How to Train Surgical Residents to Perform Laparoscopic

Roux-en-Y Gastric Bypass Safely

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Background: As a result of increasing numbers of patients with morbid obesity there is a worldwide demand for bariatric surgeons. The Roux-en-Y gastric bypass, nowadays mostly laparoscopically (LRYGB) performed, has been proven to be a highly effective surgical treatment for morbid obesity. This procedure is technically demanding and requires a long learning curve. Little is known about implementing these demanding techniques in the training of the surgical resident. The aim of this study was to evaluate the safety and feasibility of the introduction of the LRYGB in the training of surgical residents.

Patients and Methods: All patients who underwent LRYGB between March 2006 and July 2010 were retrospectively analyzed. The procedure was performed by a surgical resident under strict supervision of a bariatric surgeon (Group I) or by a bariatric surgeon (Group II). Primary endpoint was the occurrence of complications. Secondary endpoints included operative time, days of admission, rate of readmission, and re-appearance on the ED within 30 days.

Results: A total of 409 patients were found eligible, 83 patients in Group I and 326 in Group II. There was a significant difference in operation time (129 minutes in Group I versus 116 minutes in Group II; p<0.001) and days of admission. Postoperative complication rate, reappearance on the ED and numbers of readmission did not differ between the two groups. **Conclusions:** Our data suggest that, under stringent supervision and with sufficient laparoscopic practice, implementation of LRYGB as part of surgical training is safe only resulting in slightly longer operative time. Complication rates, days of admission, the rate of re-admission and re-appearance at the ED within 30 days was similar between the both groups. Our results should be interpreted considering the fact that all procedures in group I were performed in a training environment. Therefore, occasional intervention of a bariatric surgeon, when necessary, was inevitable.

Background

Morbid obesity has grown to epidemic proportions worldwide. This has led to an exponential growth in numbers of bariatric surgery ^(1, 2). In large cohort studies the Roux-en-Y gastric (RYGB) bypass, nowadays mostly laparoscopically performed (LRYGB), is considered to lead to the most effective short term and long term outcomes. However, the role of the laparoscopic sleeve gastrectomy is still to be determined ⁽³⁻¹³⁾. LRYGB is a technically challenging procedure, demanding advanced skills, such as intracorporeal bowel reconstruction and suturing. Arbitrarily, 50 to 150 procedures have been reported to eliminate the learning curve ^(2, 14-21). As a direct consequence of these expanding demands, a shortage of fully trained bariatric surgeons has emerged in many countries. So far, medical literature considering learning curves in bariatric surgery has mainly focussed on instructing already certified surgeons during bariatric fellowships ^(11, 14, 16, 22, 23). However, scarce data are available considering incorporation of these techniques in regular surgical training of residents ⁽²⁾. The aim of this study was to investigate whether, under stringent supervision and with sufficient laparoscopic experience, surgical residents can safely perform all steps of LRYGB. The primary endpoint of this study was the rate of complications. Secondary outcome measures included operative time, days of admission, rate of readmission, and reappeareance on the ED within 30 days. It was not our intention to discuss the long-term outcomes of the procedures. Also we will propose a structured, step-by-step programme to introduce these demanding laparoscopic techniques in the training of surgical residents.

Patients and Methods

Patients

All patients who were operated for morbid obesity at a major General Teaching Hospital (Maasstad Ziekenhuis, Rotterdam, the Netherlands) between March 2006 and July 2010 were retrospectively analyzed. All patients met the standard International Federation for the Surgery of Obesity (IFSO) criteria for bariatric surgery (BMI >40 kg/m² or >35 kg/m² with at least two co-morbidities and repetitive dietary failure). Work-up consisted of thorough examination by a multidisciplinary team consisting of a specialist for internal diseases, a psychologist, a nurse practitioner, a dietician and a bariatric surgeon. Al procedures were performed in the presence of a bariatric surgeon either as surgeon or as first assistant. Data of all patients who underwent LRYGB were extracted and divided into two groups; In Group I, the LRYGB was entirely performed by a resident under direct and stringent supervision of a bariatric surgeon. In Group II, a bariatric surgeon performed the entire procedure with a resident as first assistant. Patients were not randomised to either group I or II. However, the selection of patients was, to some degree, a random process; an independent person was responsible for the construction of the operation schedule. Among the two bariatric surgeons it was agreed that the last procedure of the day was performed by a resident.

