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Safety of One-Stage Conversion Surgery after Failed Laparoscopic Adjustable Gastric Banding

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Abstract: Background: Obesity continues to be a leading public health concern associated with many comorbidities and major hindering effect on the daily lifestyle of many people around the world. Surgical treatment for obesity has proved that it is the best and most effective, durable means of preventing the life-threatening complications and serious problems associated with morbid obesity. Due to its historical popularity, AGB are still present in many individuals. With growing evidence of weight regain or complications, many stand to benefit from band removal and conversion to a stapled bariatric procedure (Lap sleeve gastrectomy as an example)**. Objective:** Re-assessing the safety and outcome of one-stage conversion of failed Laparoscopic adjustable gastric banding (LAGB) to laparoscopic sleeve gastrectomy (LSG). **Patients and Methods:** In this prospective randomized study, 30 patients are selected in Ain Shams University hospitals between June 2018 and March 2019 for assessment of safety of one stage conversion surgery after failed lap. adjustable gastric band. **Results:** Our study is aiming at evaluating the safety of one stage conversion surgery after failed lap. gastric banding. In which 30 patients (24 females and 6 males) with mean age of 41.83±12.42, BMI of 49.73± 6.77, mean history of banding of 9.75±3.10 and all have normal upper GI endoscopy prior to the surgery are followed up after the one stage conversion surgery. Only three developed post operative complications (10%of total cases). **Conclusion:** LAGB does not provide durable or meaningful weight loss for 44% of patients because of either inadequate weight loss or adequate weight loss with unmanageable symptoms. Single stage conversion surgery from lap. adjustable Gastric banding to lap. Sleeve gastrectomy is a totally safe technique.

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Keywords: Laparoscopic sleeve gastrectomy, laparoscopic adjustable gastric banding, obesity, conversation surgery

1. Introduction

Obesity continues to be a leading public health concern associated with many comorbidities that significantly decrease life expectancy and Surgery remains the only effective treatment modality for morbid obesity, resulting in long-term weight loss and sustained improvement in weight-related comorbidities [(1)].

In Egypt 30.3% of the adult population are considered obese according to the latest figures. The highest percentage of any country in the Mediterranean region and the 4th in the middle east only preceded by Saudi Arabia, Kuwait and the United Arab Emirates. The sex distribution of obesity in Egypt seems to be far from balanced with females (39.5 %) being twice as much affected compared to the male population (18.2%). There is also quite a discrepancy between the urban and rural populations with the former being more affected by obesity than the latter possibly as a result of a more sedentary lifestyle and other environmental factors [(2)].

Overweight and obesity are associated with increased rate of type II diabetes mellitus, hypertension, cardiovascular diseases, dyslipidemia, arthritis, non-alcoholic steatohepatitis, gall bladder diseases, sleep-apnea syndrome and several cancers. Mortality increases with increasing body mass index (BMI). Mortality rate is twelve times than that in young normal-weight men [(3)].

Recent reports have described morbid obesity as a continuing epidemic. The failure of various diets to achieve a long-term weight loss has prompted a growing number of morbidly obese patients to seek surgical treatment [(4)].

Treatment must begin with long-term lifestyle changes, including increased physical activity and dietary modifications. For overweight and obese individuals for whom lifestyle changes alone are insufficient, pharmacotherapy may be added. However, patients who choose adjunctive pharmacotherapy should be advised of the risks and benefits of drug therapy, the lack of long- term safety

data, and the temporary and modest nature of the weight loss that can be achieved with these agents [5].

Although medical management of morbid obesity patients made some progress, however, a persistent weight reduction can hardly be achieved in these patients. For extreme cases of obesity, only surgical intervention can produce substantial weight loss [6].

Bariatric surgery is a generic term for weight loss surgery. The three most commonly performed bariatric surgery procedures are adjustable gastric banding (AGB), gastric bypass and sleeve gastrectomy (SG). Bariatric surgery is recommended as a treatment option when all appropriate non-surgical measures have been unsuccessful for adults with morbid obesity (body mass index (BMI) 40 kg/m2 or more) or a lower BMI together with other significant disease; it is recommended as a first-line option for adults with a BMI more than 50 kg/m2 [7].

