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Original article

Laparoscopic Roux-en-Y gastric bypass for BMI <35 kg/m^2: a tailored approach

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Abstract

Background: Patients with a body mass index (BMI) <35 kg/m^2 who are obese, have uncontrolled co-morbidities, and have tried to lose weight with no success do not meet the "traditional" criteria for obesity surgery, and no other treatment is being offered to them.

Methods: A total of 37 obese patients (30 women and 7 men) had been undergoing clinical treatment with no resolution or improvement of their life-threatening co-morbidities. The mean BMI was 32.5 kg/m^2. Their age ranged from 28 to 45 years. All patients had type 2 diabetes mellitus, hypertension, and lipid disorder. Gastroesophageal reflux disease was present in 7 patients and sleep apnea in 3. These patients underwent the same preoperative evaluation as other patients for gastric bypass. The patients were required to have approval from their primary care physician. All patients provided written informed consent. Laparoscopic Roux-en-Y gastric bypass was performed. After extensive explanation and documentation, the Brazilian insurance companies approved the procedure in 3 cases, and international (non-American) insurance companies approved the procedure in 4 cases.

Results: The follow-up range was 6–48 months. The mean excess weight loss was 81%. Thirty-six patients had total remission of their co-morbidities. One patient still had mild hypertension, but with a reduction in the number of antihypertensive drugs used. No surgery-related complications occurred.

Conclusion: Obese patients with a BMI of <35 kg/m^2 and severe co-morbidities can benefit from laparoscopic Roux-en-Y gastric bypass. This treatment option should be offered to this group of patients.

Keywords: Bariatric surgery; Obesity; BMI <35 kg/m^2; Criteria for surgery

Obesity is defined as a body mass index (BMI) of >30 kg/m^2 [1]. Obesity is steadily rising in developed countries, such as the United States, and in developing ones, such as Brazil. It is estimated that >30% of Americans adults are obese [2].

A major concern for the bariatric patient is the increase in morbidity and mortality due to associated diseases, such as type 2 diabetes mellitus, hypertension, and lipid disorders. Patients with a BMI >30 kg/m^2 have a 70% increased risk of death compared with patients with a BMI between 22.5 and 24.9 kg/m^2 [3]. Obesity is responsible for the death of >300,000 persons annually [4].

Obesity treatments include diet, drug therapy, and surgical procedures. Diet, augmented by drug therapy and behavioral modification, has had poor long-term results [5]. Surgery has been the only method proved effective in maintaining long-term weight loss [6]. The 1991 National Institutes of Health Consensus set strict limits for bariatric surgery. Using these criteria, a BMI of ≥35 kg/m^2 with associated diseases is required for approval of operative treatment.

However, one group of patients has a BMI between 30 and 35 kg/m^2, are obese, have uncontrolled and life-threatening co-morbidities, and have tried to lose weight (lifestyle modification and pharmacotherapy) with no success. This

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group does not meet the traditional criteria for obesity surgery, and no other treatment is routinely offered to them.

We investigated the safety and efficacy of a "tailored surgical approach" for this group of patients.

Methods

We selected patients for our tailored surgical approach using the following criteria: BMI between 32 and 35 kg/m^2; presence of at least three co-morbidities; failure of medical treatments (lifestyle modification and pharmacotherapy); presence of central obesity; and approval by their primary care physician. The patients underwent the same preoperative evaluation as other patients for gastric bypass.

The primary care physicians were responsible for the diagnosis of type 2 diabetes mellitus, hypertension, lipid disorder, gastroesophageal reflux disease (GERD), and sleep apnea. Type 2 diabetes was diagnosed if the patient presented with two fasting serum glucose results ≥120 mg/dL. Hypertension was diagnosed if the systolic blood pressure was ≥140 mm Hg and/or the diastolic blood pressure was ≥90 mm Hg. Patients with lipid disorder presented with a total cholesterol level of ≥240 mg/dL, low-density lipoprotein (LDL) ≥130 mg/dL, high-density lipoprotein (HDL) ≤40 mg/dL (men) or ≤50 mg/dL (women), and/or triglycerides ≥170 mg/dL. The sleep polysomnography findings were used to determine the presence of sleep apnea. GERD was diagnosed according to clinical symptoms, endoscopic findings (grade III esophagitis), and a positive esophageal manometric/pH test.

The presence of central obesity was determined by the National Cholesterol Education Program criteria for waist circumference (>102 cm in men and >88 cm in women) [7].

