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Factors Affecting Morbidity and Mortality of Roux-en-Y Gastric Bypass for Clinically Severe Obesity: An Analysis of 1,000 Consecutive Open Cases by a Single Surgeon

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Abstract
Introduction Determinants of perioperative risk for RYGB are not well defined.
Methods Retrospective analysis of comorbidities was used to evaluate predictors of perioperative risk in 1,000 consecutive patients having open RYGB by univariate analyses and logistic regression.
Results One hundred forty-six men, 854 women; average age 38.3±11.2 years; mean BMI 51.8±10.5 (range 24–116) were evaluated. Average hospital stay (LOS) was 3.8 days; 87% <3 days. 91.3% of procedures were without major complication. The most common complications were incisional hernia 3.5%, intestinal obstruction 1.9%, and leak 1.6%. 31 patients required reoperation within 30 days (3.1%). A 30-day mortality was 1.2%. Logistic regression evaluating predictors of operative mortality correlated strongly with coronary artery disease (CAD) ($p<0.01$), sleep apnea ($p=0.03$), and age ($p=0.042$). BMI>50 (0.6 vs 2.3%, $p=0.03$) and male sex were associated with increased mortality (1.3 vs. 4.0%, $p=0.02$). Sex-specific logistic regression demonstrated males with angiographically proven CAD were more likely to die ($p=0.028$) than matched cohorts. Age ($p=0.033$) and sleep apnea ($p=0.040$) were significant predictors of death for women.
Conclusion Perioperative mortality after RYGB appears to be affected by sex, BMI, age, CAD, and sleep apnea. Strategies employing risk stratification should be developed for bariatric surgery.

Keywords Obesity · Morbid obesity · Roux-en-Y gastric bypass · Morbidity · Mortality

Introduction

Obesity is currently the number one public health problem in the United States, affecting one-third of all Americans (http:/www.surgeongeneral.gov/topics/obesity). Approximately 5 to 8% have clinically severe or morbid obesity and are candidates for bariatric surgery.

This obesity epidemic has been accompanied by a geometric rise in the number of bariatric surgical procedures. The American Society for Bariatric Surgery (ASBS) estimates that the number of bariatric surgery procedures has increased from approximately 20,000 in 1996 to over 140,000 in 2004 (http://www.asbs.org). During this period, membership in the ASBS has also increased fivefold, suggesting that many more surgeons are performing these procedures. The most common bariatric procedure performed in the United States is Roux-en-Y gastric bypass (RYGB).[1]

The explosive growth of bariatric surgery has garnered much attention in the media, with much speculation about

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the risks, both short- and long-term, of RYGB. Unfortunately, to date, little information from large series is available concerning the operative mortality of RYGB and those factors that predict mortality. In 2002, Livingston et al.[2] reported an operative mortality of 1.3% in 1,067 patients after open RYGB and found that only age over 55 years correlated with perioperative mortality. More recently, Fernandez et al.[3] analyzed their patient cohort of 1,431 patients having open RYGB and found a 1.9% mortality, which was associated with age, weight, longer limb gastric bypass, and the occurrence of a leak or pulmonary embolism.

This report is a multivariate analysis of preoperative mortality and morbidity in 1,000 consecutive open RYGBs performed over a 5-year period by a single surgeon (LF) in at a single institution.

Materials and Methods

Bariatric Surgery Program The bariatric surgery program at St. Luke's–Roosevelt Hospital Center in New York City was initiated in April 1999 and the first operation performed in June 1999. The basis of this report consists of 1,000 consecutive open RYGBs (primary cases and revisions) performed by a single surgeon, LF, between June 1999 and June 2004.

Clinical Protocol and Surgical Technique All patients were evaluated preoperatively and met generally accepted criteria outlined by the NIH at its Consensus Development Conference on Gastrointestinal Surgery for Severe Obesity.[4] In addition, all patients were routinely evaluated by a registered dietitian experienced in the treatment of obesity. Mental health and other specialty consultations were only obtained if they were felt to be clinically indicated or were required by an insurance carrier. All patients were evaluated by an attending anesthesiologist before surgery.

