

Analysis of Reoperations After Laparoscopic Adjustable Gastric Banding

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ABSTRACT

Background and Objectives: Laparoscopic adjustable gastric banding is considered the least invasive surgical option for the treatment of morbid obesity. Its initial popularity has been marred by recent long-term studies showing high complication rates. We sought to examine our experience with gastric banding and factors leading to reoperation.

Methods: We reviewed retrospective data of 305 patients who underwent laparoscopic adjustable gastric banding between 2004 and 2011 at a single institution, 42 patients of whom required a reoperation, constituting 13.8%. Patients undergoing elective reoperations for port protrusion from weight loss as a purely cosmetic issue were excluded (n = 10). Patients' demographic data, weight loss, time to reoperation, and complications were analyzed.

Results: Of 305 patients, 42 (13.8%) required reoperations: 26 underwent band removal (8.5%) and 16 underwent port revision (5.2%). The mean weight and body mass index for all patients who underwent reoperations were 122.6 kg and 45.0 kg/m², respectively. The most common complication leading to band removal was gastric prolapse (n = 14, 4.6%). The most common indication for port revision was a nonfunctioning port (n = 10, 3.3%).

Conclusion: Laparoscopic adjustable gastric banding was initially popularized as a minimally invasive gastric-restrictive procedure with low morbidity. Our study showed a 13.8% reoperation rate at 3 years' follow-up. Most early reoperations (<2 years) were performed for port revision, whereas later reoperations (>2 years) were likely to be performed for band removal. Laparoscopic adjustable gastric banding is associated with high reoperation rates; therefore bariatric surgeons should carefully consider

other surgical weight-loss options tailored to the needs of the individual patient that may have lower complication and reoperation rates.

Key Words: Gastric band, Complications, Reoperation.

INTRODUCTION

Laparoscopic gastric banding (LAGB) was first approved by the Food and Drug Administration in 2001.¹ In the following decade, it became the most popular surgical weight-loss procedure among morbidly obese individuals.² It was considered a breakthrough in bariatric surgery because of its minimal invasiveness, reversibility, and adjustability.³

Recently, long-term outcomes have shown a high complication rate associated with LAGB, forcing many surgeons to shun the procedure.⁴ Reoperation rates range from 16% to 60% and have been shown to increase proportionally with time.⁵⁻⁷ Reported complications include band prolapse, erosion, intractable nausea and vomiting, dysphagia, insufficient weight loss, port malfunction, and the need for a revisional weight-loss procedure after failure.⁸

Despite published complications, studies as recent as 2012 continue to support LAGB as the initial surgical procedure in patients with morbid obesity.⁹ We sought to examine our complication rate and the most common reasons for reoperation after LAGB. Given its reoperation rate, should LAGB be deemed an archaic procedure?

METHODS

We retrospectively analyzed all patients who underwent LAGB at a single university-affiliated teaching institution from 2004 through 2011. Patients who underwent LAGB as a primary operation and subsequently required a reoperation because of a complication or port issue were included in the study. All surgical procedures, including laparoscopic gastric band placement and reoperation, were performed by 1 of 2 bariatric surgeons who completed a minimally invasive bariatric surgery fellowship. Patients undergoing elective reoperations for port protrusion

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DOI: 10.4293/JSLS.2014.00210

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sion from weight loss as a purely cosmetic issue were excluded (n = 10). These procedures were deemed elective and excluded to avoid falsely elevating the reoperation rate limited to medical reasons.

A combination of the Lap-Band VG and AP systems (Allergan, Irvin, California), as well as the Realize-C band (Ethicon, Somerville, New Jersey), were used for all 305 LAGB procedures performed, including the 42 patients requiring a reoperation. The pars flaccida approach was used in the placement of all bands. This technique entailed opening of the lesser omentum, dissection at the base of the right crus, and creation of a retrogastric channel around which the band was placed. All hiatal hernia repairs found intraoperatively were repaired primarily with permanent suture. The injection port was secured to the anterior rectus sheath and muscle with nonabsorbable suture for the Lap-Bands and with a self-clamping mechanism for the Realize-C band. All bands were placed as elective procedures, and patients were discharged home on the same operative day. The bands were not filled intraoperatively, and upper gastrointestinal contrast studies were not routinely performed before discharge.

