Surg Endosc
DOI 10.1007/s00464-015-4205-y

Assessment of perioperative complications following primary bariatric surgery according to the Clavien–Dindo classification: comparison of sleeve gastrectomy and Roux-Y gastric bypass

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Received: 4 December 2014 / Accepted: 31 March 2015

Abstract

Background Laparoscopic Roux-Y gastric bypass (LRYGBP) is the gold-standard procedure for the treatment of morbid obesity. It has been reported to be somewhat more efficient and durable than laparoscopic sleeve gastrectomy (LSG). However, it is considered more invasive and, therefore, more hazardous. There is a lack of unity in complication reporting following bariatric surgery. Thus, there is a possible misconception regarding the relative safety of the two major bariatric procedures performed worldwide. This may have contributed to a shift in practice with LSG gaining momentum "at the expense" of LRYGBP. The aim of this study was to evaluate the relative safety of primary LSG and LRYGBP according to the Clavien–Dindo complication grading system.

Methods A total of 2651 and 554 patients underwent primary LSG and LRYGBP, respectively at three high-volume centers. Thirty-day perioperative complications were recorded and graded. Length of hospital stays (LOS) and readmission rates were collected as well.

Results Complications occurred in 110 (3.7 %) and 24 (4.3 %) patients following LSG and LRYGBP, respectively ($p = 0.9$). No significant difference was found between the groups regarding overall and complication-grade-specific rates. Individual complication types were unevenly distributed, but not significantly so. Patients with complications were older than those without (47 and 43 years, respectively; $p = 0.01$). Gender was not a risk factor for complication. Median LOS and readmission rates were not significantly different.

Conclusions LSG and LRYGBP are equally safe, at least in the perioperative period. Acknowledging and conveying this finding to surgeons and patients alike is important and might cause a pendulum shift in the distribution of bariatric procedures performed.

Keywords Bariatric · Complications · Sleeve gastrectomy · Gastric bypass · Clavien–Dindo classification

Bariatric or weight loss surgery (WLS) has become the mainstay of treatment for morbid obesity with many thousands of procedures performed annually [1]. It has been documented as a highly effective weight loss tool, improving obesity-related comorbidities, quality of life and survival [2, 3]. The quoted mortality rate is well beneath 1 % in the vast majority of series and is proportional to the volume of the reporting center [4–6]. Despite these positive results, all bariatric procedures have inherent complications which invariably affect patient disposition and well-being and occur in 10–40 % of cases [7, 8]. This extremely wide range is probably attributed to a lack of unity in adverse surgical outcome reporting, and not to differences in

Presented at the 22nd EAES Congress, June 25–28, 2014, Paris, France.

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expertise. While mortality is an easily quantifiable outcome parameter, overall morbidity and its severity are poorly defined, hindering comparison between different centers. The most serious complications following WLS are postoperative leak, venous thromboembolic adverse events (i.e., deep venous thrombosis, portomesenteric thrombosis and pulmonary embolism) and bleeding [9–12].

The most frequently performed bariatric procedures are laparoscopic sleeve gastrectomy (LSG) and laparoscopic Roux-en-Y gastric bypass (LRYGBP) [13–16]. The specific method selected depends on several objective parameters (e.g., total excess weight, comorbidity profile, previous interventions, patient habitus and eating behavior) and subjective parameters (e.g., surgeon experience and preference, trends in practice and patient preference). The quoted "safety" of the procedure greatly influences this decision [17]. In this respect, many surgeons believe LSG to be safer than LRYGBP and convey this to the patients, not to mention the popular notion stating the same [18]. Among other reasons, this has caused a dramatic shift in practice so that LSG is rapidly gaining momentum, "at the expense" of LRYGBP [13–15, 16].

In 1992, a novel approach was presented for ranking complications by severity based on the therapies used to treat them [19]. The same authors revised this grading system in 2004, introducing a new five-scale classification system with the aim of presenting an objective, simple, reliable and reproducible way of reporting all complications after surgery [20]. From January 2004 to March 2009, 214 citations of this classification system were reported, none of which included WLS [21]. The current study compared the postoperative complications of LSG and LRYGBP according to the Clavien–Dindo (CD) classification in order to objectively quantitate procedure safety.

