

Functional Laparoscopic Roux-en-Y Gastric Bypass with Fundectomy and Gastric Remnant Exploration (LRYGBfse): Learning Curve Assessment Using the Cumulative Sum Analysis Methodology (CUSUM)

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ABSTRACT

Introduction: The functional laparoscopic gastric bypass with fundectomy and gastric remnant exploration (LRYGBfse) has been described in attempt to overcome the intrinsic limitations of the LRYGB with promising results. However, the detailed learning curve related to this innovative procedure has not been assessed.

Materials and Methods: Retrospective multicenter study from December 2010 to January 2015. Data were prospectively collected from one surgeon experienced in laparoscopic surgery. The cumulative summation methodology (CUSUM) was applied to visualize the learning curve of LRYGBfse.

Results: Overall, 293 LRYGBfse were included. The majority were females (58%) and the median age of was 41.3 years (range 26-58). The median preoperative body mass index was 44.9 kg/m² (range 36.4-50.3). The median operative time (OT) was 197 min (range 124-327). The 90-day morbidity rate was 1.32%. The CUSUM showed that the number of consecutive procedures needed to reach competency was 107 thus identifying two distinct phases of the curve. The comparative analysis did not show statistically significant differences for demographics, preoperative BMI, comorbidities, reoperation (1.86% vs. 0.53%; $p=0.064$) and overall complications (1.8% vs. 1.07%; $p=0.47$) between the two phases. OT (232 vs. 185 minutes; $p=0.017$) and hospital length of stay (6 vs. 4; $p=0.041$) were significantly reduced in the second phase.

Conclusions: The functional LRYGBfse seems feasible and safe even in the first phase of the learning curve. Our data seem to suggest that 107 procedures are required to gain LRYGBfse competence with a significant decrease of operative time and hospital length of stay.

Key words: functional laparoscopic gastric bypass with fundectomy and gastric remnant exploration (LRYGBfse), CUSUM, learning curve, operative time

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INTRODUCTION

The laparoscopic Roux en-Y gastric bypass (LRYGB) is a worldwide performed

operation for obesity and is considered by many the gold standard treatment because its exceptional outcomes in term of weight loss, comorbid resolution, and quality of life improvement (1-4). The challenging diagnosis and treatment of emerging diseases in the gastric remnant, duodenum, and common bile duct constitute an intrinsic limitation (5-7). Mastery of LRYGBP is reported to require a steep learning curve where operative time and morbidity rate may be augmented (8). Nowadays, most authors agree that the LRYGB learning curve involves 75-100 cases per surgeon (9-10).

The functional laparoscopic gastric bypass with fundectomy and gastric remnant exploration (LRYGBfse) has been described in attempt to overcome the intrinsic limitations of the LRYGB (11-13). The procedure consists in the creation of a small gastric pouch (about 20-30 cc) by resecting the gastric fundus. A polytetrafluoroethylene banding (ePTFE) is placed at the gastro-gastric communication (7 cm below the cardia) to divert the bolus through the alimentary limb with duodenal and jejunal functional exclusion. The endoscopic exploration of the remnant and duodenum is feasible via gentle endoscope advancement through the gastro-gastric communication. Previous studies reported the promising results of the LRYGBfse in term of weight-loss, comorbid resolution and quality of life improvement (14) however, the learning curve related with LRYGBfse has not been appraised yet.

This study aimed to evaluate surgeon learning curve for LRYGBfse using the cumulative summation methodology (CUSUM).

MATERIALS AND METHODS

Patient selection

Between December 2010 and January 2015, we conducted a prospective multicenter study on LRYGBfse. Data were entered into a dedicated dataset and reviewed retrospectively. All the procedures were performed by one senior surgeons (GL) experienced in laparoscopic surgery. All included patients met the National Institute consensus for bariatric surgery (15) and the Italian guidelines, according to the IFSO (International Federation for the Surgery of Obesity and Metabolic Disorders) guidelines, for surgery in the morbidly obese patient (<http://www.sicob.it>). All subjects provided written informed agreement to be part of the study. The study was approved by the local Research Ethics Committee. Primary aim was to assess one surgeon

learning curve to attain competency with the LRYGBfse.