Routine preoperative studies included: electrocardiogram, chest x-ray, gallbladder ultrasonography, serum electrolytes, glucose, HbA1c, calcium, albumin, lipid profile, liver function tests, complete blood count, platelets, prothrombin time, partial thromboplastin time, INR, and urinalysis. Over time, additional preoperative studies, including serum insulin, iron, ferritin, vitamin B_{12}, 25-OH vitamin D, and thiamine (vitamin B_1) were added.

RYGB was performed in a standard fashion with the following common elements: (1) open technique; (2) 20–30 ml pouch, nondivided stomach, TA 90B (US Surgical, Norwalk, CT, USA) applied twice; (3) hand-sewn two-layer retrocolic, antegastric gastrojejunostomy, 12 mm in length, tested with methylene blue under pressure intraoperatively; (4) side-to-side, functional end-to-end jejunojejunostomy with dispSAble GIA (US Surgical) or LC (Ethicon Endosurgery, Sommerville, NJ, USA) 75 mm staplers, and TA55 (US Surgical) or TX 60 (Ethicon Endosurgery) staplers and routinely oversewn with 3–0 silk Lembert sutures. The biliopancreatic limb-length measured 75 cm along the antimesenteric border for patients with BMI less than 50 and 150 cm for patients with BMI greater than or equal to 50. The Roux or alimentary limb-length was 150 cm in all patients. For the initial 14 cases, the stomach was divided using the GIA-100 stapler. This technique was abandoned and switched to the nondivided stomach after a stapler malfunction led to a leak.

Closed suction drains were placed in all revisions, patients with BMI>55, or if clinically indicated (e.g., identification of an intraoperative leak, technically difficult anastomosis). Drains were removed as clinically indicated. Fascia was closed with a running looped #1 PDS (Ethicon, Sommerville) and infiltrated with 0.25% bupivacaine. The subcutaneous space was drained with a #10 Jackson–Pratt drain and the skin was closed with a running subcuticular stitch.

The gallbladder was removed if gallstones were documented by preoperative ultrasound. Incisional or umbilical hernias were primarily repaired if encountered, oftentimes through a separate periumbilical incision.

Invasive monitoring was not used routinely and Foley catheters were only placed if patients required invasive hemodynamic monitoring or in the case of revisions or when patients had multiple prior abdominal operations. Nasogastric tubes were left in placed as clinically indicated (intraoperative leak identified) or in patients with BMI>55. All patients received perioperative antibiotics for 24 h, cefazolin (2 g intravenously every 8 h for three total doses) or clindamycin (900 mg intravenously every 6 h for four doses). Prophylaxis against deep vein thrombosis consisted of 5,000 units of unfractionated heparin administered subcutaneously every 8 h and pneumatic compression stockings until ambulatory. All patients were given a PCA pump (patient-controlled analgesia) for pain. Patients were routinely cared for on a regular surgical floor, equipped for severely obese patients. Patients with significant SA or documented CAD were usually observed in the recovery room overnight, and only rarely admitted to the intensive care unit. On the morning of postoperative day 1, patients were routinely studied with gastrografin upper-GI studies. If no leak was identified, they were given liquids for lunch and advanced to soft food (yogurt, apple sauce, and cottage cheese) for dinner and switched to oral pain medications. Drains were usually removed before discharge. Patients were discharged on POD #2 or #3 as indicated with the following medications: a codeine-derivative for pain, prenatal vitamins, iron polysaccharide, calcium citrate, ursodeoxycholic acid, if the gallbladder was present.

After hospital discharge, patients were scheduled to be seen at 2 and 8 weeks, 6, 12, 18, 24 months, and yearly thereafter. All routine follow-up appointments included nutritional counseling and those after 2 weeks included laboratory studies [serum electrolytes, glucose, HbA1c, calcium, albumin, lipid profile, liver function tests, complete blood count, platelets, serum insulin, iron, ferritin, vitamin B_{12}, 25-OH vitamin D, and thiamine (vitamin B_1)]. Follow-up was 74% at 1 year, 68% at 2 years, 59% at 3 years, 53% at 4 years, and 48% at 5 years.

