Re-Appraisal Learning Curve of Laparoscopic Roux-En Y Gastric Bypass: Results of One Hundred and Eight Cases From A Low Volume Unit

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Abstract

Background The study aim was to reevaluate the learning curve of laparoscopic Roux-en Y gastric bypass (LRYGB) in the modern era considering a single surgeon's experience.

Methods Except those with body mass index (BMI) >50 kg/m^2 needs further discussion; all other patients who met the regional criteria and underwent primary LRYGB were retrospectively enrolled. Those who underwent surgery in 2016-17, 2018 and 2019 by a single surgeon with 10+ years of laparoscopic experience were assigned to groups A, B and C, respectively. Patient demographics and 30-day outcome data, including operation time, length of stay (LOS), emergency room visits, readmission, and reoperation, were compared between groups.

Results One hundred and eight patients met the inclusion criteria; 36, 38, and 34 patients were assigned to groups A, B and C, respectively. There were no differences in age, sex distribution or common comorbidities between groups, except group B had a lower BMI (35.1 kg/m^2 vs. 37.0 kg/m^2) and a higher rate of hypertension (44.7% vs. 22.2%) than group A. The operation time was markedly reduced (96.1 min and 114.9 min, respectively), and the LOS was shortened (2.2 days and 2.9 days, respectively) in group B compared to group A and remained stationary in group C, with no further reduction in 30-day complications.

Conclusion The learning process for LRYGB can be shortened to approximately 30 cases if conducted selectively and by experienced laparoscopic surgeons. Further follow-up is required to verify the long-term safety and its applicability to other patient subgroups.

Background

The prevalence of obesity has nearly tripled over the past four decades[1]. Bariatric surgery has been shown to be the only treatment with long-term effectiveness for morbid obesity and obesity-related comorbidities [2]. Until recently, laparoscopic Roux-en Y gastric bypass (LRYGB) was the standard bariatric-metabolic procedure and was performed secondarily after laparoscopic sleeve gastrectomy (LSG) [3]. However, it is generally considered more technically demanding and has higher complication rates than LSG [4]. Accordingly, a steep learning curve (LC) was generally required to meet its safety standards[5]. As a result, only a handful of studies have addressed the learning process in a low-volume center [6].

Traditionally, surgical procedures were mostly learned through observation, on-the-spot assistance or field practice. As time progressed, new era of surgical education platforms emerged[7]. Online media resources are frequently used to facilitate and improve the learning process [8] and served as valuable method in our learning process. Starting with one-anastomosis gastric bypass (OAGB-MGB), we then modify our practice because arguments and controversies emerged such as the long-term consequences of bile reflux and nutrition problems [9]. As practicing laparoscopic surgeons with 10 + years of experience in various gastrointestinal surgeries and proficient in suturing techniques, we deemed we were ready to incorporate LRYGB as our treatment modality after attending education courses, dry lab training and conferences consisting of live demonstrations as well as applying our initial successive experience in performing OAGB-MGB[10]. Moreover, since Wittgrove et al. first established LRYGB [11], several vital steps of the original

technique have been modified. For example, the preferable placement of the Roux limb has changed from the retro-gastric/retro-colic [12, 13] to the ante-colic position. Common techniques utilized in gastrojejunostomy have shifted from circular-stapled [12, 14, 15] to linear-stapled anastomosis or a total hand sewn technique. To address enterotomy defects, the method shifted from stapled closure [15] to perform a sutured closure to avoid stenosis. There is a tendency to routinely closure of mesentery defects; however, in the past, some choose to left open for technical reasons [16].

The aim of this study was to reappraise the learning curve of LRYGB under the aforementioned modern background in a low-volume unit. Our primary goal was to verify its safety according to the proficiency of medical staff, with a focus on 30-day per-operative outcomes.

Methods

From January 2016 to December 2019, all data of consecutive patients who underwent primary LRYGB under the care of a single surgeon were collected retrospectively from a prospectively maintained database after obtaining institutional review board approval. Patients were eligible for inclusion if they met the regional criteria proposed by the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) [17]. There are no specific selection criteria except a body mass index (BMI) >50 kg/m^2, as gastric bypass is generally less effective in these patients [18], and they have a higher rate of complications than patients with a lower BMI [19]. Nevertheless, the final decision was made using a shared decision-making process after fully considering the benefits, risks and potential long-term outcomes of each procedure.