Bariatric surgery procedures are indicated for patients with clinically severe obesity. Currently, these procedures are the most successful and durable treatment for obesity [8].

Due to its historical popularity, AGB are still present in many individuals. With growing evidence of weight regain or complications, many stand to benefit from band removal and conversion to a stapled bariatric procedure (Lap sleeve gastrectomy as an example) [9].

Lapasroscopic Sleeve Gastrectomy remains one of the safest and most effective modern surgical options for the treatment of morbid obesity [1].

In addition to the primary weight-losing effect, LSG tends to cause improvement of several obesity-related comorbidities. According to a recent systematic review, LSG caused improvement of type 2 diabetes mellitus, hypertension, hyperlipidemia, sleep apnea and joint pain [10].

As surgeon experience increases with demand for conversions, staging and the type of stapled bariatric procedure performed have both received considerable attention. A 2016 meta-analysis of 11 studies by Dang et al. comparing the two techniques suggested that a one-stage procedure has similar rates of morbidity to two-stage procedures [11]. Other large single-center studies have supported the safety and feasibility of one-stage conversion [12] as well as non-inferior morbidity compared to two-stage conversion [13].

Laparoscopic sleeve gastrectomy is a new and effective procedure for the surgical management of morbid obesity. Therefore, the number of patients undergoing this procedure will continue to rise. Basic understanding of common complications and available treatment options is essential for all practising general surgeons. By early diagnosis and treatment of these complications, patient morbidity and mortality might be reduced [14].

Aim of the Work

Re-assessing the safety and outcome of one-stage conversion of failed Laparoscopic adjustable gastric banding (LAGB) to laparoscopic sleeve gastrectomy (LSG).

2. Patients and Methods

In this prospective randomized study, 30 patients are selected in Ain Shams University hospitals between June 2018 and March 2019 for assessment of safety of one stage conversion surgery after failed lap. adjustable gastric band.

Inclusion Criteria:

Male and Female patients ranging from age of 18 to 70 years old. The adjustable gasric band operation was done laparoscopically. BMI ≥35 with comorbidities or ≥ 40 with no comorbidities.

Exclusion Criteria:

Local complication of the band e.g. erosions, ulcerations, slippage, pouch and esophageal dilatation. Open adjustable gastric band.

Data collection:

Cases prospectively collected or followed up from Bariatric Unit in Ain Shams University hospitals during the study period under supervision of thesis supervisors.

Preoperative preparation:

Careful history taking. Searching for symptoms suggestive of complications as vomiting or pain. General condition assessment. Measuring BMI and estimation of degree of weight loss after the initial operation.

Investigations:

All patients have preoperative abdominal US, Pulmonary function test, ECG, full blood picture, liver and kidney function and upper GI endoscopy [15].

Operative:

General anaesthesia. Single dose antibiotic at induction of anaesthesia (Cephalosporin 1gm). Low molecular weight heparin at the night before the surgery.

Position:

Supine with open legs. Trendlenburg position once ports have been placed. Creation of pneumoperitoneum and trocars insetions: a small stab was made at the umbilical scar allowing the introduction of the veress needle; insufflation was done to establish carbon dioxide penumoperitonum up to 14 mmHg. Five ports technique: 5 mm subxiphoid trocar (for liver retractor). 5 mm left hypochondrial (left working port). 12 mm right hypochondrial (right working port). 10 mm supraumbilical for the camera man. 5 mm left anterior axillary line subcostal for the assistant. Cut the scar tissue around the band. Cut the

tubing and band. Pull out the band from around the stomach. During the initial operation, the upper part of the stomach (fundus) is usually sutured to the part of the stomach above the band to prevent band migration. Some general surgeons tend to leave the adhesions and those sutures in place during the Lap Band removal surgery. However, it is very important to remove those sutures and lyse the adhesions. This will restore the original anatomy of the stomach and make subsequent or later revision surgery much easier. After removing the gastric band, removal or incision of the perigastric capsule (dense scar tissue around the upper part of the stomach or esophagus) will reduce the chance of obstruction after surgery. The subcutaneous port is removed. Devascularization of greater curvature from the greater omentum using ultrasounic harmonic scalpelc. Insertion of 36 fr.Boujie. Stapler introduction and then firstly using one green reload, then gold reload we may use another blue reload, and continue stapling using black and purple reloads respectively till the end. Methylene blue test was done to make sure of sealed staple line and no intraoperative leakage Omental fixation was done by full thickness stitches to the stapling line using PDS 2-0, till the antrum (to avoid stricture). Before finalizing, elevating of the mean blood pressure (MBP) > 90 mmHg as a test for hemostasis. Finally inserting an intra-abdominal drain.

