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Two-stage laparoscopic biliopancreatic diversion with duodenal switch as treatment of high-risk super-obese patients: analysis of complications

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Abstract
Introduction The aim of this study is to retrospectively analyze the incidence of complications after two-stage laparoscopic biliopancreatic diversion with duodenal switch (Lap BPD-DS) in high-risk super-obese patients and explore the possible predictive factors of specific complications after laparoscopic sleeve gastrectomy (SG).
Methods High-risk patients—body mass index (BMI) > 50 kg/m^2 with at least two major comorbidities: type 2 diabetes, obstructive sleep apnea syndrome (OSAS), hypertension—undergoing two-stage laparoscopic BPD-DS were retrospectively analysed. The SG pouch volume was 100–150 ml; in the second stage, the common channel and the alimentary loop were 100 cm and 150 cm, respectively.
Results Eighty-seven patients (50 female, 57.5%) underwent SG (two open). The mean age was 41.8 ± 10.22 years with BMI of 55.2 ± 6.69 kg/m^2. Four patients had Prader–Willy syndrome. Fourteen (16.46%) patients (6 female, 42.8%) had postoperative complications such as bleeding, fistula, pulmonary embolism, transitory acute renal failure, and abdominal abscess. One patient died at postoperative day 5 of pulmonary embolism. One patient was reoperated for hemoperitoneum by laparoscopy. The risk of complications after SG was lower in patients where reinforcement of the suture line was used (0.492), while it was higher in men (1.780). Neither difference was statistically significant [p = not significant (NS)]. After 9–24 months, 27 patients (BMI 43 ± 8 kg/m^2) underwent a second stage of BPD-DS (two open). Major postoperative complications were registered in eight patients (29.6%): three bleeding, four duodeno-ileal stenosis and one rhabdomyolysis. Two cases of internal hernia required laparoscopic reoperation. The reoperation rate was 1/85 (1.2%) after SG and 2/27 (7.4%) after second stage.
Conclusions Complications after SG greatly decrease after the learning curve period and can be successfully managed without need of reoperation. Suture-line reinforcement, at least selectively in the middle-upper portion of the staple line and in super-super-obese patients, is recommended to decrease the incidence of specific complications.

Keywords Biliopancreatic diversion · Sleeve gastrectomy · Complications · Risk factors · Morbid obesity

The two-stage laparoscopic biliopancreatic diversion with duodenal switch (Lap BPD-DS) approach to treat obese patients is an acceptable way to treat super-super-obese patients (BMI > 60 kg/m^2): the first stage, consisting of a sleeve gastrectomy (SG), provides exceptional short-term weight loss and represents a bridge to a definitive complex malabsorptive procedure.

The SG was added as a modification to the biliopancreatic diversion (BPD) proposed by Scopinaro. It was combined with a duodenal switch (DS) in 1988 and was first performed laparoscopically in 2000 [1–4].

Ren et al. [2], in a series of 40 consecutive patients, reported a major complication rate of 38% associated with

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the one-stage Lap BPD-DS in patients with a BMI > 65 kg/m^2, compared with 8% for patients with a BMI of 40–60 kg/m^2. Based on these results, the two-stage operative approach was introduced for super-super-obese patients (BMI > 60 kg/m^2) consisting of an initial SG [5], followed 6–12 months later by the more definitive BPD-DS. This approach allows high-risk patients to undergo first a simpler and faster operation that affords good initial weight loss, followed by a definitive weight-loss operation that is better tolerated after the patient's BMI has dropped.

Even though the SG is a quick and relatively safe operation, specific complications have been described in the literature: suture-line bleeding (0–6.4%), leakage (0–1.4%), stricture and reflux [6]. A reoperation rate of 1.9% and mortality rate of 0–3.2% have also been reported [7–9].

The aim of this paper was to report the specific complications after the two-stage Lap BPD-DS, analysing the independent variables that could predict the occurrence of the major complications.

