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RESEARCH ARTICLE

Establishing Laparoscopic Roux-en-Y Gastric Bypass: Perioperative Outcome and Characteristics of the Learning Curve

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Abstract
Background Bariatric surgery was established at several Norwegian hospitals in 2004. This study evaluates the perioperative outcome and the learning curves for two surgeons while introducing laparoscopic Roux-en-Y gastric bypass (LRYGB).
Methods Morbidly obese patients undergoing primary LRYGB were included. Lengths of surgery and postoperative hospital stay, and 30-day rates of morbidity, reoperations, and readmissions were set as indicators of the learning curve. Learning effects were evaluated by graphical analyses and comparing the first and last 40 procedures for both surgeons.
Results The 292 included patients had a mean age of 40.0± 9.5 years and a mean body mass index (BMI) of 46.7± 5.3 kg/m^2. The mean length of surgery was 101±55 min. Complications occurred in 43 patients (14.7%), with no conversions to open surgery in the primary procedure and no mortality. Reoperations were performed in 14 patients (4.8%), of which five patients required open surgery. The median length of stay was 3 days (range 1–77), and 19 patients (6.5%) were readmitted. High patient age, but not high BMI, was associated with an increased risk of complication. For both surgeons, lengths of surgery and hospital stay were significantly reduced ($p<0.001$), leveling out after 100 procedures. Reductions in the rates of morbidity, reoperations and readmissions were not found.
Conclusion LRYGB was introduced with an acceptable morbidity rate and no mortality. Only the length of surgery and postoperative hospital stay were suitable indicators of a learning curve, which comprised about 100 cases.

Keywords Bariatric surgery · Morbidity · Learning · Intraoperative complications

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Introduction

In the USA, the prevalence of obesity in the adult population, defined as a body mass index (BMI) ≥30 kg/m^2, is more than 30% [1]. In Norway, 20% of adults are obese, and the prevalence is increasing [2]. The prevalence of morbid obesity, defined as having a BMI of ≥40 kg/m^2, or ≥35 kg/m^2 with coexisting obesity-related morbidity, is about 2% [3]. Bariatric surgery provides a significant and sustained weight loss [4], improvement of obesity related comorbidities [5], and may decrease long-term mortality [6, 7]. After requests by the Norwegian Directorate for Health and Social Affairs, bariatric surgery was made widely available in Norway in 2004. A team of two bariatric surgeons was established at our university hospital [8, 9].

Laparoscopic Roux-en-Y gastric bypass (LRYGB) is a technically demanding operation. Previous studies suggest that the learning curve includes 100 cases for reaching a morbidity rate similar to open procedures, or a significant reduction in morbidity [10, 11]. Experience in advanced laparoscopy may shorten the learning curve for LRYGB [12]. In the present study, the length of surgery and postoperative hospital stay, and 30-day rates of morbidity, reoperations and readmissions were evaluated as possible indicators of learning effects for two surgeons.

Materials and Methods

Morbidly obese patients undergoing LRYGB from the start-up of bariatric surgery in June 2004 until October 2007, were included. The patients who had a previous bariatric procedure were excluded (n=11). Other laparoscopic bariatric procedures performed in the study period were biliopancreatic diversion with duodenal switch (n=31), gastric sleeve resections (n=20), and gastric banding (n=1).

Clinical data were retrieved retrospectively from patient charts from June 2004 to December 2005. Subsequent data collection was done prospectively on designated forms. The perioperative period was defined as within 30 days of surgery. Major complications were defined as either life-threatening complications or complications that required reoperation. The patients were followed at regular intervals postoperatively, with the first outpatient visit at 6 weeks.

Experience in Laparoscopy and Bariatric Surgery

There was no previous institutional experience in bariatric surgery prior to the study period. All primary LRYGB procedures performed at the institution were made by one of two surgeons (A or B) as first operator and are included in the study. Both had experience in laparoscopic gastrointestinal surgery including appendectomy, cholecystectomy, and fundoplication. Surgeon A had performed a limited number of open gastric bypass procedures at another institution and had experience in advanced thoracolaparoscopic procedures including bile duct surgery, esophageal myotomy, splenectomy, adrenalectomy, and pancreatic and colorectal resections. The surgeons visited several hospitals with experience in bariatric surgery before start-up. Surgeon A performed 23 procedures with surgeon B assisting in 15 of them before surgeon B commenced as first operator. Surgeon B performed all steps of the procedure from the first operation without additional training, and was assisted by surgeon A in the first 77 procedures.

