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The Relationship of BMI with Demographic and Clinical Characteristics in the Longitudinal Assessment of Bariatric Surgery (LABS)

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Abstract

Background—Body Mass Index (BMI) is often used to characterize patient risk in bariatric surgery. Its relationship with other risk factors has not been well characterized.

Objectives—To evaluate the relationship between BMI and demographic/clinical characteristics of patients undergoing bariatric surgery.

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Setting—10 clinical centers in the United States between March 1, 2005, and March 26, 2007.

Methods—The Longitudinal Assessment of Bariatric Surgery-1 (LABS-1) is a study of 30-day outcomes in patients undergoing bariatric procedures. The sample for this study includes participants with a BMI ≥40 kg/m^2 and no history of bariatric procedures. This analysis examined relationships between BMI strata and several demographic/clinical characteristics.

Results—Of 2559 patients (23% male, 10% Black/African-American, 9% age≥ 60 years) with a BMI ≥40 kg/m^2, 29% had a BMI of 50–<60 kg/m^2, and 12% had a BMI ≥60 kg/m^2. The percentage of males and Black/African-Americans increased with higher BMI category and the percentage of older patients (age≥ 60 years) decreased. Patients with higher BMI were more likely to have a history of several comorbid conditions (hypertension, diabetes, congestive heart failure, asthma, poor functional status, sleep apnea, pulmonary hypertension, venothromboembolism, or venous edema with ulcerations) than patients with a BMI of 40–<50 kg/m^2 after adjusting for age, race, sex and ethnicity.

Conclusion—Higher BMI was associated with several patient characteristics that have been linked to less weight loss, more adverse outcomes and increased healthcare utilization in prior studies. Outcomes analysis must consider the potential for confounding of BMI with demographic and clinical characteristics.

INTRODUCTION

Most of the data concerning outcomes of commonly performed bariatric surgical procedures come from small, single-center case series or limited datasets [1]. Determining which patients are likely to have favorable, or poor, outcomes after surgery is challenging because potential predictor and outcome variables are not always collected in a standard fashion, because success can be judged in different, and not always, comparable ways, and because factors related to outcomes are inter-related. Gathering accurate data that are associated with outcomes in bariatric surgery and performing appropriate analyses are essential to identify those at high-risk of adverse outcome and those most likely to benefit from surgery. In addition to the scientific benefits that accrue from such investigations, better outcome predictors will help to improve the informed consent process.

Important adverse outcomes in bariatric surgery, such as perioperative death and reoperations, occur infrequently and appear to be occurring less often over time [2]. Several factors may account for this trend including increased surgical experience, improved equipment, more procedures done in high volume centers [3], dedicated multidisciplinary bariatric teams, and patient selection. Determining which patients are at highest risk for these relatively infrequent events in a prospective study requires a standardized pre-surgical evaluation of patient characteristics and assessment of out-of-hospital outcomes in large cohorts. When factors associated with adverse outcomes (e.g., comorbidities) are also associated with other risk factors for those outcomes (e.g., body mass index [BMI]), an even larger cohort is required to have adequate statistical power to identify independent risk factors.

In the absence of large clinical cohorts, administrative and claims databases have been used to examine predictors of adverse outcomes. Many of these datasets include no clinical information beyond diagnostic and procedure coding and offer only the most basic descriptive information about the patient (sex, age and insurance status for example, but not weight, height, medications or severity of conditions). Furthermore, there is little standardization across hospital abstractors with respect to definitions of data submitted to administrative databases. Despite these limitations, administrative data have been used to identify several patient characteristics associated with increased risk of adverse outcome including older age [4], male sex [4] and Medicare/Medicaid status [4,5]. Smaller clinical series [6–8] and analysis of a Veterans

Administration hospital system registry [9] have confirmed these findings and demonstrated that patients with higher BMIs and more co-morbid conditions have increased perioperative risks.

Higher BMI seems to be an intuitive risk factor for adverse post-surgery outcomes, but it may be just a surrogate metric of risk, reflecting the risk of the variables associated with BMI. Recently, a stratification algorithm based on BMI>50, male sex, hypertension and risk of pulmonary embolus was proposed to identify those at highest risk for perioperative death [10]. With only 31 events occurring over a 10-year time period, the adequacy of this single-center's data to account for many of the inter-relationships among risk factors is problematic. Thus, the resulting stratification algorithm may not prove to predict accurately the risk of post-surgical mortality in the general bariatric population.

