and not experiencing regular weight loss. Fluoroscopic guidance was utilized for both port access and during oral ingestion of contrast to allow for optimal band tightness. A thin stream of barium passing through the band, appropriate hold-up above the band, and no significant reflux of barium from the gastric pouch into the proximal esophagus are considered components of an ideal study. The volume of saline instilled was determined by the appearance of the flow of contrast

during fluoroscopy. Any esophageal or pouch dilatation seen on contrast study prompted complete removal of all saline from the band and follow-up evaluation in 2 weeks to 4 weeks. Follow-up appointments for band adjustments are made based on the aforementioned criteria of consuming solid food, not sensing satiety, and not experiencing regular weight loss. Patients had their bands adjusted as often as necessary to obtain adequate restriction and to achieve ideal weight loss.

Weight loss data were collected prospectively at the time of adjustment and through follow-up telephone interviews. All patients who had a band in place at the time of this report were included in the analysis.

RESULTS

Seven (2.8%) patients had their bands removed laparoscopically, 3 for band slippage, 1 for early band erosion, 1 for gastric strangulation, 1 for conversion to gastric bypass, and 1 per patient request. These patients were excluded from weight loss data analysis. Of the remaining 241 patients, 141 patients had a minimum of 6-month follow-up and were included in the following analysis of data. The average age of the patients was 42 years (range, 18 to 71). Thirty patients were male (21%); 111 were female (79%). Mean preoperative weight and body mass index (BMI) for all 141 patients were 144.4 kg (range, 92.3 to 214.1) and 50.9 kg/m² (range, 35.6 to 73.8), respectively. Mean postoperative BMI and percentage excess weight loss (%EWL) were 40.9 kg/m² and 40.0%, respectively, with a mean follow-up of 11 months.

Patients were further divided into 3 groups according to the length of follow-up: 6 to 12 months, 12 to 18 months, and 18 to 23 months. There were 85 patients with 6 to 12 months of follow-up. Patients in this group underwent a mean of 3.3 (range, 1 to 10) adjustments. There were 36 patients with 12 to 18 months of follow-up. Mean number of adjustments for this group was 4.7 (range, 1 to 10). Twenty patients had 18 to 23 months of follow-up and underwent a mean of 6.6 (range, 4 to 10) adjustments. Percentages of excess weight loss were 35.3% (range, -2.1 to 81.0), 44.4% (range, 13.6 to 98.9), and 52.1% (range, 13.3 to 80.1) for the 6 to 12 month, 12 to 18 month, and 18 to 23 month follow-up periods, respectively. Follow-up BMIs were 42.3 kg/m² (range, 27.8 to 65.3), 39.3 kg/m² (range, 25.2 to 54.0) and 37.9 kg/m² (range, 29.1 to 48.5) for the 6 to 12 month, 12 to 18 month, and 18 to 23 month follow-up groups, respectively.

Nine (3.6%) band slippages occurred in 7 patients. Six of

these slipped bands were revised laparoscopically and 3 were removed, 2 for recurrent band slippages and 1 per patient request. One (0.4%) early band erosion occurred necessitating band removal. Eleven (4.4%) port revisions were necessary, 9 for catheter leakage, 1 for flipped port, and 1 for a malfunctioning port. At least 2 of the catheter leaks were thought to be iatrogenic in nature secondary to injury to the catheter during port access. These 2 catheter injuries occurred before routine use of fluoroscopy for port access. No postadjustment band erosions, port-site infections, or port injuries occurred. The average band adjustment (time from one patient to the next) is estimated as 10 minutes.

DISCUSSION

Band adjustment is a critical component in the success of LAGB. Methods described include simple filling of the band without any radiologic guidance, the use of fluoroscopy, the possibility of a combination of both, and even the use of dynamic radio isotopic scintigraphy using radiolabeled yogurt.^{1,3-10} Favretti et al¹¹ described a method of adjustment in the office without any radiological guidance based solely on patient symptomatology. This does not afford the opportunity to individualize the volume of fluid added or removed from the band. The authors claim that this method of adjustment is simple, quick, and effective. They caution, however, that the office-based adjustment protocol could possibly lead to missed complications, and they go on to further recommend individualized use of radiographically guided adjustments as a method to identify and treat complications, such as esophageal or pouch dilatation, band erosion as well as stomal obstruction.¹¹

LAGB was approved for use in the United States by the Food and Drug Administration (FDA) in June 2001. To date, limited data are available on postoperative management of patients undergoing LAGB in the US. The initial US experience has been criticized for reporting suboptimal weight loss results compared with weight loss results reported in international studies.⁴ However, review of the adjustment methods used in the FDA "A" clinical trial demonstrates that adjustments were made every 3 months to 6 months, according to radiologic band lumen diameter.³ In some patients, bands were tightened even when esophageal dilatation was noted on preadjustment contrast studies.¹ It is felt that this practice led to overaggressive band tightening and possibly resulted in the high rate of complications of pouch and esophageal dilatation and poor weight loss (34.5% and 37.8% EWL at 12 and 24

months).^{3,7} Subsequent adoption of methods utilized by international surgeons who perform adjustments based on patient appetite and weight loss has resulted in improved results. Rubenstein et al⁵ reported their 3-year follow-up experience in 63 patients from the FDA “B” trial with average %EWL of 27.2% at 6 months, 38.3% at 1 year, 46.6% at 2 years, and 53.6% at 3 years. Band adjustments in this study were performed with the routine use of fluoroscopy to evaluate for the adequacy of the adjustment. However, the authors did not mention whether adjustments were on a predetermined schedule, based on patient symptomatology or whether the volume of saline used was adjusted based on the fluoroscopic findings.⁵ Ren et al³ also reported excellent weight loss results with %EWL of 35.6% at 9 months and 41.6% at 12 months using similar techniques of band adjustments.

We report similar results with our method of patient-driven band adjustment frequency. Percentage EWLs in our study of 35.3%, 44.4%, and 52.1% for the 6 to 12 month, 21 to 18 month and 18 to 23 month follow-up patients are comparable to those reported by international studies.^{12–14} Individualized band adjustment based on fluoroscopic guidance is likely to reduce the number of subsequent patient visits for additional tightening of a loose band or removal of fluid from a band in a patient with dysphagia. Additionally, the routine use of cine-esophagography at the time of band adjustments allows early detection of complications, such as esophageal and pouch dilatation or band slippage. Many of these early signs can be addressed by removing fluid from the band and reevaluation in 2 weeks to 4 weeks for follow-up contrast study, thus potentially reducing long-term complications. The complication rates in our study requiring repeat operative interventions are acceptable and consistent with reoperation rates reported in international studies. Additionally, the use of fluoroscopy has prevented injury to the port or catheter during port access. We experienced 2 such injuries during our first 100 patients who had adjustments done without the benefit of fluoroscopy. With the ability to direct the needle into the port under radiologic guidance, inadvertent puncture or laceration of the port or catheter is avoided. Finally, any leak in the system due to port malfunction is easily detected during fluoroscopic examination. If we are unable to draw back fluid or if no change occurs in the appearance of the flow of oral contrast through the band with inflation, injectable contrast is infused through the port. Extravasation of contrast and point of leakage are easily identified, leading to port revisions performed as outpatient surgery as necessary.

CONCLUSION

Our data suggest that patient-driven band adjustment results in superior weight loss. In addition, fluoroscopic guidance may optimize the result of each adjustment and minimize the incidence of adjustment-related complications. Prospectively randomized studies may further support these results.

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