Post operative follow up:

Mobilization after 2 hours. During the hospital stay period we followed up the patient by vital data suspecting leakage with fever 38.5 celsius degrees and tachycardia with heart rate over 120 beat per minute and the drain and hemorrhage with tachycardia and abdominal examination. Within the second day post-operatively we did the Gastrografine meal contrast study, started the oral sips, and discharge the patient after removal of drain if present. Computed tomography (CT) of the abdomen with intravenous and oral water soluble contrast was considered as a part of the diagnostic workup of patients with suspected leak. After 14 days postoperative at the time of the 1st visit, removal of stitches were done, diet was changed into smashed well chewed food. We follow up degree of weight loss over the following 6 months of the operation.

Statistical Analysis

Data were collected, revised, coded and entered to the Statistical Package for Social Science (IBM SPSS) version 23. The quantitative data were presented as mean, standard deviations and ranges. Also qualitative variables were presented as number and percentages. The comparison between groups regarding qualitative data was done by using ***Chi-square test.*** The comparison between two independent groups with quantitative data and parametric distribution were done by using ***Independent t-test*** The confidence interval was set to 95% and the margin of error accepted was set to 5%. So, the p-value was considered significant as the following: P-value > 0.05: Non significant (NS). P-value < 0.05: Significant (S). P-value < 0.01: Highly significant (HS).

3. Results

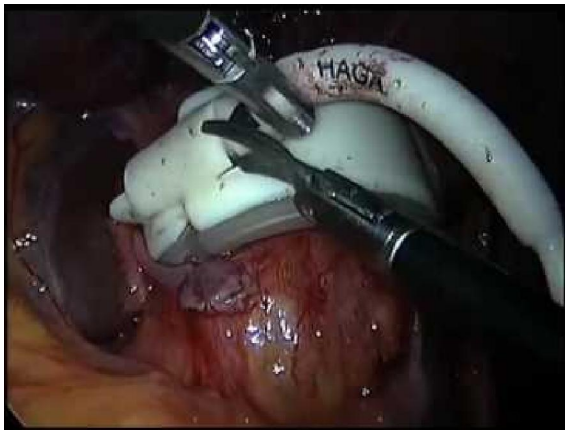

Figure (1): Lap. Gastric band removal

Figure (2): Removed gastric band.

Table (1): Demographic data and history of the studied patients

		No. = 30
Age	Mean±SD	41.83 ± 12.42
	Range	22 – 66
Gender	Female	24 (80.0%)
	Male	6 (20.0%)
BMI	Mean±SD	49.73 ± 6.77
	Range	40 – 65
History of the band	Mean±SD	9.75 ± 3.10
	Range	1.5 – 16
Upper GIT endoscopy	Normal	30 (100.0%)

Table (2): Perigastric localized collection results among the studied patients.

Perigastric localized collection	**No.**	**%**
Negative	27	90.0%
Positive	3	10.0%
Total	***30***	***100.0%***

Table (3): Drain, amount, leakage, weight loss after 6 months and management of the studied patients.

		No. = 30
Drain	NIL	22 (73.3%)
	Serous	5 (16.7%)
	Gastric	1 (3.3%)
	Coffee ground	1 (3.3%)
	Bloody	1 (3.3%)
Amount	Mean±SD	75.00 ± 37.80
	Range	50 – 150
Leakage	No	29 (96.7%)
	Yes	1 (3.3%)
Wt. Loss after 6 months	Mean±SD	12.93 ± 4.86
	Range	4 – 22
Management	Conservative management with IV fluid and packed RBCs	1 (33.3%)
	Endoscopic stenting and laparoscopic peritoneal lavage	1 (33.3%)
	Pig tail insertion for drainage of the collection	1 (33.3%)

Figure (3): 3D gastroscopy: megastent.

Figure (4): Megastent with intraperitoneal drain.