The purpose of this report is to evaluate the relationships between BMI and other potentially important risk factors for adverse outcome in patients undergoing bariatric surgery. Identifying the extent to which BMI is associated with other risk factors is expected to be important in accurately predicting outcomes for patients considering bariatric surgery. The hypothesis being tested was that the most commonly considered risk factor, higher BMI, was associated with other risk factors commonly related to less weight loss, adverse outcomes and increased healthcare utilization (e.g., male sex, older age, Black/African-American race, Hispanic ethnicity, and comorbid conditions).

METHODS

Participants

The Longitudinal Assessment of Bariatric Surgery (LABS) is a prospective, multi-center observational cohort study [11]. LABS contains multiple components; LABS-1 is a 30-day safety study in consecutive patients 18 years or older undergoing bariatric surgical procedures by LABS certified surgeons at: University of Pittsburgh Medical Center (Pennsylvania), Columbia-Presbyterian Hospital or Cornell University (New York), East Carolina Medical Center (North Carolina), the MeritCare Health Systems through the Neuropsychiatric Research Institute (North Dakota), Sacramento Bariatric (California), University of Washington Medical Center or Virginia Mason Medical Center (Washington), and Oregon Health and Sciences University or Legacy Good Samaritan Hospital (Oregon). The Data Coordinating Center is at the University of Pittsburgh, Graduate School of Public Health. The LABS-1 protocol and consent form were approved by the Institutional Review Board at each institution.

This analysis included 2,559 LABS-1 participants with a BMI of at least 40 kg/m^2 and no previous bariatric procedure, who underwent a bariatric surgical procedure between March 1, 2005-March 26, 2007. Patients with a BMI below 40 kg/m^2 were excluded from this analysis because many insurers require presence of one or more co-morbidities in these patients. In addition, patients who had had a previous bariatric procedure were excluded because they represented a more heterogeneous group of patients undergoing a wider variety of procedures.

Data definitions

The LABS-1 pre-operative evaluation was completed through in-person interviews, physical evaluation and chart review. Standardized protocols were used to measure weight and height within 30 days prior to surgery. Within 90 days prior to surgery LABS-certified data collectors assessed history of comorbidities (hypertension, diabetes mellitus, congestive heart failure, asthma, functional status as measured by ability to walk unassisted for 200 feet, deep vein thrombosis/pulmonary embolism (DVT/PE), sleep apnea, ischemic heart disease, pulmonary hypertension, and venous edema with ulcerations) and indications of severity (e.g. use of CPAP or BiPAP machine for sleep apnea) based on patient self-report and chart review. The data point venous edema with ulcerations was added to the LABS-1 pre-operative evaluation after study initiation and was therefore missing in the first 359 participants. Details of the LABS-1 pre-operative, operative and post-operative data collection forms and definitions include demographic, clinical, laboratory, anthropomorphic, and adverse outcome components are published [11]. Data were entered twice using a web-based data entry system developed, distributed and maintained by the Data Coordinating Center.

Data analysis

Age was grouped as less than 30, 30–<40, 40–<50, 50–<60, 60+ years. Demographic and clinical data were tabulated by BMI strata (40–<50 kg/m^2, 50–<60 kg/m^2 and ≥60 kg/m^2). The Mantel-Haenszel test for trend [12] was used to test for a relationship between BMI strata and each of several demographic and clinical characteristics. In addition, a series of logistic regression models were used to estimate the odds of having specific comorbid conditions for the higher BMI strata (BMI 50–<60 kg/m^2 and BMI ≥60 kg/m^2) compared to BMI 40–<50 kg/m^2 adjusting for age, sex, race and ethnicity.

RESULTS

Demographic and clinical characteristics of the total sample and by BMI stratum are presented in Table 1. The sample was 23% male, 10% Black/African-American, 7% Hispanic and 9% at least 60 years of age. Over half (58%) of the patients had a BMI between 40–<50 kg/m^2, 29% had a BMI between 50–<60 kg/m^2 and 12% had a BMI ≥60 kg/m^2. The proportion of males and of Blacks/African-Americans increased with each successive BMI category. However, there was not a significant trend in ethnicity (i.e. proportions Hispanic) by BMI group, and there was a significant inverse relationship between age and BMI, such that the proportion of older patients (age ≥60 years) was smaller in the higher BMI groups than in the lower BMI groups.

