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# Laparoscopic Roux-en-Y gastric bypass is as safe as laparoscopic sleeve gastrectomy. Results of a comparative cohort study



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ARTICLEINFO	A B S T R A C T
Keywords: Safety Treatment outcomes Learning curve Bariatric surgery Sleeve gastrectomy Laparoscopic roux-en-y gastric bypass	<i>Background</i> : A meta-analysis and six randomized controlled trials show higher 30-day complication rates with laparoscopic Roux-en-Y gastric bypass (LRYGB) than with laparoscopic sleeve gastrectomy (LSG). <i>Aim</i> : To identify any difference in 30-day outcomes of patients treated with LRYGB or LSG when a standardized technique and identical post-operative protocol was followed with all procedures being conducted either by or under the supervision of a single consultant surgeon who had significant experience in bariatric surgery prior to commencing independent practice. <i>Methods</i> : A prospectively collected database of all patients under primary LRYGB or LSG, between March 2010 and February 2017, was analyzed. Data on demographics, length-of-stay (LOS), conversion to open, 30-day complications and mortality were reviewed. <i>Results</i> : Over a seven-year period, 485 patients (LRYGB-279 and LSG-206) were included. There were no significant demographic differences and no difference in the pre-operative risk scoring [American Society of Anesthesiologists (ASA) and obesity surgery mortality risk score (OSMRS)] between the groups. There was no significant difference between the groups in terms of LOS (p = 0.275), complications (p = 0.920), re-admissions (p = 0.593) or re-operations (p = 0.366) within 30-days. There were no conversions to open or in-patient mortality in either group. <i>Conclusions</i> : Unlike previous studies, we found no difference in early complication rates between LRYGB and LSG in a comparable cohort when performed by a surgeon with sufficient experience in bariatric surgery.

# 1. Introduction

The prevalence of obesity has continued to increase significantly over recent decades with the United States reporting rates of 35% in males and 40% in females [1,2]. It is widely accepted that bariatric surgery effectively treats obesity with improved control of diabetes, hypertension, hyperlipidemia and cardiovascular risk [3-7]. However, the choice of operation for each patient is a topic of debate. Of the two most commonly performed bariatric procedures, in 2013, laparoscopic sleeve gastrectomy (LSG) was the most common in the United States and laparoscopic Roux-en-Y gastric bypass (LRYGB), in Europe [8]. LSG as a standalone bariatric procedure is newer than LRYGB [9,10]. LSG is perceived to be an easier procedure with shorter learning curve and has lower rates of early complications than LRYGB [11-14]. We have previously demonstrated that bariatric fellowship prior to independent practice allows the surgeon to overcome the learning curve for LRYGB [15]. The aim of our study was to compare the early post-operative outcomes (30-day) of all patients undergoing primary LSG or LRYGB in a single surgeon cohort who had completed the learning curve for LRYGB [15] prior to commencing independent practice within an established large specialist academic referral Centre for bariatric surgery in East London, United Kingdom. To our knowledge, this is the largest comparable cohort study by a single surgeon beyond the learning curve for both the procedures.

# 2. Methods

We analyzed a prospectively maintained database (from March 2010 until February 2017) of all patients who underwent primary LRYGB or LSG under a single surgeon The study was conducted in accordance to the Declaration of Helsinki and patient confidentiality was maintained. The patient demographics, length of hospital stays, conversion to open surgery, perioperative complications and mortality were analyzed. Perioperative complications were considered to be complications occurring within 30 days of surgery. Complications were identified via database analysis and clinical note review. The Obesity

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Surgery Mortality Risk Score (OS-MRS) [16] and American Society of anesthesiologist's (ASA) Physical Status classification grade were used for risk stratification of patients. The OS-MRS combines 5 pre-operative variables; BMI, gender, age, hypertension, Venous Thrombo-embolic risk to produce a risk stratification score for patients undergoing bariatric surgery. Scores of 0–1 are classified as group "A", score 2 to 3 equals 'B' (intermediate) risk group and 4 to 5 as 'C' (high) risk group. The 30-day outcomes for patients undergoing LSG or LRYGB were then compared.

All patients were operated according to national guidelines at the time of surgery [17]. Patient preference was a major factor in surgery selection. LSG was not performed on patients with Barrett's esophagus or large hiatal herniae. Thromboprophylaxis was used in all patients with the routine use of TED<sup>TM</sup> (Thrombo-Embolic-Deterrent) anti-embolism stockings and lower limb pneumatic compression devices both intra- and postoperatively until discharge from hospital, combined with chemoprophylaxis (enoxaparin) starting six hours after surgery and continuing for 1–2 weeks after discharge.