Operative Technique and Perioperative Management

Initially, an open approach was used for establishing pneumoperitoneum. Later, Verre's needle was introduced, and eventually, the Endopath® Xcel™ access system was preferred. Otherwise, the operative technique was not modified throughout the study period. The first 12 mm trocar was placed 15 cm below the xiphoid process in the midline. Additionally, two 12-mm trocars and one 5-mm trocar were introduced, and the liver was mobilized with the Nathanson retractor. The lesser curvature of the stomach was dissected 6 cm below the gastrooesophageal junction. The stomach was divided horizontally and vertically to the angle of His with multiple linear stapler firings. The gastric pouch (approximately 25 ml) was opened in the distal staple line. The small bowel was measured 50 cm from the ligament of Treitz, and brought antecolic. An antegastric gastrojejunostomy was created with a 45-mm linear stapler

Table 1 Patient characteristics*

	All patients (N=292)	Surgeon A (N=140)	Surgeon B (N=152)
Age, years	40.0±9.5	40.5±9.8	39.4±9.2
Sex, female	222 (76)	100 (71)	122 (80)
BMI, kg/m^2	46.7±5.3	46.7±5.0	46.7±5.6
Previous abdominal surgery	108 (37)	50 (36)	58 (38)
Joint pain	167 (57)	74 (53)	93 (61)
Hypertension	96 (33)	52 (37)	44 (29)
Asthma	80 (27)	36 (26)	44 (29)
Diabetes	76 (26)	33 (24)	43 (28)
Depression	74 (25)	34 (24)	40 (26)
Gastroesophageal reflux	59 (20)	34 (24)	25 (16)
Sleep apnoea	57 (20)	33 (24)	24 (16)
Hypothyreosis	52 (18)	25 (18)	27 (18)
Hyperlipidemia	50 (17)	26 (19)	24 (16)
Coronary artery disease	5 (2)	5 (4)	0 (0)

Numbers are N (%) or mean±SD.
*For coronary artery disease: p=0.02, otherwise no significant differences in the comorbidities in the patients operated by surgeon A and B.

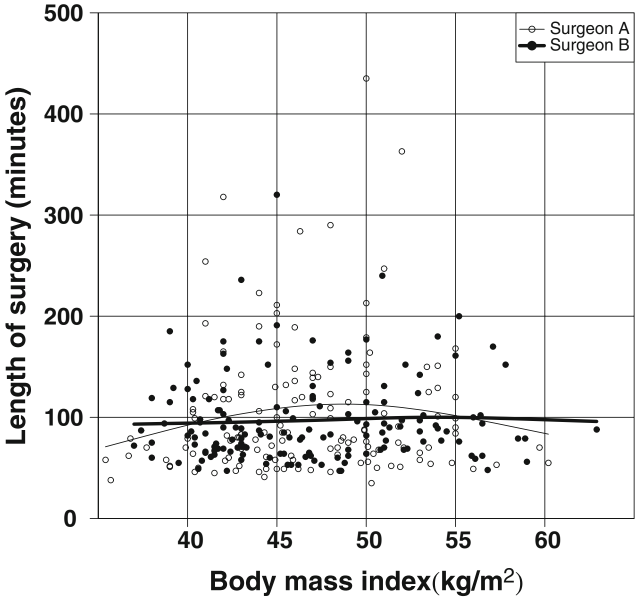

Fig. 1 Association between length of surgery and preoperative patient BMI for surgeon A (r=0.08, p=0.33) and surgeon B (r=0.05, p=0.56)

between the gastric pouch and the jejunum, and the anastomosis was closed with suture. The omentum was not routinely transected. The standard length of the alimentary limb was 150 cm. A side-to-side jejunojejunostomy was performed with a 45-mm linear stapler and closed with suture. The jejunum was divided proximal to the gastrojejunostomy between the two anastomoses. Mesenteric defects were not closed. Methylene blue was used to test the gastrojejunostomy for leakage. The trocar fascial defects were not closed after the introduction of the Xcel™ trocars.