Variables

The following parameters were included in the analysis: gender, age, weight, Body Mass Index (BMI), the American Society of Anesthesiologists (ASA) score, and surgical history (i.e., previous bariatric procedures). The operative data included: primary operator (resident or bariatric surgeon), conversion to open RYGB, operative time and post-operative methylene blue leak test results. The primary endpoint was the rate of complications. These were graded according to a validated and standardized 5-point-scale complication score as has been done in previous reports⁽²⁴⁾. Secondary outcome measures included operative time. Timing started directly after intubation and ended after the last skin suture. So it included positioning and preparation of the patient. Further secondary outcome measures included days of admission,

rate of readmission, and re-appearance on the ED within 30 days. Patients, who underwent one-step conversion from gastric banding into LRYGB, were excluded. On the other hand, patients who had their gastric band laparoscopically removed several weeks prior to LRYGB or patients with a previous sleeve gastrectomy were enrolled.

Surgical Management

The LRYGB can be divided into three fundamental and technically more demanding steps.

Creating the Gastric Pouch (Figure 1.) After correct positioning of the trocars, the peritoneum was opened at the "angle of His" upon the left crus. Next, the gastrohepatic omentum was opened at the lesser curvature of the stomach at around 5 cm distal to the esophageal gastric junction, hereby creating a tunnel dorsal to the stomach. Then, using 60 mm endostaplers, the stomach was transected creating an approximately 15 cc gastric pouch.

Creating the Proximal Anastomosis (Figure 2.) After identifying the right position for the gastrojejunal anastomosis on the gastric pouch, two supporting sutures were applied. The target length of the bilio-pancreatic limb was in all cases approximately 50cm. A jejunal loop was pulled up, far enough to ensure a tension free subsequent anastomosis. The harmonic ace was then used to create a small opening in both the gastric pouch and jejunum after which the gastro-jejunostomy was dorsally stapled with a 30 mm longitudinally positioned endostapler. The remaining defect on the anterior side was closed through continuous 1-0 suturing. By administering methylene blue through the nasogastric tube, the integrity of the proximal anastomosis was tested. In case of leakage the consultant briefly took over the operation and performed the necessary additional stitches.

Creating the Distal Anastomosis (Figure 3.) Distal to the gastrojejunal anastomosis, 100 cm of jejunum was measured for creating the alimentary limb (150 cm if BMI >50) ⁽²⁵⁾. The harmonic ace was used to create a small opening at the measured location and also at around 10 cm proximal to the gastrojejunal anastomosis in the biliopancreatic limb. Considering an antecolic and antegastric position of the limb, the anastomosis was created using a 45 mm endostapler dorsally ⁽²⁶⁾. Next, the remaining jejunal defect was closed through continuous 1-0

suturing. Ultimately, transecting the jejunum approximately 5 cm proximal to the gastrojejunal anastomosis, using an endostapler, completed the Roux-en-Y reconstruction. Finally a drain was positioned adjacent the proximal anastomosis. The drain was allowed to be extracted after a subsequent leak-test (either by performing a contrast swallow or methylene blue examination) was negative on postoperative day two.

Training of residents

Group I consisted of five residents, all of which were differentiating in G.I. surgery or were particularly laparoscopically interested, Group II consisted of 2 bariatric surgeons. The resident had to prove mastery of the necessary laparoscopic techniques to participate in LRYGB procedures. This was achieved through the attendance of the Basic Laparoscopic Skills Course and the Advanced Laparoscopic Suturing Course. The manufacturer of the stapler devices, which are used in our clinic, also organised an annual Bariatric Surgery Course which was obligatory for all residents who participated in LRYGB procedures. Application of these skills were extensively trained with the use of take-home training boxes. Additionally, residents had the opportunity to exercise in our hospital skills lab. Before assisting LRYGB, residents were also expected to have performed at least 100 less demanding laparoscopic procedures (i.e. laparoscopic appendectomy, laparoscopic cholecystectomy or laparoscopic adjustable gastric banding procedures).

As describes in the surgical management section the LRYGB was divided into three standardized fundamental steps: 1) Creating the gastric pouch, 2) Constructing the proximal anastomosis (gastro-jejunostomy), and 3) Constructing the distal anastomosis (jejunojejunostomy). After assisting 10 LRYGB's, the resident was allowed to practise one technical step per procedure to avoid needlessly prolonged operating time. Creating the distal anastomosis was the first step which was practised in vivo, then came creating the gastric pouch. The last step was the construction of the proximal anastomosis. This was a standardized order which was the same for every trainee. Not before the resident mastered all three steps of the LRYGB, as was judged by both bariatric surgeons, was he allowed to

perform the entire procedure. Of course under constant supervision of a bariatric surgeon. A patient was allocated to Group I provided that a resident performed all three steps independently. The five residents that participated in these series were the first residents in our clinic that were trained to perform LRYGB. There were no other residents that began the training but did not reach mastery.

