

Impact of laparoscopic sleeve gastrectomy on obesity-associated co-morbidities: A two-year follow-up prospective study

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Abstract

Objectives: To determine the effects imposed by laparoscopic sleeve gastrectomy (LSG) on obesity-associated co-morbidities.

Patients & methods: The study included 40 patients; 13 morbid obese and 27 obese patients. All patients were evaluated preoperatively for existence and severity of co-morbidities and determination of Homeostasis Model Assessment of Insulin Resistance (HOMA-IR). All patients underwent LSG; operative time, hospital stay, and intraoperative and postoperative (PO) complications were registered. Postoperative monitoring included evaluation of the percentage of excess weight loss (%EWL) and the percentage of excess body mass index loss (%EBMIL) at 3, 6, 12 and 24 months after surgery; the frequency of associated co-morbidities and HOMA-IR index was evaluated at 6, 12 and 24 months after surgery.

Results: Mean operative time was 157.8±17 minutes and mean duration of hospital stay was 5.5±0.9 days. No conversion to open surgery. All patients showed progressive weight loss throughout the follow-up period with progressively increasing %EWL and %EBMIL. BMI strata showed significant progressive change throughout follow-up period; 27 women were overweight and only 13 women were obese. All obesity-associated co-morbidities showed progressive improvement or resolution. At end of follow-up, 7 patients still had co-morbidities, 9 patients had improved co-morbidities and 24 patients had resolved co-morbidities with an improvement and resolution rates of 22.5% and 60%, respectively and only 11 co-morbidities were recorded at end of follow-up in various combinations in the 7 non-responders. Preoperatively, all patients were insulin resistant; however, at the end of follow-up period HOMA-IR index of all patients was within the non-resistant range.

Conclusion: Bariatric surgery effectively improves obesity-associated co-morbidities and could be considered as non-pharmacological therapeutic modality for these co-morbidities. Laparoscopic gastric sleeve is a safe and effective appropriate surgical procedure for morbidly obese patients with associated co-morbidities.

Key words: Laparoscopic sleeve gastrectomy, obesity, co-morbidities, insulin resistance.

Introduction:

Obesity behaves like an epidemic with escalating progress up to a fact that the number of overweight and obese people in the world overtook the number of malnourished.^{1,2} As the obesity epidemic increases, health problems associated with obesity became more frequently than ever before; in 2007, 41% of women were classified as obese, with a BMI of 30 or higher.

A wide spectrum of health problems has been associated with obesity, including cardiovascular disease, diabetes, metabolic syndrome and osteoarthritis.³

Sleeve gastrectomy (SG) is a relatively new bariatric procedure involving resection of most of the stomach along the greater curvature to leave only a narrow tube ("sleeve") between the gastroesophageal junction and pylorus. The

remainder of the gastrointestinal tract is not altered. The procedure is typically performed laparoscopically.^{4,5}

Systematic reviews of bariatric procedures found that SG is comparable to Roux-en-Y gastric bypass (RYGP) with respect to weight loss and improvement in the components of the metabolic syndrome. Compared with RYGP, SG has several advantages including the relative simplicity resulting in a shorter duration of surgery and fewer complications. The pylorus is preserved, so patients are less likely to experience dumping syndrome. In SG, the small bowel and mesentery are not altered; as such, there are fewer nutritional deficiencies, there is no added risk of internal hernia, and the entire upper gastrointestinal tract remains accessible for endoscopy. A further advantage of SG is that there is no permanent large foreign body installed as in adjustable gastric banding (AGB), another popular bariatric procedure.^{6,7}

In addition to the usual risks associated with surgery in general and in obese patients in particular, there are disadvantages and risks associated with SG compared with other bariatric techniques. Unlike AGB, SG is irreversible, and there is a risk of gastric stenosis requiring treatment with dilators. The sleeve may become permanently dilated with overeating. Since the lumen cannot be easily adjusted as in AGB, a second malabsorptive procedure such as RYGP may have to be performed to promote further weight loss.^{8,9}

The current study aimed to determine the effects imposed by laparoscopic sleeve gastrectomy on obesity-associated comorbidities

Patients and methods:

