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Original article

Natural history and metabolic consequences of morbid obesity for patients denied coverage for bariatric surgery

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Abstract

Background: Patients satisfying the National Institutes of Health criteria and deemed appropriate candidates often do not undergo bariatric surgery for insurance-related reasons. Our objective was to explore the natural history of these patients compared with that of those who underwent laparoscopic Roux-en-Y gastric bypass (LRYGB).

Methods: The medical records of the patients evaluated for LRYGB from 2001 to 2007 were retrospectively reviewed. The presence of co-morbidities was assessed at the initial evaluation and within a 3-year follow-up period for patients who had undergone LRYGB and those denied surgery. The statistical analysis included chi-square tests.

Results: A total of 189 patients were in the denied cohort and 587 in the LRYGB cohort. The age, gender, and body mass index were similar between the 2 cohorts at the initial evaluation. The percentage of patients with a diagnosis of a co-morbidity in the denied and LRYGB cohorts at the initial evaluation was 20% and 25% with diabetes mellitus, 51% and 43% with hypertension, 20% and 22% with obstructive sleep apnea, 34% and 24% with lipid disorders, and 62% and 49% with gastroesophageal reflux disease, respectively. The body mass index at the initial evaluation and during follow-up was 47.3 and 46.8 kg/m^2 in the denied cohort (n = 165, $P = .236$) and 48.5 and 30.5 kg/m^2 in the LRYGB cohort (n = 544, $P < .001$), respectively. During the follow-up period, a greater incidence of new-onset diabetes ($P < .001$), hypertension ($P < .001$), obstructive sleep apnea ($P < .001$), gastroesophageal reflux disease ($P < .001$), and lipid disorders ($P < .001$) was observed in the denied cohort.

Conclusion: Patients denied LRYGB had a greater incidence of new co-morbidities diagnosed within a short follow-up period, without a significant change in their body mass index. (Surg Obes Relat Dis 2010;6:591–596.)

Keywords: Laparoscopic gastric bypass; Insurance; Denial; Co-morbidities; Morbid obesity

The unprecedented increase in the number of overweight (body mass index [BMI] ≥25 kg/m^2) and obese (BMI ≥30 kg/m^2) persons has been estimated to encompass about 1.7 billion individuals [1]. The percentage of overweight adults is greatest in the United States, where approximately two thirds of the population are overweight and almost one half are obese [1]. The increase in the rate of obesity has been associated with an increased incidence of many obesity-related co-morbidities, including type 2 diabetes mellitus (T2DM), lipid disorders, cardiovascular disease, hypertension (HTN), obstructive sleep apnea (OSA), gastroesopha-

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geal reflux disease (GERD), arthritis and joint pain, depression, polycystic ovarian syndrome, menstrual irregularities, and urinary incontinence [2–5]. These obesity-related co-morbidities affect not only the quality of life, but also the life expectancy [6].

Surgical therapy is currently the only effective long-term treatment of obesity [2]. The National Institutes of Health have established guidelines for surgical therapy for morbid obesity that require potential patients to have a BMI of ≥40 kg/m^2 or a BMI of 35–40 kg/m^2 with significant obesity-related co-morbidities [2]. The introduction of minimally invasive techniques to bariatric surgery has had a drastic effect on the evolution of this field. Although many studies have previously demonstrated the safety, efficacy, and resolution of major co-morbidities after bariatric surgery [7], laparoscopy has played a major role in establishing widespread public acceptance. The use of bariatric surgery has increased markedly during the past several years, from <10,000 cases in 1996 to approximately 70,000 cases in 2002 and 170,000 cases in 2005 in the United States [8].

A study previously conducted at our institution found that a significant reason that potential patients did not undergo laparoscopic Roux-en-Y gastric bypass surgery (LRYGB) was insurance denial or unattainable insurance prerequisites [9].