Data Analysis.

The statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 16.0 (SPSS, Chicago, IL). The Kolmogorov-Smirnov test was used to test for normality of the data. The Levene's test was applied to assess homogeneity of variance between data. Since most numeric variables did not show normal distribution or equal variance, all items were regarded as nonparametric for the statistical analysis. A Mann-Whitney U-test (numeric data) or Chi-square analysis (nominal and ordinal data) was performed in order to assess statistical significance of difference between the two groups. A p-value <0.05 was taken as level of statistical significance. Numeric data are expressed as medians with P25-P75; nominal and ordinal data are shown as numbers with percentages. Correlation between the operation duration and the time since introduction of the surgical procedure was assessed using a Spearman Rank Correlation test. A p-value <0.05 was taken as level of statistical significance.

Results

Between January 2006 and July 2010 409 patients underwent LRYGB, 83 patients in Group I and 326 in Group II. General characteristics of this series are outlined in **Table 1.** Median BMI at time of surgery was 42.6 kg/m² (P_{25} - P_{75} 40.0-45.0) in group I and 43.8 kg/m² (P_{25} - P_{75} 40.0-47) in group II. The median age was 39.8 years (P_{25} - P_{75} 32-48) in group I and 39.4 years (P_{25} - P_{75} 33-46) in group II. The percentage of female patients was 92 % in group I and 84 % in group II. There were no significant differences in the baseline characteristics between Group I and II.

Operative Time and Days of Hospitalisation. Data regarding operative time and days of hospitalisation are outlined in **Table 2.** and **Figure 4.** The median operating time for both groups was calculated from the moment residents started performing LRYGB and was 129 minutes (P_{25} - P_{75} 116-155) in Group I and 116 minutes (P_{25} - P_{75} 95-142) in Group II (p <0.001). There was a significant difference in operative time between the five participating residents (p = 0.001). However, this difference was mainly attributable to one resident. Noteworthy is that this particular resident was the first who was introduced to this training programme. In the first two years after introduction of LRYGB in our hospital, all procedures were performed by bariatric surgeons only. It is notable that operative time rapidly reduced over time as experience in performing LRYGB enhanced. This was confirmed by the significant negative correlation between time since introduction and operation time (Spearman Rank Correlation Coefficient, R_s = -0,583; p<0.01). Furthermore it was evident that by the time the residents were allowed to perform LRYGB's, they had comparable operation times as the experienced bariatric surgeons. The median number of days of admission was shorter in Group I compared to Group II, respectively 3 days (3-5) and 4 days (3-5), which is a significant difference.

Conversions to open RYGB. Regarding conversion to laparotomy, in five cases (2%) such was required, all five in Group II. Reasons for conversion were mainly as a result of inadequate exposure due to intra-abdominal obesity (n=2) or extensive adhesions (n=2). In one patient, the indication for conversion was to correct an accidentally created paradoxical jejuno-jejunostomy. Four conversions occurred within the first 2 years of experience with LRYGB.

Mortality, complications, and re-interventions (*Table 2.*) There was no mortality in these series. There were no significant differences in the occurrence of complications between Group I and II. The majority of complications consisted of transient pain (n=25; 37%), transient passage problems (n=10; 15 %), urinary tract infections (n=7; 10%) and marginal ulcers (n=6; 9%). It is noteworthy that no difference was seen in the occurrence of complications between the five residents (p=0.799).

Fourteen (5%) patients had a complication requiring intervention. Of these patients, six (2%) underwent gastroscopy, one in Group I and 5 in Group II. Five (1%) underwent relaparoscopy, all five in Group II, and 3 (<1%) patients were re-explored by means of a laparotomy. Indications for re-exploration were small bowel obstruction (n=4), one in group I and three in Group II. Two patients in Group II required re-exploration as a result of an anastomotic leak; noteworthy is that one of these patients was operated during the first half year after the introduction of LRYGB in our clinic. One patient in Group II presented at the ED with an anastomotic haemorrhage requiring relaparotomy and one patient in Group II was re-operated after developing a post-operative fever during which no abnormalities were found.