Materials and methods

High-risk super-obese patients (BMI > 50 kg/m^2) who underwent the two-stage Lap BPD-DS with a laparoscopic sleeve gastrectomy as the first stage followed by the second stage biliopancreatic diversion with duodenal switch between October 2002 and April 2007 were prospectively enrolled in the study. The data were collected prospectively using a computerised database devoted to bariatric surgery patients.

Only patients that fulfilled the following criteria were prospectively enrolled in the study: (1) super-obese, BMI > 50 kg/m^2 (including reoperation); (2) at least two major comorbidities: type 2 diabetes under treatment with oral antidiabetic drugs or insulin, severe obstructive sleep apnea syndrome (OSAS) requiring continuous positive airflow pressure (C-PAP) therapy, or hypertension under medical treatment. Preoperative work-up was the same as described in a previous article [10].

The sleeve gastrectomy was performed over a 48-Fr bougie to obtain a gastric pouch of 100–150 ml. The BPD-DS was completed as described in our previous article following the technique described by Gagner: duodeno-ileostomy end-to-side (CEEA 21, Covidien, Mansfield, MA) and ileo-ileostomy side-to-side (linear stapler white cartridge 45 × 25 mm, Covidien, Mansfield, MA), common channel 100 cm, and alimentary loop 150 cm [2, 10].

The following data were prospectively collected on a computerized database: sex, age, BMI, weight, comorbidities, duration of surgery, use of staple-line reinforcement, reoperation, eventual complications and treatment of complication with outcome.

Statistical analysis

The *T*-test and chi-square tests were used to compare the groups of patients. Means were calculated with standard deviation and logistic regression was used to analyse the independent variability in the sleeve gastrectomy patients using SPSS software.

Results

Eighty-seven high-risk super-obese patients (50 women, 57.5%; 37 men, 42.5%) were selected to undergo laparoscopic SG as the first stage of the Lap BPD-DS. Mean age was 41.8 ± 10.22 years and mean BMI was 55.7 ± 6.69 kg/m^2. Four patients (4.6%) had Prader–Willy syndrome, and 17 patients (19.3%) had a BMI ≥ 60 kg/m^2.

There were three (3.4%) conversions (mean BMI = 66.7 kg/m^2) to open surgery due to massive hepatomegaly in the SG patients. In one case, the BPD-DS was carried out in a single stage. Mean operative time for all surgeries was 122 ± 50.68 min.

Eleven (12.5%) were revisional surgeries for insufficient weight loss; the indication for the procedure in ten of these cases was revision for failure of adjustable gastric banding (BMI > 50 kg/m^2).

Fourteen (16.47%) patients (six women) had postoperative complications. The mean BMI of these patients was 41.8 ± 10.22 kg/m^2 and 55.2 ± 6.69 kg/m^2 respectively, with three of these patients having type II diabetes and nine having hypertension (Table 1).

Four patients had the suture line reinforced with either bovine pericardium (three patients) (Synovis, St. Paul, MN, USA) or SeamGuard (one patient) (Gore, Flagstaff, AZ, USA).

Eight patients had suture-line bleeding. Of these, four patients had melena and one had hematemesis between the first and the fifth postoperative day. Esophagogastroscopy revealed bleeding from the inner side of the staple line and the patients received blood transfusions. A total of two patients had extraluminal bleeding (hemoperitoneum) but only one required reoperation to stop the bleeding. This patient had an acute drop of the hematocrit with hypotension and tachycardia and was reoperated by laparoscopy on the first postoperative day. The bleeding was from a retrogastric vessel that was clipped.

One patient died 24 months after SG from aortic dissection.

Two patients had pulmonary embolism: one had concomitant bleeding from the suture line, the other patient presented with pulmonary embolism plus myocardial infarction at postoperative day 3 and died on postoperative day 5.