LRYGB was performed using a four-abdominal trocar technique and a Nathanson liver retractor [15,18]. A standardized operative technique was used in all cases. All cases were performed by the senior author (SA), or by a senior trainee assisted by the senior author as described previously [15] LSG was performed using a four-abdominal trocar technique and a Nathanson liver retractor [18]. Complications were defined as any deviation from the normal post-operative course. All complications were recorded and stratified according to the Clavien-Dindo classification [19]. A standardized identical postoperative protocol and enhanced recovery principles were followed for all the patients in both the groups [Fig. 1]. Patients were encouraged to drink clear fluids from recovery and mobilized on the day of surgery. A standardized medication plan was followed in all cases. Incentive breathing exercises were undertaken at the bedside. Patients were permitted free fluids via a straw on the first postoperative day. Discharge was planned at day two, post-operatively. All patients were followed up by the bariatric specialist nurse at two weeks after surgery by either clinic or telephone appointment and reviewed by the senior author or his team subsequently at six to eight weeks post-operatively.

Data was entered into a custom made Filemaker database and analyzed with Statistical Package for the Social Sciences (SPSS). Nonparametric data was analyzed with Chi-square ( $\chi$ 2) test or Fisher's exact test when numbers were small. Parametric data was analyzed using unpaired *t*-test. Categorical data was analyzed with Mann–Whitney *U* test. Statistical significance was determined to be a p value of < 0.05. The study was reported according to the STROCSS criteria [20].

#### 3. Results

Over the seven-year period, 485 patients were included in the study. Of these, 279 (57.5%) underwent LRYGB and 206 (42.5%) underwent LSG. The demographic characteristics of the groups are detailed in Table 1. There were no significant differences between the two groups in demographics (age, gender and body mass index (BMI)) or in pre-operative risk stratification (ASA grade and OS-MRS).

The 30-day or perioperative outcomes for both the groups are shown in Table 2. There was no significant difference in length of stay (p = 0.275) and total complications (p = 0.92) between the two groups. The overall 30-day complication rate across the two cohorts was 4.74% (23/485 patients). There were 13 (4.66%) complications in the LRYGB group compared to 10 (4.85%) in the LSG group with no significant difference between the groups (p = 0.920). Out of 23 patients, seven (2.51%) in the LRYGB group, and seven (3.40%) in the LSG group were readmitted after discharge within 30-days (p = 0.593). Three LSG patients presented with dysphagia; investigations showed no abnormality, and the symptoms settled with conservative management. Four patients in the LRYGB group were readmitted with abdominal pain; one patient had an anastomotic ulcer confirmed on endoscopy,

and the remaining three had no abnormalities detected with their symptoms settling without intervention. The most common postoperative complication was chest infection [five (1.79%) patients in the LRYGB group and two (0.97%) patients in the LSG group; p = 0.704]. No patients underwent open conversion at surgery and there were no anastomotic/staple line leak or in-patient deaths in either cohort.

Complications were classified as per the Clavien-Dindo classification (Table 3). There was no significant difference in the distribution of complications (p = 0.144).

There was no significant difference in re-operation rates (Table 4) between the two groups (p = 0.366) and no anastomotic/staple line leak in either group. In the LSG group, one patient suffered a thermal injury, from an energized instrument with bipolar component, to the posterior gastric wall during the dissection. Post-operative bleeding from the remnant stomach staple line occurred in two cases in the LRYGB group. Two patients in the LRYGB group and two in the LSG group underwent negative laparoscopy for post-operative pain.

Over the seven years of the study period there was a shift in type of surgery performed (Table 5). At the start of the study period the most common procedure performed was LRYGB, however this shifted at the end of the study in favour of LSG. Despite this there was no significant difference in complication rate within or between the groups at any time point (p = 0.792).

There was one death in each of the cohorts out of hospital within 30 days, unrelated to surgery in both cases.

#### 4. Discussion

Our study demonstrated no significant difference in early (30-day) post-operative outcomes between LRYGB and LSG performed by a single surgeon with significant experience [15] in a comparable cohort of patients. This directly contradicts the results of three published metaanalyses; two of which show a significantly lower early complication rate in LSG when compared to LRYGB [21–23]. One was a meta-analysis of randomized controlled trials (RCTs) involving 396 patients [21]. Another was a meta-analysis of RCTs and retrospective cohort studies involving 18,766 patients [22]. Another study with 695 patients found significant reduction in major complications with LSG compared to LRYGB but no difference in the minor complications [23].