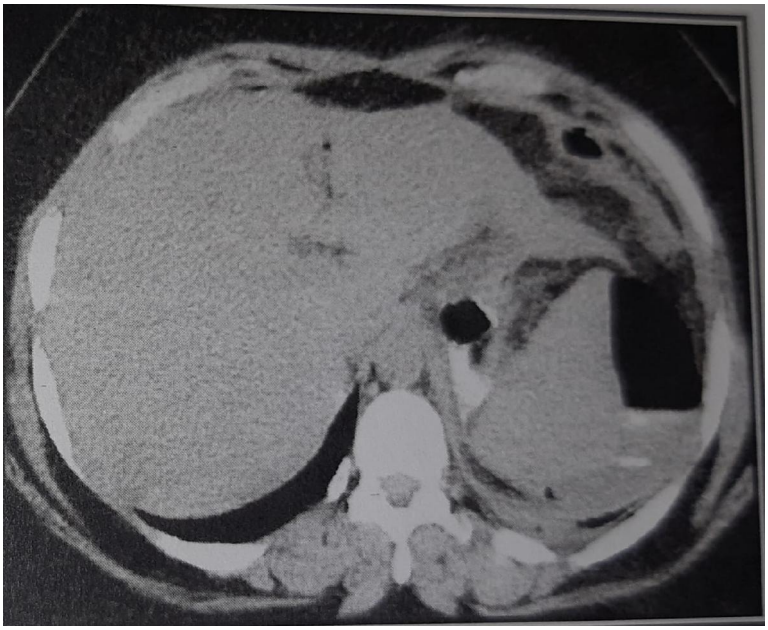

Figure (5): CT showing leakage.

Table (4): Relation of perigastric localized collection with demographic data and history of the studied patients

		Perigastric localized collection		Test value	P-value	Sig.
		Negative	Positive			
		No. = 27	No. = 3			
Age	Mean ± SD	43.30 ± 11.97	28.67 ± 9.07	2.039•	0.051	NS
	Range	27 – 66	22 – 39			
Gender	Female	21 (77.8%)	3 (100.0%)	0.833*	0.361	NS
	Male	6 (22.2%)	0 (0.0%)			
BMI	Mean ± SD	49.96 ± 6.98	47.67 ± 4.93	0.550•	0.586	NS
	Range	40 – 65	42 – 51			
History of the band	Mean ± SD	10.02 ± 3.08	7.33 ± 2.52	1.448•	0.159	NS
	Range	1.5 – 16	5 – 10			
Upper git endoscopy	Normal	27 (100.0%)	3 (100.0%)	NA	NA	NA

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test; •: Independent t-test

The previous table shows that there was no statistically significant relation found between perigastric localized collection results and demographic data or history of the studied patients.

Table (5): Relation of perigastric localized collection with clinical data of the studied patients.

		Perigastric localized collection		Test value•	P-value	Sig.
		Negative	Positive			
		No. = 27	No. = 3			
Pulse	Mean±SD	83.04 ± 7.39	121.67 ± 10.41	-8.300	0.000	HS
	Range	69 – 100	110 – 130			
MBP	Mean±SD	89.07 ± 7.08	80.00 ± 26.46	1.518	0.140	NS
	Range	75 – 100	60 – 110			
Temp.	Mean±SD	37.00 ± 0.00	37.43 ± 1.02	-2.608	0.014	S
	Range	37 – 37	36.7 – 38.6			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
•: Independent t-test

The previous table shows that there was statistically significant increase in pulse and temperature with positive perigastric localized collection with p-value < 0.001 and 0.014 respectively while no statistically significant relation found between perigastric localized collection and mean arterial blood pressure with p-value = 0.140.

Table (6): Relation of perigastric localized collection with drain, amount, leakage and weight loss at 6 months of the studied patients.

