

Research Articles

Outpatient Laparoscopic Adjustable Gastric Banding in Super-obese Patients

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Background: Laparoscopic adjustable gastric banding (LAGB) is a safe and effective treatment for morbid obesity that is well suited to outpatient surgery. Super-obese patients (BMI ≥ 50) are often viewed as higher risk patients, with their surgical procedures limited to hospital operating-rooms. We report our experience performing LAGB for super-obese patients in a freestanding ambulatory surgery center and describe the program elements that make this feasible and safe.

Methods: Database records containing 1,780 consecutive patients from program inception (November 2002 to November 2006) were searched for patients with a BMI >49.9 undergoing an outpatient LAGB and reviewed to identify complications.

Results: 320 super-obese patients underwent an outpatient LAGB. Mean preoperative weight was 155.2 kg (range 112.3-220.5 kg), and mean BMI was 55.4 kg/m² (range 50.0-71.1 kg/m²). 53 patients (16.6%) had BMI >60 . There were no deaths, significant cardiopulmonary complications, significant intraoperative bleeding, conversion to open laparotomy, or hospital admissions. 3 patients (0.1%) developed gastric edema causing transient obstruction, and 1 developed a delayed colon perforation from electrocautery incurred during adhesiolysis. No complication arose or was more difficult to manage as a result of the procedure being done on an outpatient basis.

Conclusions: Outpatient LAGB can be safely performed in super-obese patients with a complication rate similar to lower BMI patients. Patient selection and preoperative preparation are essential to achieve excellent outcomes. The decision to offer an outpa-

tient LAGB should rest on the overall physiological condition rather than BMI or weight alone.

Key words: Gastric banding, morbid obesity, Lap-Band, laparoscopic adjustable gastric banding, super obesity, outpatient surgery

Introduction

Laparoscopic adjustable gastric banding (LAGB) is a safe and effective treatment for morbid obesity, providing durable weight loss, health benefits and improved quality of life. For a variety of reasons including its low risk profile, LAGB is well suited to the outpatient surgery setting. The operation is generally completed in under 1 hour, does not involve a GI anastomosis, is performed laparoscopically, has a short post-anesthesia recovery time, and is well tolerated by patients. We have previously reported our early experience with performing LAGB as an outpatient procedure,¹ and have increasingly preferred the outpatient setting for this operation. We have now placed over 1,947 LAGBs, 1,610 (82.7%) of which have been performed in an outpatient facility. The ambulatory surgery setting can have several advantages over inpatient surgery, including significant cost reduction, increased efficiency, a specialized care environment specifically designed for obese patients, increased patient satisfaction, and decreased complications. As a result, our current

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preference is to perform LAGB in the outpatient setting for all appropriate patients, provided that the operation can be accomplished safely.

Super-obese patients (body mass index [BMI] ≥ 50) have often been viewed as higher risk surgical patients irrespective of the type of operation being performed. Surgical procedures in this group of patients have often been limited to hospital operating-rooms, and these patients have been denied the opportunity to have their operation performed in an ambulatory surgical center solely on the basis of their weight. As our bariatric program matured and our team developed increasing experience with higher BMI patients, we began to offer LAGB to our super-obese patients in an appropriately staffed and equipped ambulatory surgical center. We believe that the keys to successfully performing outpatient laparoscopic gastric banding in super-obese patients are appropriate patient selection, patient preparation (especially preoperative weight loss), a well-equipped facility, and an experienced, dedicated bariatric team. We report our experience with performing LAGB for super-obese patients in a freestanding ambulatory surgery center setting, and describe the elements of our program that are important in making this feasible and safe.