Table 1 Demographic of the patients (sleeve gastrectomy $n = 85$)

	Complications (%)	No complications (%)	
Number of patients	14 (16.04%)	71 (83.6%)	
Sex (female)	6 (42.8%)	43 (59.1%)	NS $p = 0.34 \times 2$
Age (years)	44.66 ± 12.18	41.26 ± 9.76	NS $p = 0.24$ *t*-test
BMI (kg/m^2)	55.2 ± 7.45	55.2 ± 6.58	NS $p = 0.97$ *t*-test
Diabetes	3 (21.4%)	11 (15.5%)	
Hypertension	9 (64.2%)	41 (57,7%)	
Reoperations	2 (14.2%)	9 (12.6%)	
Reinforcement	4 (28.5%)	25 (35.2%)	
Hospital stay (days)	8.2 ± 4.5	4.7 ± 1.3	$p = 0.02$

Three patients developed a fistula: two in the upper portion of the staple line, and one in the middle portion of the staple line. These patients all presented with fever, vomiting and leukocytosis. These patients were treated with percutaneous drainage, two of which also additionally required an endoprosthesis at the upper staple line/gastro-oesophageal junction. All patients were treated with antibiotic therapy, TPN, and high-dose intravenous proton pump inhibitor (PPI) (Fig. 1).

Patients with complications had mean hospital stay of 8 ± 4.5 days, whereas patients that did not experience any complication had mean hospital stay of 4.7 ± 1.3 days ($p < 0.05$).

Logistic regression was performed to predict the occurrence of specific complications in patients who underwent laparoscopic SG (first stage). We considered the occurrence of complications as a dependent variable and age >60 years old, BMI > 60 kg/m^2, sex, reoperation for failure of previous procedure and reinforcement of the suture line, as independent variables (Table 2).

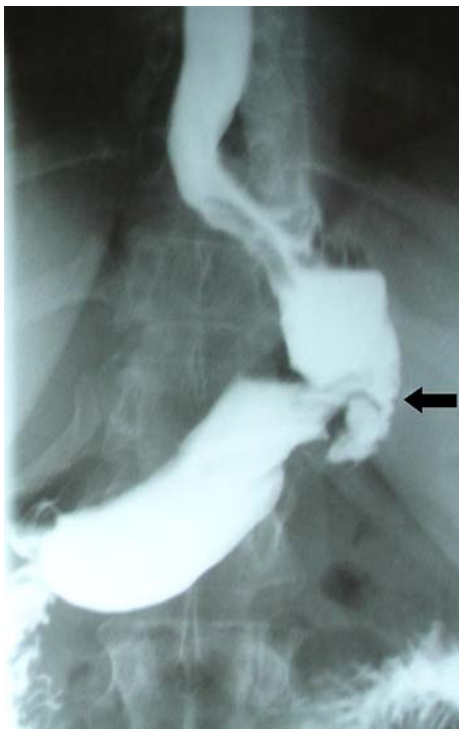

Fig. 1 Gastric fistula after laparoscopic sleeve gastrectomy

The risk of complication after laparoscopic SG was lower in patients with suture-line reinforcement (0.492) and higher in male patients (1.780), but neither of these differences was proven to be statistically significant [p = not significant (NS)].

The changes in BMI in patients who underwent the laparoscopic SG procedure are shown in Fig. 2. At 18 months, a mean BMI decrease of 15 kg/m^2 was observed.

For the first 40 cases in this study, the incidence of major complications was 9/40 (22.5%), which was higher than the last 45 cases which had a complication rate of 5/47 (10.6%). In the last 50 patients, the incidence of staple-line bleeding was also markedly decreased due to the selective use of staple-line reinforcement as well as improved surgical skills due to the learning curve of the surgeon.

Within 9–24 months after the first procedure, 27 patients, mean BMI 45.7 ± 7.6 kg/m^2, underwent the second procedure of BPD-DS (duodeno-ileostomy, ileo-ileostomy, common channel 100 cm). In two of these cases, the second stage was completed open (one case was converted at the first stage; the other patient had a permanent colostomy).