		Perigastric localized collection		Test value	P-value	Sig.
		Negative	Positive			
		No. = 27	No. = 3			
Drain	NIL	22 (81.5%)	0 (0.0%)	30.000*	0.000	HS
	Serous	5 (18.5%)	0 (0.0%)			
	Gastric	0 (0.0%)	1 (33.3%)			
	Coffee ground	0 (0.0%)	1 (33.3%)			
	Bloody	0 (0.0%)	1 (33.3%)			
amount	Mean±SD	60.00 ± 22.36	100.00 ± 50.00	-1.604•	0.160	NS
	Range	50 – 100	50 – 150			
Leakage	No	27 (100.0%)	2 (66.7%)	9.310*	0.002	HS
	Yes	0 (0.0%)	1 (33.3%)			
Wt. Loss after 6 months	Mean±SD	13.20 ± 4.77	10.50 ± 6.06	0.912•	0.369	NS
	Range	4 – 22	5 – 17			

P-value >0.05: Non significant (NS); P-value <0.05: Significant (S); P-value< 0.01: highly significant (HS)
*: Chi-square test; •: Independent t-test

The previous table shows that there was statistically significant increase in the incidence of leakage in cases with positive perigastric localized collection with p-value = 0.002 while no statistically significant relation found between perigastric localized collection and amount or weight loss after 6 months with p-value = 0.160 and 0.369 respectively.

4. Discussion

Obesity continues to be a leading public health concern associated with many comorbidities that significantly decrease life expectancy [(1)].

Weight reduction can be achieved by several non-surgical methods that include; diet control, physical exercise, and/or drug therapy but these methods often elicit compensatory changes in appetite and energy expenditure that make weight loss of more than 5 to 10 percent unlikely to be sustained for more than 5 years [(16)].

In contrast, surgery typically causes substantial long term sustained weight loss [(17)]. In the same aspect, the rising prevalence of morbid obesity and super-obese patients (BMI >50 Kg/m²) who are seeking treatment had led to that surgery became the choice which provides adequate EWL in comparison to non-surgical methods [(18)].

Over the last 20 years, bariatric surgery has come to play a significant role in confronting this problem, using either restrictive or mixed restrictive and malabsorptive techniques [(19)].

Over the last 2 decades, LAGB has been a commonly performed bariatric procedure for over a decade and has had acceptable short-term results [(20)].

However, increasing experience with this procedure has revealed a high complication rate, insufficient weight loss, and weight regain in long-term follow-up requiring revisional surgery in up to 60% of patients in some centers [(21)].

Existing evidence suggest that a failed LAGB is best managed with conversion to another bariatric procedure that can provide durable treatment for obesity, such as RYGB and LSG [(22)].

Many patients elect to undergo a RYGB or LSG as a salvage procedure to help maintain or restore weight loss. The concept of single-stage procedures is appealing due to theoretically saving the patient the risks and cost of a second surgery, as well as avoiding weight gain between the procedures. A systematic review published in 2016 stated that both single-stage RYGB and LSG are feasible and safe but suggested the need for further investigation [(11)].

Laparoscopic sleeve gastrectomy (LSG) has become an increasingly popular restrictive surgical procedure for the treatment of morbid obesity [(23)].

Our study is aiming at evaluating the safety of one stage conversion surgery after failed lap. gastric banding. in which 30 patients (24 females and 6 males) with mean age of 41.83±12.42, BMI of 49.73± 6.77, mean history of banding of 9.75±3.10 and all have normal upper gi endoscopy prior to the surgery are followed up after the one stage conversion

surgery. Only three developed post operative complications (10%of total cases).

The three complications were: Leakage: Managed by endoscopic stenting and laparoccopic peritonial lavage. **Hemorrhage**: Managed conservatively with I.V. fluids and packed RBCs. **Hematoma**: Managed by pig tail insertion for drainade of the collection.

A 2016 meta-analysis of 11 studies by Dang et al. comparing one stage conversion surgery to two stages suggested that a one-stage procedure has similar rates of morbidity to two-stage procedures [(11)].

The historic critique of one-step procedures is the potential for increased risk of anastomotic leaks due to fibrosis that is present immediately after removal of the band [(24)].

Revisional surgeries from LAGB, in general, have already been established to be associated with higher gastric leak rates but potentially this could be further exacerbated by immediate rather than delayed surgery [(25)].

The concern raised was that creating a fresh staple line through scarred and thickened tissue could lead to poor integrity of the anastomosis due to a fragile gastric wall [(26)].