Operative time (OT) was defined as the time between skin incision and closure. Collected data: age, sex, preoperative weight (kg), body mass index (BMI), intraoperative complications, postoperative complications (90-day morbidity), and readmission rates (90 days). A complication was defined as any deviation from the normal postoperative course and ranked according to the Dindo-Clavien severity classification (16).

Surgical technique

Preoperative evaluation and surgical procedures have been described previously (11-12). Briefly, after the placement of a 36-Fr orogastric probe, fundectomy is completed with EndoGIA™ linear stapler firings (Medtronic, Minneapolis, MN, USA) to create a 20-30cc gastric pouch. A polytetrafluoroethylene banding (ePTFE) is placed at the gastro-gastric communication (7 cm below the cardia) and gently closed after bougie retraction. The bypass is completed by the creation of an antecolic Roux-en-Y 150 cm alimentary and 150 cm biliopancreatic limb. Linear side-to-side gastrojejunal and jejuno-jejunal anastomosis (45-mm EndoGIA™) are fashioned (*fig. 1*). Petersen's defect is routinely closed.

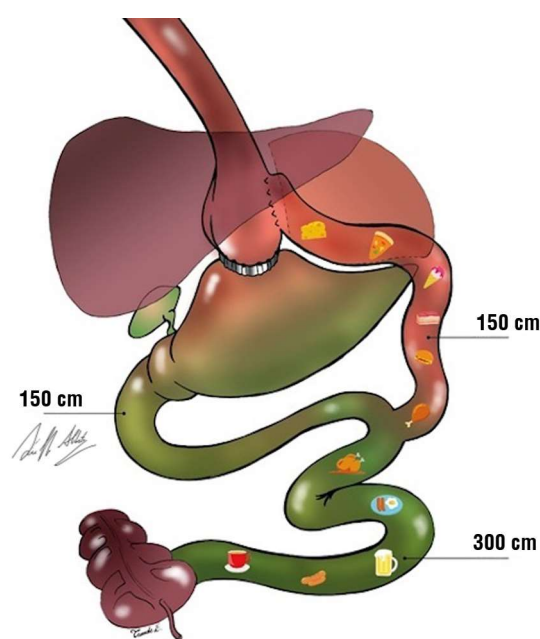


Figure 1 - The functional laparoscopic gastric bypass with fundectomy and gastric remnant exploration (LRYGBfse) technique.

Cumulative sum analysis

The CUSUM technique was used for the learning curve quantitative assessment (17-18). The CUSUM is the running total of differences between the individual data points and the mean of all the data points (19-20). The CUSUM was used to evaluate the OT for all 293 cases. To compute the CUSUM, the cases were ordered chronologically. The CUSUM of the first case was the difference between the OT for the first case and the mean OT for all the cases. The CUSUM of the second case was the previous case's CUSUM added to the difference between the OT for the second case and the mean OT for all the cases. The process was continued for all included patients. As in the study by Bokhari et al. (21), risk adjusted CUSUM was not performed because no deaths occurred in this series and the postoperative complication rate was low (n=4).

Statistical analysis

Continuous data are reported as median and range. Categorical data are reported using absolute and percentage frequencies. Chi-square or Mann-Whitney tests were performed as proper. Two-sided p values were calculated. P value equal or less than 0.05 was considered statistically significant. R version 3.2.2 software was used for statistical analysis (22).

RESULTS

During the study period, 293 consecutive LRYGBfse were included. The patients were 170 women (58%) and the median age of was 41.3 years (range 26-58). The median preoperative BMI was 44.9 kg/m² (range 36.4-50.3) and the median preoperative weight was 128.9 kg (range 98-152.1). Baseline demographics are presented in *table 1*.

