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ORIGINAL CONTRIBUTIONS

Complications After Laparoscopic Roux-en-Y Gastric Bypass in 1573 Consecutive Patients: Are There Predictors?

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Abstract
Background Roux-en-Y gastric bypass (RYGBP), one of the commonest performed bariatric procedures, remains a technically challenging operation associated with significant morbidity in high-risk patients. This study was conducted in order to identify predictors of complications after laparoscopic RYGBP.
Methods Our prospectively established database has been assessed to review 30-day and in-hospital complications graded according to a validated scoring system (Clavien–Dindo) and separated into minor (Clavien–Dindo I–IIIa) and major (Clavien–Dindo IIIb–IV) complications. Patient- and procedure-related factors were analyzed using univariate analysis. Significant factors associated with morbidity were introduced into a multivariate analysis to identify independent predictors.
Results Between 1999 and 2012, 1573 patients underwent laparoscopic RYGBP, 374 male and 1199 female. Mean age was 41 years, and mean body mass index (BMI) was 44.5 kg/m^2. One hundred fifty-nine procedures were reoperations. One hundred fifty (9.5 %) patients developed at least one complication, and 43 (2.7 %) had major complications, leading to death in one case (0.06 %). Risk factors for morbidity were male gender (p=0.006) and overall experience of the team (p<0.0001). Prolonged 3-day antibiotic therapy was associated with significantly reduced overall (p<0.0001) and major (p=0.005) complication rates. Major complications were associated with smoking (p=0.016).
Conclusions The most significant individual risk factors for early complications after RYGBP are male gender, limited surgical experience, and single dose of antibiotics. RYGBP should be performed by experienced teams. Smoking should be discontinued before surgery. Prolonged antibiotic therapy could be considered, especially if a circular stapled gastrojejunostomy is performed with the anvil introduced transorally.

Keywords Roux-en-Y gastric bypass · Complications · Risk factors · Morbid obesity · Laparoscopy

Introduction

The worldwide prevalence of obesity has been increasing markedly over the past 20 years, leading to a growing number of severe obesity-related comorbidities. When facing severe or morbid obesity, conservative therapies are usually unsuccessful in the long term. As a result, bariatric and metabolic surgery has gained widespread acceptance, not only as the most effective treatment regarding long-term weight loss but also because of its superior effects on quality of life and comorbidities, including diabetes, sleep apnea, dyslipidemia, and hypertension.

Among the several surgical options, and despite the ongoing development of new procedures, Roux-en Y gastric bypass (RYGBP) is still considered as the gold standard in bariatric surgery, as it represents, for many authors, the best compromise between long-term effectiveness and safety [1–5]. Its results in terms of weight loss are acceptable, its complication rate, both in the short as well as in the long term, is reasonable, and patient tolerance is excellent in most cases. RYGBP is

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also considered to be the revisional procedure of choice after failure or complication of other bariatric procedures such as gastric banding or vertical banded gastroplasty. It has been in use for almost 50 years and is nowadays predominantly performed by laparoscopy since the introduction of this technique in 1994 [6]. Laparoscopy has indeed greatly contributed to a reduction in surgery-related morbidity and mortality in this high-risk patient population [7–12]. Despite these improvements, early complications after RYGBP are still arising and are not uncommon. Early overall morbidity can be as high as 18–23 %, and mortality rates up to 1.5 % have been reported [1, 13–18].

The aim of our study was to identify risk factors for early complications. In this paper, we present our experience with Roux-en-Y gastric bypass over a 14-year period, focusing on early postoperative morbidity, with the intent to uncover risk factors for overall and major complications.

Patients and Methods

After failure of conservative therapy, patients with a body mass index (BMI) of 40 kg/m^2, or >35 kg/m^2, with at least one severe comorbidity who were potential candidates for surgical treatment of obesity participated in a three-session course on bariatric surgery [19]. If they confirmed their interest for an operation, they were then evaluated in a standard fashion by a multidisciplinary team, including an endocrinologist specialized in the care of obese patients, dieticians, psychologists, and a bariatric surgeon. Contraindications were as described by the Consensus Development Conference Panel of the National institute of Health, and the Consensus on obesity treatment in Switzerland [20, 21]. After indication for bariatric surgery had been confirmed, and in the absence of contraindication, patients were submitted to preoperative tests including routine upper gastrointestinal endoscopy, abdominal echography, and nocturnal oxymetry. If indicated by clinical history or examination, additional screening included cardiological or pneumological investigations.