Mean operative time of these 27 cases was 201 ± 27 min with the patients having a preoperative mean

Table 2 Prediction of complication after sleeve gastrectomy

	p-value	Coefficient
Complication, constant variable	0.1387	0.011
Age (years)	0.2224	1.039
BMI (kg/m^2)	0.6534	1.022
Sex: male	0.3495	1.780
Reoperation	0.8609	0.816
Reinforcement	0.3230	0.492

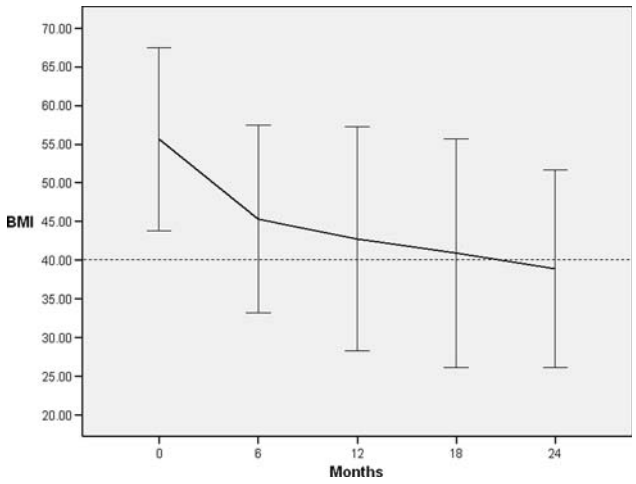

Fig. 2 BMI evolution in patients who underwent laparoscopic sleeve gastrectomy

American Society of Anaesthesiologists (ASA) score of 2.7 ± 0.8.

Major postoperative complications were recorded in eight patients (29.6 %): three with bleeding, four with stenosis of the duodeno-ileal anastomosis, and one with rhabdomyolysis with anastomotic ulcer and abscess of the abdominal wall (Fig. 3). Two cases of internal hernia required laparoscopic reoperation (Table 3).

The reoperation rate was 1/85 (1.2%) after the first-stage laparoscopic SG, and 2/27 (7.4%) after the second-stage BPD-DS.

The second stage was contraindicated in 8 of the 76 patients (10.5%) evaluated at follow-up of 12 months: 3 patients due to diagnosis of stage-I liver cirrhosis, 2 for severe myocardiopathy, 1 for hypocalcemia after total thyroidectomy for cancer, 1 for psychiatric disorder and 1 for renal cancer. In addition, after 12-month follow-up, 18 patients (23.6%) refused the second-stage BPD-DS. Fifteen of these showed satisfactory weight loss (BMI < 35 kg/m^2) and resolution/improvement of comorbidities. Eight cases were lost at follow-up (Fig. 4).

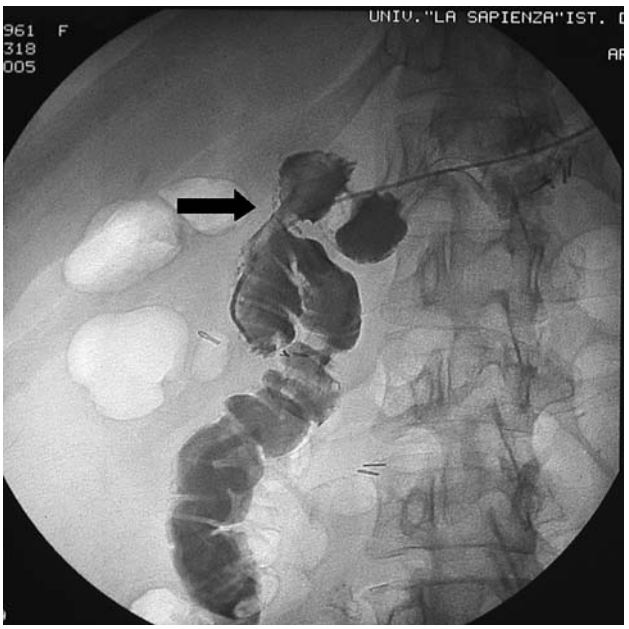

Fig. 3 Stenosis of the duodeno-ileal anastomosis

Discussion

The aim of this article was to analyze the safety of the laparoscopic SG and the BPD-DS in super-obese patients, and eventually determine if there are factors that can predict the occurrence of complications after SG.