The present study was conducted at Departments of General Surgery and Internal Medicine, Benha University Hospital since May 2008 till May 2010 to allow a minimum of 2-years follow-up period for the last case operated on. After obtaining written fully informed patients' consents, the study included 40 morbid obese patients. Obesity grades were defined after the WHO expert consultation¹⁰ as BMI <24.9 as average, 25-<30 kg/m² as overweight, BMI ≥30-35 kg/m² as obese and

BMI ≥35 kg/m² as morbid obese. Only patients with BMI >30-35 kg/m² were enrolled in the study. BMI was calculated as weight (kg)/height (m²).¹¹

All patients were evaluated preoperatively for existence and severity of co-morbidities and fasting preoperative blood samples were obtained for estimation of fasting blood glucose and serum insulin for calculation of Homeostasis Model Assessment of Insulin Resistance (HOMA-IR)¹² according to the formula $HOMA-IR = I \times G / 22.5$, where I is fasting plasma insulin level (μIU/ml) and G is fasting blood glucose in mg/dl, considering an abnormal HOMA-index >3.8.¹³

Preoperative assessment and preparation:

Individualized perioperative management was required based on preoperative history and physical examination. Diabetic patients were maintained on subcutaneous injection of regular insulin every 6 hours with dose adjusted according to regular urine examination for glucose so as to maintain FBG level <160 mg/dl, with no ketonuria. Hypertensive patients were maintained on Ca-channel blockers and β-adrenergic agonists so as to maintain SAP≤130, DAP≤90 mmHg. Patients receiving treatment for chronic obstructive pulmonary diseases (COPD) were maintained on bronchodilators and β-adrenergic agonists. All patients with medical diseases were continued postoperatively on the same lines of treatment applied preoperatively.

Operative procedure:

With the patient intubated in supine position, and the surgeon standing between patients legs, pneumoperitoneum was established to 15 mmHg through optical 12-mm optiview trocar positioned one and half handbreadth below the Xiphoid process, the patient was then placed in reverse Trendelenburg position; lowering the abdominal viscera and freeing the operative field in the upper abdomen. Then, one 5-mm trocar was placed epigastric subxiphoid position for the insertion of the liver retractor; two working 12-mm trocars were placed on the right and left middle clavicular lines, respectively and one 5-mm trocar was placed on the left anterior axillary line for stomach retraction. Initial decompression of the stomach

with nasogastric tube was performed. After the identification of the gastric antrum at about the distal 7 cm from the pylorus on the greater curvature, the greater omentum was dissected from the greater curvature of the stomach with dividing the gastrocolic and gastrosplenic ligaments up to the esophagogastric junction, **Figure(1)**. The posterior stomach wall was visualized and fine adhesions to the pancreas were divided and the lesser sac totally freed. The left side of the junction was cleared off fat to avoid later compromise of the stapling during creation of the sleeve and left crus was completely exposed, **Figure(2)**. The cutting stapler (60 cm long, 4.1-mm staple-height, and green cartridge) Intestinal-Anastomosis (GIA) stapler was introduced through a right trocar towards the left shoulder, and was placed at the point of the initial dissection on the greater curvature, creating a vertical on the gastric wall, **Figure(3)**. Then a 36-Fr bougie was

inserted down to the pylorus and sequential firings of the Endo GIA with 60 mm - 3.5 mm linear staplers were applied over it **Figure(4)**, up to the esophagogastric junction leaving about 1 cm of fat pad along the lesser curvature (~3 cm width) to assure adequate blood supply on the lesser curvature for the sleeve. The vagus nerves anteriorly and posteriorly were preserved for normal gastric emptying. Reinforcement of the staple line was commenced in all cases by interrupted monofilament absorbable sutures to avoid the risk of postoperative bleeding and leakage, **Figure(5)**. The resected greater curvature including most of fundus was extracted via epigastric or right paramedian trocar-site after being dilated to two-finger diameter. No drains were needed and a nasogastric tube was left in place. Operative time, hospital stay, intraoperative and postoperative complications were registered.