Roux-en-Y gastric bypass has been offered to our morbidly obese patients since 1999. Before this date, other bariatric procedures including jejunoileal bypass, bilio-pancreatic diversion, vertical banded gastroplasty, and laparoscopic gastric banding had been performed in our institutions for more than 20 years. Before initiating the laparoscopic gastric bypass program, the senior surgeon had had extensive experience with advanced laparoscopic surgery including fundoplication, hernia repair using TEPP, gastric banding, gastrectomy, colonic resection, among others. After the first 150 cases, a second surgeon was progressively trained, who also became independent after about 100 cases. All patients have been operated by one of these two bariatric surgeons, or by residents in training under their direct supervision. All patients gave informed consent. In order to analyze the possible role of experience in the development of complications, the series was divided into four equal quartiles: group 1 (1999–25.11.2003), group 2 (26.11.2003–12.2.2007), group 3 (13.2.2007-16.2.2010), and group 4 (17.2.2010–31.12.2012).

Operative Technique and Perioperative Care

At the induction of anesthesia, and according to available recommendations for clean-contaminated cases at the time, patients were given an intravenous dose of antibiotics (amoxicillin-clavulanate 2.2 g, or ciprofloxacin 400 mg and metronidazol 500 mg). Due to a high incidence of wound and intra-abdominal infections (5.8 and 1.8 %, respectively), the single prophylactic dose of antibiotic was replaced by a 3-day course at the end of 2004 with the hope to reduce their rate. Thromboembolic prophylaxis using low molecular weight heparin at a dose adapted to the patient's body weight was started either the evening before surgery or at the induction of anesthesia, and was continued until the end of second week after surgery. Additional prophylaxis was provided during the entire study period in one of our department (HDC) using gradual compression stockings during surgery and until full mobilization, while intermittent pneumatic compression devices during surgery and until full mobilization was introduced in the other (CHUV) since 2010. Proton pump inhibitors were started the day after surgery and maintained for 1 month.

The operative technique has been described in details elsewhere [22]. Briefly, the operation was performed through six trocars using a 10-mm 45° angled scope. To form a small 10–15 ml proximal gastric pouch, the stomach was divided just below the cardia using a linear stapler. The jejunum was divided between 30 and 50 cm from the angle of Treitz. The gastrojejunostomy was performed using a 21-mm circular stapler, the anvil of which was introduced transorally. The gastrojejunostomy has been performed on the posterior aspect of the gastric pouch in our first 639 patients, but it has incorporated the gastric pouch staple line afterwards [23]. The Roux limb was brought up through a retro-gastric and retro-colic route in most patients, but the ante-colic route was used in 109 (6,9 %) out of 1573 patients. A side-to-side jejunojejunostomy was performed using a linear stapler, with a Roux limb of 100 cm in patients with a BMI up to 48 and 150 cm if the BMI was higher. Mesenteric windows were closed routinely. This was done with interrupted absorbable sutures during our early experience. Separate nonabsorbable stitches were used as of November 2002, and running nonabsorbable sutures were introduced as of March 2004. Cholecystectomy was performed in patients known to have gallstones and in most other patients as prophylaxis against the development of gallstones during rapid weight loss [24].

Ambulation was started a few hours after surgery. A water-soluble contrast study was routinely performed on the first postoperative day to check for leaks at the GJS and for adequate passage. If it proved normal, oral liquids were started the same day, and the patients were progressively advanced to a semiliquid diet, which was maintained for 4 weeks.

Classification of Complications

All surgical and nonsurgical complications arising during the first postoperative month or the same hospital stay were taken into account for the purpose of this study. Strictures, which developed usually after the first postoperative month, were not taken into account. Complications were categorized according to severity using the Clavien–Dindo classification system [25]. Life-threatening complications or those requiring reoperation (Clavien IIIb–V) were considered as major complications. Patient with multiple complications were counted only once, and the complication with the highest grade was used for analysis. The group of patients with complications was further analyzed to assess for possible risk factors for major complications.