The objective of the present study was to determine the natural clinical course and incidence of new-onset T2DM, HTN, OSA, GERD, and lipid disorders over time in patients denied LRYGB by their insurance company compared with that of patients who had undergone LRYGB. T2DM, HTN, OSA, GERD, and lipid disorders were selected as the study co-morbidities owing to their significant effect on survival and the well-documented evidence that bariatric surgery contributes to the improvement and/or resolution of these co-morbidities.

Methods

Gundersen Lutheran is an integrated healthcare system with a 325-bed community teaching hospital and a long-standing comprehensive electronic medical record system. After institutional review board approval, the electronic medical records of the patients who had undergone an initial evaluation for LRYGB from 2001 to 2007 were retrospectively reviewed. The patients were identified by querying the database of a previous study [9] completed at our institution and our institution's electronic medical record system and prospectively collected bariatric database. Patients denied LRYGB for an insurance-related reason who had either a follow-up visit at ≥1 year or a documented weight measurement at ≥6 months after the initial evaluation or a new diagnosis of T2DM, HTN, OSA, GERD, or lipid disorder were included in the denied cohort. The patients who had been approved by their insurance and subsequently underwent LRYGB and had had a visit with any healthcare provider >1 year postoperatively were included in the LRYGB cohort.

The presence of T2DM, HTN, OSA, GERD, and lipid disorders was assessed at the initial evaluation in the bariatric clinic and during the subsequent follow-up period for all patients. The analysis of follow-up data was adjusted according to the pre-existing conditions. Patients with a previous diagnosis of a study co-morbidity at the initial evaluation were excluded from the follow-up analysis for that co-morbidity because they would have been ineligible to acquire the same diagnosis again. As such, the overall number of patients included in the analysis of each co-morbidity was adjusted from the initial evaluation throughout the follow-up period. The follow-up period for patients in the LRYGB cohort included the interval between the initial evaluation and surgery and the postoperative follow-up period. The presence of co-morbidities was determined by the patients' healthcare providers, as documented in their electronic medical record. During the follow-up period, HTN was considered present for patients with a new diagnosis and/or a blood pressure measurement of ≥140/90 mm Hg, and new-onset OSA was verified from the polysomnography reports. The incidence of co-morbidities during follow-up was analyzed only for those patients who had not had the respective obesity-related co-morbidity at their initial evaluation.

All LRYGB patients had met the National Institutes of Health criteria for bariatric surgery. Our operative technique has previously been described in detail [10]. In brief, an approximately 20-cm^3 gastric pouch was created. A jejunojejunostomy was constructed in a stapled, side-to-side fashion, and the Roux limb was brought through the retrocolic, retrogastric tunnel. The biliopancreatic limb was approximately 30–40 cm, and the Roux limb was 50–75 cm. Gastrojejunostomy was performed using a linear stapled technique, and all 3 mesenteric defects were closed with permanent sutures.

Statistical analysis included chi-square tests to compare the incidence of new diagnoses during the follow-up period for patients without a previous diagnosis. Student t tests (paired and 2 sample) were used for the age and BMI comparisons. $P < .05$ was considered significant.

Results

A total of 587 patients were included in the LRYGB cohort and 189 in the denied cohort (Fig. 1). The initial age, gender, and BMI were similar between the 2 cohorts (Table 1). The presence of previously diagnosed T2DM and OSA was similar among the patients in the 2 cohorts at the initial evaluation; however, the percentages of GERD, lipid disorders, and HTN were greater in the denied cohort (Table 1). The median follow-up period was 36 months from the initial evaluation for the denied cohort. The follow-up for the LRYGB cohort consisted of the interval from the initial