Patients and methods

Detailed, prospectively managed databases of all WLS are kept by the authors, accounting for procedures performed in three high-volume centers (performing >500 varied bariatric procedures per year). These databases were retrospectively queried for all primary LSG and LRYGBP (without previous bariatric interventions) performed between June 2007 and June 2014.

Surgical technique: All surgeries were performed by the authors, all well beyond their learning curve for both procedures.

LSG was performed using a four-port technique to resect the greater curvature of the stomach with endoscopic linear staplers (Echelon 60 Endopath Stapler®, Ethicon Endosurgery, Cincinnati, OH, or Endo GIA™ Staplers with Tri-Staple™ reloads, Covidien, Norwalk, CT) alongside a round-tipped silicone bougie (Pilling® Hurst Bougie Tungsten, Teleflex Medical, High Wycomb, UK). A fifth port was occasionally added for additional retraction. Endoscopic clips were used liberally for hemostasis of the stapler line. The bougie sizes used in the procedure were 32F and 34F, according to surgeon preference.

LRYGBP was performed using a 4–5-port technique. A 20–30-ml proximal gastric pouch was fashioned using endoscopic linear staplers (Echelon 60 Endopath Stapler®, Ethicon Endosurgery, Cincinnati, OH, or Endo GIA™ Staplers with Tri-Staple™ reloads, Covidien, Norwalk, CT). Gastroenterostomy and jejunojejunostomy were performed using linear stapling with hand-sewn enterotomy closure, using single-layer, continuous 2/0 polyglactin-braided suture (Ethicon Endosurgery, Cincinnati, OH). The alimentary limb was antecolic antegastric and measured 100–150 cm. The biliopancreatic limb was 50–60 cm.

All patients were treated with sequential compression devices until full ambulation and subcutaneous low-molecular-weight heparin for 2 weeks postoperatively.

Perioperative complications recorded were graded according to the Clavien–Dindo classification (Table 1). Statistical analysis was performed to evaluate the difference between the two procedures by complication grade. Average lengths of hospital stay, 30-day emergency room visits and hospital readmission rates were also recorded.

Statistical analysis: Analysis of data was performed using SPSS 11.0 statistical analysis software (SPSS Inc., Chicago, IL, USA). Distributions of continuous variables were assessed for normality using the Kolmogorov–Smirnov test (cutoff at $p = 0.01$). Normally distributed continuous variables were described as mean ± standard deviation, while continuous variables with distributions significantly deviating from normal were described using mean (minimum–maximum). Continuous variables were compared by using Student's t test for independent samples. Categorical variables were described using frequency distributions and are presented as frequency (%). Categorical variables were compared using the Chi-square or Fisher's exact test as necessary. All tests are two-tailed and considered significant at $p < 0.05$.

This study was approved by the institutional review boards of the three institutions.

Results

During the study period, 2651 and 554 morbidly obese patients underwent LSG and LRYGBP as primary weight loss procedures in three high-volume bariatric centers, respectively. Average BMI and age were 43.0 kg/m^2 (range 35–72 kg/m^2), 42 years (range 19–71 years) and 43.1 kg/m^2 (range 35–67 kg/m2), 43 years (range 21–68 years),

Table 1 Clavien–Dindo classification of surgical complications

Grade	
1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions
	Acceptable therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy
	This grade also includes wound infections opened at the bedside
2	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions, antibiotics and total parenteral nutrition are also included
3	Requiring surgical, endoscopic or radiological intervention
3a	Intervention under regional/local anesthesia
3b	Intervention under general anesthesia
4	Life-threatening complication requiring intensive care/intensive care unit management
4a	Single-organ dysfunction
4b	Multi-organ dysfunction
5	Patient demise

respectively. Comorbidity and gender distribution were similar with no statistically significant difference between the groups (Table 2). Median length of hospital stays was 2 days for both groups and, expectedly, longer in patients who suffered complications, regardless of type of surgery, but dependent on complication grade (data not shown).