Analysis of Data

A computerized bariatric database has been created since the introduction of laparoscopic bariatric surgery in our department in 1995, and has been maintained prospectively ever since. It includes patients' preoperative characteristics, operative and perioperative details, weight loss results, and early and late morbidity. A retrospective analysis of this database was performed with the aim of identifying predictors for early morbidity. Only patients operated by laparoscopy were included, whether or not conversion to laparotomy was performed. Patients who developed complications were further analyzed in order to look for factors possibly associated with major complications. Factors considered included BMI, age, gender, history of smoking, abnormal glucose metabolism (diabetes, elevated fasting blood glucose, or insulin resistance), hypertension, sleep apnea, duration of surgery, previous bariatric surgery, teaching, duration of antibiotic prophylaxis, and overall operative experience (divided into quartiles of equal numbers of patients). Univariate analysis was performed using the Student's test for continuous variables, and with the χ^2 test or Fisher's exact test for categorical variables, as appropriate. Factors found to impact significantly on univariate analysis were then introduced into a multivariate stepwise logistic regression model to identify independent risk factors for major complications. A subgroup analysis was performed for the group of patients who had primary RYGBP. Statistical significance was accepted with $p \leq 0.05$.

Results

Between June 1999 and December 2012, a total of 1573 patients underwent laparoscopic RYGBP in our two institutions, 374 men and 1199 women with a mean age of 41 (SD=10.9; range, 18–69) and mean BMI of 44.5 kg/m^2 (SD=7.7; range, 17.7–76.2). Of these, 1414 were primary operations and 159 were reoperations after failed and/or complicated prior bariatric procedures. Table 1 shows the preoperative characteristics of our patients. The mean operative time was 151.6 min (SD=43.6; range, 85–300) and was significantly longer in reoperations than in primary procedures (187 versus 148 min, $p<0.001$). The median postoperative hospital stay was 4 days (range, 2–72). Conversion to open surgery was necessary in seven patients (0.4 %). Duration of stay exceeded 10 days in 43 (2.7 %) patients, including 14 (0.9 %) who stayed longer than 20 days and 6 (0.4 %) who stayed beyond the first month.

A total of 150 (9.5 %) patients developed at least one postoperative complication (Table 2), including 43 (2.7 %) patients who developed major complications (Table 3). One patient died on postoperative day (POD) 5 (mortality rate, 0.06 %). Death was the direct consequence of postanoxic encephalopathy secondary to prolonged hypotension during induction of anesthesia for reoperation on POD 2 (leak at the remnant staple line). All leaks, and all but two intraluminal hemorrhages, developed during the first postoperative week. There were no differences between patients who developed complications with respect to weight, BMI, or age. Duration of operation was slightly longer in patients with complications (163 versus 151 min, $p=0.001$). The postoperative hospital stay was significantly prolonged in patients with complications (7.87 versus 4.05 days, $p<0.0001$), especially in patients with major complications (18.02 versus 4.05 days, $p<0.0001$)

Reoperation for early major complications was necessary in 42 patients. It was performed laparoscopically in 30 patients, but required a laparotomy in 10 cases. Of the two patients who developed a left pleural empyema, one required a thoracotomy for decortications on POD 7, and another one

Table 1 Preoperative characteristics of the patients in the study

Number of patients	1573
Male/female	374/1199
Mean age (range)	40.9 (18–69)
Mean BMI	44.9 (17.7–76.2)
Superobese	292 (18.5 %)
Coronary heart disease	48 (3.0 %)
Abnormal glucose metabolism	906 (57.6 %)
Sleep apnea syndrome	819 (52 %)
Hypertension	765 (48.6 %)
Previous bariatric surgery	159 (10.1 %)

Table 2 Number of patients who developed postoperative complication

Type of complication	Number	Percent
Wound infection	31	1.97
Intra-abdominal infection	13	0.83
Intestinal occlusion	15	0.95
Leak	20	1.27
Intraluminal hemorrhage	29	1.84
Extraluminal hemorrhage	14	0.89
Respiratory complications	16	1.02
Thrombo-embolism	13	0.83
Rhabdomyolysis	8	0.50
Others	16	1.02
Total patients with complications	150	9.47
Total patients with major complications	43	2.67

could be treated by thoracoscopy. One pelvic abscess was drained transrectally. Five patients required more than one reoperation. Readmission occurred in 31 patients, the most common reasons for which were respiratory complications (n=6), intraluminal hemorrhage (n=5), and intraabdominal infection (n=5).