The patients were given single peroperative intravenous doses of doxycycline 400 mg and metronidazole 1,500 mg. In the study period, the thrombosis prophylaxis changed from administration of low molecular weight heparin the day before surgery, to 500 ml of Macrodex® peroperatively. The day after surgery, low molecular weight heparin was administered subcutaneously according to weight and continued until 10 days after discharge. The patients were allowed a liquid diet from the first postoperative day, a semiliquid diet after 1 week, and gradually returning to food intake after 2 weeks.

Learning Curve

The length of surgery and postoperative hospital stay, and 30-day rates of morbidity, reoperations, and readmissions were set as indicators of the learning curve to assess the experience acquired throughout the study period. Comple-

Table 2 Perioperative complications*

	Total (N=292)	Surgeon A (N=140)	Surgeon B (N=152)
Patients with complications**	43 (14.7)	20 (14.3)	23 (15.1)
Patients with major complications	14 (4.8)	4 (2.9)	10 (6.6)
Hemorrhage (total)	17 (5.8)	9	8
intraluminal	8 (2.7)	4	4
subcutaneous	4 (1.4)	3	1
intraabdominal	4 (1.4)	1	3
vaginal	1 (0.3)	1	0
Pneumonia	6 (2.1)	1	5
Anastomotic leak (gastrojejunostomy)	4 (1.4)	0	4
Instrumental bowel perforation	4 (1.4)	1	3
Wound infection	4 (1.4)	2	2
Lung atelectasis	4 (1.4)	1	3
Intra-abdominal abscess	2 (0.7)	0	2
Septicemia	2 (0.7)	0	2
Dysphagia	2 (0.7)	1	1
Acute cholecystitis	2 (0.7)	2	0
Incisional hernia	1 (0.3)	1	0
Dilatation of gastric remnant	1 (0.3)	1	0
Respiratory failure	1 (0.3)	1	0
Anorexia	1 (0.3)	1	0
Ventricular fibrillation	1 (0.3)	0	1
Stenosis of gastroenterostomy	1 (0.3)	0	1
Abdominal pain	1 (0.3)	0	1
Syncope	1 (0.3)	1	0
Decubitus ulcer	1 (0.3)	1	0

Numbers are N (%)
*No significant differences between surgeon A and B in rates of overall complications (p=0.87) or major complications (p=0.17).
**In total, there were 56 complications in 43 patients.

tion of the learning curve was evaluated by the graphs as the point at which all indicators amenable for graphical analysis had levelled off. For statistical evaluation, the first 40 and last 40 procedures performed by the surgeons were compared individually. The number 40 was chosen based on previous reports of the learning curve of LRYGB as 100 procedures. Thus, performing the first 40 procedures, a surgeon should be in the early part of the learning curve. Potential differences between early and late experience should not be too much affected by the increasing experience acquired that, based on previous reports, culminates at about 100 procedures. We also compared the first 100 with the subsequent procedures for both surgeons to evaluate all procedures performed prior to and following completion of the reported learning curve for LRYGB.

Statistical Analyses

A chi-square test or Fisher's Exact test was used to compare proportions between groups. A Student's t test or Mann–Whitney test (if a normal distribution could not be assumed after logarithmic transformation) was used to compare continuous variables. The association between two continuous variables was estimated with Spearman correlation. For evaluation of potential differences in the patient characteristics (patient heterogeneity) throughout the study period, the patients were arranged in three groups according to operation dates, and the groups were then compared with respect to age, sex, BMI, and rate of previous abdominal surgery. To graph the curve for the estimated odds ratio (OR) for complication related to patient BMI, a logistic regression model was used to estimate the OR for complication with a 95% confidence interval (CI), adjusted for age, gender, number of procedures, length of surgery, and surgeon. The OR for complication related to patient age was adjusted for BMI, gender, number of procedures, length of surgery, and surgeon. To graph the probability curves of perioperative complications, the operation dates were sorted in increasing order for each surgeon. The increasing orders were saved in a new variable called "number of procedures". The probability of complications as a function of surgeon experience was estimated by fitting regression spline curves, using the function "smooth. spline". Normally distributed values were reported as mean with standard deviation (SD), and non-normally distributed values as median with range. A two-sided p value <0.05 was considered statistically significant. The statistical analyses were performed in SPSS version 15.0 for Windows. The graphs were created with the R software, version 2.6.0 for Windows.