Data collected included age, sex, weight, body mass index (BMI), average weight loss expressed as a percentage of total weight loss, and reason for reoperation. Preoperative BMI (in kilograms per square meter) was categorized based on the World Health Organization's International BMI Classification of overweight and obesity in adults as follows: overweight/preobese, BMI of 25.00 to 29.99 kg/m²; obese class I (severe obesity), 30 to 34.99 kg/m²; obese class II (morbid obesity), 35.00 to 39.99 kg/m²; and obese class III (super obese), ≥ 40 kg/m². Average weight loss after surgery was further classified as patients with a percent total weight loss between 0% and 10%, between 11% and 20%, between 21% and 30%, between 31% and 40%, or between 41% and 50%. The length of time to reoperation was divided as follows: 1 to 12 months, 13 to 24 months, 25 to 36 months, and ≥ 37 months.

Factors requiring reoperation comprised 4 categories: prolapsed band with or without obstruction, reflux and dysphagia, poor weight loss, and gastric erosion. Indications for port revision included port malfunction, malrotation of the port, and other. The "other" category included port infection, port-site hernia, and chronic abdominal pain stemming from the presence of the port itself. Port malfunction was defined as accessibility without the ability to fill or deflate the band.

We further distinguished "emergent" from "elective" cases based on whether the patient presented in acute distress

Table 1.
Demographic Variables of Patients Requiring Reoperation After Laparoscopic Adjustable Gastric Banding

Variable	Band Removal Group	Port Revision Group
Mean age, y	48.7 \pm 8.8	47.8 \pm 7.9
Gender, n		
Male	5	2
Female	21	14
Common comorbidities/ conditions, ^a n		
Hypertension	12	10
Hyperlipidemia	4	5
Diabetes mellitus	4	8
Gastroesophageal reflux	5	7
Cardiac disease	2	2
Pulmonary disease	3	5
Prior abdominal surgery	11	4
Psychiatric diagnosis	5	2

^aCommon comorbidities/conditions are exclusive of each other.

through the emergency department or the patient underwent a procedure that was scheduled in advance and presented through the same-day surgery center.

RESULTS

Demographic Data

Three hundred five laparoscopic adjustable gastric bands were placed at our institution between 2004 and 2011. Of these patients, 42 required a reoperation for band removal (n = 26) or port revision (n = 16). The reoperation group comprised 35 women and 7 men, with an overall mean age of 48.4 \pm 8.4 years (range, 28–66 years).

The band removal group comprised 21 women and 5 men, with an overall mean age of 48.7 \pm 8.8 years. Port revision was performed in 14 women and 2 men, with an overall mean age 47.8 \pm 7.9 years. Most of the patients who underwent reoperations were women. Common medical comorbidities in this patient population included hypertension, hyperlipidemia, diabetes mellitus, and psychiatric disorders, among others (**Table 1**).

Table 2.
Laparoscopic Band Type Versus Number of Reoperations

Laparoscopic Band Type	Band Removals, n	Port Revisions, n	No. of Bands Placed	Overall Reoperation Rate, ^a %
Lap-Band AP or VG	19	12	231	13.4
Realize-C	7	4	74	14.9

^aThe reoperation rate was calculated by dividing the sum of reoperations for each band type by the total number of bands of that type placed (eg, [19 + 12]/231 for Lap-Band).

Band Type

Of 305 bands placed during the period of study, 231 were Lap-Band VG or AP systems and 74 were Realize-C bands. The particular Lap-Band used, either VG or AP, was not always specified in the patients' operative reports, and we therefore do not distinguish between these further. Our institution saw a shift toward the implantation of Realize-C bands toward the latter part of 2009 based on surgeon preference. Among the 26 reoperations performed for band removal, Lap-Bands were removed in 19 and Realize-C bands were removed in 7. Among the 16 reoperations performed for port revision, 12 were Lap-Band cases and 4 were Realize-C band cases. The overall reoperation rate for the Lap-Band AP or VG was 13.4%, whereas that for the Realize-C band was 14.9% (**Table 2**).