Table 4 shows differences between complication rates for several variables using univariate analysis. Among patient-related risk factors, only male gender was found as a predictor (p=0.006). There was a trend for more complications in patients with coronary heart disease (p=0.07). Neither age, BMI, nor any comorbidity was predictive of overall morbidity. Revisional surgery was associated with a slightly higher, although not statistically different, early morbidity (12.6 versus 9.1 %, p=0.15). Procedure-related factors associated with overall complications were the overall experience of the team divided into quartiles (p<0.001, Fig. 1), the teaching status of the procedure (p=0.003), and the hospital in which the procedure was performed (p=0.03). Prolonged antibiotic therapy for 3 days was associated with significantly reduced overall (p<0.0001) as well as major (p=0.005) complication rates. It significantly reduced postoperative infections, both superficial (p<0.0001) or intra-abdominal (p=0.007) when compared with a single-dose prophylaxis. No other factor was predictive of major morbidity, although there was a trend towards fewer major complications with increasing overall experience of the team (p=0.07). Among patients with early morbidity, however, smoking was associated with a higher risk to develop major complications (p=0.016). In the subgroup of patients who underwent RYGBP as a primary procedure, risk factors for complications using univariate analysis were male sex (p=0.001), hypertension (p=0.048), experience of the team (p<0.0001), and the institution where the procedure was performed (p=0.025).

Table 3 Number of patients who developed major complication

Type of complication	Number	Percent
Intestinal occlusion	15	0.95
Intra-abdominal infection	6	0.38
Hemorrhage	7	0.45
Leak gastro-jejunostomy	7	0.45
Leak jejunojejunostomy	3	0.19
Leak gastric remnant	4	0.25
Central pulmonary embolism	1	0.06
Left pleural empyema	2	0.13
Gallstone peritonitis (leak accessory biliary duct)	1	0.06
Total major complications	46	
Total patients with major complications	43	2.7

Multivariate analysis (Table 5) shows that early experience of the team, male sex, and single-dose antibiotic prophylaxis were associated with increased overall morbidity in the whole group, whereas only experience of the team and prolonged antibiotic therapy remained significant in the subgroup with primary RYGBP.

Discussion

The overall early postoperative morbidity of 9.5 % observed in the present study is consistent with the literature, where rates vary from as low as 0.23 % to as high as 31.8 %, depending on the institution and how complications are defined [14–16, 18, 26, 27]. In the same line, our major complication rate of 2.7 %, as well as our mortality, are comparable to figures reported elsewhere [22, 28–35]. In a recent meta-analysis, Buchwald et al. [28] found a 0.16 % mortality rate for laparoscopic RYGBP, an improvement from the 0.41 % calculated for the open procedure.

Numerous studies have shown complications to be associated with a variety of factors, including access (laparoscopic versus open) [1, 16, 36], older age [13, 22, 30], early surgeon experience [16, 26, 27, 37], greater BMI [38], or weight [37]. Hospital volume [26, 27, 39], operative time [36, 40], and obesity-related comorbidities [16, 30, 41] have also previously been reported as risk factors of postoperative morbidity.

In our series, only three factors were independent predictors of complications after RYGBP: male gender, single dose of antibiotics, and overall experience of the team. In the subgroup of patients who underwent RYGBP as a primary procedure, the significance of male sex was only borderline. Male gender has been identified as a risk factor for complications and/or mortality in several studies, and our results mirror the literature on this aspect [22, 31, 32, 35, 41]. One of the usual explanations for this, with which we concur, lies in the more central distribution of adipose tissue in males, with more intra-abdominal fat and very often a large liver due to massive steatosis. This reduces working space and limits visualization,