Perioperative results are summarized in *table 2*. The median OT was 197 min (range, 124–327). No intraoperative complications or conversions to open procedure occurred. The postoperative 90-day morbidity rate was 1.32% (n=4). In one patient the postoperative course was complicated by gastro-jejunal anastomotic bleeding successfully managed with endoscopic clipping (Grade IIIa). In three patients, a reoperation (Grade IIIb) was required because intra-abdominal bleeding, internal hernia and intestinal occlusion sustained by trocar site hernia. The median postoperative hospital length of stay was 4 days (range 2–12) and median intensive care unit length of stay was 1 (range 1–3). None of the

Table 1 - Baseline patients' demographics. Data are presented as median (IQR), and n (%). Legend. BMI: Body mass index; GERD gastroesophageal reflux disease; OSAS: Obstructive sleep apnea syndrome. Data are presented as median (range) for continuous variables and as number (percentage) for categorical variables

No. patients	n=293
Age, years, median (range)	41.3 (26-58)
Female, n (%)	170 (58)
Pre-op body weight (Kg), median (range)	128.9 (98-152)
Pre-op BMI (Kg/m ²), median (range)	44.9 (36.4-50.3)
BMI 35 - <40 kg/m ² , n (%)	54 (18.4)
BMI 40 - <50 kg/m ² , n (%)	204 (69.9)
BMI 50 - <60 kg/m ² , n (%)	35 (12.7)
Comorbidities	
Hypertension, n (%)	167 (57.1)
Dyslipidemia, n (%)	145 (49.5)
GERD, n (%)	112 (38.2)
Diabetes, n (%)	95 (32.4)
OSAS, n (%)	66 (22.5)
Depression, n (%)	34 (11.8)

patients required postoperative mechanical ventilator assistance. The overall mortality was 0% (95% CI 0.0–0.5%).

The raw OT data were plotted in chronological order (*fig. 2*). The CUSUM learning curve is depicted in *fig. 3*. The CUSUM-LRYGBfse showed that the number of operations required to reach competency and overcome the learning curve was 107. Comparison of parameters between the two phases identified by CUSUM analysis is described *table 3*. No differences were found in term of patient demographics comparing the two surgical phases. Postoperative complications

Table 2 - Perioperative outcomes. OT operative time; ICU intensive care unit; HLOS hospital length of stay. Data are presented as median (range) for continuous variables and as number (percentage) for categorical variables.

Perioperative outcomes	No. 293
Median OT (mins) (range)	197 (124-327)
Intraoperative complications, n (%)	0 (0)
Intraoperative blood loss (ml), (range)	75 (0-185)
Conversion to open, n (%)	0 (0)
Reoperation, n (%)	3 (1.02%)
Overall complications; n (%)	4 (1.36)
Anastomotic bleeding	1
Intra-abdominal bleeding	1
Internal hernia	1
Trocar site hernia	1
ICU, median (range)	1 (1-3)
HLOS, median (range)	4 (3-12)
Mortality	0 (0%)

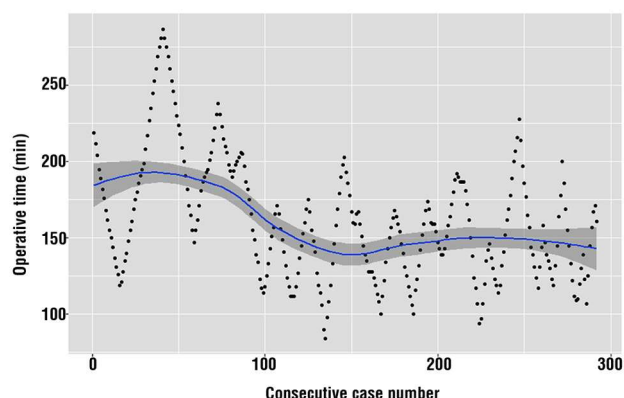


Figure 2 - Learning curve: operative time in minutes (Y axis) plotted against consecutive case number (X axis). The blue line represents the learning curve using loess fit with relative 95% confidence bands.