To assess the learning process, patients were divided into three groups based on their surgery time and case distributions: group A included initial patients who underwent primary LRYGB during 2016-17. Groups B and C included patients who underwent surgery during 2018 and 2019, respectively. All patients underwent complete preoperative evaluations. The recorded parameters included patient demographic factors and anthropometric data as well as all relevant outcome measures, including the operation time, length of stay (LOS) and 30-day complications, such as emergency room (ER) visit, readmission, reoperation and conversion.

Surgical technique

LRYGB was performed with a four-abdominal trocar technique and a Nathanson liver retractor. This surgical technique utilized a linear stapler to create a lesser curve-based, 30-ml vertical gastric pouch over a 32 Fr. calibrating tube with 100-cm ante-colic, ante-gastric Roux limb and 100-cm biliopancreatic limb. The enterotomies for both anastomoses were hand-sewn closed. Both mesenteric defects were routinely closed with nonabsorbable sutures.

Data collection and statistical analysis

The Statistical Package for the Social Sciences software version 20.0 (SPSS Inc., Chicago, Illinois, USA) was used to perform the statistical analyses. Descriptive results regarding continuous variables are presented as the means ± standard deviations, and categorical variables are presented as counts and percentages. Data were analyzed using Fisher's exact test for categorical data, and the unpaired t test was used for parametric data when appropriate. Tests for statistical significance were two-sided, with a level of significance of 0.05.

Results

From January 2016 to December 2019, a total of two hundred and four patients underwent bariatric or metabolic procedures in our unit. Among them, three patients underwent a nonprimary procedure, five patients underwent LSG, and 39 patients underwent OAGB-MGB during 2016-17. In 2018, two patients underwent a nonprimary procedure; two patients underwent LSG, and 18 patients underwent OAGB-MGB. In 2019, six patients underwent a nonprimary procedure; one patient underwent LSG, and 20 patients underwent OAGB-MGB. All the patients who did not fulfill the inclusion criteria were excluded from the analysis, leaving one hundred and eight patients enrolled in this study. Of these, 36 patients who underwent primary LRYGB during 2016-17 were assigned to group A. The other 38 and 34 patients who underwent primary LRYGB in 2018 and 2019 were assigned to group B and group C, respectively.

The demographic details and clinical characteristics are outlined in Table 1. There were no significant differences between group B and group A with respect to age, sex, preoperative weight or incidence of common comorbidities. However, patients in group B had a significantly lower BMI (35.1 ± 3.8 kg/m^2 vs. 37.0± 3.6 kg/m^2; p=0.03) and had a higher rate of hypertension (HTN) (44.7% vs. 22.8%; p=0.04) than those in group A. Group C was not different in terms of age, female proportion, or baseline BMI than group B, but group C had a tendency toward a higher rate of diabetes mellitus (32.4% vs. 21.1%; p=0.28) and a lower rate of HTN (35.3% vs. 44.7%; p=0.41) than group B.

The surgical characteristics and outcomes are listed in Table 2. As shown, only one concomitant procedure, partial gastrectomy for benign lesions, was carried out in group A. The mean operation time was significantly decreased in group B compared to group A (96.1 min vs. 114.9 min, respectively; p<0.001) and was similar between group B and group C (96.1 min vs. 92.1 min; p=0.20). The mean LOS was also markedly shortened in group B compared to that in group A (2.2 ± 0.5 days vs. 2.9 ± 0.8 days; p < 0.001) and was similar, at 2.2 days, between group C and group B (p=0.70). All procedures were complete with a laparoscopic approach without open conversion. The rate of 30-day complications was not different between groups B and A (2.6% vs. 2.8%; p= 0.97) or between groups C and B (2.9% vs. 2.6%; p=0.62).

A total of five patients experienced 30-day adverse events and three of them were classified as with complications. One patient in group A was readmitted for gastrojejunostomy stenosis on postoperative day (POD) 30, which was relieved under a single session of balloon dilatation. In group B, two patients visited the ER after discharge; one visited for nonspecific focal abdominal pain. Another patient with hematemesis on POD 9 was readmitted and recovered uneventfully after proper medical treatment. In group C, one patient was noted to have self-limiting melena that subsided under supportive treatment. Another patient visited the ER for lower back pain. The rates of 30-day ER visits and 30-day readmission were not different between the groups. There was no reported anastomotic leakage, reoperation or mortality throughout the study period.