Table 4 Univariate analysis of risk factors for overall and major complications

Variable	Whole series				Primary RYGBP			
	Percent overall complications	*p* value	Percent major complications	*p* value	Percent overall complications	*p* value	Percent major complications	*p* value
Experience		*<0.0001*		0.078		*<0.0001*		0.092
1st quarter	17.35		4.34		15.87		4.19	
2nd quarter	11.20		3.05		12.71		3.11	
3rd quarter	5.08		1.52		5.22		1.37	
4th quarter	4.33		2.04		3.88		1.94	
Teaching		*0.003*		0.704		0.07		0.312
Yes	5.7		2.49		7.16		1.98	
No	10.62		2.82		10.22		2.94	
Sex		*0.006*		0.315		*0.001*		0.859
Male	13.10		3.48		13.18		2.60	
Female	8.35		2.50		8.36		2.79	
Superobesity		0.449		0.435		0.311		0.761
Yes	10.65		2.06		10.18		2.58	
No	9.21		2.89		9.31		2.78	
Hypertension		0.134		0.274		*0.048*		0.340
Yes	10.98		3.40		10.56		3.20	
No	8.02		2.07		7.47		2.09	
Abnormal glucose metabolism		0.903		0. .816		0.429		0. .713
Yes	9.27		2.76		10.00		2.85	
No	9.49		2.56		8.32		2.50	
Coronary heart disease		0.075		0.952		0.316		0.977
Yes	18.75		2.08		15.91		2.20	
No	9.10		2.72		9.26		2.61	
Sleep apnea syndrome		0.781		0.705		0.941		0.625
Yes	9.16		2.81		9.51		2.89	
No	9.57		2.50		9.42		2.45	
Age>50 years		0.402		0.981		0.538		0.600
Yes	10.60		2.72		10.22		2.24	
No	9.14		2.74		9.07		2.78	
Prolonged antibiotic prophylaxis		*<0.0001*		*0.005*		*<0.0001*		*0.003*
Yes	5.67		1.95		5.67		1.75	
No	17.57		4.44		17.57		4.50	
Site		*0.031*		0.559		*0.025*		0.400
HDC Monthey	7.68		2.46		7.33		2.41	
CHUV Lausanne	10.88		2.95		10.84		3.03	

p-values in italic indicate significant difference

and is reflected by longer operative times in male compared with female patients (163 versus 149 min, $p<0.001$). In our series, men also tend to have a higher preoperative BMI than women (46.3 versus 43.2) and significantly more major co-morbidities (data not shown).

The role of prolonged antibiotic therapy has not been reported before, and may be due, at least in part, to the operative technique. We routinely perform a circular-stapled gastrojejunostomy with the anvil introduced transorally using a gastric tube. This results in contamination of the operative field with germs originating in the oral cavity. Others have noted a higher port-site infection rate with circular-stapled anastomosis than with a linear stapled one [42]. Bacteriological studies from postoperative infections in our patients have indeed shown mostly germs from the oral cavity, such as streptococcus anginosus or streptococcus constellatus. Because of this, and a relatively high rate of postoperative infections in our early experience, we replaced a single

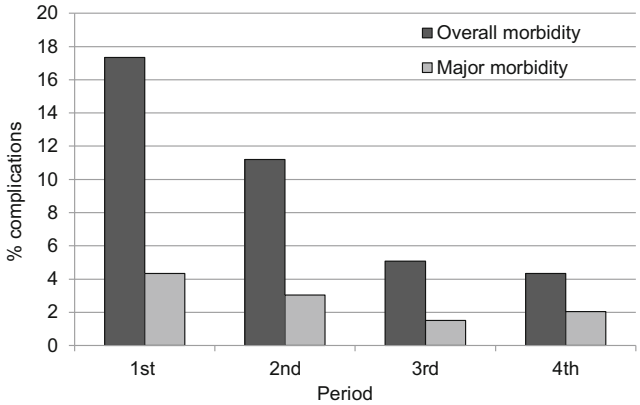

Fig. 1 Overall and major morbidity according to the experience of the team divided into equal quartiles. Overall morbidity: $p = 0.01$ between first and second, $p = 0.001$ between first + second and third + fourth. Major morbidity: $p = 0.02$ between first + second and third + fourth

preoperative prophylactic dose of antibiotics with an antibiotic treatment for 3 days at the end of 2004. This was followed by a marked drop of infection rates, from 5.1 to 0.4 % for trocar-site infections and from 2.2 to 0.2 % for intra-abdominal infections, figures that have now remained stable for years (unpublished data). The fact that prolonged antibiotic therapy also reduced the overall number of complications came to our surprise, and we do not have an explanation for this. More studies, ideally prospective and randomized, will be necessary to confirm our findings. Moreover, while certainly helpful in our hands with the transoral technique, prolonged antibiotic treatment may not be beneficial if other techniques are used for the gastrojejunostomy, like linear stapling or hand suturing, or if the anvil is introduced though the abdomen.