Body Mass Index

The mean preoperative BMI was 45.1 kg/m² (range, 31–65 kg/m²) for all 42 patients who underwent reoperations. None of the patients were categorized as preobese or obese class I, whereas 8 patients (19%) were obese class II, with 6 patients (14.3%) requiring reoperation for band removal and 2 patients (4.7%) requiring reoperation for port revision. The overwhelming majority of our patients were classified as obese class III, comprising 34 patients (81% of the study population). In this group 20 patients (47.7%) required band removal and 14 (33.3%) required port revision (**Table 3**).

Weight Gain

The mean preoperative weight was 122.6 kg (range, 74.4–164 kg) for all 42 patients who underwent reoperations. Among these patients, the mean preoperative weight was 126 kg in those who underwent band removal versus 117 kg in those who underwent port revision. After LAGB, 5 reoperation patients (11.9%) gained weight and the weight of 1 patient (2.4%) remained unchanged. These patients gained an average of 7.3 kg. This average, however, was

skewed by the weight of 1 patient who gained 20.4 kg postoperatively. Excluding this outlier resulted in an average weight gain of 2.9 kg for the remaining 4 patients in this group. Weight gain or lack of weight loss may be attributed to noncompliance with postoperative care, including failure to attend follow-up band adjustments or support groups or failure to adhere to a proper diet. Weight gain is represented in our study as 0% weight loss (**Table 4**).

Weight Loss

Thirty-six reoperation patients had an estimated 19.4% total weight loss after their original procedure; the remaining 6 patients undergoing reoperation either gained weight or lost no weight. The band removal group had an average of 23.0% total weight loss compared with 13.7% total weight loss in the port revision group. This finding could be attributed to the fact that reoperations for port revision occurred earlier whereas those for band removal occurred later.

Weight lost was categorized into 5 groups based on percent total weight loss: 0% to 10% (n = 13), 11% to 20% (n = 10), 21% to 30% (n = 8), 31% to 40% (n = 7), and 41% to 50% (n = 4). In the group with 0% to 10% total weight loss, 6 patients (14.3%) underwent band removal whereas 7 (16.7%) underwent port revision. In the group with 11% to 20% total weight loss, 4 patients (9.5%) underwent band removal and 6 (14.3%) underwent port revision. In the group with 21% and 30% total weight loss, 7 patients (16.7%) underwent band removal whereas 1 (2.4%) underwent port revision. In the group with 31% to 40% total weight loss, 5 patients (12.0%) underwent band removal and 2 (4.8%) underwent port revision. Lastly, in the group with 41% to 50% total weight loss, all 4 patients (9.5%) underwent band removal (**Table 4**).

Table 3.
Preoperative BMI^a Versus Number of Reoperations

BMI	Band Removal Group, n	Port Revision Group, n	% of Reoperations	Overall Reoperation Rate, %
30.00–34.99 kg/m ² (class I)	0	0	0	0
35.00–39.99 kg/m ² (class II)	6	2	19.0	2.6
≥40.00 kg/m ² (class III)	20	14	81.0	11.1

^aBMI = body mass index based on World Health Organization classification.

Table 4.

Percent Total Weight Loss Versus Number of Reoperations at Time of Reoperation

Total Weight Loss	Band Removal Group, n	Port Revision Group, n	% of Reoperations	Overall Reoperation Rate, %
0%–10%	6	7	31	4.3
11%–20%	4	6	23.8	3.3
21%–30%	7	1	19.0	2.6
31%–40%	5	2	16.7	2.3
41%–50%	4	0	9.5	1.3

Table 5.

Duration to Reoperation Versus Number of Reoperations

Duration	Band Removal Group, n	Port Revision Group, n	% of Reoperations	% of Bands Placed
0–12 mo	5	8	31.0	4.3
13–24 mo	6	5	26.2	3.6
25–36 mo	6	2	19.0	2.6
≥37 mo	9	1	23.8	3.3

Time to Reoperation

Within the first postoperative year, 13 of 305 patients (4.3%) required reoperations: 5 (1.6%) underwent band removal and 8 (2.6%) underwent port revision. Within 2 years, 24 patients (7.9%) underwent reoperations, with 11 band removals (3.6%) and 13 port revisions (4.3%). Thirty-two patients underwent reoperation within 3 years (10.5%), comprising 17 band removals (5.6%) and 15 port revisions (5.0%). An additional 10 patients (3.3%) underwent reoperation beyond 3 years: 9 (8.5%) underwent band removal and 1 (5.2%) underwent port revision (Table 5).