Results

Patient Characteristics

A total of 292 consecutive patients were included (Table 1). The patient characteristics and comorbidities were not significantly different in the patients operated by surgeon

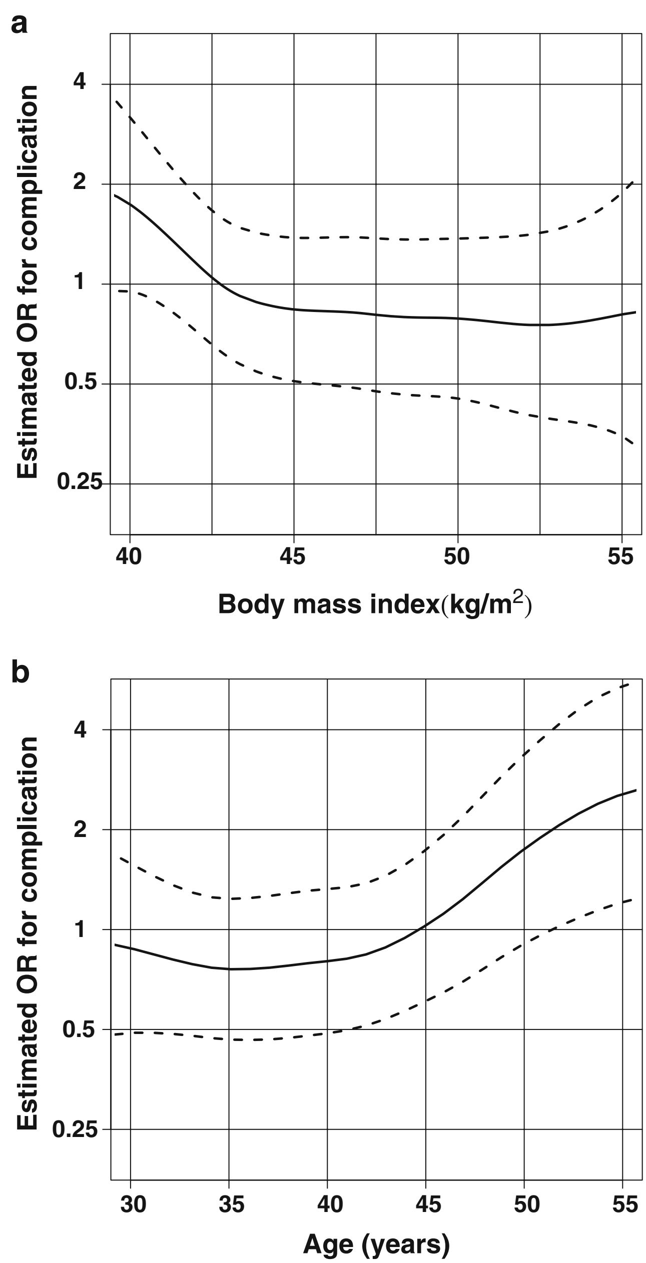

Fig. 2 **a** Estimated odds ratio (OR) for complication (solid line) with 95% confidence intervals (dashed lines) related to patient BMI. The estimated OR was adjusted for age, gender, number of procedures, length of surgery, and surgeon. **b** Estimated odds ratio (OR) for complication (solid line) with 95% confidence intervals (dashed lines) related to patient age. The estimated OR was adjusted for BMI, gender, number of procedures, length of surgery, and surgeon

Table 3 Indications for reoperation*

Indication	Total (N=292)	Surgeon A (N=140)	Surgeon B (N=152)
Total	14 (4.8)	4 (2.9)	10 (6.6)
Anastomotic leak	4	0	4
Instrumental bowel perforation	4	1	3
Dilatation of gastric remnant	1	1	0
Intraabdominal hemorrhage	1	0	1
Incisional hernia	1	1	0
Stenosis of gastroenterostomy[a]	1	0	1
Bleeding from troacar site	1	1	0
Fever, suspicion of anastomotic leak[b]	1	0	1

Numbers are N (%)
*No significant difference between surgeon A and B in rate of reoperations (p=0.17).
[a] Reoperated following vomiting and ventricular fibrillation.
[b] Later diagnosed with pneumonia.