Materials and Methods

Database records containing all 1,780 consecutive patients undergoing LAGB between program inception (November 2002) and November 2006 were searched to identify those patients with a BMI >49.9 kg/m² whose operation was performed in an ambulatory surgery center. This identified 320 (22.1%) such super-obese patients. Fifty-three (16.6%) of these patients had a BMI >60 (super-super obese). We reviewed these data records to identify the incidence of intraoperative and perioperative complications that might be difficult to manage in an outpatient facility. These included difficult airway or intubation management, anesthetic complications, conversion to open laparotomy (for hepatomegaly, bleeding, or visualization difficulties), significant intraoperative bleeding requiring transfusion, long operative times, postoperative stoma obstruction/gastric edema, and transfer/admission to the hospital. Late complications are also reported, although they are very

unlikely to be related to operative location (hospital vs ambulatory surgery center).

Standard NIH criteria were used as a guideline in patient selection for weight loss surgery,² and all patients underwent LAGB. Preoperative excess body weight was calculated as the amount in kg $>$ BMI 25 kg/m².³ All patients underwent a comprehensive preoperative evaluation, and all co-existing medical conditions were optimally controlled with particular emphasis on hypertension, asthma, and diabetes. Patients were selectively referred for additional testing or specialty consultation only as indicated by their medical history and physical examination, not as a routine practice. For example, patients with preexisting cardiac disease or those with symptoms of possible heart disease were referred for preoperative cardiology clearance and possible echocardiogram and/or nuclear stress testing. Although shortness of breath on exertion is common in the super-obese population, pulmonary function testing was only requested in patients whose dyspnea was severe and considered out of the ordinary for their weight. Super-obese patients are at particularly high risk for obstructive sleep apnea, and identification and preoperative treatment of patients with moderate to severe sleep apnea is important in preventing perioperative airway and cardiopulmonary complications. Sleep apnea screening was required for all patients with witnessed apnea or Dixon's BASHIM score >3 ,⁴ and patients with significant sleep apnea were treated with continuous positive airway pressure (CPAP).

Three experienced surgeons placed all of the laparoscopic adjustable bands (LAP-BAND System, Inamed/Allergan, Irvine, CA) using a standardized method as previously described.¹ All patients received 5000 units unfractionated heparin subcutaneously within 1 hour prior to anesthesia induction, and pneumatic compression devices were placed on the lower extremities for deep vein thrombosis (DVT) prophylaxis. We also recommended that patients discontinue all estrogen-containing medications 1 month before surgery. The band was placed using the pars flaccida technique in all cases.⁵

A dedicated team of three outpatient anesthesiologists administered all anesthetics in a standardized fashion as previously described.¹ The importance of the anesthetic management of the super-obese patient cannot be over-emphasized. Issues involving

difficult airways are anticipated in advance, and a wide array of devices and techniques are available for instantaneous use. A full range of anesthesia equipment is immediately available to manage the difficult airway, including a variety of laryngoscope blades, Eschmann stylets, intubating and standard laryngeal mask airways (LMAs), and a fiberoptic bronchoscope. This equipment is organized in a standard difficult airway cart that is always available in the operating-room. Surgeons, anesthesiologists, and recovery room nurses are committed to using pain control strategies that eliminate or at least minimize the need for narcotic analgesics. Local infiltration of the incisions with a long-acting local anesthetic (bupivacaine), the intraoperative use of small doses of ketamine, non-steroidal analgesics, and anti-inflammatory steroids all play a role in this area. The anesthetic technique also used multiple modalities to prevent postoperative nausea and vomiting, including the scopolamine patch, ondansetron, and dexamethasone. Together, this allowed excellent postoperative pain control with minimal postoperative nausea.