Figure (1)

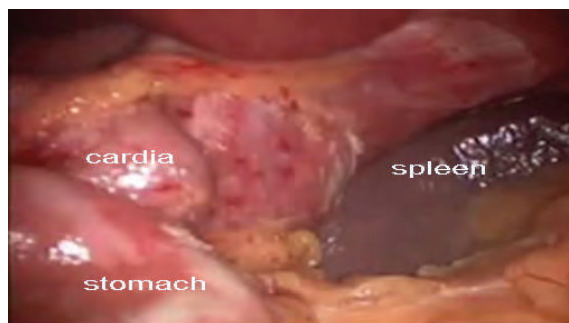


Figure (2)



Figure (3)



Figure (4)

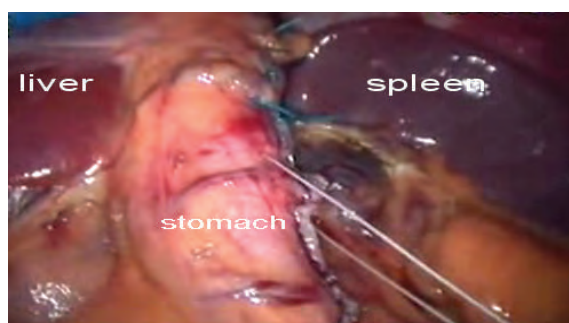


Figure (5)

Postoperative care:

Patients were maintained in semi-setting position throughout the postoperative period with keeping an eye on pulmonary function and continuous capillary hemoglobin oxygen saturation (SpO₂) monitoring. The nasogastric tube was removed on the 1st postoperative day, after a normal upper GI series with gastrographin, and after assurance of anastomotic line competence oral soft fluid was allowed and patients felt able to return home were discharged starting from the 2nd postoperative day with instructions to follow a liquid diet for four weeks.

Postoperative monitoring:

1. Body weight and body mass index were evaluated at 3, 6, 12 and 24 months after surgery and the percentage of excess weight loss (%EWL) and the percentage of excess BMI loss (%EBMIL) were calculated as follows: %EWL = [(Preoperative - Follow-up weight) / Preoperative weight] x 100
%EBMIL = 100 - [(Follow-up BMI - 25 / Preoperative BMI - 25) x 100].
2. Associated co-morbidities were evaluated at 6, 12 and 24 months after surgery.
3. HOMA-IR index was evaluated at 6, 12 and 24 months after surgery.

Results:

The study included 40 patients; 14 males and 26 females with mean age 29.5±2.2; range: 26-34 years. Thirteen patients were morbid obese with mean BMI of 41.5±1; range: 40.1-43.1 kg/m², while the other 27 patients were obese with mean BMI of 38.4±1.1; range: 36.5-39.7 kg/m². All patients were grade III according to the American Society of Anesthesiologists grading (ASA grade III), as all of them were at least obese and had at least one co-morbidity or multiple co-morbidities in varied combinations. Twenty-three patients were type-2 diabetics, 13 patients were dyslipidemic, 21 patients were hypertensive, 26 patients had obstructive sleep apnea syndrome (OSAS), 17 patients had depression/anxiety manifestations and 27 patients had knee or hip joint pain, **Table(1)**.

All patients passed smoothly without intraoperative complications or conversion to open procedure. Mean operative time was 157.8±17; range: 130-180 minutes and mean duration of hospital stay was 5.5±0.9; range: 4-7 days. Six patients stayed in hospital for 7 days, 11 patients for 6 days, 18 patients for 5 days and 5 patients returned home on the 4th PO day. All patients were instructed to continue on their medical therapy for strict control of their co-morbidities according to the regimen applied for preoperative preparation. Three patients were re-admitted; two diabetic patients developed wound infection and were admitted for control of their diabetes and wound infection responded to conservative therapy, while the 3rd patient had a severe asthmatic attack that was managed and patient returned home within hours. Five patients developed esophagitis due to gastro-esophageal reflux disease (GERD), all responded well to conservative medical therapy. Throughout the follow-up period no mortalities were recorded **Table(2)**.

All patients showed progressive weight loss throughout the follow-up period with progressively increasing %EWL and %EBMIL, **Figure(6)**. BMI strata showed significant progressive change throughout follow-up period; 27 women were overweight and only 13 women were obese, **Figure(7)**.

All obesity-associated co-morbidities showed progressive improvement or resolution. At end of follow-up, 7 patients still had co-morbidities, 9 patients had improved co-morbidities and 24 patients had resolved co-morbidities with an improvement and resolution rates of 22.5% and 60%, respectively and only 11 co-morbidities were recorded at end of follow-up in various combinations in the 7 non-responders, **Table(4)**.