Port revision accounted for a slight majority of reoperations during the first 2 years, occurring in 54.2% of reop-

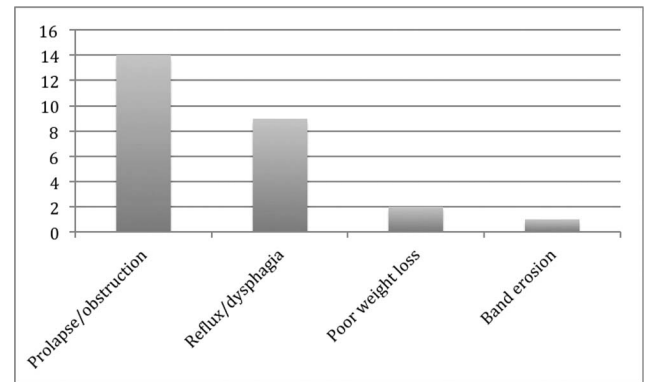


Figure 1. Most band removals were performed for prolapse with or without obstruction and for reflux or dysphagia.

eration cases. Port malfunction was the most common cause. Band removal was the most common reason for reoperation after 2 years, accounting for 83.3% of cases. Prolapse with or without gastric obstruction predominated after 3 years, accounting for 44.4% of reoperations (n = 4) during this period. Reflux/dysphagia and poor weight loss each accounted for 22.2% of reoperations (n = 2) after 3 years, followed by band erosion (11.1%, n = 1).

Complications

Four complications were recognized in the 26 patients who underwent band removal: anterior gastric prolapse with or without obstruction (n = 14), severe reflux/dysphagia (n = 9), poor weight loss (n = 2), and gastric erosion (n = 1) (Figure 1). In all cases of gastric prolapse, severe reflux, dysphagia, poor weight loss, and gastric erosion, the bands were completely removed. No attempt at revision surgery was made. It was customary for our bariatric surgeons to perform revision weight-loss surgery as a 2-stage procedure.

Of the 16 patients who underwent port revision, the indications were divided into 3 categories: port malfunction,

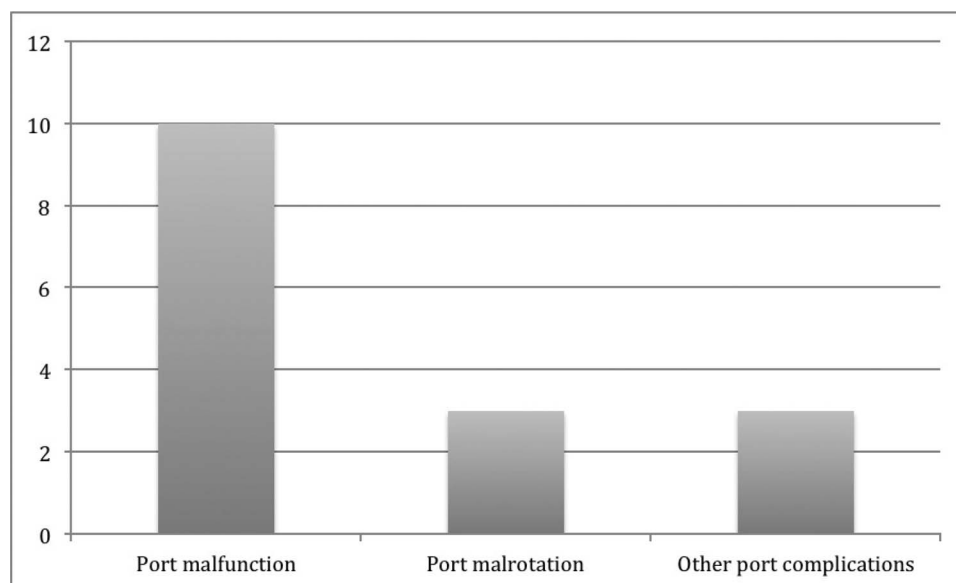


Figure 2. Reoperations for port revision were mainly performed for nonfunctioning ports. Malrotation of the port and “other” complications, including port infection and nonspecific abdominal pain from the port, represented lesser reasons for reoperation.

defined as port accessibility with the inability to fill or deflate the band (n = 10); malrotation of the port (n = 3); and other (n = 3, 1.0%). “Other” complications included port infection, port-site hernia, and chronic abdominal pain (**Figure 2**).