In June 2007, the American Society for Metabolic and Bariatric Surgery released a position statement considering the sleeve gastrectomy as a possible surgical option to treat obesity. The statement gives a detailed review of the SG reported in the literature, with overall complication rates ranging from 0% to 24% and a reported mortality rate of 0.39% in 775 operations [11]. The most common adverse event was reported to be staple-line leakage requiring reoperation. Other complications such as splenic injury, hernia and stricture are less frequently reported (Table 4).

Gumbs et al. [9] reported on complications after SG described in the literature to date. There were four reported mortalities (<1%), one due to a traumatic trocar insertion, the second in the perioperative period, the third due to primary peritonitis 3 weeks after surgery even though no leak or bowel ischemia were identified on autopsy and the fourth due to a pulmonary embolism 3 months after surgery [5, 7, 9, 12–17].

Perhaps the greatest concern preventing surgeons from embracing SG is the long staple line created along the stomach, which can bleed or leak. The most frequent postoperative complication, in our series, was suture-line bleeding. Analyzing the incidence of this event in the first 40 cases, and then in the next 47 consecutive cases, the complication rate fell from 6/40 to 2/47. The above data, as well as the marked reduction of the operating time (122 versus 76 min, $p = 0.41$) suggest that the learning curve of the surgeon may play a major role in preventing bleeding. Seventeen patients had BMI > 60 kg/m^2 and the complication rate of this subgroup was 33.3%, compared with 15.3% in patients with BMI < 60 kg/m^2. This fact underlies that BMI > 60 kg/m^2 represents the greatest risk factor for postoperative complications.

Our data showed that the use of suture-line reinforcement (buttress material, running suture or fibrin glue) during the creation of the SG tended to decrease the development of complications more than age, BMI,

Table 3 Complications observed after the second stage

Complication	*N*	Time after surgery	Treatment
Bleeding	3	2–3 days	Blood transfusion
Stenosis of duodeno-ileal anastomosis	4	1–3 months	2 endoscopic dilation, 2 radiologic dilation
Rhabdomyolysis with acute renal failure	1	2 days	ICU
Internal hernia	2	16 and 24 months	Laparoscopic reoperation

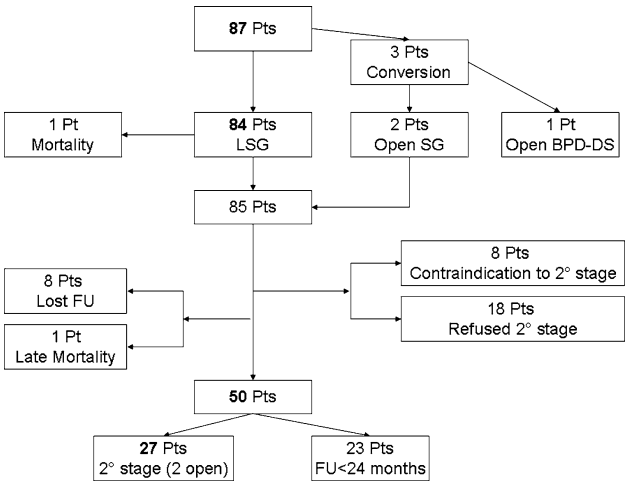

Fig. 4 Study group flow chart

Table 4 Complications after 646 laparoscopic sleeve gastrectomy in the literature (from [9] Table 2)