Complications occurring within 30 days postoperatively were recorded in 110 (3.8 %) and 24 (4.3 %) patients following LSG and LRYGBP, respectively. Though slightly higher in the LRYGBP group, the overall morbidity was statistically similar ($p = 0.9$). Gender distribution was similar between the two groups as well as between the patients with complications and the entire cohort. Average age was higher in patients who had complications than in those who did not (47.5 years and 43.1 years, respectively; $p = 0.01$), but similar between patients in the two procedure types (LSG—47.3 years, LRYGBP—49 years; $p = 0.55$)

When broken down to Clavien–Dindo grading, the lack of statistically different differences remained (Table 3).

Table 3 Perioperative (<30 days) complications distribution by Clavien–Dindo (CD) grade

CD grade	LSG *n* (%)	LRYGB *n* (%)	*p* value
All	110 (3.8)	24 (4.3)	0.9
1	19 (0.7)	2 (0.3)	0.5
2	43 (1.6)	13 (2.3)	0.3
3a	18 (0.7)	5 (0.9)	0.7
3b	22 (0.8)	2 (.3)	0.4
4a	5 (0.2)	1 (0.1)	0.6
4b	2 (0.07)	1 (0.1)	0.9
5	1 (0.04)	0	0.4

Regarding the distribution of complication types, we found only slight trends without a significant difference between the two procedures. Thus, there was a higher proportion of bleeding within the patients with

Table 2 Demographic, anthropometric and comorbidity characteristics of primary bariatric surgery cohort

	LSG ($n = 2651$)	LRYGBP ($n = 554$)	*p* value
Age years (range)	42 (19–71)	43 (21–68)	NS
Female %	74 %	70 %	NS
BMI Kg/m^2 (range)	43.0 (35–72)	43.1 (25–67)	NS
HTN (%)	920 (32 %)	166 (30 %)	NS
T2DM (%)	869 (33 %)	174 (31 %)	NS
OSAS (%)	562 (21 %)	93 (17 %)	NS
Chol (%)	1411 (53 %)	271 (49 %)	NS
GERD %)	560 (21 %)	120 (22 %)	NS

LSG laparoscopic sleeve gastrectomy, *LRYGB* laparoscopic Roux-Y gastric bypass, *BMI* body mass index, *HTN* hypertension, *T2DM* type 2 diabetes mellitus, *OSAS* obstructive sleep apnea syndrome, *Chol* dyslipidemia, *GERD* gastroesophageal reflux disease, *NS* nonsignificant complications after LSG, when compared to LRYGBP (60 vs. 54 %, respectively; $p = 0.7$; 95 % CI 0.88–1.2), as well as leaks (20 vs. 12.5 %, respectively; $p = 0.6$; 95 % CI 0.91–1.29). More venous thromboembolic events were recorded following LRYGBP, when compared to LSG (4.2 vs. 3.6 %; $p = 0.9$; 95 % CI 0.62–1.5).

Specific complication types were unevenly distributed between various Clavien–Dindo grades, but no significant distribution difference was found between the two procedures.

Absolute complication rates were similar between the two procedures (Table 4).

Thirty-day emergency room visits and hospital readmission rates were similar between the groups, though slightly higher in patients following LSG (2.1 and 1.8 % in LSG and LRYGBP, respectively). This difference was not statistically different ($p = 0.9$).