Discussion

Herein, we reported the outcomes of initial 108 patients who underwent LRYGB over a 4-yr period in a low-volume hospital, indicating LC. Comparing the results among the 3 groups; significant improvements in the operation time and LOS with an acceptably low rate of complications was observed after the initial 36 cases

(group A). The present study demonstrated that the LC of LRYGB can be safely reduced to 30 + cases in the modern era under a unique setting.

Because of increasingly complex techniques and the dependence on advanced instruments, the acquisition of new laparoscopic skills is considered to be difficult. When conducting LRYGB in morbidly obese patients, there are likely several other inherent technical barriers, such as body habitus, multistep reconstructive procedures that involve multi-abdominal quadrants and laparoscopic suturing and knot tying skills. Therefore, it was once rated as a 9.5 on a difficulty scale of 10, indicating substantial technical difficulty[20]. These skill-related prerequisites can result in adverse consequences in the early phase of practice, especially in a low-volume practice [6]. Traditionally, various educational programs, such as workshops[21], bariatric fellowships[22] and systematic training programs[23], have been available to facilitate this process. In recent years, new-era platforms have emerged, providing another kind of auxiliary training approach[7]. Their popularity among medical professionals has been increasing, as they generally enable more visual and auditory interactions than journals or text books [24]. A systematic review for the impact of e-learning demonstrates significant gains in knowledge compared with traditional teaching patterns [25]. In our self-learning process, apart from traditional learning methods, these online multimedia materials provide considerable references and guidance despite the lack of objective tools for gauging their impact.

Considering a single surgeon's perspective, we retrieved comparative data in the literature discussing the relevant process by a single surgeon (Table 3). Among them, variability in surgical techniques exists. Moreover, several modifications of traditional methods have occurred, such as retro-colic placement of the Roux limb [12, 13] or a circular-stapled anastomosis [12, 14, 15] had largely been fall out of favor. Meanwhile, there are differences among studies in terms of backgrounds, annual hospital volumes or former laparoscopic/bariatric experience levels. Though with undisputable importance and heightened awareness for proper fellowship training [26], there is no standard approach of teaching provided and accredited bariatric programs are not globally available. For example, while carried out during different periods, some hospitals conduct other laparoscopic bariatric procedures [27, 28] or perform open bariatric surgeries beforehand [13], others just started after complete with fellowship training [14, 16] or are based solely on advanced laparoscopic skills [12, 15, 29]. Additionally, there were with considerably different case selection criteria. In general, fellowship trained bariatric surgeons or those conduct after preceding bariatric experience appears to have a shorter LC and implement a more efficient practice. For instance, after completing a month-long mini-fellowship, Shen *et al*. achieved a considerably decreased complication rate and proficiency after only 30 cases [16]. In particular, they utilized the case selection criteria following IFSO Asian-Pacific guidelines, similar to our research [17]. However, they reported an initial complication rate of 26.7%, which included a 6.7% conversion, 10% reoperation and 5% leakage rate. While surgeons at high-volume hospitals often have the opportunity to master the procedure in a short period of time with preferable results [30], Shin *et al*. participated as assistants in 30 surgeries and conducted the first few surgeries under proctoring. They analyzed their first one hundred cases within 5 months and concluded that the LC plateaued after 50 surgeries [14]. While they realize with marked decreasing operation times (113 min pre-LC and 73 min post-LC), they indicated that there was no further notable reduction in complications after the LC. With particularly vast prior experience in LAP BAND ®, Ballesta-Lopez *et al*. also published a large series with marked decreased operative time and LOS after the first 100 surgeries[28]. Particularly, as one of only two studies, in