Clinical Data and Data Analysis Clinical and laboratory data were PC-based database prospectively maintained since the program's inception in 1999. Data collected included: age, sex, height weight, BMI, race/ethnicity, payer status, obesity-related comorbidities, operative procedure, duration of stay, mortality, major complications, and death. Complications were classified as systemic (prolonged intubation, deep venous thrombosis, pulmonary embolism, and myocardial infarction/fatal arrhythmia) or technical (incisional hernia, intestinal obstruction, leak/perforation, dehiscence, GI bleeding, anastomotic stricture, and anastomotic ulcer). Deaths were analyzed with respect to BMI, demographics, comorbidities, and complications.

Superficial wound infections were not included; the incidence of urinary tract infections was not tracked. Nutritional complications were not evaluated because all patients were routinely maintained on vitamins, iron, and calcium supplements postoperatively; it would be impossible to determine the true incidence of any of these nutritional deficiencies.

Univariate analyses and logistic regression with SPSS 11.0 were used to determine significance.

Results

The population consisted of 854 women and 146 men. Their demographic characteristics are summarized in Table 1. The prevalence of obesity-related comorbid conditions is shown in Table 2.

The most common comorbidites encountered were dyspnea on exertion (94%), joint pain/arthritis (92%), and gastroesophageal reflux disease (59%). The comorbidites typically associated with systemic disease included hypertension (HTN, 39%), obstructive sleep apnea (SA, 24%), dyslipidemia (46%), and asthma (15%). Approximately 23% of the patient population suffered from type II diabetes mellitus (DM). At time of initial evaluation, 13.0% of this diabetic patient subset had a prior history of insulin-dependent DM, 57.6% had noninsulin dependent DM, and 23% had a previous diagnosis of DM intermittently controlled on diet or were newly diagnosed with DM during their preoperative evaluation. Six percent of the patient population had angiographically documented histories of coronary artery disease (CAD) but were deemed suitable risk by their respective specialists.

Procedures and Duration of Hospital Stay There were 966 primary RYGB and 34 revisions of failed bariatric procedures (21—VBG, 5—RYGB, 8—other; all performed at outside institutions) to RYGB. The median length of stay for primary procedures was 2.4 days compared to 3.7 days for revisions. Average (LOS) for all patients having primary RYGB was 3.8 days with 87% of the group leaving in 3 days or less.

Complications Overall, 91% of the procedures were without systemic or technical complications.

The incidence of complications in relation to BMI is summarized in Table 3. Overall, systemic complications occurred rarely, but did not usually correlate with BMI. The most common technical complications were incisional hernia (3.5%), intestinal obstruction (1.9%), and leak/perforation (1.6%).

Thirty-one patients (3.1%) required reoperation within 30 days of the original procedure. The indications for reoperation within 30 days were leak/perforation (11), intestinal obstruction (9), bleeding (4), rule-out leak (2), dehiscence (4), and subphrenic abscess (1).

Indications for late operations (>30 days postoperatively) included incisional hernia repair in 35 patients, intestinal obstruction in 10 patients, and repair of leaks/

Table 1 Demographic Characteristics by Sex and Race

	Women	Men	Total	*p*-Value
Age (years)	38±1.0 (15–73)	40±11.9 (15–65)	38±11.17 (15–73)	0.064
Weight (kg)	134±27 (84–263)	170±43 (81–345)	139±33 (82–345)	<0.01
BMI (kg/m^2)	51±10 (35–1,000)	55±13 (24–116)	51±10 (24–116)	<0.01
Caucasian	(28%) 238/853	(53%) 78/147	32%	<0.01
African–American	(30%) 253/853	(20%) 29/147	28%	0.01
Hispanic	(42%)358/853	(27%)40/147	40%	<0.01
Other	(0.5%) 4/853	(0%) 0/147	0.4%	0.41

Table 2 Prevalence of Obesity-Related Comorbid Conditions by Sex

	Women (*N*=853) (%)	Men (*N*=147) (%)	Total (%)	*p*-Value
Type II diabetes mellitus	177 (21)	54 (37)	23	<0.01
Hypertension	310 (36)	79 (54)	39	<0.01
CAD/CHF	29 (3)	26 (18)	6	<0.01
Dyslipidemia	376 (44)	80 (54)	47	0.02
Sleep apnea	172 (20)	63 (43)	24	<0.01
Asthma	135 (16)	16 (11)	15	0.12
Dyspnea on exertion	811 (95)	127 (86)	48	<0.01
GERD	513 (60)	77 (52)	59	0.08
Osteoarthritis	791 (93)	126 (87)	92	<0.01
Urinary stress incontinence	430/(50)	5 (3)	44	<0.01
Irregular menses	276 (32)	NA	32	NA

CAD/CHF coronary artery disease/congestive heart failure, *GERD* gastroesophageal reflux disease

perforations in five patients who were experiencing ongoing postoperative complications. No patients required reoperation for refractory anastomatic stricture or ulcer. One patient developed a gastrogastric fistula after repair of an early leak, which was treated expectantly since it was clinically insignificant. No late gastrogastric fistulae were identified.