Our study matches the results of a meta-analysis of 15,722 patients, that found no increased risk of leak or mortality after LRYGB when compared to LSG [24]. However, it is not clear from the meta-analyses or the individual papers if the individual surgeons were beyond their learning curve for either procedure.

In multiple cohort studies and small RCTs, the overall short-term complication rate following LSG was 8.4–13.2% [12,25] and following LRYGB was 10.0–27.4% [26,27]. The reported complication rates of LRYGB and LSG in different studies is detailed in Table 5. In comparison, the overall complication rate in our study is low (4.66% in the LRYGB group and 4.85% in the LSG group). In our study, the readmission rate was also low (2.51% for LRYGB and 3.4% in LSG group) and comparable with other studies reporting readmission rate of 2.2–20% after LRYGB and 2.2–3.3% after LSG [25,27–29].

Mortality rates in the published literature are consistently low, ranging from 0 to 0.95% for LRYGB and 0-0.2% for LSG [12,24–27,30,31]. The reported leak rates from sleeve gastrectomy vary from 0 to 3% compared to 0-8.3% for LRYGB [12,24–27,30,31]. In our study, there were no inpatient mortalities or anastomotic leaks in either group.

We have already demonstrated that bariatric fellowship overcomes the learning curve effect and moreover, the surgeries on all patients in our cohort were performed or directly supervised by a post-fellowship surgeon who has published their outcomes to show the effect that fellowship has on outcomes in LRYGB [15]. In comparison, most published studies contain little information on the stage of the learning curve [25,26,30,32,33]. One study included data of the surgeons who

Day of Surgery	Day 1	Day 2	At Discharge				
<ul> <li>In recovery</li> <li>Sips of water with straw</li> <li>Clear fluids with straw</li> <li>Mobilise to toilet/sit out of bed</li> <li>Deep breathing exercises</li> <li>Analgesia - (Paracetamol IV +/- Morphine IM)</li> <li>Ondansetron IV</li> <li>Antibiotics 3x post-op doses</li> <li>Omeprazole IV</li> <li>Saline Nebulisers</li> </ul>	<ul> <li>On ward</li> <li>Free fluids with straw</li> <li>Chest physiotherapy</li> <li>Mobilise on ward</li> <li>Peppermint water</li> <li>Saline nebulisers</li> <li>Analgesia -(Paracetamol IV +/- PR Diclofenac +/- Codeine phosphate liquid.</li> <li>Stop Morphine</li> <li>Omeprazole IV</li> <li>Ondansetron IV</li> <li>Blood tests</li> <li>Bariatric Specialist Nurse Review</li> <li>Dietician review</li> </ul>	<ul> <li>On ward <ul> <li>As per post-op day 1</li> <li>Increase mobility</li> <li>Remove drain if haemoserrous</li> <li>Aim to discharge</li> </ul> </li> <li>Discharge <ul> <li>Discharge if SP criteria met:</li> <li>Pain controlled</li> <li>Pulse &lt;90</li> <li>Pipe (drain) haemoserous and removed</li> <li>CRP declining trend</li> <li>Passed wind (flatus)</li> </ul> </li> </ul>	<ul> <li>TTA (Take away medications)</li> <li>Enoxaparin 40mg OD SC for 14 days</li> <li>TED® Stockings for 30 days</li> <li>Lansoprazole Fastab® 30mg OD for 6 months</li> <li>Chewable Multivitamins and minerals - life long</li> <li>Analgesia (soluble Paracetamol and liquid Codeine phosphate)</li> <li>Lactulose – 10ml BD 14 days</li> </ul> Documentation <ul> <li>Diet sheet (4 stage)</li> <li>Instruction sheet with emergency contact numbers</li> </ul> Follow Up <ul> <li>Blood glucose and blood pressure monitoring with GP at 1 week</li> <li>Bariatric Specialist Nurse 2 weeks (face to face or telephone)</li> <li>Surgeon 6-8 weeks</li> </ul>				
<ul> <li><u>Throughout Hospital Stay</u></li> <li>Twice daily senior ward rounds (Registrar +/- Consultant)</li> </ul>							

- VTE prophylaxis TED stockings, pneumatic calf compression devices whilst immobile and LMWH
- CPAP is discouraged if SaO2 is >93%
- In diabetic patients insulin sliding scale is discontinued 24hrs post-op if BM <10

# Fig. 1.

#### Table 1

Comparison of demographic characteristics between LRYGB and SG. LRYGB: laparoscopic Roux en Y gastric bypass, SG: laparoscopic sleeve gastrectomy, BMI: body mass index, ASA: American Society of Anaesthesiologist's, OS-MRS: Obesity Surgery Mortality Risk Score, SD: standard deviation, IQR: interquartile range.