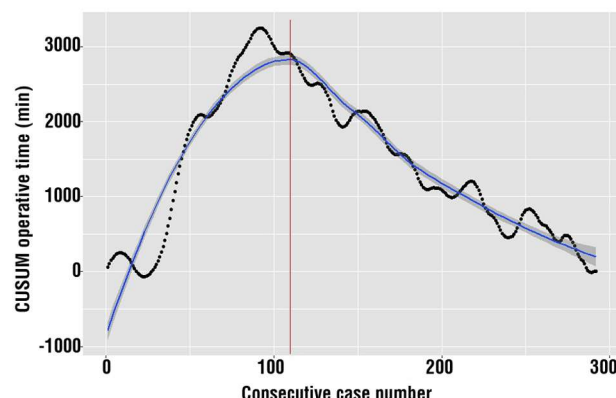


Figure 3 - Cumulative sum (CUSUM) for operative time (Y axis) plotted against consecutive case number (X axis). The blue line represents the CUSUM learning curve using loess fit with relative 95% confidence bands. The vertical red line indicates the turning point at which the surgeon transitions from phase 1 to phase 2 and overcome the OT-learning curve (n=107).

(1.9% vs. 1.1; $p=0.967$) reoperation (1.9% vs. 0.5%; $p=0.625$) and 90-day hospital readmission (0.9% vs. 0.0%; $p=0.879$) were also comparable. OT (232 vs. 185 minutes; $p=0.017$) and HLOS (6 vs. 4 days; $p=0.041$) were significantly reduced between phase 1 vs. phase 2.

Table 3 - Comparisons between phases of patient characteristics and perioperative outcomes. Legend. BMI: Body mass index; GERD gastroesophageal reflux disease; OSAS: Obstructive sleep apnea syndrome. Data are presented as median (range) for continuous variables and as number (percentage) for categorical variables.

	Phase 1 (No. 107)	Phase 2 (No. 186)	p value
Demographics			
Age, years, median (range)	40.9 (27-58)	42.3 (26-57)	0.53
Female, n (%)	62 (57.9)	108 (58.1)	0.99
Pre-op body weight (Kg), median (range)	127.9 (98-149)	130.4 (99-152)	0.69
Pre-op BMI (Kg/m ²), median (range)	44.2 (36.4-50.1)	45.7 (37.8-50.3)	0.87
Comorbidities			
Hypertension, n (%)	58 (54.2)	109 (58.6)	0.542
Dyslipidemia, n (%)	54 (50.5)	91 (48.9)	0.894
GERD, n (%)	39 (36.4)	73 (39.2)	0.727
Diabetes, n (%)	37 (34.6)	58 (31.2)	0.639
OSAS, n (%)	26 (24.3)	40 (21.5)	0.685
Depression, n (%)	11 (10.3)	23 (12.4)	0.729
Perioperative outcomes			
Median OT (mins) (range)	232 (154-327)	185 (124-264)	0.017
Intraoperative complications, n (%)	0 (0)	0 (0)	ns
Intraoperative blood loss (ml), (range)	95 (50-185)	50 (0-120)	0.64
Conversion to open, n (%)	0 (0)	0 (0)	ns
Reoperation, n (%)	2 (1.9)	1 (0.5)	0.625
Overall complications, n (%)	2 (1.9)	2 (1.1)	0.967
ICU, median (range)	1 (1-3)	1 (1-2)	0.53
HLOS, median (range)	6 (4-12)	4 (3-7)	0.041
Hospital readmission	1 (0.9)	0 (0)	0.879
Mortality, n (%)	0 (0)	0 (0)	ns

DISCUSSION

The functional LRYGBfse seems feasible and safe while the possibility to endoscopically access the gastric remnant is a major advantage over the standard LRYGB. Using operative time as referral outcome, CUSUM-LRYGBfse curve presents its inflection point at the 107th case and implies that 106 procedures are needed to gain competence with this surgical procedure.

The learning curve has been definite as the whole learning process until the individual gathers enough experience to reach a plateau (23-24). It can be assessed using several outcome measures (i.e. operative time, postoperative complications, blood loss, conversion to open, etc.) that can be divided in two clusters: patient outcome variables and surgical efficiency variables (25). Operative time and postoperative complications have an important role for each cluster and are denoted as main parameters for the definition of the bariatric learning curve (26).