Deaths Thirty-day mortality was 1.2%. Overall mortality attributable to surgery was 1.5%. Patients with late deaths due to unrelated events, such as motor vehicle accidents (*N*=2) or drug overdoses (*N*=1), were excluded and not classified as mortalities in the analysis. Mortality correlated with BMI, with four (0.8%) patients having a BMI<50 dying compared to 11 (2.1%) patients with BMI≥50 (p= 0.03) (Table 3).

Causes of death after RYGB, along with their timing and relationship to BMI are shown in Table 4. Two patients died of fatal arrhythmias on POD #3 and #4. Both were males, ages 48 and 54, with BMIs>50, DM, CAD, HTN, and SA. Autopsies were performed in both instances and no other precipitating factors were identified. One patient, a 43-year-old woman with a BMI 59, died of a pulmonary embolism (identified at autopsy) at home after 2 weeks.

Six patients died from MSOF after postoperative leaks, three from the gastrojejunostomy and three from perforations of the distal small bowel within the common channel. Of these, four occurred and were diagnosed within 48 h of the initial RYGB and all were emergently explored. All four developed MSOF and expired between 14 and 211 days postoperatively. Of the remaining two deaths, one patient, 46-year-old woman with a BMI 79 and a history of chronic ventilator dependence due to a paralyzed left

Table 3 Incidence of Complications after RYGB

Complication	BMI<50 (%) (*N*=481)	BMI>50 (%) (*N*=515)	Total (%)	*p*-Value
Systemic complications				
Prolonged intubation	3 (0.6)	8 (1.5)	1.1	0.16 (NS)
Deep venous thrombosis	0 (0)	2 (0.4)	0.2	NS
Pulmonary embolism	0 (0)	3 (0.6)	0.3	NS
MI/fatal arrhythmia	1 (0.2)	1 (0.2)	0.2	NS
Technical complications				
Incisional hernia	10 (2.1)	25 (4.8)	3.5	0.019
Intestinal obstruction	10 (2.1)	9 (1.7)	1.9	NS
Leak	7 (1.5)	9 (1.9)	1.6	NS
Dehiscence	2 (0.4)	2 (0.4)	0.4	NS
GI bleeding requiring transfusion	3 (0.6)	6 (1.2)	0.9	NS
Anastomotic ulcer	2 (0.4)	0 (0)	0.2	NS
Anastomotic Stricture	6 (1.2)	2 (0.4)	0.8	NS
Death	4 (0.8)	11 (2.1)	1.5	.03

Table 4 Causes of Early and Late Deaths Related to BMI

Cause of death	Early (<30 days) (*N*=11)		Late (>30 days) (*N*=4)	
	BMI< 50	BMI≥ 50	BMI< 50	BMI≥ 50
MI/arrhythmia	0	2	0	0
Pulmonary/PE	0	1	0	0
MSOF 2^0 leak	1	2	1	2
MSOF 2^0 bowel obstruction	0	1	0	0
MSOF cause unknown	1	1	0	0
Bleeding complications	1	2	0	0

PE Pulmonary embolism, *MSOF* multisystem organ failure

hemidiaphragm on chronic steroid therapy developed a late leak and multiple intestinal fistulae and eventually succumbed to MSOF. The other patient, a 43-year-old woman, BMI 43, had undergone a laparoscopic RYGB at another institution that was complicated by a strangulated internal hernia, massive intestinal gangrene, and short-bowel syndrome. She underwent a reversal of her RYGB with reconstruction of her GI tract, but developed multiple small bowel fistulae 2 weeks postoperatively and died of MSOF several months later.