Discussion

The most commonly utilized bariatric procedures worldwide are LSG and LRYGBP [13–15, 16]. The method of choice for WLS depends on many parameters, both objective and subjective. There are several reports in the literature comparing these two operations, with mixed conclusions. Some authors conclude that LRYGBP is slightly more efficient than LSG, with reportedly superior and more durable percent excess weight/BMI loss and better resolution of metabolic comorbidities (mainly type 2 diabetes mellitus) [22, 23].Others report non-inferiority, or even superiority of LSG [24–26]. The same is true regarding the quoted safety of these two procedures. There are studies documenting fewer complications in LSG than in LRYGBP [25, 26], and others which have found similar or even less complications in LRYGBP [18, 27, 28]. In contrast to most types of elective surgeries, patient preference is of utmost importance in choosing the bariatric procedure. Most surgeons explain the various options, respective advantages and drawbacks and allow the patient to choose [27, 29]. However, it is not uncommon to encounter pre-decided patients who arrive to the initial consultation, knowing which procedure they want. They are usually "armed" with prior information, gleaned from both reliable (professional literature or prior medical consultations) as well as less reliable sources (hearsay, popular internet forums, etc.). It is sometimes very difficult to dissuade patients from their "procedure of choice" to the one expected to be better suited for them by the bariatric team. The perceived complexity and safety of the procedure plays a major role in both the surgeon and the patient's tendency to offer or choose one procedure over the other. LSG is undoubtedly less complex than LRYGBP and logically, should be the safer technique. Though probably not the only reason, this has caused a worldwide shift in trends of procedure choice toward higher utilization of LSG than LRYBGP [13–16].

Table 4 Absolute 30-day complication rates

	LSG	LRYGBP	*p* value
Bleeding n (%)	66 (2.5 %)	16 (2.8 %)	0.7
Leak n (%)	22 (0.8 %)	4 (0.7 %)	0.9
VTE n (%)	4 (0.2 %)	1 (0.2 %)	0.7
Obstruction n (%)	3 (0.1 %)	1 (0.2 %)	0.8

LSG laparoscopic sleeve gastrectomy, *LRYGBP* laparoscopic Roux-Y gastric bypass, *VTE* venous thromboembolic event

However, the incidence of complications following WLS varies widely between reports. There appears to be two types of reporting strategies:

a. Reporting on the various incidences of specific complication entities (i.e., percentage/number of patients with postoperative leaks, bleeding, wound infection, etc.) [18, 23, 30, 31].
b. Division to "major" and "minor" complications [27, 32, 33].

Even in the latter, there appears to be great inconsistency. Some authors define morbidities as "major" when they are life threatening vs. "minor", which are not. Others dub "major" complications in which an additional intervention (endoscopic, surgical or other) was necessary versus "minor" when no such interventions were used. Other authors assign specific complication entities to a "major" complication group (usually leak, bleeding, VTE and others) and different specific complications are labeled "minor" (usually dehydration, wound infection, urinary tract infection, etc.). This lack of unity makes an objective comparison between different series complex and problematic.

The inherent problem in this classification strategy revolves on the fact that a specific complication might have a spectrum of clinical manifestations which dictate different therapeutic choices. A bleeding patient might require fluid replacement, blood products, percutaneous drainage of hematoma or surgical exploration, depending on the severity of the clinical impact. This is true for all complication entities but is not taken into account by the aforementioned classifications.

Utilizing the Clavien–Dindo classification helps eliminate this confusion and allows for accurate and uniform complication grading and reporting.

In our study, 30-day complications occurring in a large cohort of primary WLS patients were divided according to this classification. Only a limited number of studies have done the same, and for much smaller cohorts [25, 26]. We found a similar complication rate and, more importantly, an even distribution of complication grades between the two groups. The "blend" of complication types was slightly different but not significantly so. Length of hospital stays and readmission rates were, likewise, similar.

The current study has several limitations including its retrospective, observational design. Arguably, a prospective randomization of patients to either LSG or LRYGBP might have yielded different complication rates. Furthermore, only early, 30-day complications were included, thus removing from the equation typical late complications differing in occurrence after each procedure. These would include macro- and micronutrient deficiencies, marginal ulcers and internal hernias more likely after LRYGBP, and new-onset gastroesophageal reflux, stomach dilatation and a worrisome "new" entity of chronic, difficult-to-treat gastric fistulae after LSG [34–36].

We conclude that LRYGBP and LSG are equally safe, at least in the short term. With the growing number of patients subjected to LSG and the emerging reports on long-term results and complications thereof [12, 34–37], perhaps reevaluation with a possible "pendulum shift" of bariatric procedure utilization is in order.

Disclosures Drs. D. Goitein, A. Raziel, A. Szold and N. Sakran have no conflict of interest to disclose.

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