These authors theorized that removing the band first and allowing time for the fibrosis to resolve might reduce perioperative morbidity. Tan et al., however, found that histopathologic changes following band removal persist for at least 3 years following removal and might be irreversible, which would mean that single versus staged revision would make no difference in the presence of inflammatory markers. Through analyzing the histologic properties of the SG staple line taken from surgical specimens, the authors demonstrated signs of both acute and chronic inflammation in gastric tissue specimens irrespective of time from LAGB removal [(27)].

Therefore, it is not surprising that we found no significant increase in anastomotic leak rates after one-step procedures in this meta-analysis.

In a study by A. Aminian et al. Data of 11,320 patients were analyzed, including 10,997 cases of primary LSG (97.1%) and 323 cases of conversion of LAGB to LSG in a single stage (2.9%) [(28)].

This study represents a large population of patients undergoing either primary LSG or conversion of gastric band to sleeve in a single stage. This database has been used to evaluate early postoperative outcomes after major surgeries focusing on risk-reduction and overall quality improvement in multiple studies. The present results indicate the overall safety of LSG with 30-day readmission, reoperation, and mortality rates of 3.8%, 1.6%, and.1%, respectively. Data analysis also shows comparable postoperative outcomes among the 2 study groups except for the longer operative time (needed for additional steps of band/port removal) and higher incidence of minor complications including UTI (probably related to the higher frequency of urinary catheter use) and wound infection (probably at the subcutaneous band port site) in the revisional group compared with the primary LSG patients. The 30-day mortality rate in this study did not differ significantly between primary LSG (.1%) and revisional groups (.3%). The mortality rate is similar to the previous reports on mortality trends in bariatric surgery, revealing a total mortality rate of.28% at 1st 30 day [(29)].

In 2011 Gagniere et al. found that waiting six months between gastric band removal and performing LSG did not reduce morbidity as compared with concomitant surgery [(25)].

Between February 2007 and January 2012, 90 patients (77 women and 13 men) underwent LSG as a revisional procedure for failed LAGB at a single bariatric center with three operating surgeons. A retrospective review of a prospectively collected database was performed by **Yazbek et al.** [(30)], The indication for band removal was failure to achieve sufficient weight loss results with the band in 52 cases (14 with a BMI of 50 or more before the LAGB), intolerance to the band in two cases, band slippage in 30 cases, erosion in two cases, external infection in one case, and complete blockage in three cases. Revisions were accomplished in one stage in 88 patients. Two patients with erosion were treated in two stages: the band was removed in the first stage and the sleeve gastrectomy was performed 6 months later.

In this series of 90 patients, we had 5.5 % leaks (five patients), 4.4 % hemorrhage or gastric hematoma (four patients), and 2.4 % parietal hematoma (two patients). We had 6.6 % conversions to open surgery (six patients): two for intense abdominal adhesions, one for colonic perforation, one for splenic laceration, and two for sleeve strictures which were treated by gastrogastric anastomosis.

In a study by **Pencovich et al.** [(31)] one hundred and nine patients underwent revision of a failed LAGB to a LSG. There were 78 females and 31 males Ninety-six patients (88%) underwent a one-stage conversion, while the remaining 13 patients underwent a staged approach with the band being removed in the primary procedure and the sleeve gastrectomy performed several months later.

Fourteen patients (12.8%) developed early (within 30 days) post-operative complications. These included a sleeve stricture, 2 leaks (1.8%), 3 post-operative bleeding (2.8%), 4 intra-abdominal collections (3.7%), and 4 hematomas (3.7%). All post-operative complication occurred in patients that underwent a one-step procedure.

Pencovich et al. [31] suggests that conversion of failed LAGB to LSG is both safe and effective. A staged approach might be safer, with a small sub-group in our series showing no complications when the sleeve was performed several months after excising the band.

In another study by **Alqahtani et al.** [32] the data base of 209 patients who underwent 1-stage conversion between September 2007 and September 2015 by a single surgeon were abstracted (142 females and 67 males).

One patient from the 1-stage group was readmitted 2 weeks after surgery with a postoperative leak. He had percutaneous drainage and multiple endoscopic stent place-ment and reposition that eventually resulted in leak control and complete healing.

Conclusion

LAGB does not provide durable or meaningful weight loss for 44% of patients because of either inadequate weight loss or adequate weight loss with unmanageable symptoms. Single stage conversion surgery from lap. adjustable Gastric banding to lap. Sleeve gastrectomy is a totally safe technique.

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