Three patients died from a severe systemic inflammatory response syndrome (SIRS) with MSOF accompanied by extremely high fevers, without any identifiable source. One was a 70-year-old woman with BMI 68 underwent reexploration for an early postoperative small bowel obstruction. The others were a 54-year-old woman with a BMI 47, DM, HTN, and SA and a 37-year-old male with BMI 94 and severe SA and HTN. Each developed SIRS and MSOF with temperatures of 105–107°F and hyperdynamic circulations. No intraabdominal or other sources were identified despite numerous cultures and radiologic studies.

Three patients died of bleeding complications. A 43-year-old woman with a BMI 48 suffered progressive hypotension and tachycardia in the recovery room postoperatively. These symptoms were initially addressed with rehydration allowing the patient's hematocrit to fall to a level where hypovolemic shock and resulting coagulopathy obscured efforts to surgically control or identify a single source. A 31-year-old woman with a BMI 50 was returned to the OR 4 h postoperatively for control of bleeding from the small bowel mesentery. After this second procedure, she developed SIRS, temperatures of 106°F, and MSOF, with no identifiable source of sepsis. A 54-year-old male with a BMI 56 and a history of HTN, CAD, and chronic atrial fibrillation suffered a postoperative myocardial infarction and developed a coagulopathy complicated by a massive intraspenic hematoma after restarting coumadin, which rapidly progressed to anuria and MSOF. Attempts to reverse his anticoagulation and control the bleeding angiographically were unsuccessful.

The necessity for reoperation within 30 days of the original procedure was particularly ominous. Overall, the incidence of death after a second operative procedure within 30 days was 9/31 (29%). Two of the 16 patients with a BMI<50 who required reoperation within 30 days died (12.5%) compared to 7 out of 15 patients with BMI≥ 50 (47% p=0.03). This is similar to the mortality for the entire series where 0.8% for patients with a BMI<50 died compared to 2.1% for patients with BMI≥50 (p=0.03). However, among those 15 patients classified as operative deaths for the entire series, 9 (60%) died after their second operative procedure.

Logistic regression demonstrated that CAD [LR 7.5 p< 0.01 (95% CI 2.2 to 25.3)], and SA [LR 3.3 p=0.03 (95% CI 1.1 to 10.1)], followed by age [LR 1.06 p=0.042 (95% CI 1.00 to 1.12)], were risk factors for death in all patients (Table 5). Although a small sample set, 12.7% of patients with CAD died (7/55) and 29% of patients with BMI>50 and CAD and SA died.

Although the average BMI of males was slightly greater than that of females (55.2 vs 51.2 kg/m^2, p<0.01), the two populations also differed in characteristics other than BMI. The male population had a significantly significant greater prevalence of DM, HTN, CAD, dyslipidemia, and SA. Females had a greater prevalence of pulmonary comorbidities, including asthma and dyspnea on exertion (Table 2).

When logistic regression was performed specific to the subsets of sex, males with angiographically demonstrated CAD were 30 times more likely to die [LR 30.1 p=0.028 (95% CI 1.4 to 631.4)]. Logistic regression did not identify CAD as a significant predictor when the analysis was limited to women. Predictors of death for women include

Table 5 Logistic Regression Evaluation of Patient Comorbidity as Predictors of Mortality

	p-Value	Relative Risk	95% Confidence Interval
Age	0.042	1.059	1.002–1.120
BMI	0.130	1.025	0.993–1.058
Female	0.612	0.729	0.215–2.474
DM	0.852	0.889	0.259–3.054
HTN	0.257	2.085	0.585–7.438
CAD	0.001	7.446	2.195–25.258
Dyslipidemia	0.099	0.359	0.106–1.211
Asthma	0.070	3.065	0.913–10.293
SA	0.033	3.342	1.104–10.115
SOB	0.693	0.644	0.073–5.725

age [LR 1.07 p=0.033 (95 % CI 1.0 to 1.14) and SA [LR 4.1 p=0.040 (95% CI 1.07 to 16.2)].

Logistic regression was repeated specific to race. When limited to Caucasian patients only, Caucasians with CAD were 58 times more likely to die [LR 58.8 p<0.01 (95% CI 4.8 to 716.9)] than those Caucasians without CAD. Increasing BMI was also significant among Caucasians. [LR 1.08 p=0.02 (95% CI 1.01 to 1.16)]. Evaluation of African–American patients demonstrated that only SA was significant [LR 19.1 p=0.03 (95% CI 1.29 to 282.8)]. Regression of the Hispanic population did not identify a specific factor. One-way ANOVA did not demonstrate any significant differences in prevalence of death or CAD between the three racial groups for the entire population or specific to sex.