addition to that by Andrew *et al.* [13], which were conducted with totally hand-sewn gastrojejunostomy, they reported a no negligible leakage rate of up to 9%, a 5.1% reoperation rate (mostly for leakage) and a 29.2% complication rate. In other studies with only prior advanced laparoscopic experience [12, 15, 29], the LC took slightly longer, and there was a substantially prolonged operation time compared with studies involving surgeons who completed a fellowship [14, 16, 27]. For instance, Oliak *et al.* reported a series with the highest mean BMI of 51 kg/m^2 and proposed that the LC plateaued after 75 surgeries[12]. Surgeons' operative times decreased substantially from 189 min during the first 75 cases and then decreased gradually. Notably, the perioperative complication rates were substantial among all studies both before (32%) and after LC (15%). Nguyen *et al.* evaluated 150 consecutive cases, with the longest mean operation time of 250 min before LC; they too observed that an initial lack of experience (< 75 cases) was a major factor associated with major complications and an increased reoperation rate [15]. On the other hand, with advanced laparoscopic skills and preemptive bariatric experience; Agrawal *et al.* suggest that LRYGB can be performed safely with minimal complications of only 1.4% and effectively without any LC required[27]. It is noticeable that our initial result stabilized after just 36 surgeries and we had a low initial 30-day complication rate of 2.8%. Only the difference is their research was after completion of fellowship training[27]. However, concordant with these forenamed studies, a sharp improvement in terms of operation time was observed in current study after LC. As findings of Shin *et al.*[14], we observed no further decrease in the complication rate after LC. Only one patient presented with stenosis, and two other patients presented with hemorrhagic complications: one with hematemesis and one with melena. Considering the reported stenosis rate between 2.2% and 10% [12, 14, 16, 29] and the hemorrhagic complication rate ranges from 1–3.3% during the learning process [14, 15, 29], we deemed our initial results to be acceptable. Furthermore, there was no mortality, leakage, conversion or other major complications. While prolonged hospital stay is not uncommon after such a procedure. Nguyen *et al.* noted that 11% of their cases had LOS over 4 days [15]' and the LOS is reported to range between 6 to 6.4 days before the LC and 4.8 to 5 days after the LC[16, 29]. We observed a notably shorter LOS, with a mean of 2.9 days before the LC and 2.2 days thereafter. In addition, only 2.8% of our patients required hospitalization for more than 3 days. Our LC and timespan to reach competency are in line with findings from a systemic review that reported between 30–70 surgeries [31]. It is worth mention that the consistent outcome obtained in group B and group C can be considered an early achievement of proficiency because we reached this goal within less than 70 accumulative surgeries, while historically, it usually takes between 70–150 surgeries[31].

There are likely many factors contributing to our early desirable results. First, in contrast to most studies with an unselective patient approach [13–15, 28, 29], patients with a BMI > 50 were preferably offered alternative treatment modalities considering safety and long-term effectiveness [18, 32]. As a result of this selective approach, the mean BMI of 36.1 kg/m^2 in our series was significantly lower than former studies, which ranged from 43 to 51 kg/m^2 [12, 29]. Second, as guidelines regarding tailored per-operative care were established in 2016 [33], a pragmatic enhanced recovery protocol was gradually adopted in our unit ever since. Furthermore, our preceding experience in OAGB-MGB may transferred to subsequent LRYGB and increase its safety [10]. Likewise, comprehensive care and improved techniques have been demonstrated in other studies across different periods [34]. Because only two aforementioned studies included cases after 2010[16, 27], we believe that general improvements further contribute to this desirable result.

Limitations

Limited by the selective approach, our result may not be generalizable for all patient subgroups. Nevertheless, a desirable outcome can be accomplished during the learning process via this selective approach. Moreover, because of its retrospective design and nonrandomized nature, the presence of clinical heterogeneity between groups may compromise its comparativeness.

Conclusion

In conclusion, a gradual LC for LRYGB with acceptably low complication rate, shortened operation time and LOS can be achieved in unique settings. Additional data regarding long-term efficacy, safety and generalizability are required.

List Of Abbreviations

LRYGB, Laparoscopic Roux-en Y gastric bypass; BMI, body mass index;

LOS, length of stay; LSG, laparoscopic sleeve gastrectomy; LC, learning curve;

OAGB-MGB, one-anastomosis gastric bypass;

IFSO, International Federation for the Surgery of Obesity and Metabolic Disorders;

ER, emergency room; HTN, hypertension; POD, postoperative day;

Declarations

Ethical approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of institutional and/or national research committees and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The research project was approved by local Institutional Review Board. Informed consent was waived because no data regarding the cases were disclosed.

Consent for publication

Written informed consent for publication was waived because no clinical details and/or clinical images regarding the cases were disclosed.

Availability of data and materials

The datasets generated during and/or analyzed during the current study are not publicly available due to restrictions from local Institutional Review Board but are available from the corresponding author on reasonable request and with permission from the local Institutional Review Board.