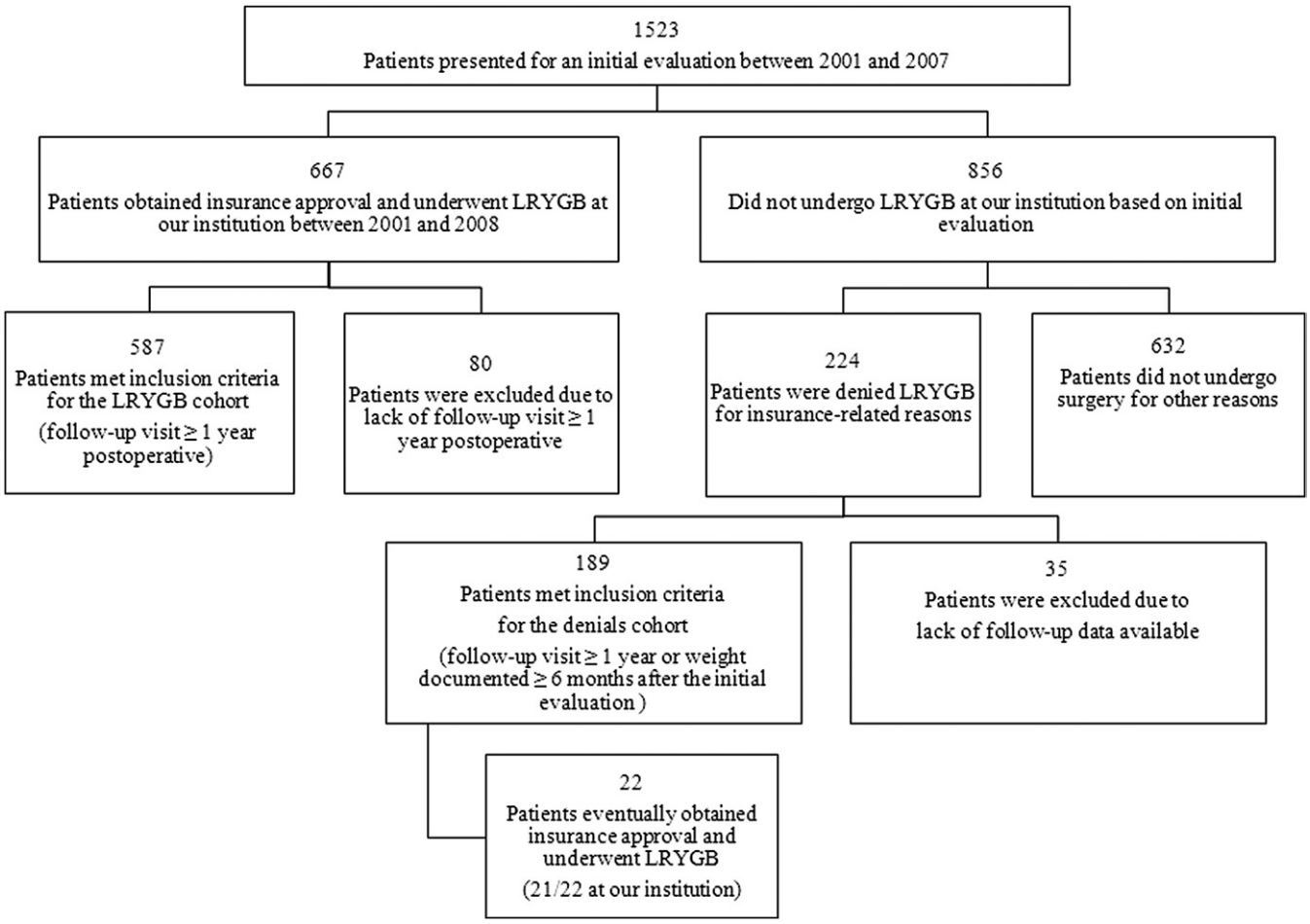

Fig. 1. Definition of study population.

evaluation to surgery (median 7 months) and the postoperative follow-up period (median 36 months). The initial BMI and 2-year follow-up BMI for the patients with complete data was 47.3 and 46.8 kg/m^2 in the denied cohort (n = 165, P = .236) and was 48.5 and 30.5 kg/m^2 in the LRYGB cohort (n = 544, P <.001), respectively. The mean %EWL was 72.2% in the LRYGB cohort. During the 3-year postoperative period, the incidence of new co-morbidities in the LRYGB cohort was .2% for T2DM, .9% for HTN, .4% for OSA, .7% for GERD, and .2% for lipid disorders. During the follow-up period, significant increases in the incidence of new-onset co-morbidities were observed for T2DM, HTN, OSA, GERD, and lipid disorders in the denied cohort compared with the LRYGB cohort for patients without a previous diagnosis (Fig. 2).