LRYGB has been shown to be associated with a steep learning curve principally because the difficult procedural steps and advanced technical ability such as intracorporeal knot fashioning and suturing in a limited and constricted working space (27). To date, articles investigating the learning curve for LRYGB based their scrutiny on chronological cases split into predefined segments, with univariate analysis performed to compare means across groups. Specifically, as reported by a recent review, the LRYGB learning curve has been reported to be widely distributed ranging from 30 to 500 cases (26). Specifically, Shen et al. demonstrated that proficiency with considerable decrease in operative time and postoperative complications may be achieved with 30 cases (28). In contrast, Shiroka et al. and Jacobsen et al. found that 100 procedures are necessary to halve operative time (29-30) while El-Kadre et al. demonstrated that 500 procedures are necessary to significantly reduce the risk of postoperative adverse event (31). Notably, heterogeneity related to such a wide distribution is attributable to different patient and surgeon-related factors such as preoperative BMI, surgeon experience, training, and proficiency definition.

The cumulative-sum (CUSUM) method was introduced 50 years ago in the United Kingdom (UK) and has been proposed as an effective tool for analysis of the learning process (32). Initially used in industrial quality controls, the CUSUM-method was first used 10 years ago as a means of monitoring surgical performance (25). CUSUM is a tendency representation of a series of repeated procedures calibrate to the

mean value. Despite its limitations, it has been suggested CUSUM is the best tool for quality control in health care clinical domains (18). This sensitive methodology is feasible as it permits one to work with an unknown, increasing sample size and seem to be more efficient than the rest of the medical quality tools detecting changes (19). In addition, CUSUM analysis defines experience as a continuous variable (33-34). In bariatric surgery, the CUSUM method has already been used to assess robotic Roux-en-Y gastric bypass (35) and laparoscopic sleeve gastrectomy (36) but no reports have been published describing the number of cases that a surgeon is required to have worked on train and become proficient with LRYGBfse. This new surgical technique has been defined with the intent to overwhelm the limitations of the standard operation without altering its results (10-11). In the present series the CUSUM curve shows its inflection point at the 107th case and implies that 106 procedures are needed to gain competency with LRYGBfse. Interestingly, this result seems similar to previous series reporting data for LRYGB. Specifically, Ballesta-Lopez et al. (37) and Jacobsen et al. (20) that reported a significant reduction in OT after the first 100 LRYGB while a 2012 review concluded that 105 cases are necessary to non-fellowship trained surgeons to complete LRYGB-learning curve (38-39).

The comparative analysis for phase 1 vs. phase 2 did not show statistically significant differences for patient demographics, preoperative BMI and patients' comorbidities. A higher complication rate is expected during the first phase of the surgeon learning curve with anastomotic leak being one of the most dreaded complications. In our series, we did not observe any anastomotic leak while postoperative complication rates were similar comparing the two learning phases (1.9% vs. 1.1%; $p=0.967$). Interestingly, from a clinical point of view, a trend toward reduction may be supposed. This is similar to Shikora et al. that described a trend toward reduced postoperative complications after the first 100 LRYGB (28). These data seem to further corroborate the feasibility and safety of LRYGBfse in the first phase of the learning curve in the hands of surgeons' experiences in minimally invasive surgery. Furthermore, despite the result did not reach statistical significance, a trend toward reduced reoperation rate was observed (1.9% vs. 0.5%; $p=0.625$) between the two phases. Finally, similarly to what reported by Sovik et al. (40) in the setting of LRYGB, we observed a statistically significant decrease of HLOS ($p=0.041$).

The present study has some limitations. First,

previous laparoscopic practice, training and mentoring might have an influence on learning curve. Therefore, these results may not be generally applicable. Second, no comparison was performed with the standard LRYGB. However, this was not the aim of the study. Third, as the number of complications was limited, a CUSUM-adjusted postoperative complications analysis was not feasible.

CONCLUSIONS

The functional LRYGBfse seems feasible and safe even in the first phase of the learning curve. Our data seem to suggest that, using operative time as referral outcome, 106 procedures are required to gain competence with LRYGBfse with a significant decrease of mean operative time and reduced hospital length of stay.

Conflict of Interest

The authors declare no competing interests.

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Ethical statement

All procedures performed in studies involving human participants were in accordance with the standards of the local Ethics Committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors.

Informed consent

Informed consent was obtained from each individual participant included in the study.

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