Reoperations*	29
Leak	6
Prolonged ventilator requirements**	5
Strictures	5
Renal insufficiency	4
Postoperative hemorrhage	2
Atelectasis	2
Pulmonary embolus†	2
Delayed gastric emptying	2
Gastric dilation	1
Prolonged vomiting	1
Subphrenic abscess	1
Trocar-site infection	1
Urinary tract infection	1
Splenic injury	1
Trocar site hernia	1
Death	4

* Indications not reported; ** >24 h ventilator requirements, † resulted in death

reoperation and sex: 0.492 for suture-line reinforcement versus 1.780 for male patients. Even if our data are not statistically significant, the decrease in complication rate that we were able to obtain is important.

It is almost intuitive that the best results in terms of preventing bleeding come from using suture-line reinforcement; the stomach has a thick wall with three layers of very well-vascularized muscle, and the long suture line needed to perform the SG gives the patient an increased risk of endoluminal and/or extraluminal bleeding. The use of bovine pericardium has been reported to not always be helpful in securing the suture line. While some authors consider it safe, others do not recommend the use of this material. Consten et al. found a fragment of the bovine pericardium used to reinforce the SG in the patient's vomit 4 weeks after the operation, indicating intraluminal migration of the reinforcing strips [18]. In another paper, they also described the use of a bioabsorbable polymer membrane (SeamGuard, Gore, Flagstaff, AZ, USA) to reinforce the staple line. Two groups of patients with and without SeamGuard were compared; perioperative blood loss was significantly higher in the group without SeamGuard (120 versus 210 ml, $p < 0.05$). Also, median length of hospital stay was higher in the group where SeamGuard was not used: 4.6 days (range 4–12 days) compared with 3.8 days (range 2–8 days) [19]. To reduce bleeding, Baltasar et al. used a continuous inverting seroserosal suture to invaginate the staples using polydioxanone from the angle of His to the mid-suture line followed by a second polydioxanone to the end of the staple line. This resulted in a decrease in leaks and better control of bleeding [7].

In our study, to reduce the incidence of bleeding and leaks from the staple line, we had the suture line reinforced in 25 out of 87 patients. Twenty-three patients had the bovine pericardium, three patients a manual continuous suture with PDS 00, and one patient the SeamGuard. Only one patient with the bovine pericardium experienced hematemesis at postoperative day 1 and was treated with blood transfusions.

Lee et al. reported a complication rate of 7.4% after vertical gastrectomy (VG), which included 5% readmission not requiring surgery, 2.8% reoperation and 4.6% major complications [8]. They also reported a complication rate increase to 48.2% when the duodenal switch was added at the same time as the VG. It is not clear from the article which complications arose from adding the DS to the VG. The complications may have been due to a specific metabolic problem from the DS, or could be attributed to the long staple line used to create the VG [8].

Out of the 85 patients in our study who had the SG, only 27 underwent the second stage BPD-DS. There were several reasons for this. In a number of cases, the patient elected to stay with the SG only. Fifteen patients refused to undergo the BPD-DS, being very satisfied with their current status (BMI < 35 kg/m^2). However, in eight patients, the second stage was contraindicated due to evidence of concomitant diseases (cardiomyopathy, cirrhosis and/or psychosis).

It is still unclear if the sleeve gastrectomy can be considered a definitive operation to treat obesity since long-term data are not currently available in the literature, but the patients' satisfaction and the positive results obtained so far can be a good enough reason to postpone the second stage.

Conclusions

Complications after sleeve gastrectomy greatly decrease after the learning curve period for the surgeon, and many can be successfully managed without need of reoperation.

Age and reoperation do not seem to be important variables in the developing of complications after sleeve gastrectomy. Suture-line reinforcement, both in the middle-upper portion of the staple line, and in super-super-obese patients, is recommended to decrease the incidence of specific complications.

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