Preoperatively, all patients were insulin resistant, irrespective of being diabetic or not with significantly higher HOMA-IR index of diabetics compared to non-diabetics. However, at the end of follow-up period HOMA-IR index of all patients was within the non-resistant range, **Table(5)**.

Table (1): Patients' enrollment data.

Data				Findings
Age (years)				29.5±2.2 (26-34)
Gender	Males			14 (35%)
	Females			26 (65%)
Anthropometric measures	Weight (kg)			103.6±6 (93-116.2)
	Height (cm)			162.2±3.2 (158-172)
	BMI (kg/m²)	Obese	Number	27 (67.5%)
			Index	38.4±1.1 (36.5-39.7)
		Morbid obese	Number	13 (32.5%)
			Index	41.5±1 (40.1-43.1)
		Total BMI		39.37±1.8 (36.5-53.1)
Co-morbidities	DM			23 (57.5%)
	Dyslipidemia			13 (32.5%)
	Hypertension			21 (52.5%)
	OSAS			26 (65%)
	Joint pain			27 (67.5%)
	Depression/anxiety			17 (42.5%)

Data are presented as mean±SD & numbers; ranges & percentages are in parenthesis.

Table (2): Operative and postoperative data.

Data				Findings
Operative time (min)				157.8±17 (130-180)
Hospital stay data	4 days			5 (12.5%)
	5 days			18 (55)
	6 days			11 (27.5%)
	7 days			6 (15%)
	Total (days)			5.5±0.9 (4-7)
PO complication	Surgery related	Esophagitis secondary to GERD		5 (12.5%)
	Co-morbidity related	Diabetic wound infection		2 (5%)
		Asthmatic attack		1 (2.5%)

Data are presented as mean±SD & numbers; ranges & percentages are in parenthesis.

PO: postoperative.

GERD: gastro-esophageal reflux disease.

Table (3): Operative and postoperative data.

	Weight	Height	BMI	%EWL	%EBMIL
Preoperative	103.6±6	162.2±3.2	39.37±1.8		
3-m PO	98.1±5.2	162.2±3.2	37.3±1.6	5.2±1.3	14.4±3.2
6-m PO	92.1±4.3	162.2±3.2	35±1.3	11.1±1.8	30.3±4.1
12-m PO	87.2±3.8	162.2±3.2	33.1±1.2	15.8±1.9	43.4±4.1
24-m PO	79.4±5.3	162.2±3.2	30.2±1.5	23.3±3.1	64.3±7.5

Data are presented as mean±SD.

Table (4): Frequency of co-morbidities recorded throughout follow-up period.

	Preoperative	6-m PO	12-m PO	24-m PO
DM	23	17	3	0
Dyslipidemia	13	10	9	1
Hypertension	21	16	6	3
OSAS	26	20	9	3
Joint pain	27	21	10	2
Depression/anxiety	17	14	4	2
Total	127	98	41	11

Data are presented as numbers.

Table (5): Insulin resistance data.

		Preoperative	3-m PO	6-m PO	12-m PO	24-m PO
FBG (mg/dl)	Diabetic	222.2±58.4	190.3±36.7	170.2±29.5	119±13.8	112.5±5.4
	Non-diabetic	106.4±5	104.8±3.1	102.5±3	103±3.9	102.4±4.7
	Total	173±72	153±50.9	141.5±40.5	112.2±13.4	108.2±7.2
FSI (mIU/dl)	Diabetic	11.1±2.3	10.1±1.8	7.7±1.4	5.3±1.7	3.8±0.4
	Non-diabetic	6.8±1.5	5.9±1.3	4.7±0.6	3.8±0.4	3±0.6
	Total	9.3±2.9	8.3±2.7	6.4±1.9	4.7±1.5	3.5±0.6
HOMA-IR index	Diabetic	5.9±1.4	4.7±0.9	3.3±0.9	1.6±0.8	1.1±0.1
	Non-diabetic	1.8±0.4	1.5±0.3	1.2±0.2	0.97±0.11	0.76±0.15
	Total	4.1±2.3	3.3±1.7	2.4±1.23	1.34±0.65	0.93±0.2

Data are presented as mean±SD.