Authors' contributions

Hung-Chieh Lo designed the study, performed the surgical procedures, followed the patients, and participated in the data analysis and writing of the manuscript. Sheng-Mao Wu contributed to the data analysis. All authors have read and approved the final version to be published.

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Tables

Table 1. Demographic and clinical characteristics of the patients, mean (SD)

	Group A (N=36)	Group B (N=38)	Group A vs. B p-value	Group C (N=34)	Group B vs. C p-value
Age (years)	35.3 ±10.3	38.5 ± 9.1	0.16	39.6 ± 9.2	0.62
Sex, n (%)					
Male	14 (38.9)	15 (39.5)	0.96	15 (44.1)	0.69
Female	22 (61.1)	23 (60.5)		19 (55.9)	
Preoperative weight (kg)	102.8 ± 16.7	95.8 ± 17.1	0.08	98.7 ± 16.0	0.44
BMI (kg/m^2)	37.0 ± 3.6	35.1 ± 3.8	0.03	36.3 ± 3.2	0.13
Comorbidities, n (%)					
Diabetes mellitus	10 (27.7)	8 (21.1)	0.50	11 (32.4)	0.28
Hypertension	8 (22.2)	17 (44.7)	0.04	12 (35.3)	0.41
Dyslipidemia	18 (50)	21 (55.3)	0.65	18 (52.9)	0.84
BMI, Body mass index					
Data are expressed as the means ± standard deviations or as numbers and percentages					

Table 2. Surgical perspectives and outcomes, mean (SD)

	Group A (N=36)	Group B (N=38)	Group A vs. B p-value	Group C (N=34)	Group B vs. C p-value
Concomitant procedure, n (%)	1(2.8)	0	0.30	0	
Op time (min)	114.9 ± 29.1	96.1 ± 13.5	< 0.001	92.1 ± 12.1	0.20
LOS (days)	2.9 ± 0.8	2.2 ± 0.5	< 0.001	2.2 ± 0.4	0.70
Conversion	0	0		0	
30-day complications, n (%)	1 (2.8)	1 (2.6)	0.97	1 (2.9)	0.62
Stenosis	1	0		0	
Melena	0	0		1	
Hematemesis	0	1		0	
30-day ER visit, n (%)	0	2 (5.3)	0.16	1 (2.9)	0.62
30-day Readmission, n (%)	1 (2.8)	1 (2.6)	0.97	0	0.34
30-day Mortality, n (%)	0	0		0	
Op, Operation; LOS, Length of stay; ER, Emergency room					

Table 3. List of historical studies involving a single surgeon

Authors	Study period	Background	Patients (n) / Groups / inclusion criteria	Age[a] (years)/ BMI[a] (kg/m^2)	LC	Mean Op time (min)		Complications (%)	
						Pre-LC	Post-LC	Pre-LC	Post-LC
Agrawal et al. [27]	10-11	Advanced scope fellowship laparoscope bariatric	74 1 group primary procedures	45.1 47.7	Not required	160	n/a	1.4	n/a
Shen et al. [16]	09-11	Advanced scope fellowship	60 2 groups IFSO-APCcriteria[b]	34.2 41.5	30	120	80	26.7	6.7
Shin et al. [14]	03	Advanced scope fellowship	100 2 groups unselective	42.6 47.6	50	113	73	32	8
Oliak et al. [12]	99-01	Advanced scope	225 3 groups primary procedures	40 51	75	189	125	32	15
Huang et al. [29]	05-07	Advanced scope	100 2 groups unselective	31.2 43	50	217	105	15	3
Nguyen et al. [15]	n/a	Advanced scope	150 2 groups unselective	40 47	75	250	n/a	12	1
Andrew et al. [13]	02-04	Open bariatric	201 3 groups unselective	37 49.2	70	145	118	19.4	11.9
Ballesta-Lopez et al. [28]	00-04	Advanced scope LAP BAND®	600 6 groups unselective	38.7 44.4	100	166	109	29.2	14

| Current study | 16-19 | Advanced scope laparoscope bariatric | 108 3 groups primary procedures | 37.8 36.1 | 30+ | 115 | 96 | 2.8 | 2.6 |

LC, Learning curve; Op, Operation; BMI, Body mass index; n/a, No data available

[a] Mean

[b] IFSO-APC criteria stands for International Federation for the Surgery of Obesity and Metabolic Disorders Asia Pacific Chapter criteria [17]