On further review of the LAGB reoperations, we found that 9 were performed on an emergent basis. Eight required emergent band removal for band prolapse with obstruction. One emergent port revision was performed because of band obstruction and inability to access the port.

DISCUSSION

LAGB has been considered by many surgeons as the treatment of choice for morbid obesity because of positive early results and operative simplicity. However, recent long-term studies have forced the surgical community to reconsider its safety. We reviewed 305 LAGB patients from 2004 through 2011, of whom 42 (13.8%) subsequently underwent reoperations for band removal or port revision. This finding is slightly lower than the rates reported in the literature.⁵⁻⁷ We did, however, exclude those patients reoperated on solely for cosmetic purposes for port protrusion.

Most of the bands placed in our patients were Lap-Bands (AP or VG). However, we avoid drawing conclusions regarding whether a particular type of band resulted in

lower reoperation rates for several reasons. First, the sample size for the Lap-Bands (n = 231) was much larger than that for the Realize-C band (n = 74) in our patient population. More Lap-Bands were removed, but more Lap-Bands were also implanted. In addition, Lap-Bands were the only laparoscopic adjustable gastric band type placed in our patients before 2009. Therefore we have longer-term follow-up data for the Lap-Bands than for the Realize-C bands. The overall reoperation rates appear to be comparable between the Lap-Bands and the Realize-C bands: 13.4% and 14.9%, respectively (**Table 2**).

Reviewing the results of other LAGB studies showed high complication and reoperation rates. Kasza et al⁷ conducted a prospective study of 130 LAGB patients over a period of 2 years, assessing the adequacy of weight loss and reoperation rates. They reported a 16.7% reoperation rate, with most patients not achieving a 50% estimated weight loss. They concluded that LAGB may not be the optimal bariatric procedure for patients with a BMI greater than 50 kg/m². Most reoperations in our study occurred in obese class III (super-obese) patients with preoperative BMIs >40 kg/m² (n = 34, 81%).

Michalik et al¹⁰ reported a 20.1% morbidity rate and 16.1% reoperation rate in a 5-year study involving 160 patients. They argued that a complication does not herald the end of obesity treatment because the band is easily removed and substituted for another bariatric procedure. This con-

clusion, however, does not stress the mortality risk from LAGB and associated reoperations. Gagner et al¹¹ attempted to elucidate the incidence and possible causes of unreported LAGB operative and late deaths by sending anonymous questionnaires to American Society for Bariatric Surgery members. Of the 1437 questionnaires sent, 453 (31%) were returned. Thirty-five surgeons (9%) reported ≥ 1 operative death and a total of 36 operative deaths, 19 late deaths, and 5 reoperation deaths. The etiologies of these 62 deaths included the following: 20 of cardiac origin (33%), 11 thromboembolic events (18%), 10 viscus perforations (16%), 3 hemorrhagic deaths (5%), and 18 miscellaneous deaths. The authors concluded that late deaths, mostly due to cardiac or thromboembolic complications from LAGB and reoperations, were under-reported.

Long-term outcomes of LAGB appear to be relatively poor. In a 12-year study by Himpens et al⁴ assessing outcomes in 82 LAGB patients, band erosion occurred in nearly 1 of 3 patients and almost 50% of patients required band removal. Additional long-term studies have described an increasing band failure rate directly proportional to the time from band placement. Naef et al⁸ enrolled 167 LAGB patients in a 12-year prospective clinical trial from 1998 to 2009. The early complication rate (< 30 days) was 7.8%, whereas late complications (> 30 days) occurred in 40.1%. Late complications included 60 major complications: 3 band infections, 2 band migrations, 11 band leakages, 2 slippages/pouch dilations, 2 band intolerance cases, and 40 esophageal dilations. The overall reoperation rate was 20.4% ($n = 34$), whereas the procedure failure rates after 2, 5, 8, and 10 years were 25.7%, 24.3%, 25.7%, and 31.6%, respectively. Similarly, Stroh et al¹² analyzed 200 LAGB patients over a period of 14 years, with a 30.5% reoperation rate, increasing by 2.2% for every year of follow-up. Our short-term data also show an increasing reoperation rate proportional to the time from band placement: 4.3% within the first year, 7.5% within the second year, and 10.5% within 3 years (**Table 5**).