A barium esophagram is not performed routinely before discharge, but fluoroscopy is readily available and can be performed selectively if dysphagia to liquids occurs. Patients were typically discharged within 2 hours of completion of the operation, were contacted by phone the following day, and returned to the office in 1 to 2 weeks for a routine check. Our postoperative management has been previously described.⁶

All operations were performed in one of two ambulatory surgical centers that are equipped to safely manage high BMI patients and meet the standards outlined by the American College of Surgeons for facilities performing bariatric surgery.⁷ One of these is a single specialty center specializing in the treatment of morbidly obese patients (Northwest Weight Loss Surgery). Most of our equipment has a 227.2 kg weight limit, including chairs, floor-mounted toilets, wheelchairs, and stretchers. The operating tables can accommodate patients weighing up to 500 kg. Patients are transferred from the operating table to a gurney for transport to the recovery area using a HoverMatt (HoverTech International, Bethlehem, PA). Patients otherwise walk themselves to the operating-room, from the recovery gurney to a recliner for secondary recovery, and from the recliner to their car on discharge from the center.

Patients were considered for an outpatient LAGB if after health screening and surgical consultation they had no specific contraindications to outpatient surgery, and were deemed appropriate candidates. Our specific contraindications have been published previously, and include significant cardiopulmonary impairment and co-morbidity, inadequately controlled significant co-morbid conditions, significantly impaired mobility (wheelchair, etc), and patients living alone without access to support.¹ We do not consider appropriately treated sleep apnea to be a contraindication to outpatient surgery. The decision whether to offer outpatient surgery to a particular patient remains a clinical judgment that evolves as the program, surgeon and anesthesiologist acquires experience safely managing higher BMI patients, but is ultimately not based solely on patient weight or BMI alone.

Results

Database screening identified 320 super-obese patients who underwent outpatient placement of a LAGB. Of these, 261 (81.6%) were female and 59 (18.4%) were male with a mean age of 45.0 years (range 19-69). Mean preoperative body weight was 155.2 kg (range 112.3-220.5 kg), mean preoperative BMI was 55.4 kg/m² (range 50.0-71.1 kg/m²), and mean preoperative excess weight was 85.1 kg (range 56.1-141.4 kg). Fifty-three patients (16.6% of total) had a BMI >60. Mean BMI decreased to 42.0 kg/m² at 1 year (79.1% follow-up), 39.2 kg/m² at 2 years (64.3% follow-up) and 34 kg/m² at 3 years. Mean percent excess BMI loss was 44.0% at 1 year and 51.1% at 2 years.

All patients in this series had their procedure completed in a freestanding ambulatory surgery center and were discharged the same day. Other super-obese patients in our program had their LAGB procedure performed in the hospital operating-room during the study period and often were discharged the day of surgery, but these patients were not included in this series. The LAGB procedures were performed in the hospital operating-room for those patients with contraindications for outpatient surgery as described above or for insurance coverage reasons. Average operating time was 54.4 minutes (range 32-97) in

super-obese patients (BMI >50) compared to 52 minutes in our patients with a BMI <50. No patient required postoperative admission to the hospital.

A 10-cm band was placed in 127 cases (39.7%) and the larger Vanguard (VG) band was placed in 193 cases (60.3%). The VG band was preferred in patients with thicker perigastric or visceral fat around the gastric cardia and was commonly used in males and patients with diabetes. In 17 (5.3%), a significant hiatal hernia was encountered and repaired by reducing the stomach into the abdomen, dividing peritoneal attachments as needed and reapproximating the diaphragmatic crura posterior to the esophagus with interrupted 2-0 Ethibond suture (Ethicon Surgery, Cincinnati, OH) at the time of band placement.⁸

Intraoperative and Perioperative Complications

General endotracheal anesthesia was successfully administered to all patients in a standardized fashion by a dedicated team of anesthesiologists as previously described. No patient required awake intubation to manage a difficult airway. Rarely, patients with a tendency toward obstructive apnea were initially extubated to a laryngeal mask airway (LMA) until more fully awake. Patients with sleep apnea were instructed to bring their CPAP machine with them to the surgical center. While CPAP was rarely needed in the recovery room, sleep apnea patients were explicitly instructed to continue use of the device at home while sleeping during the postoperative period. There were no significant intraoperative or postoperative anesthetic complications.