People with a BMI between 32 and 35 kg/m^2 who did not meet all the other criteria did not undergo surgery and were not included in this study.

Three Brazilian and four international (non-American) insurance companies approved the surgical procedure after extensive paperwork. All patients provided written informed consent.

The patients underwent laparoscopic antecolic and antegastric Roux-en-Y gastric bypass with a 50-cm biliary limb and 150-cm alimentary limb. The 1.2-cm gastrojejunostomy was created with a linear stapler. Routine intraoperative endoscopy was performed to test the gastrojejunostomy. The same surgical team performed all operations.

The operative time, length of hospital stay, morbidity, mortality, postoperative weight loss, and resolution of co-morbidities were evaluated. The same surgeon who performed all the operations was responsible for all follow-up visits at 7, 30, and 90 days and 6, 12, 18, 24, 36, and 48 months postoperatively. We did not use telephone interviews or nurses to perform this task. Postoperative blood tests (fasting glucose, cholesterol, triglycerides, LDL, and HDL) were performed at 6, 12, 18, 36, and 48 months.

Statistical analysis comparing the preoperative and postoperative values was obtained.

Table 1
Total number of co-morbidities

Co-morbidity	Patients (n)
Hypertension	37
Diabetes type 2	37
Lipid disorder	37
Gastroesphogeal reflex disease	7
Sleep apnea	3

Table 2
Number of patients at each point of follow-up

Time Point (mo)	Patients (n)
6	37
12	33
18	27
36	20
48	9

Results

A total of 37 patients (30 women and 7 men) met the inclusion criteria. The average age was 34 years (range 28–45). The mean preoperative BMI was 32.5 ± 0.88 kg/m^2 (range 32–34.9). Table 1 lists the co-morbidities. The mean waist circumference for men was 104 cm (range 97–111) and for women was 90 cm (range 84–100).

Patients with type 2 diabetes mellitus used at least two oral antidiabetic drugs. None of them were using insulin. All patients with a lipid disorder were using statins. All patients with sleep apnea required continuous positive airway pressure when sleeping. Patients with GERD used proton pump inhibitors continuously. Hypertensive patients used a combination of diuretics, β-blockers, angiotensin-II receptor antagonists, calcium channel blockers, and/or angiotensin-converting enzyme inhibitors.

Laparoscopic access was possible in all cases. The mean operative time was 56 minutes. No intraoperative or postoperative complications occurred. The mean hospital stay was 30 ± 2.1 hours (range 20–33). No patient died.

The mean follow-up period was 20 ± 5.4 months (range 6–48). No patient was lost to follow-up (Table 2).

Of the 37 patients, 36 had total remission of their co-morbidities (diabetes, hypertension, lipid disorder, GERD, and sleep apnea). One patient with diabetes, hypertension, and lipid disorder had only mild hypertension postoperatively. This patient required a diuretic drug (hydrochlorothiazide), a beta-blocker (atenolol), and an angiotensin-converting enzyme inhibitor (enalapril) preoperatively. Eleven months after surgery, this patient only required the angiotensin-converting enzyme inhibitor. No diabetic patient required any oral antidiabetic

Table 3
Mean value and range of preoperative and postoperative blood tests

Test	Mean (mg/dL)		Range (mg/dL)	
	Preoperative	Postoperative	Preoperative	Postoperative
Fasting glucose	146*	88*	126–242	60–94
Cholesterol	252*	172*	248–322	161–190
Triglycerides	204*	156*	173–226	72–163
LDL	148*	115*	130–161	101–127
HDL				
Men	31	41	27–38	40–51
Women	36*	50*	28–47	49–58

LDL = low-density lipoprotein; HDL = high-density lipoprotein.
* $P < .01$.

drugs postoperatively, and all had normal fasting glucose results and a glycosylated hemoglobin level of <6%. Patients with lipid disorder presented with normal total cholesterol, HDL, LDL, and triglyceride values. Table 3 shows the mean and range of the preoperative and postoperative blood test results. The difference between the mean preoperative and postoperative results for fasting glucose, cholesterol, triglyceride, LDL, and HDL levels (in women) was statistically significant. The difference in the mean preoperative and postoperative HDL level in men did not achieve statistical significance. Patients with sleep apnea no longer used continuous positive airway pressure. No postoperative symptoms of GERD were reported. Table 4 shows the excess weight loss during follow-up.

Discussion

More than a decade has past since the National Institutes of Health criteria for bariatric surgery were established. Since then, the morbidity and mortality rates associated with the operative procedure have considerably decreased owing to the use of laparoscopy, the development of perioperative care, and a better understanding of obesity [8–11].