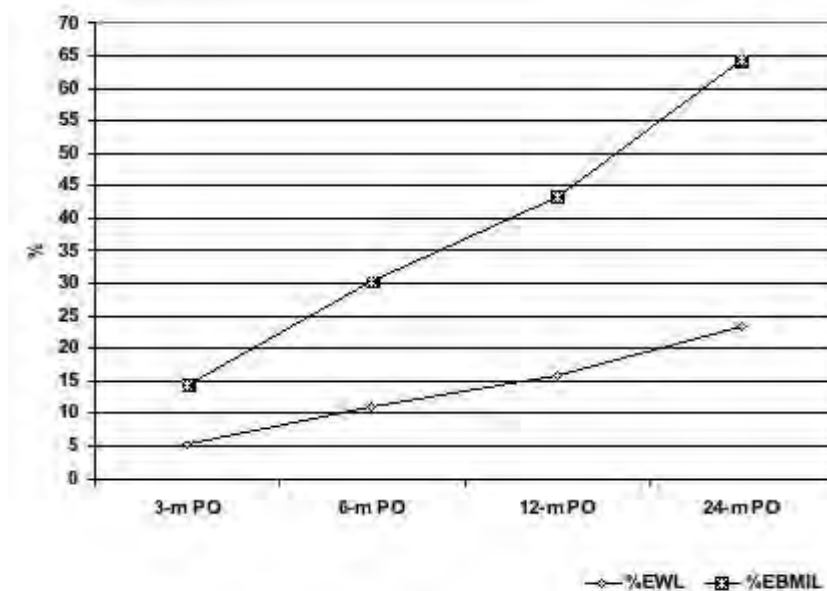


Figure (6): Mean %EWL and %EBMIL recorded throughout follow-up period

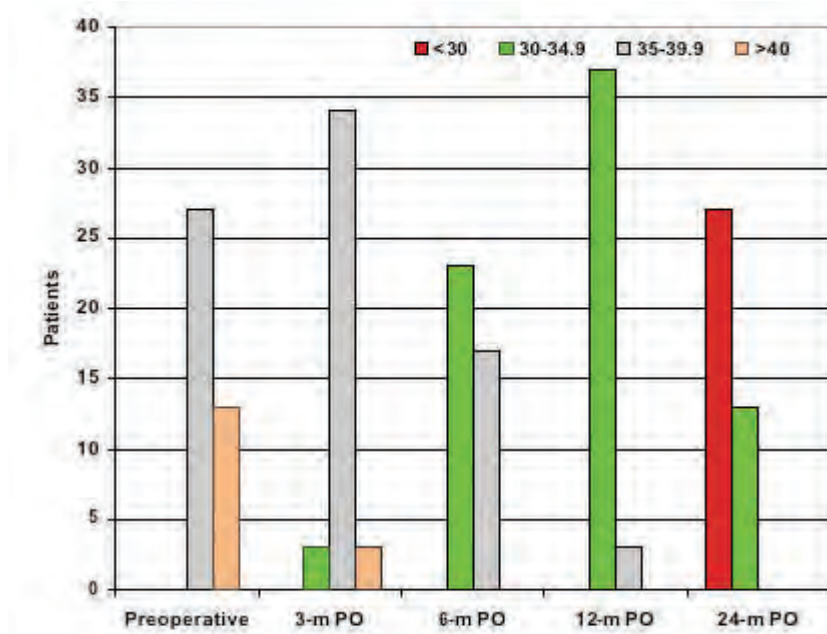


Figure (7): Patients' distribution according to BMI strata recorded throughout follow-up period.

Discussion:

The current study aimed to evaluate gastric sleeve surgery as a modality of bariatric surgery on obesity-associated co-morbidities; all enrolled patients had co-morbidities for a total number of co-morbidities of 127 co-morbidities in varied distribution among studied patients. At 24-month follow-up period 116 co-morbidities either resolved totally or improved with a target success rate of 91.3%.

Interestingly, diabetes mellitus completely disappeared as co-morbidity.

These data are in line with that reported in literature; Hinojosa et al.¹⁴ reported that weight loss associated with laparoscopic gastric bypass substantially improves and/or resolves hypertension in the majority of patients and improvement occurs as early as 1 month postoperatively and is more frequently in patients with a shorter preoperative duration

of disease. Rao et al.¹⁵ found that weight loss brought about a significant improvement in apnea hypoapnea index and continuous positive airway pressure requirements and laparoscopically placed adjustable gastric band placement should be considered a broadly effective therapy for sleep apnoea in the severely obese patient.