There were no deaths or significant cardiopulmonary complications. No patient required transfer to the hospital for admission, and no patient experienced significant intraoperative bleeding or required blood transfusion. There were no conversions to open laparotomy and no patient developed a lower extremity DVT or pulmonary embolus. All operative times were considered reasonable for an outpatient procedure, and patients were typically discharged from the center within 2 hours. This was not significantly different from the patients whose BMI was <50 kg/m².

Postoperative stoma occlusion or gastric edema causing transient obstruction to ingestion of liquids occurred in three patients (0.1%). Obstruction was

usually recognized in the post-anesthesia recovery area prior to discharge, when the patient experienced dysphagia or regurgitation when swallowing liquids and was evaluated with a barium esophagram. In this series, stoma occlusion occurred exclusively in patients implanted with a 10-cm band, and the incidence of this complication has decreased with the availability of the VG band. Patients with stoma occlusion were treated with daily outpatient IV hydration until the occlusion resolved (3-14 days), although the option of replacing the 10-cm band with a VG band was always available to patients if they preferred immediate replacement. One patient developed an upper extremity venous thrombosis secondary to a peripherally inserted central line placement that resolved with a period of anticoagulation without sequelae. To date, no patient has developed aspiration pneumonia as a result of stoma occlusion treated with simple IV hydration.

One patient was admitted to the hospital 2 days following an apparently uneventful outpatient Lap-Band placement with a delayed transverse colon perforation secondary to an electrocautery injury incurred during adhesion takedown to allow band placement. The perforation was closed and the band explanted. The patient recovered uneventfully.

Late Complications

Late complications occurred in 10 patients (3.1%), a rate lower than our entire patient population. These included one slipped band (0.3%), two eroded bands (0.6%), and seven port problems (2.2%) requiring port repositioning or port replacement for port or tubing leak. The slipped band was repositioned laparoscopically during a subsequent outpatient procedure. Port complications have been easily treated with an outpatient procedure performed under local anesthesia. One patient developed a port infection that required port removal and delayed port replacement. Two older patients presented 1.9 and 1.7 years after band placement with eroded bands that were treated with band explantation and they are awaiting band replacement. These have been the only band erosions in our entire cohort of 1,947 patients. All patients with complications have recovered fully. No complication developed as a result of performing the procedure in an outpatient

setting, and none of the complications that did develop were more difficult to manage because the procedure was performed on an outpatient basis.

Discussion

This study shows that with careful planning and management, outpatient laparoscopic gastric banding can be safely performed in super-obese patients with a low complication rate that is similar to what we have observed in lower BMI patients. Postoperative stoma obstruction or gastric edema occurred at a low rate, was easily managed with outpatient IV hydration, and can largely be avoided by placing a larger diameter VG band in susceptible patients. Complications that would be difficult to manage in an ambulatory surgery facility such as difficult airway or intubation management, anesthetic complications, conversion to open laparotomy for hepatomegaly, bleeding, or visualization difficulties, significant intraoperative bleeding requiring transfusion, long operative times, or transfer for admission to the hospital did not occur. This allowed the majority of our super-obese patients to take advantage of the benefits of our specialized outpatient LAGB program, and most of our patients are truly motivated to undergo the procedure in the outpatient setting.

Although all of our outpatient LAGB procedures are performed in a standardized manner designed to optimize outcomes and minimize complications, successful outpatient LAGB in super-obese patients requires particular attention to several key elements. These include appropriate patient selection and preparation, a fully equipped and prepared bariatric ambulatory surgery center, experienced bariatric anesthesiologists and anesthetic protocols, and a skilled, experienced OR team capable of reliably completing the LAGB procedure on average in ≤ 1 hour.

Patient selection is essential to achieve excellent outcomes in the super-obese patient population. The decision whether to offer a specific patient an outpatient Lap-Band procedure should rest primarily on the patient's overall physiological condition and ability to tolerate a general anesthetic rather than their BMI or weight alone. Patients with significant cardiopulmonary co-morbidity are more likely to require inpatient hospitalization and support services, and are

not candidates for an outpatient surgical procedure. In our program, these patients are aggressively treated and offered an inpatient operation where specialized support services such as an intensive care unit and specialty consultation are available.