Hispanic patients had significantly less SA than either the Caucasian or African–American patients (18.1 vs 25.6 and 27.4%, respectively (p=0.01)). When examined specifically in relation to sex, there were no differences among prevalence of SA in the males. African–American women, however, had the greatest prevalence of SA (26.4%) compared to Caucasian (18.9%) and Hispanic (15.7%) women (p<0.01).

Discussion

The tremendous growth of bariatric surgery over the past several years has spawned much interest in its complications and mortality, first in the media, but most recently in the public health arena as well. Health and malpractice insurance carriers as well as governmental agencies and professional societies are evaluating the risks of bariatric surgery and the surgeons that perform it. In several states, insurance companies have stopped covering bariatric surgery at the same time that the Centers for Medicare and Medicaid Services have approved coverage for them. Several malpractice carriers have stopped issuing policies for surgeons performing bariatric procedures while others are categorizing bariatric surgery as a high-risk subspecialty area, similar to obstetrics and neurosurgery, and increasing premiums accordingly. In each of these instances, the overriding fear or consideration appears to be that the risks associated with bariatric surgery are excessively high.

Much of the information being utilized in this regard has come form series utilizing pooled data from multiple smaller series or government databases.[1,5–9] Buchwald et al.[5] performed a metaanalysis of 16,944 patients which included 7,074 patients that underwent gastric bypass (open and laparoscopic) in 44 studies with a 30-day mortality rate of 0.5%. Several authors have reported that complication rates of bariatric surgery were inversely correlated with case loads, reporting mortality rates of in the range of 0.1–0.5% for surgeons more than 100 or 150 cases per year.[6–8] Flum et al.[9] recently reported 30- and 90-day mortality rates of 2.0 and 2.8%, respectively in Medicare beneficiaries having bariatric surgery, with men having higher rates than women and those over 65 years of age having higher rates than those younger than 65. Many of these series lack data concerning BMI and comorbidities, making risk assessment difficult or impossible. In one large series from a single-center, Christou et al.[10] reported a 30-day mortality of 0.4% in 1,035 patients undergoing RYGB, of whom 820 had open RYGB. No details about preexisting comorbidities or perioperative complications were given.

The results of these pooled series differ from those in several large series of open gastric bypasses[2,3,11]. Livingston et al.[2] reported an operative mortality of 1.3% in 1,067 patients after open RYGB. In his series, mean BMI was 53.6 kg/m^2, mean age 42.3 years, and the incidence of comorbidities was diabetes (23%), hypertension (48%), and sleep apnea (39%). Only male sex was predictive of severe life-threatening complications; mortality in patients over 55 years was significantly greater than in patients under 55 (3.5 vs 1.1%, p<0.05). More recently, Fernandez et al.[3] analyzed their patient cohort of 1,431 patients having open RYGB and found a 1.9% mortality, which was associated with age, weight, longer limb gastric bypass, and the occurrence of a leak or pulmonary embolism. In that series, the mean BMI was 53.3, mean age 40.7 years, and incidence of serious comorbidities was diabetes (19.5%), hypertension (51%), and sleep apnea (33%). In both of these series, the BMI was higher, the patients were older and the incidence of serious comorbidities, such as diabetes, hypertension, dyslipidemia, and sleep apnea, higher. Pories et al.[11] reported a 1.5% perioperative mortality rate, with 0.8% dying of sepsis, 0.5% dying of pulmonary embolism, and 0.2% of an unknown cause. Additional information regarding the incidence of leaks, bowel obstructions and other complications was not reported as these were not the focus of the original paper.

Similarly, in the present series, the 30-day mortality rate was 1.2% in 1,000 patients with a mean BMI of 52 kg/m^2. The prevalence of preoperative comorbidities was comparable to the larger series (diabetes—23%, hypertension—39%, dyslipidemia—46%, coronary artery disease/congestive heart failure—5.5%, sleep apnea—23.5%, and asthma—15%) and generally higher than in the pooled series. The incidence of leaks and postoperative small bowel obstruction in our series was comparable to the other series. The incidence of pulmonary embolism was less than those reported, perhaps related to the use of both pneumatic compression stockings and subcutaneous heparin and early ambulation with a shorter length of stay. Although the incidence of incisional hernia in our series was low (3.5%), this may well be affected by our suboptimal follow-up.