A and B, except for a higher number of patients with coronary artery disease operated by surgeon A (p=0.02). Assessment of patient heterogeneity revealed a higher patient age in the final third part of the study period as compared to the second part (42.1±9.2 vs. 37.7±9.9 years, p=0.001). The proportion of female patients, patient BMI, and the rate of previous abdominal surgery were not significantly different throughout the study period.

Perioperative Outcome

The mean length of surgery for all patients was 101±55 min, not different between surgeon A and B (105 vs. 97 min, p=0.74). The length of surgery did not correlate with patient BMI for either of the two surgeons (Fig. 1).

No primary procedures were converted to open surgery, and there was no mortality. A total of 43 patients (14.7%) had one or several complications, and major complications occurred in 14 patients (4.8%; Table 2). Blood transfusions were given to 14 patients (4.8%). The rates of overall and major complications did not differ between surgeon A and B (p=0.87 and p=0.17, respectively). The odds ratio (OR)

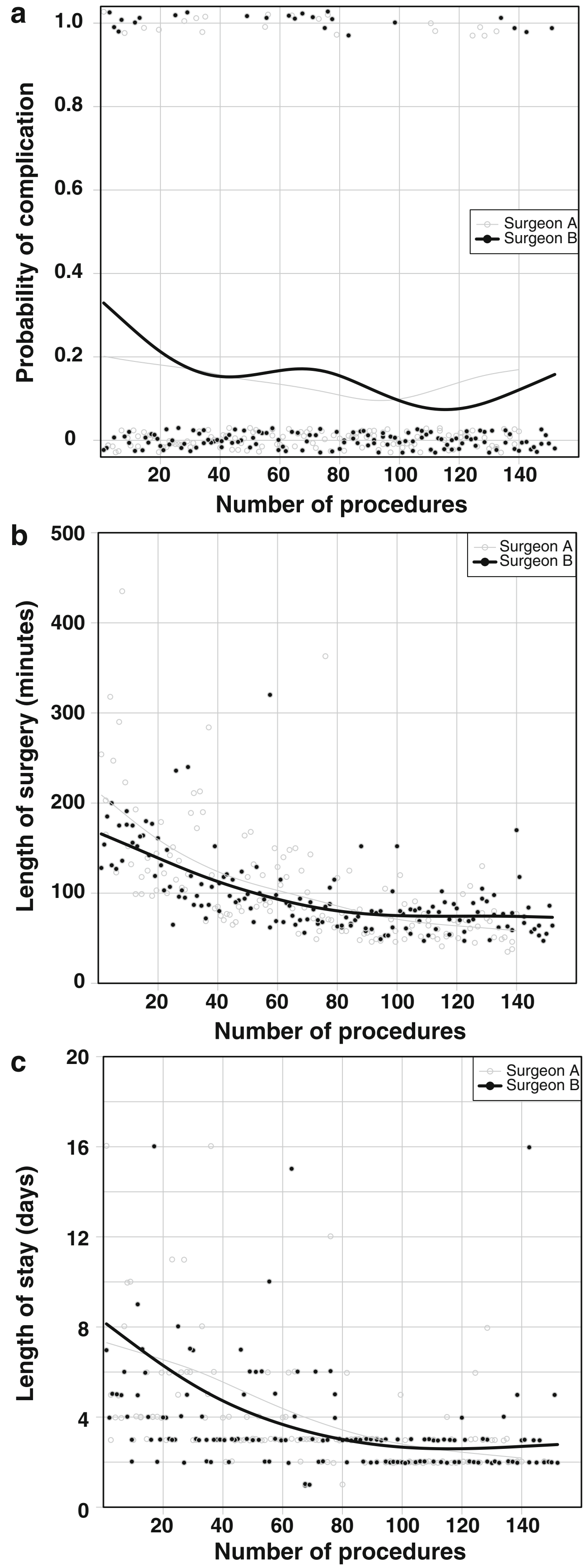

Fig. 3 **a** Probability of a postoperative complication (minor or major) occurring in relationship to the number of procedures per surgeon. Each dot on the upper line represents a complication for surgeon A or B. **b** Association between length of surgery and number of procedures for surgeon A (r=−0.72, p<0.001) and surgeon B (r=−0.65, p<0.001). **c** Association between postoperative length of hospital stay and number of procedures for surgeon A (r=−0.64, p<0.001) and surgeon B (r=−0.49, p<0.001)

Table 4 Indicators of the learning curve for two surgeons performing 292 LRYGB procedures. The first 40 and last 40 procedures were compared

	Surgeon A			Surgeon B		
	First 40	Last 40	*p* value	First 40	Last 40	*p* value
All complications	8 (20)	6 (15)	NS	8 (20)	4 (10)	NS
Major complications	3 (7.5)	1 (2.5)	NS	5 (12.5)	3 (7.5)	NS
Length of surgery, minutes	164±75	66±21	<0.001	138±43	76±23	<0.001
Length of stay, days	5 (3–77)	2 (2–8)	<0.001	4 (2–69)	2 (2–16)	<0.001
Reoperations	3 (7.5)	1 (2.5)	NS	5 (12.5)	3 (7.5)	NS
Readmissions	4 (10.0)	3 (7.5)	NS	3 (7.5)	1 (2.5)	NS

Numbers are N (%), mean±SD, or median (range). NS: not significant.

for complication was reduced for patients with BMI from 40 to 43 kg/m^2, and leveled off with BMI between 43 and 55 kg/m^2 (Fig. 2a). The OR for complication was two to three times higher for the older patients as compared to the younger ones (Fig. 2b).