LRYGB (	(n = 279) SG $(n = 206)$	р
Age (y) (Mean/SD)         44.6 (10           Gender (M:F)         217:62           BMI (kg/m²) (Mean/SD)         47.9 (5.1           ASA Grade (Median/IQR)         2 (2-3)           OS-MRS (Median/IQR)         A (A-B)	0.1) 44.3 (10.2) 152:54 67) 48.7 (7.60) 2 (2-3) B (A-B)	0.519 0.333 0.240 0.978 0.226

had not performed the procedure previously [25]. The lower complication rates in our study may be linked to the relatively higher experience of the surgeon performing or supervising the complex operations.

Standardization of the operative techniques (LSG and LRYGB) and post-operative protocol may have also led to low overall complication rates. It acts to abrogate the effect of pooled data from multiple surgeons with multiple operative techniques for LRYGB (hand sewn, fully stapled, circular stapled) and LSG [12,25,30]. Standardization of operative technique plays a vital role in ensuring better outcomes in patients undergoing LRYGB and LSG [34,35]. Variable policies for concomitant cholecystectomy also may skew the complication rates

#### Table 2

Comparison between LRYGB and SG in terms of LOS and perioperative outcomes. LRYGB: laparoscopic Roux-en-Y gastric bypass, SG: laparoscopic sleeve gastrectomy, SD: standard deviation, LOS: length of stay. \*severe complications defined as Clavien Dindo  $\geq$  IIIa.

Perioperative outcomes	LRYGB (n = 279)	SG (n = 206)	р
LOS (d) (Mean/SD)	2.40 (0.843)	2.63 (2.93)	0.275
Total complications (n) (%)	13 (4.66%)	10 (4.85%)	0.920
Severe complications*	6 (2.15%)	3 (1.46%)	1.000
Chest infection	5 (1.79%)	2 (0.97%)	0.704
Abdominal pain – normal	3 (1.08%)	3 (1.46%)	0.700
investigations			
Dysphagia – normal investigations	0	3 (1.46%)	0.080
Staple line bleeding	2 (0.717%)	0	0.510
Chest pain	0	1 (0.485%)	-
Mesocolic hernia	1 (0.385%)	0	-
Biliary colic	1 (0.385%)	0	-
Anastomotic ulcer	1 (0.385%)	0	-
Thermal gastric injury	0	1 (0.485%)	-
Anastomotic/staple line leak	0	0	-
Conversion to open	0	0	-
In-patient mortality	0	0	-

[12,25,30]. Using a standardized post-operative protocol has been validated by several studies and a meta-analysis assessing the safety and efficacy of enhanced recovery and standardization of operative techniques [28,29,34–37]. Wide variations in postoperative practices and

#### Table 3

Complications as categorised by Clavien-Dindo classification.

Complications	LRYGB (n = 279) (n) (%)	SG (n = 206) (n) (%)	р
Grade I	3 (1.07)	6 (2.91)	0.789
Grade II	4 (1.43)	1 (0.485)	0.401
Grade IIIa	1 (0.358)	0	-
Grade IIIb	4 (1.43)	2 (0.971)	1.000
Grade IVa	1 (0.358)	1 (0.485)	-
Grade IVb	0	0	-
Grade V	0	0	-

#### Table 4

Comparison of re-operations between LRYGB and SG groups. LRYGB: laparoscopic Roux-en-Y gastric bypass, SG: laparoscopic sleeve gastrectomy.

Re-operations	LRYGB (n = 279)	SG (n = 206)	р
Total Negative laparoscopy	5 (1.79%) 2	3 (1.45%) 2	0.366 -
Internal hernia Thermal gastric injury	2 1 0	0 0 1	-

#### Table 5

Complication rates reported in different methodological studies.

Trials	Cases			Complicat	Complication rates	
	Total n	SG	RNYGB	SG	RNYGB	
Randomized trials						
Helmio et al. [24]	238	121	117	13.2%	26.3%	
Kehagias et al. [25]	60	30	30	13.0%	10.0%	
Peterli et al. [12]	217	107	110	8.4%	17.2%	
Zhang et al. [31]	64	32	32	12.5%	6.3%	
Pooled cohort studies						
Goitein et al. [29]	3205	2651	554	3.70%	4.30%	
Cohort studies						
Lee et al. [39]	579	109	470	10.1%	9.4%	
Topart et al. [40]	448	88	360			
Vidal et al. [26]	249	114	135	8.7%	27.4%	
Albeladi et al. [30]	70	34	36	8.8%	25%	

the implementation of the enhanced recovery program may however confound the rates of complications seen within these studies [25,26].