Re-appearance on Emergency Department (ED) and Readmission within 30 Days. As seen in **Table 2.** 46 (11%) patients returned to the emergency department within 30 days, 8 (10%) in Group I and 38 (12%) in Goup II (p>0.05), mainly due to post-operative pain and passage problems. 30 (7%) patients; four (5%) in Group I and 26 (8%) in Group II (p>0.05) were readmitted for various problems. The main reasons for readmission were pain (n=6; 2%), bowel obstruction (n=5; 1%), one in Group I and four in Group II, and transient passage problems (n=5; 1%).

Methylene Leak Test. In Group I no positive postoperative leak tests were encountered, whereas two patients in Group II had positive leaktests. Both patients who had positive post-operative leak tests subsequently suffered from anastomotic leak resulting in multiple re-interventions and extensive ICU admission.

Discussion

The data of this study suggest that a technically demanding operation like LRYGB can safely be introduced during the training of surgical residents. This is contrary to current trends to grant surgical fellows or certified bariatric surgeons the restricted rights to perform this surgery. The increasing number of morbid obese patients worldwide and the concomitant demand for bariatric surgery is reflected in the growing interest for bariatric fellowships and bariatric training programmes. Fellowship programmes have proven to significantly eliminate the learning curve without increase of perioperative complications ⁽²²⁾. So far most of literature on training bariatric surgeons has focused on already certified surgeons. Our clinic is a major General District Training Hospital and a high volume LRYGB-centre with between 150 and 200 procedures a year, all procedures are assisted or performed by one of our senior residents, therefore the exposure for the residents to LRYGB is large.

We found no statistical differences regarding the main adverse outcomes of LRYGB, comparing operations totally performed by surgical residents or by surgeons. Reported mortality rates in a meta-analysis by Buchwald et al involving 19,677 patients after LRYGB was 0.16% ⁽⁵⁾. Fortunately, during the complete follow-up of these series of both Group I and II, none of the patients died. All five conversions to open RYGB occurred in group II, four of which were operated in the first years of experience with LRYGB. It is notable that as experienced increased the number of necessary conversions to open RYGB decreased. Correlation analysis on time since introduction of LRYGB and rate of conversion to open RYGB emphasises this significant decline, illustrating the learning curve of the bariatric surgeons.

We graded all complications according to a validated and standardized 5-point-scale complication score. Anastomotic leak rate in Group I and II was 0% and 1%, respectively, which is better than the leak rate of 2% as reported in previous studies ^(5, 6). According to literature 1-2% of LRYGB is complicated by small bowel obstruction. We encountered 1% in both group I and II. Also the rate of anastomotic haemorrhage (0,4%) in our group is better than the reported 2% (6). The encountered total complication rate in the entire group was

19% (Group I 22%, Group II 18%). This number is significantly better than the reported 34% by Nguyen et.al (27). Reported rates on re-intervention in literature range from 8% to 14 % ^(27, 28). This is higher than the 2% and 5 % in we encountered in Group I and II, respectively.

Operation time differed significantly between the two groups, bariatric surgeons appear to complete the procedure thirteen minutes faster than the residents. The first two years, bariatric surgeons exclusively performed all LRYGB. During these years operating time significantly decreased as experience with LRYGB grew. Correlation analysis on time since introduction of LRYGB and operation time emphasises this significant decrease (p<0.01). Interestingly, by the time residents were introduced to performing LRYGB they approached operating times of the bariatric surgeons at that time (**Figure 4.**). This suggests that, after sufficient laparoscopic training, extensive exposure to the procedure and close supervision by experienced bariatric surgeons, residents pass over the steepest part of the learning curve, emphasizing the value of a profound training programme.

The significant difference in days of admission between the two groups can be explained by the first two years since introduction of the LRYGB. At that time, patients were exclusively operated by bariatric surgeons. Due to lack of experience in post-operative care; even patients without complications were admitted for 5 days to a week to closely monitor recuperation consequently leading to longer admission times. Later, uncomplicated patients were discharged on the third post-operative day. When we excluded the first two years, the difference in days of hospitalisation disappeared. Both in Group I and II the median number of days of admission was 3 (3-5) days (p>0.05)

Obviously all procedures in Group I were performed in a training environment. Therefore, occasional intervention of a bariatric surgeon was inevitable. This should be taken into account when assessing the data. The current study design does not allow an answer to the question whether residents could safely perform an unsupervised LRYGB. However this was never our intention. The aim of this study was to investigate whether implementing these laparoscopic techniques in the training of the surgical resident is feasible and safe. The main limitation of this study is its retrospective design. Randomised controlled trials are warranted

to provide evidence. However, the results of these series could act as a guideline for the development of such a trial.