Reoperations were performed in 14 patients (4.8%) after a median of 3 days (range 1–15; Table 3). All primary reoperations except one were managed by laparoscopy. The rates of reoperations were not significantly different for the surgeons (4/140 vs. 10/152, p=0.17). Multiple reoperations were necessary in 4 of the 14 patients, and all eventually required open surgery.

The median postoperative length of stay was 3 days (1–77); similar for patients operated by surgeon A and B (3 vs. 3 days, p=0.20). A total of 19 patients (6.5%) were readmitted within 30 days, similar for the patients operated by surgeon A or B (10 vs. 9 patients, p=0.81).

Indicators of the Learning Curve

For both surgeons, the probability of a postoperative complication was reduced throughout the study period but did not plateau (Fig. 3a). The length of surgery gradually declined with the number of operations for both surgeons and leveled off after approximately 100 procedures (Fig. 3b). Similar findings were observed for postoperative length of hospital stay (Fig. 3c). Readmissions and reoperations were evenly distributed throughout the study period and could not be evaluated graphically as indicators of the learning curve.

Comparison of the first and last 40 procedures for surgeon A and B individually demonstrated no significant reductions in the rates of complications, reoperations, and readmissions; however, the length of surgery and the postoperative length of hospital stay were shorter (Table 4). These statistical findings were reproduced by comparing the first 100 with the subsequent procedures for both surgeons.

Discussion

In this study of 292 consecutive primary LRYGB, the morbidity rate was 14.7%, and the rate of major complications was 4.8%. This is comparable to the 17.0% morbidity rate and 4.7% rate of major complications in a large European series of primary LRYGB [13]. In a report of 750 LRYGB, Shikora et al. [11] described a morbidity rate at 11–13% after the first 100 cases, indicating a potential for a low and stable morbidity rate after LRYGB with growing experience.

We observed an anastomotic leak rate (all in the gastrojejunostomy) of 1.4%. Andrew et al. [14] presented a reduction of leak rates (not significant) in 201 consecutive patients from 6.0% in the first 67 patients to 1.5% in the last 67. We have not seen a similar pattern, as the leaks occurred quite evenly distributed in the study period. Disturbingly, a 1.4% rate of instrumental small bowel perforations due to excessive traction, all demanding reoperations, was found. Three out of four bowel perforations occurred early in the study period.