The most common indication for reoperation in our study was anterior gastric prolapse ($n = 14$), which occurred in 4.6% of our patients. Additional patients may have had gastric prolapse but were asymptomatic and did not require reoperation. Gastric erosion appeared to be a relatively rare and late complication of LAGB ($n = 1$), accounting for 0.3% of reoperations in our study.

In a study of 2909 LAGB patients, Carelli et al¹³ also reported band slippage to be the most common complication, affecting 4.5% of patients, and reported the rate of

erosion to be 0.2%. These rates closely parallel those seen in our study. Cherian et al¹⁴ reported an LAGB erosion rate of 1.96% ($n = 18$) in a study of 865 LAGB procedures performed over a period of 5 years, with a relatively early median time to presentation of just 7 months. They predicted further increases in incidence with longer follow-up periods. The band erosion ratio has been reported as high as 1:3 by Himpens et al⁴ in a study of 151 LAGB patients over a period of 12 years, contributing to a 60% reoperation rate. Differences in band material, postoperative care, and surgical technique may account for the varied band erosion rates reported in the literature.

Port-related problems leading to reoperation, including malfunction and malrotation, accounted for 5.2% ($n = 16$) of the total laparoscopic adjustable gastric bands placed. Tog et al¹⁵ found port access or tubing problems to be the most common complication of LAGB, which subsequently required port revision. Their reported incidence of port revision was 8.7% ($n = 167$) in 1928 LAGB patients over a period of 9 years. They found that the incidence of port-related problems progressively increased with duration after placement of the original band. In addition, 27% of port revision patients required ≥ 2 corrective procedures. These data reaffirm the increased overall complication rate seen with long-term follow-up.

A 13.8% reoperation rate in LAGB patients places our institution in the lower range of the 16% to 60% reoperation rate seen in the current literature.^{5-7,12} LAGB, once thought to be a weight-loss procedure with low morbidity, has been shown to have one of the highest reoperation rates when compared with gastric bypass or sleeve gastrectomy.^{16,17} A recent case-matched study of 442 patients by Romy et al¹⁶ showed more failures, more long-term complications, and more reoperations after gastric banding when compared with Roux-en-Y gastric bypass. They showed that initial results from gastric banding were short-lived and resulted in more complications after 6 years. Sleeve gastrectomy, though a relatively new weight-loss procedure, was also shown to result in fewer complications than gastric banding. Boza et al¹⁷ observed 1000 consecutive laparoscopic sleeve gastrectomy patients over a period of 3 years and found early complications in 3.4% ($n = 34$) and late complications in 2.0% ($n = 20$), with a 0.7% reoperation rate ($n = 7$).

Study Limitations

There are limitations to our study. First, we performed a single-institution retrospective analysis with a relatively

small sample size. Second, we have collected only short-term follow-up results. Additional complications, as reported by the aforementioned long-term follow-up studies, may have been missed.^{4,8} Finally, we do not know the degree of patient migration. This would include patients who had their band placed at our institution but were reoperated on at an outside institution. It is difficult to draw a correlation between the average weight loss and likelihood of requiring a reoperation. With modest weight loss initially, it seems that patients were more willing to keep their original band and undergo a port revision than to completely relinquish the band. Most of the patients who had a weight gain or no change in weight underwent band removal.

Data regarding weight regain after band removal were found to be highly inconsistent and therefore not included in this study. After removal of their laparoscopic adjustable gastric bands, many patients did not present for follow-up after the initial postoperative visit. Those who chose to present for follow-up after this visit did so at varying intervals. Some patients were observed to have presented for follow-up <1 month postoperatively; others, at 1 mo; and yet others, at 3 mo or 6 mo postoperatively. Most of these patients did not present for follow-up at regularly scheduled intervals in such a manner as to allow specification of the amount of weight regain in any one particular period. Furthermore, some patients also underwent a second bariatric procedure after removal of their band in different periods.

CONCLUSION

Given the high complication and reoperation rates associated with gastric banding, bariatric surgeons should consider other surgical alternatives to help their patients achieve their weight-loss goals. These alternatives include the standard laparoscopic Roux-en-Y gastric bypass and the increasingly popular laparoscopic sleeve gastrectomy procedure, as well as less commonly performed operations such as duodenal switch or vertical banded gastroplasty.

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