Our analysis also shows a clear association between surgical experience and overall and major adverse outcomes. It took us several hundred cases to reach an acceptably low morbidity, which did not stabilize before the third quartile of our study. The learning curve for laparoscopic Roux-en-Y gastric bypass has been shown to be long, including between 75 and 150 cases for the most optimistic authors [43, 44]. It may have taken longer in our hands because we were among the first to perform laparoscopic RYGBP in Europe, and the first in Switzerland, when we started in 1999. As a result, we could not benefit from proctoring at this time. It is also worth mentioning that, with increasing experience, we have made several alterations in our operative technique and perioperative management, which may also have contributed to lowering the complication rate. These include oversewing of some of the staple lines, closing mesenteric defects with running nonabsorbable sutures, an antiobstruction stitch at the jejunojejunostomy, choice of staple heights for mechanical sutures, avoiding ketorolac for pain control and aggressive treatment of postoperative hypertension, very early postoperative mobilization, and incorporating the staple line of the pouch when performing the circular stapled gastrojejunostomy [23], among others.

On the other hand, our study shows that the fact that the operation is done, in part or totally, by a trainee, does not add to its morbidity. This likely has two explanations. Firstly, only the easiest cases are done by trainees, at least during the early phase of their learning curve. Secondly, an attending surgeon with personal experience of more than 150 cases participated in all the procedures from beginning to the end, and did not hesitate to take over in case of difficulty. Adequate supervision is essential during training for highly complex procedures such as laparoscopic RYGBP.

There was a nonsignificant increase in the overall complication rate after reoperations as compared to primary procedures, although several authors have pointed out that revisional RYGBP has increased morbidity [45, 46]. In 2005, Jones considered the risks associated with revisonal surgery to be 10 times greater than in primary cases. More recently, however, several authors have shown that laparoscopic revisional gastric bypass can be performed safely by experienced surgeons [47–49].

The literature is conflicting regarding the role of obesity-related comorbidities in predicting morbidity. Sleep apnea syndrome, hypertension, and diabetes have been identified as predictors of complication in some studies [16, 30] but not in others [22, 50]. None of the comorbidities tested in the present study was associated with increased morbidity, especially major morbidity, although there was a trend on univariate analysis for more overall complications in patients with coronary heart disease in the whole group, and for

Table 5 Multivariate analysis of risk factors for overall morbidity

Variable	Entire series			Primary RYGBP		
	Odds ratio	95 % CI	*p* value	Odds ratio	95 % CI	*p* value
Academic hospital	1.165	0.960–0.414	0.12	0.825	0.679–1.003	0.054
Male sex	1.264	1.046–1.503	*0.015*	1.216	0.669–1.009	0.061
Team experience	0.740	0.565–0.970	*0.029*	0.732	0.551–0.971	*0.031*
Prolonged antibiotic therapy	0.685	0.542–0.868	*0.002*	0.644	0.500–0.829	*0.001*
Teaching	0.775	0.656–1.065	0.12	–	–	–
Hypertension	–	–	–	1.279	0.869–1.884	0.213

p-values in italic indicate significant difference

patients with hypertension after primary RYGBP. Several groups have tried to develop risk scores for both mortality and morbidity in bariatric surgery, especially after gastric bypass. Livingstone in 2002 identified male gender and superobesity as the most powerful risk factors for major complications [22]. Authors from East Carolina and Virginia have found age, male gender, diabetes, sleep apnea, and the type of procedure (revisional versus open versus laparoscopic) to be independently predicting leaks, whereas leaks, body weight, hypertension, and the type of procedure were risk factors for mortality [41]. In a subpopulation analysis, pulmonary embolism was also a risk factor for early death [51]. De Maria et al., in 2075 patients, found four independent risk factors for 90-day mortality: superobesity, hypertension, male sex, and high risk for pulmonary embolism, to which they added age >45, to propose the OS-MRS. The latter has been validated prospectively and used in retrospective studies [32, 35, 52]. One has to keep in mind that this risk score has been developed and validated mostly in patients operated by laparotomy, with mortality sometimes 10 times higher than the one currently reported in many laparoscopic series. Results can therefore probably not be directly transferred to patient groups operated with the laparoscopic approach [35]. On the basis of data from the National Surgical Quality Improvement Program (NSQIP), another group has developed a risk model for mortality after bariatric surgery, where not only some similar factors (BMI, coronary heart disease, age, and type of intervention) but also others (peripheral vascular disease, use of steroids) were identified [53].