Multisystem organ failure accounted for 11 deaths in our series (73%). In six patients, this resulted from leaks or perforations; in one it followed a bowel obstruction, in two it followed postoperative hemorrhage and in two patients, the cause was never determined. In each of these instances, the complication was identified early and appropriate treatment and supportive care instituted. In four of the patients, the clinical course of SIRS and MSOF was characterized by extremely high temperatures (>105°F), with no apparent source ever identified. To our knowledge, this "syndrome" has not been reported, but may be due to the fact that the enormous adipose tissue stores in these patients may act as a "metabolic sink", releasing cytokines and other mediators and perpetuating this extreme systemic inflammatory response. Two of the deaths were due to fatal arrhythmias, both in patients with known CAD, who were extensively evaluated preoperatively. The death due to pulmonary embolism occurred after discharge, even though the patient received prophylaxis with both heparin and pneumatic compression stockings in the hospital. The remaining death due to exsanguination was clearly preventable.

Although males were significantly heavier and had higher BMIs than women, sex was not an independent predictor of morbidity. However, the presence of angiographically documented coronary artery disease was particularly ominous in men. Males with angiographically demonstrated CAD were 30 times more likely to die. In women, predictors of death included age and SA, but not CAD. With respect to race, Caucasian males with BMI>50 and CAD were most likely to die, whereas SA was a predictor in African–American men. There were no predictors in Hispanics. Despite the increased mortality in Caucasian males with CAD, these patients were not candidates for cardiac revascularization and extreme weight loss was the only intervention thought to make a beneficial health impact.

Based upon our data and those of others[2,3,11], it appears that the risk of open RYGB is in the range of 1–2%. Risk appears to be adversely affected by increasing BMI and those factors with which it is often associated namely male sex and coronary artery disease. How this compares with the perioperative mortality after laparoscopic RYGB is still unclear because many series of patients having laparoscopic RYGB do not include patients with the highest BMIs, above 60 or 70 kg/m^2, or patients having revisional surgery.

A perioperative mortality rate of 1.2% after RYGB compares favorably with that after other common surgical procedures. For example, perioperative mortality after elective surgery for abdominal aortic aneurysms has been reported at 3.1–4.7% overall, 1.0–2.7% in patients under 65 years of age, and 3.5–5.2% in patients over 65 years of age.[12] Using Medicare data adjusted for high volume surgeons, Birkmeyer et al.[13] reported perioperative mortality rates of 4.5% for colectomy, 8.6% for gastrectomy, 8.4% for esophagectomy, 3.8% for pancreatic resection, 4.0% for pulmonary lobectomy, and 10.7% for pneumonectomy. While it is true that all of these patients were over 65 years of age, the fact still remains that these perioperative mortality rates are all substantially greater than that after RYGB (even in Medicare recipients, as recently reported[9]) and neither the public, the press, the insurance industry, or various state Departments of Health are appalled or alarmed, or calling for a moratorium on those procedures. This is not meant to suggest that every effort should not be made to lessen the risks of bariatric surgery and to improve operative mortality, but rather to inject some proportionality into the discussion. The importance of such careful analysis of bariatric surgical data, including its limitations, and the need to continue to offer bariatric surgery to those patients for whom it constitutes the best available treatment has recently been emphasized.[14] In his 2004 PERSPECTIVE, Surgery for Severe Obesity, Steinbrook[15] quotes Robert Brolin, MD, cautioning physicians and the public "...to reconcile the fact that the operation has a real mortality and it will continue to have a real mortality under the best of circumstances. Some of these patients are just profound operative risks for any kind of surgical intervention...The sickest ones are the ones who benefit the most, but they are also the highest risk".

Conclusion

RYGB can be performed with acceptable perioperative morbidity in patients over a wide range of BMIs. Patients with BMI≥50 have a higher morality for both initial operations and after reexploration. Age, coronary artery disease, and obstructive sleep apnea correlate with perioperative mortality. These three comorbidities were more prevalent in these patients and may contribute to this finding.

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