Of note, 22 patients had initially been denied LRYGB by their insurance but subsequently underwent surgery. These patients were included in the denied cohort until the date of surgery. Although the subsequent follow-up data were excluded, none of these patients developed a new diagnosis of any study co-morbidities after their surgery. Of these 22 patients, 15 (68%) had had a change in their insurance company before their approval and subsequent LRYGB, and 1 had had a change in insurance policy that resulted in coverage for LRYGB. The insurance data were unavailable for 6 patients.

Table 1
Demographic data and prevalence of comorbidities for the denials and LRYGB cohorts at the time of initial evaluation

Characteristic	Denied cohort (n = 189)	LRYGB cohort (n = 587)	P value
Demographic data			
Women	155 (82)	490 (83)	.640
Mean age (yr)	40.9 ± 8.9	42.1 ± 9.5	.118
Mean initial BMI (kg/m^2)	47.8 ± 8.6	48.4 ± 7.0	.430
Co-morbidities present at initial evaluation (n)			
T2DM	37 (20)	145 (25)	.175
OSA	37 (20)	131 (22)	.455
HTN	96 (51)	253 (43)	.048
GERD	117 (62)	288 (49)	.001
Lipid disorders	64 (34)	141 (24)	.006

LRYGB = laparoscopic Roux-en-Y gastric bypass; BMI = body mass index; T2DM = type 2 diabetes mellitus; OSA = obstructive sleep apnea; HTN = hypertension; GERD = gastroesophageal reflux disease.

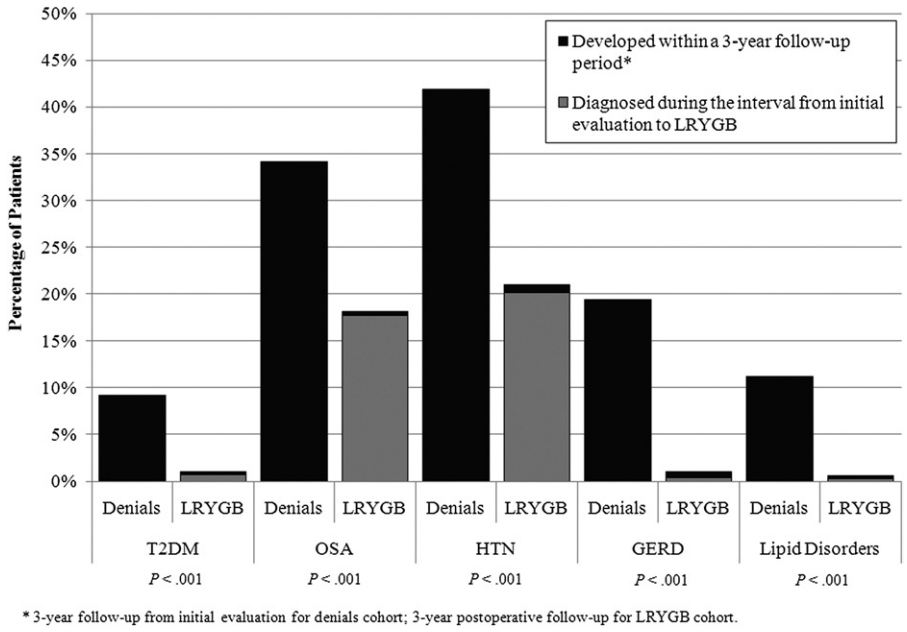

Fig. 2. Incidence of new-onset co-morbidities after initial evaluation among patients without previous diagnosis in denied and LRYGB cohorts.