As in any surgical procedure involving a general anesthetic, patient preparation is important in achieving a safe, low-risk operation. The spectrum of weight-related co-morbid conditions in bariatric patients is now well recognized. Preoperative screening for and optimal treatment of these conditions is an important part of preparing patients for outpatient bariatric surgery. It should not be assumed that the patient's primary care physician has always done this. However, we do not routinely obtain a battery of preoperative diagnostic tests on every bariatric surgery patient, but instead selectively request preoperative tests based on the patient's medical history and physical examination with the goal being to minimize the risk of the surgical event. Obstructive sleep apnea is common in super-obese patients, and is often unrecognized prior to the bariatric surgery consultation. Identification and preoperative treatment of patients with moderate to severe sleep apnea is important in preventing perioperative airway and cardiopulmonary complications. Once treated, however, we do not view sleep apnea as a contraindication to outpatient LAGB.

From a surgical point of view, preoperative weight loss significantly reduces the difficulty of the operation in super-obese patients by decreasing liver volume and markedly improving exposure of the gastroesophageal junction. This can generally be achieved by placing patients on a very low calorie, liquid protein diet (< 800 kcal/day) such as Medifast (Jason Pharmaceuticals, Inc., Owings Mills, MD) or Optifast (Novartis, Minneapolis, MD) for 2 to 4 weeks before the operation.^{9,10} Alternatively, some patients are able to lose 5-15 kg on a standard low calorie, low carbohydrate diet program. In our experience, preoperative weight loss has been a major advance in bariatric patient preparation, especially in super-obese patients, and has markedly reduced the problems associated with hepatomegaly, such as conversion to laparotomy for poor visualization, increased bleeding risk, and prolonged operative times.

Outpatient bariatric surgery requires a fully equipped ambulatory surgery center which has been carefully prepared to safely manage high BMI

patients. As the average weight of an ambulatory surgical patient has been steadily increasing, upgrading a center's capacity to care for obese patients will improve patient care and safety across all surgical specialties. Equipment size and weight limits should be appropriate for bariatric patients. Transport and transfer equipment capable of handling bariatric patients is necessary and will decrease staff injuries as well. Equipment to safely manage the bariatric difficult airway must be available to the anesthesiologist. High quality, high resolution laparoscopy equipment and long bariatric instruments are essential. A transfer agreement with a hospital that is equipped to care for bariatric surgery patients is important, even though transfer to the hospital was not necessary in this series of patients.

The anesthetic management of the super-obese patient is critically important in successfully performing outpatient LAGB in super-obese patients. Experienced anesthesiologists using anesthetic protocols that are optimized for outpatient bariatric surgery as described above are essential for achieving excellent outcomes. Particular attention must be paid to airway issues, use of short-acting anesthetic agents, avoiding postoperative nausea and vomiting, and pain control techniques which minimize the use of narcotics.

It is our impression that outpatient LAGB in super-obese patients should only be performed by a skilled, experienced team that is capable of reliably completing the LAGB procedure on average in about 1 hour. Total patient time at the ambulatory surgery center would average between 2 and 4 hours. This requires an experienced bariatric surgeon with advanced laparoscopic skills, able to efficiently manage surgical conditions common to the super-obese patient such as hepatomegaly and the "sea of fat". It also requires an excellent, experienced laparoscopic assistant and skilled anesthesiologists. Post-anesthesia recovery room nurses and other personnel must be experienced with recovering bariatric patients in an ambulatory surgery environment. This study demonstrates that in such a center, outpatient LAGB can be safely performed in

super-obese patients with excellent outcomes and a complication rate that is comparable to lower BMI patients. In such "centers of excellence", the decision whether to offer a particular patient an outpatient LAGB should be based on overall physiologic condition, rather than BMI or weight alone.

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