In conclusion our data suggest that, under stringent supervision and with sufficient laparoscopic practice, implementation of LRYGB as part of surgical training is safe, only resulting in a slightly longer operation time. Complication rates, days of admission and reintervention rates are similar for residents as for attending surgeons. Teaching residents in training to perform LRYGB does not eliminate the need for bariatric fellowship training programmes. However it will result in well-prepared potential bariatric surgeons with a possible head start to their colleagues. Also, it is imaginable that a bariatric training as presented will improve general laparoscopic skills leading to proficient young surgeons.

Summary

A retrospective analysis on 409 patients that underwent laparoscopic Roux-en-Y gastric by either a surgical resident or a bariatric surgeon. The data suggest that under stringent supervision and with sufficient laparoscopic practice, implementation of LRYGB as part of surgical training is safe.

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Figure 1.



Figure 2.



Figure 3.



Figure 4.



Table 1.

	Overall (N=409)	Group I (N=83)	Group II (N=326)	P-value
Female [†]	351 (86)	76 (92)	275 (84)	0.093 ++
Age [±]	39.4 (33-46)	39.8 (32-48)	39.4 (33-46)	0.700 +
BMI [±]	43.5 (40.0-46.3)	42.6 (40.0-45.0)	43.8 (40.0-47)	0.121 +
ASA-score [†]				0.957 ++
ASA 1	43 (10.5)	8 (9.6)	35 (10.7)	
ASA 2	346 (84.6)	71 (85.5)	275 (84.4)	
ASA 3	20 (4.9)	4 (4.8)	16 (4.9)	
Previous BP [†]	78 (19.1)	14 (16.9)	64 (19.6)	0.567 ++

Table 1. Characteristics of the study population by group

⁺ Mann-Whitney U-test. ⁺⁺ Pearson Chi-square test. [±] Data are displayed as median, with the first and third quartile given within brackets. [†] Patient numbers are displayed, with the percentages given within brackets. BMI, Body Mass Index given in kg/m². ASA, American Society of Anesthesiologists. BP, bariatric procedure (ea. Gastric sleeve or Gastric banding

Table 2.

	Overall (N=409)	Group I (N=83)	Group II (N=326)	P-value
Operative time $^{\pm}$	120 (98-144)	129 (116-155)	116 (95-142)	$< 0.001^{+}$
Admission days $^{\pm}$	4 (3-5)	3 (3-5)	4 (3-5)	0.049 +
Readmission [†]	30 (7)	4 (5)	26 (8)	0.479 ++
ED <30d [†]	46 (11)	8 (10)	38 (12)	0.700 ++
Re-exploration [†]	8 (2)	1(1)	7 (2)	0.622 ++
Complications total [†]	77 (19)	18 (22)	59 (18)	0.455 ++
Grade I^{\dagger}	51 (12)	14 (17)	37 (11)	0.174 ++
Grade II^{\dagger}	12 (3)	2 (2)	10 (3)	0.751 ++
Grade IIIa ^{\dagger}	6 (2)	1(1)	5 (2)	0.824 ++
Grade $IIIb^{\dagger}$	6 (2)	1(1)	5 (2)	0.824 ++
Grade IV^{\dagger}	2 (<1)	-	2(1)	0.474 ++
Grade V^{\dagger}	-	-	-	-
Methylene leakage PO †	2 (0.5)	-	2 (0.6)	1.000 ++
Conversion to open [†]	5 (1.2)	-	5 (1.5)	0.588 ++

Table 2. Results in the study population by group

⁺ Mann-Whitney U-test. ⁺⁺ Pearson Chi-square test. [±] Data are displayed as median, with the first and third quartile given within brackets. [†] Patient numbers are displayed, with the percentages given within brackets. [±] Operative time is given in minutes. ED, Emergency Department. Grade I Any, deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are drugs as: antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. Also includes wound infections opened at the bedside. Grade II, Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included. Grade IIIa, Intervention not under general anesthesia. Grade IV, Life-threatening complication (including CNS complications) requiring IC/ICU management. Grade V, Death of a patient ⁽²⁴⁾. PO, post-operative.