Shah et al.¹⁶ studied 15 patients with BMI 28.9 kg/m² who underwent Roux-en-Y gastric bypass and reported that all antidiabetic medications were discontinued by 1 month after surgery in 80% of patients and at 3 months and thereafter, 100% were euglycemic and no longer required diabetes medication, and their waist circumference, presence of dyslipidemia, and hypertension improved significantly. Pappachan et al.¹⁷ reported that bariatric surgery has emerged as an important and very effective treatment option for obese individuals especially in those with co-morbidities like hypertension and diabetes. Gagné et al.¹⁸ reported that after bariatric surgery diabetes had improved or went into remission in 90%, hypertension had improved or resolved in 62% and obstructive sleep apnea had improved or resolved in 96%. Moreover, Benaiges et al.¹⁹ reported that at 12 months, the overall cardiovascular risk decreased from 6.6% to 3.4% after both LGS and laparoscopic Roux-en-Y gastric bypass without a difference between both procedures.

One of the interesting outcomes of the current study is the control imposed by excess weight loss on insulin resistance as judged by HOMA-IR index which showed significant improvement compared to preoperative index. Improvement or resolution of obesity-associated co-morbidities could be attributed to the significant improvement of IR which underlay pathogenesis of these co-morbidities as documented previously; Cusi et al.²⁰ supposed that IR is characterized by selective impairment in phosphatidylinositol 3-kinase (PI 3-kinase)-dependent signaling pathways regulating metabolic actions of insulin in skeletal muscle with intact mitogen-activated protein kinase (MAPK) signaling pathways. In addition, insulin resistance is accompanied by compensatory hyperinsulinemia that serves to overcome impairment in PI 3-kinase

signaling to maintain euglycemia. However, this hyperinsulinemia is predicted to overdrive unaffected MAPK signaling that may promote pathological actions of insulin, including increased expression of vascular adhesion molecules, proliferation of vascular smooth muscle, increased expression of proinflammatory cytokines and activation of cation pumps. These factors may shift the balance between vasodilator and vasoconstrictor actions of insulin and result in predisposition to hypertension in insulin-resistant states.^{21,22}

As regards gastric sleeve as a procedure of bariatric surgeries; all patients showed a significant progressive %EWL and %EBMIL reaching a maximum at end of follow-up compared to at 3-month PO; these data indicated the applicability of laparoscopic sleeve gastrectomy as a primary and definitive line for management of obesity and morbid obesity and go in hand with Givon-Madhala et al.,²³ and Kasalicky et al.,²⁴ who reported the %EBMIL of 49% and 21% after 4 and 9-month follow-up, respectively. Also, Gagner et al.,²⁵ performed LSG for 63 super-super-obese patients with average preoperative BMI of 68 kg/m² and by 6 months postoperatively, the average BMI had decreased to 58 kg/m² and to 50 kg/m² one-year without further surgery. Moreover, Sánchez-Santos et al.,²⁶ reported a mean %EBMIL at 3 months of 38.8, 55.6 at 6 months, 68.1 at 12 months, and 72.4 at 24 months. Gagner et al.,⁵ through the Second International Consensus Summit for Sleeve Gastrectomy documented that LSG was intended as the sole operation for an average %EBMIL of about 60% through 4 years follow-up and concluded that LSG for morbid obesity is very promising as a primary operation.

The reported outcome of LSG could be attributed to the fact that LSG is putatively a purely restrictive operation that reduces the size of the gastric reservoir to 60-100 ml, permitting the intake of only small amounts of food and imparting a feeling of satiety earlier during a meal. Moreover, it has been suggested that attenuation of endogenous ghrelin levels may also contribute to the success of LSG; Ghrelin, which is thought to be a hunger-regulating peptide hormone, is mainly produced

in the fundus of the stomach and by resecting the fundus in LSG, the majority of ghrelin producing cells are removed, thus reducing plasma ghrelin levels and subsequently hunger.²⁷⁻³⁰

It could be concluded that bariatric surgery effectively improves obesity-associated co-morbidities and could be considered as non-pharmacological therapeutic modality for these co-morbidities. Laparoscopic gastric sleeve is a safe and effective appropriate surgical procedure for morbidly obese patients with associated co-morbidities.

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