Discussion

Bariatric surgery has been proved safe and effective beyond any reasonable criteria in the era of the "obesity epidemic" [4]. Several publications have previously compared the outcomes of morbidly obese patients who had undergone surgery with a comparable control group, showing the unquestionable positive effect on the resolution of co-morbidities, quality of life, and survival [7,11]. Our study also addresses the health consequences of morbid obesity, but we do so for a group of patients denied coverage for bariatric surgery by their insurance company. To our knowledge, no study has previously compared the incidence of new-onset co-morbidities in patients denied coverage for bariatric surgery with that of those who had undergone the procedure at the same institution.

The evaluation process for bariatric surgery has been shown to be an excellent screening environment for obesity-related co-morbidities, as shown by the high percentages of new diagnoses identified among the patients undergoing evaluation for surgery [12]. In our series, HTN was identified in 20% and OSA in 17% of patients who ultimately underwent LRYGB without a previous diagnosis during the interval from the initial evaluation to surgery. These data raise the question of the underdiagnosis of obesity-related co-morbidities by primary care physicians and emphasize the important role of the bariatric surgeon and a multidisciplinary team assessment. We elected to include the interval from the initial evaluation to surgery in addition to the postoperative follow-up period for the LRYGB cohort to identify any new diagnoses occurring from the surgical evaluation and referrals and to eliminate any potential screening bias, because patients in the denied cohort might have undergone similar preoperative screening and been referred for additional evaluation that resulted in the new diagnoses.

Two patients died in the denied cohort. Both occurred after the study period, at 5 and 7 years after the initial evaluation for LRYGB. Five patients died in the LRYGB cohort, at 8 months postoperatively, 21 months postoperatively, and 3, 4, and 6 years postoperatively. Data regarding the cause of death were unavailable. Because the primary clinical endpoints of the present study were obesity-related co-morbidities and not mortality, and because the number of overall mortalities was minimal, firm conclusions cannot be drawn from our data regarding the mortality rates for those undergoing LRYGB compared with those denied.

Bariatric surgery has been shown to substantially improve or resolve co-morbidities in obese patients, and many will no longer need their prescription medications after weight loss [13]. We elected to focus on 5 major obesity-related co-morbidities: T2DM, HTN, OSA, GERD, and lipid disorders. The weight loss achieved after gastric bypass and maintained for ≤8 years will reduce blood pressure, improve abnormal lipid levels, and reduce the risk of T2DM by approximately 75% [14]. A previous study from our institution clearly showed the positive effect of surgery on the hemoglobin A1c values of morbidly obese patients who underwent LRYGB [15]. Schauer et al. [16] reported the resolution of T2DM in 83% of their study group after LRYGB. Also, patients with the shortest duration and mildest form of T2DM experienced a greater rate of T2DM resolution after surgery, implying that early surgical intervention is crucial [16].

Hinojosa et al. [17] showed that LRYGB substantially improved or resolved HTN in most of their study group,

with improvement occurring as early as 1 month postoperatively and more frequently in patients with a shorter preoperative HTN duration [17].

Zlabek et al. [18] showed that LRYGB improved all lipid parameters in the study group and decreased the percentage of dyslipidemia, with fewer patients taking lipid-modifying medications postoperatively, suggesting a substantial medication cost savings with time. Recent reports by Adams et al. [19] and Sjostrom et al. [11] have conclusively documented the reduction in the rate of cancer deaths and overall mortality, as well as improvements in quality of life and the long-term resolution of co-morbidities (e.g., T2DM, heart disease) after bariatric surgery.

Several studies have assessed the relationship between obesity and OSA-hypopnea syndrome. Haines et al. [20] found that OSA is prevalent in at least 45% of bariatric surgery patients and that the preoperative BMI correlated with the severity of OSA. They concluded that weight loss surgery significantly improved the parameters of sleep quality [20].