Laparoscopic Roux-en-Y gastric bypass in this selected group of patients was associated with no morbidity or mortality. The operative time and hospital stay were similar to those for patients with a greater BMI operated on at our institution [12]. The short-term excess weight loss was slightly better than that in our, and other, bariatric surgery series of patients with a BMI >35 kg/m^2 [12–15]. Fobi et al. [16] found similar results in a preliminary report. This extremely high resolution rate was also observed in a Lap-Band multicenter study of patients with a BMI of <35 kg/m^2 [17].

Manson et al. [18] showed that body weight and mortality from all causes were directly related for middle-age women to a BMI of >32 kg/m^2. Recent data [3] have revealed an increase in all-cause mortality in a stepwise fashion with the increase in BMI among men who never smoked. Moreover, patients with a BMI between 30 and 49 kg/m^2 had all-cause mortality and cardiovascular risk that were directly related to increases in BMI.

The major limitations of our analysis were the size of the population reported (only 37 patients) and that it was an observational study. Because we were confronting the "traditional" criteria for bariatric surgery (BMI >35 kg/m^2), we had to restrict the type of patient that would be treated because of medical, ethical, and even legal issues. It is important to highlight that most of our patients were referred to us by their primary care physicians because of the lack of treatment options recommended for this specific group. Therefore, to participate in this study, patients had to be mildly obese and to present with severe and uncontrollable obesity-related co-morbidities, which greatly limited the number of candidates. Additionally, randomized controlled studies are not always possible and not always appropriate for evaluating invasive procedures, such as bariatric surgery [19].

In conclusion, mortality is directly associated with BMI, and laparoscopic antecolic and antegastric Roux-en-Y gastric bypass is safe and effective for patients with a BMI <35 kg/m^2 and severe co-morbidities. This treatment option should be offered to this group of patients.

Table 4
Excess weight loss during follow-up

Follow-up (mo)	EWL (%)
6 (37)	44
12 (33)	71.6
18 (27)	78.4
36 (20)	77
48 (9)	81

EWL = excess weight loss.
Data in parentheses are number of patients in follow-up.
Source of ideal weight Metropolitan Life Foundation. Metropolitan Height and Weight Tables. Stat Bull 1983;64:2–9.

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Editorial comment

The authors present their experience with 37 obese patients (BMI 32-35), all of whom had metabolic syndrome and underwent gastric bypass. Patients are reported to have had no morbidity or mortality and as a group had resolution of diabetes and hyper-lipidemia. We are not given data on the percentage of patients with resolution of diabetes, hyperlipidemia, or hypertension. The authors conclude that gastric bypass is a safe and effective therapy in this group of patients. The authors are to be commended on their outcomes and for bringing an important issue to the fore.

This is not the first report of a case series detailing outcomes of nonmorbidly obese patients undergoing bariatric surgery, and it is not likely to be the last [1,2]. In this age of data-driven medicine, a case series such as this can act as a stimulus to further study but can do little to change the standard of care. We agree that surgical treatment for obesity in the nonmorbidly obese with comorbidities may be appropriate. Larger studies to compare various procedures to best medical therapy are necessary.

The authors remark that randomized trials are neither always feasible nor appropriate in surgery! In fact, this group of patients presents an excellent opportunity for an appropriate prospective, randomized trial. Given that surgery in this group of patients is outside current standards of care, insurance coverage is not available in many countries. As the authors mention, adjustable gastric banding has been shown to be effective in this group of patients. Despite the incredible results achieved by the authors with gastric bypass, there is likely to be greater morbidity/mortality from an operation that requires two gastrointestinal anastomoses compared to an operation that requires none. The relative risk to benefit may be different in nonmorbidly obese patients, and there is currently inadequate data available to make such a decision. In addition, there is a documented greater ability of the nonmorbidly obese to maintain weight loss: although recidivism is 85%, it is lower than the 97% seen in the morbidly obese. All this adds up to the equipoise necessary and the ethical and practical conditions required for an excellent study. Even if these studies are not prospectively randomized, which would be ideal, large numbers can yield the true morbidity/mortality and comorbidity resolution and the degree of benefit as compared to medical weight loss. The only barrier to such a study is funding, and this might be something of interest to industry, insurance companies, and perhaps the NIH.

As for now, given the current standard of care, operations for this group of patients should only take place in the context of an IRB-approved study.

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