Postoperative hemorrhage occurred in 5.8% of the patients (Table 2). We are now addressing this by thorough hemostasis, and we believe that keeping the systolic blood pressure between 100 to 110 mmHg intraoperatively may reduce per- and postoperative bleeding. The patients are prescribed low molecular heparin for 10 days after discharge, and a prolonged thrombosis prophylaxis in some form may be justified: Brasileiro et al. [15] reported an incidence of deep venous thrombosis of 0,79% in patients receiving 40 mg/day of enoxaparin for 15 days after surgery. Thromboembolic complications were absent in the present case series.

Complications and the length of surgery were not correlated to a high patient BMI. Thus, BMI may be an uncertain risk stratification criterion for LRYGB. Some studies of open and laparoscopic gastric bypass surgery have also failed to show an association between BMI and perioperative morbidity, except for incisional hernias in open surgery [16, 17]. Other reports of open procedures have shown conflicting results, with a high BMI being correlated to both overall and major complications [18]. The finding of an association between patient age and risk of complication may reflect the increased perioperative mortality observed following LRYGB in older patients [17, 19].

In our series, there were no conversions to laparotomy, even though 37% of the patients had undergone previous abdominal surgery, making this no contraindication for laparoscopic bariatric surgery. The rates of reoperations or readmissions were not reduced in the study period. The reoperation rate of 4.8% is higher than presented in other series of LRYGB [20]. Still, we believe in an aggressive approach towards a relaparoscopy when in doubt of major complications. Our experience also demonstrates that reoperations may be managed laparoscopically in many cases.

The lengths of surgery and postoperative hospital stay were significantly reduced in the study period, reaching a plateau after 100 cases. These findings applied to both surgeons A and B, indicating that the learning curve expressed by these parameters may be comparable for both the advanced and the general laparoscopist while working in a team. The reduction of postoperative hospital length of stay indicates a learning effect not only for the surgeon, but also in the anesthetic procedure and the nursing of the patient in the ward. The accumulated experience may have made the surgeons more comfortable with an early discharge of the patients.

Suter et al. described the learning curve as 100–150 procedures, with a high rate of major complications (12.5%) in the first 70 procedures [21]. In a study of the learning curve of a skilled laparoscopic surgeon, the rate of major complications was reduced significantly from 13% in the first 75 procedures to 3% in the next 75 procedures [22]. In the present study, the rates of complications were not reduced. There are no formal training programs in bariatric surgery in Norway. Our aim is to safely introduce less experienced surgeons to bariatric surgery. At our hospital, this is currently attempted by learning the LRYGB in stages, as proposed by others [23].

We studied the learning curve for LRYGB by graphical evaluation of a set of parameters often used as indicators of learning effects. The largest number of procedures necessary for the indicators to level off graphically, i.e., no major further changes occurring, could indicate the number of procedures required to complete the learning curve. We also statistically compared the first and last procedures performed. Following 140 and 152 procedures for surgeons A and B, respectively, only the length of surgery and hospital stay were improved as evaluated by both graphical and statistical analyses. A learning effect could not be shown for the rates of complications, readmissions or reoperations. This may indicate that in attempting to statistically define a learning curve that incorporates all these parameters, a large number of procedures would have to be included due to the relatively low frequency of these events.

The definition of learning curves in surgery is controversial, and the practical application remains to be defined. Clinically relevant indicators of learning curves probably depend on the type of procedure evaluated, the institutional and surgeon's experience, and the surgical training. The learning curve should be interpreted cautiously, and the parameters used to define it should be described clearly. If the lengths of surgery and hospital stay should define the learning curve, the rate of complications would have to be low, acceptable and comparable throughout the study period.

In summary, the present study supports that LRYGB can be established safely by experienced surgeons in a hospital with no previous institutional experience in bariatric surgery. The perioperative morbidity was comparable to that of other reports, and there was no mortality. No procedures were converted to open surgery although many patients had undergone previous abdominal surgery. A high BMI was not associated with an increased length of surgery or increased complication rates. Higher patient age was associated with an increased risk of complications. A defined learning curve could only be demonstrated by the lengths of surgery and hospital stay, and included approximately 100 cases.

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