Our data also challenges the claim that the LSG is a safer operation than LRYGB. Several RCTs report higher 30-day complications with LRYGB than with LSG [12,25,27]. However, these trials included different operative techniques, multiple surgeons, and also significant heterogeneity among the stage of learning curve and the use of staple line reinforcement. Several RCTs are currently being undertaken comparing LSG and LRYGB and considering early complications as secondary endpoints [38,39].

In a cohort study from three centers, there was no difference in the complication rates between primary LRYGB and LSG, however increased age was found to be a predictor of morbidity [30]. Though the cohorts had similar demographics, there were five times more patients in the LSG cohort. Another cohort study [40] included both single anastomosis and Roux-en-Y in the gastric bypass group making it difficult to make a comparison. Another study comparing the outcomes of 360 LRYGB and 88 LSG cases in combination with biliopancreatic diversion with duodenal switch (BPD-DS) reported comparable post-operative complications between LSG and LRYGB, but the risk of bleeding was more in LSG [41]. However, the groups were not similar in terms of BMI or co-morbidities, in contrast to our study. In our study there was no difference seen in ASA, OS-MRS, age or BMI.

In the initial years of the study LRYGB was performed more frequently, but at the end of the study LSG was the most frequent

Table 6Breakdown of procedures and complication rates by year.

Year	LRYGB	LSG	LRYGB Complications	LSG Complications	p value
2010	57	2	0	0	1.00
2011	68	14	2	2	0.13
2012	50	13	2	1	0.51
2013	30	10	1	0	1.00
2014	38	31	4	2	0.68
2015	26	49	3	3	0.41
2016	9	61	1	2	0.34
2017	0	26	0	0	1.00

procedure (Table 6). This change did not have any effect on complication rates over time either within the groups or between the groups. This change reflects multiple large scale studies reporting world-wide trends in Bariatric surgery over the same period as this study with the emergence of LSG as the most common procedure [8,42–44]. The reason for this increase is multi-factorial. It is perceived as a less technically demanding procedure to perform and to learn [11–14] although two recent studies have suggested the true learning curve may be up to 100 cases [45,46]. LSG avoids the need for intestinal anastomosis and allows full endoscopic access to the duodenum and biliary tree after surgery.

LSG is also associated with excellent outcomes with regard to weight loss and co-morbidity resolution. There is divergence in the literature regarding the efficacy of weight loss between LSG and LRYGB. Some suggest no difference in outcomes [12,26,27], whereas others favour LRYGB [21,31,47]. Whilst diabetic resolution is better with LRYGB [21,22] resolution of other co-morbidities is similar between LSG and LRYGB [48–50]. LSG may also be associated with an improved quality of life (QOL) compared to LRYGB [50] at the expense of increased gastro-oesphageal reflux [51,52].

Our results will be of interest to other practicing bariatric surgical teams. They show that both LSG and LRYGB can be performed without the significant differences in complication rates when a standardized operative and post-operative protocol is followed. It highlights the importance of a team with significant experience performing these procedures on complex patients.

There are several limitations to this study. Our retrospective cohort study has no element of randomization within the groups. At present there is no agreement as to procedure selection and patient preference is part of the operative selection process. This issue has been commented on in other retrospective cohort studies in bariatric surgery [46]. This could have led to significant differences within the cohorts; however, no demographic differences were identified. The rate of each individual operation was not constant throughout the study, with an early propensity to LRYGB replaced by LSG at the end of the study, but no difference in complication rate was seen. Due to the geographical location of our institution, it is possible that patients with complications may have presented to another bariatric unit with a complication that we are not aware of, although every effort was made to exclude this scenario. We informed all patients to contact the bariatric team if they develop any complication in the post-operative period and to attend our institution rather than their local hospital. A dedicated patient advice line was also available to improve access.

#### 5. Conclusion

There seems to be no difference in early postoperative complication rates between LRYGB and LSG when procedures are performed by an experienced bariatric surgeon and when a standardized operative and post-operative protocol is followed.

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n/a.

#### Sources of funding

Nil.

# Author contribution

Lynn W – study design, data collection, analysis, writing. Ilczyszyn A FRCS (GenSurg), - study design, data collection, ana-

lysis, writing.

Rasheed S - data collection.

Davids J - data collection.

Aguilo R - data collection.

S. Agrawal - study design, analysis, writing.

#### **Conflicts of interest**

None.

#### **Research registration number**

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# Guarantor

Mr Sanjay Agrawal.

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# Informed consent

For this type of study formal consent is not required.

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# Appendix A. Supplementary data

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