GERD has been studied extensively in the morbidly obese population [5,21,22]. Although the pathophysiology of the disease in morbidly obese patients is not completely understood, the increasing incidence of GERD has paralleled that of obesity in recent years, and a possible cause–effect relationship has been the focus of several previous reports [21,22]. A high BMI increases the risk of GERD, and a dose–response relationship has been observed between an increasing BMI and the prevalence of GERD and its complications [5]. A systematic review of 15 epidemiologic studies showed that the prevalence of GERD in the Western world was 20% [21]. Nelson et al. [22] showed that RYGB might be the treatment of choice for GERD in obese patients. They reported a clear benefit, with significant improvement in the symptoms of GERD and decreased use of antireflux medications after surgery, independent of weight loss.

Despite the growing evidence showing the benefit, safety, and positive effect on quality of life and life expectancy, bariatric surgery has yet to be established as a core benefit in all health insurance plans. In our series, 94 insurance companies had insured the patients in the denied cohort. Some patients are still denied coverage for bariatric surgery by insurance companies for a variety of reasons [9,23]. The increase in the number of bariatric surgical procedures performed nationwide has been associated with an increase in the number of insurance denials. Many health insurers continue to deny coverage for bariatric surgery, in some or all cases, secondary to concerns about its expense and growing frequency [24]. When insurers deny coverage for bariatric surgery, it is usually because they apply criteria for medical necessity that are more demanding than those of the treating physician. They might rely on the interview findings, or they might decide that a particular patient's health condition puts the patient at a high risk of complications. Alternatively, they might create policies that have strict guidelines with minimal, if any, supporting medical data. For instance, many insurers require ≥6 months of mandatory prolonged preoperative dietary counseling, despite overwhelming evidence that this measure often fails, causing a high number of patients to withdraw, which in turn provides a short-term financial benefit for the insurance company [25]. Most patients presenting for consideration for bariatric surgery have already made multiple attempts at conventional weight loss. We have previously reported that no correlation has been found between the number of preoperative weight loss attempts and postoperative weight loss [26]. Accordingly, bariatric surgery accounts for many appeals of insurance coverage denials. One study of 2 large health plans in California found that 1 in 10 medical necessity appeals filed involved obesity treatment [27]. Tsuda et al. [23] reported that 47.8% of their screened cohort for bariatric surgery was denied secondary to insurance refusal. In our series, the patients included in the denied cohort included 26% of the patients evaluated for LRYGB who did not undergo surgery during the study period at our institution. Other reasons for not undergoing surgery included medical/surgical reasons, psychological reasons, unmet program requirements, unmet National Institutes of Health criteria, and patient decision.

The lack of acceptance and understanding of the significant economic advantages of bariatric surgery on healthcare expenditures has continued. Cremieux et al. [28] showed that the downstream savings associated with bariatric surgery have been estimated to offset the initial costs within 2–4 years. Before that, Finkelstein and Brown [29] in 2005 stated a return on investment within 5–10 years using a simulated model. Thus, bariatric surgery pays for itself; therefore, it is in the economic interest of third-party payors to consider bariatric surgery as a core benefit in their insurance coverage, just as the Centers of Medicare and Medicaid Services did for Medicare in its 2006 National Coverage Determination [4]. One report also concluded that more patients perform paid work than before after studying bariatric surgery outcomes and that the number of weekly hours they worked increased, with patients claiming fewer state benefits, demonstrating another economic benefit of bariatric surgery [30]. Although the effect on healthcare expenditure was not the focus of the present study, our integrated health system will allow for additional study of this in the future.

In our study, we were able to reproduce the same widely recognized benefits of gastric bypass surgery. Significant health benefits could have been achieved by early surgical intervention in a group of patients who were eligible candidates for surgery but were denied. Our data have clearly shown that if left untreated, morbid obesity results in the development of new co-morbidities within a short follow-up period compared with a very low incidence in the LRYGB cohort. Morbid obesity is a disease that requires early sur-

gical intervention for the prevention of long-term complications. As such, one would expect the number and frequency of the obesity-related co-morbidities to increase significantly during a longer follow-up period.

Conclusion

Patients who are appropriate candidates for bariatric surgery but ultimately denied coverage by their insurance company developed a high incidence of new obesity-related co-morbidities within a short follow-up period.

Disclosures

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