Other groups have looked for potential risk factors, especially for severe complication. Finks et al. analyzing 25,469 patients who received different bariatric procedures in 29 Michigan hospitals between 2006 and 2010, found not only the most important risk factor to be the type of procedure [duodenal switch (DS)>gastric bypass (RYGBP)>>sleeve gastrectomy (SG)>gastric banding (GB)], but also some patient factors (previous thromboembolic events, limited motility, coronary heart disease, age>50 years, chronic obstructive pulmonary disease, male gender, and smoking) [31]. Gupta et al. [33] studied 11,023 patients from the NSQIP and also found the type of procedure to be predictive of serious complications (DS>RYGPP>GB), apart from patient factors (coronary heart disease, limited motility, history of stroke, bleeding disorders, hypertension, and BMI). Using their results, these two groups compounded risk predicting models, but their discrimination power was only moderate [31, 33]. Maciejewski et al. [30], using the BOLD database, came up with similar results. One strength of the latter study is that it incorporates events up to 90 days postsurgery, whereas the first two are limited to 1 month. In all three studies, several limitations were noted, such as quality of registry data, the lack of a specific bariatric system, underreporting of complications, and multiple types of procedures.

Due to the very low mortality reported in the present study, no attempt could be made at analyzing risk factors for mortality. Regarding morbidity, and especially major complications, very few risk factors were identified, the only patient-related one being male sex. This may be due to the relatively small size of our study group in comparison with large US databases, or to an overall lesser risk patient group when compared with other series, where the mean BMI is often higher.

Among patients who developed complications, smoking was the most significant risk factor for serious complications (p=0.016). Smoking has both acute exposure and chronic cumulative effects on pulmonary function, both of which predispose patients to postoperative pneumonia and respiratory failure. In a large series involving almost 400,000 patients, Hawn et al. [54] have shown that current smoking increased the risk for postoperative pneumonia, surgical site infection, and death. A recent meta-analysis of randomized trials showed a relative risk reduction of 41 % for postoperative complications if smoking was discontinued before surgery, each week of cessation adding 19 % to the magnitude of the effect [55]. This finding is in agreement with another meta-analysis [56]. Trials with at least 4 weeks cessation show significantly larger effects than shorter trials [55].

The present study has a number of limitations. Despite the fact that data were collected prospectively, it is based on a retrospective analysis. Risk factors for individual complications were not analyzed, and the size of the study group may limit the detection of clinically important factors. Finally, patients were operated in two different hospitals where, despite the fact that the same surgeon is responsible, patient care may be somewhat different.

On the other hand, our study has several strengths. It is a large experience where patient management and operative technique are very homogeneous. Patient data were carefully and completely captured prospectively, and patient-follow-up is 100 % after the first year, which virtually eliminates nonrecorded events due to patients with problems seen, or readmitted, elsewhere. Another strength is the use of the now universally accepted Dindo–Clavien classification for complications, a system based on the means required to treat a given complication (i.e., its real clinical significance) rather than its mere occurrence. Typically, the vast majority of thrombo-embolic events are not life threatening and require only anticoagulation (Dindo–Clavien class 2). They are, however, considered as major complications in most of the aforementioned studies.

Conclusions

In this study, significant risk factors for overall complications after laparoscopic RYGBP were male gender, single antibiotic dose, and early experience. Smoking and early experience

were associated with major complications. Gastric bypass should preferentially be performed at centers with a large case load and by experienced bariatric surgeons. Fellowships and proctorship should be highly encouraged in order to overcome the learning curve and its associated higher risks. Men are at higher risk, and this should be taken into account in the decision-making process before surgery. Teaching in appropriate cases does not add to the morbidity provided the teacher is highly experienced. Active smoking should be strongly discouraged and discontinued before surgery. A prolonged antibiotic course could be considered, especially if the anvil is introduced transorally for circular-stapled anastomoses.

Conflict of Interest All authors declare that they have no conflict of interest.

Ethical Approval All procedures performed were in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. As this is a retrospective study, no ethical committee was sought.

Informed Consent All patients gave informed consent before operation, which included consent for the procedure as well as for follow-up, inclusion in our databases, and deidentified outcome data reporting.

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