Overall, there was a substantial burden of comorbid conditions in the study group with 83% reporting a history of at least one comorbid condition. The most prevalent conditions were: hypertension (55%), obstructive sleep apnea (48%), diabetes mellitus (33%) and asthma (24%). The inability to walk 200 feet unassisted was reported by 8%, and the other conditions examined (congestive heart failure, ischemic heart disease, pulmonary hypertension, DVT/PE and venous edema with ulcerations) each occurred in less than 5% of the sample. Patients with a higher BMI were significantly more likely to have a history of hypertension, diabetes, congenital heart failure, asthma, endotracheal intubation for asthma, poor functional status, DVT/PE, sleep apnea, CPAP use for sleep apnea, oxygen use for sleep apnea, pulmonary hypertension, and venous edema, compared to patients with lower BMI (Table 1). In addition, patients with a higher BMI were more likely than those with lower BMI to have more co-morbid conditions. For example, 94% of those with a BMI ≥60 kg/m^2 had at least one co-morbid condition compared to 86% of those with a BMI between 50–<60 kg/m^2 and 78% with a BMI between 40–<50 kg/m^2) and the proportions of participants with 4 or more comorbid conditions increased from 9% to 14% to 25% for the three BMI categories, respectively.

In multivariable analyses, the adjusted odds of having a history of hypertension, congestive heart failure, asthma, poor functional status, sleep apnea, pulmonary hypertension, or venous edema were each significantly higher (ranging from 1.4 to 13.5 times greater) for participants in the 50–>60 kg/m^2 or ≥60 kg/m^2 BMI groups compared to participants with a BMI less than 50 kg/m^2 (Table 2). In other words, BMI was associated with these comorbidities independent of age, sex, race and ethnicity. In addition, the adjusted odds of having a history of diabetes and DVT/PE were significantly higher in patients whose BMI was ≥60 kg/m^2 compared to patients in the lowest BMI stratum. The adjusted odds of reporting a history of ischemic heart disease was not significantly higher in either BMI group.

With the exception of asthma, the adjusted odds of having a history of each comorbidity examined was significantly higher for older people (ranging from 1.5 to 3.1 times greater for each 10 year increase in age). The adjusted odds of having hypertension, diabetes mellitus, congestive heart failure, sleep apnea, ischemic heart disease, and venous edema were significantly higher for males compared to females (ranging from 1.3 to 3.1 times greater). However, the adjusted odds of reporting a history of asthma and poor functional status was significantly lower for males compared to females (odds rations of 0.5 and 0.6, respectively). Sex was not significantly related to history of DVT/PE or pulmonary hypertension. In addition, the odds of hypertension was significantly higher in Blacks/African-Americans compared to others (1.5 times greater), while the odds of diagnosed sleep apnea was significantly lower (0.7 times higher) in Blacks/African-Americans. No other comorbidities were significantly related to race in multivariable analyses.

DISCUSSION

Despite the importance of developing risk prediction strategies for bariatric surgery, the available data on risk have been limited and the considerable inter-relationships of the group of candidate predictive variables have not been well described. This analysis of 2559 patients within the LABS cohort identifies associations between BMI and several factors previously reported to be associated with surgical outcomes. This study confirms that the burden of comorbid conditions for patients undergoing bariatric surgery is considerable. Unlike studies that use administrative data and identify a relatively small number of comorbid conditions in patients having bariatric surgery [13–15], this study, which used rigorous research methods and clearly defined data points assessed via self-report and patient charts, found that 83% of patients had at least one comorbid condition and over half had two or more comorbid conditions.

For nearly all of the comorbid conditions examined, the odds of having that condition increased with increasing BMI stratum compared to the lowest BMI stratum after controlling for other putative risk factors for comorbidity (sex, age, race, and ethnicity). In several reported case series, including more limited assessments of health conditions and medication use, higher BMI has been linked to worse outcome [6,8,9]. While higher BMI may confer some risk of adverse outcome simply because of technical difficulties related to operative technique and recovery, higher BMI may also exert its effect on patient risk through conditions associated with higher BMI (i.e. hypertension, diabetes mellitus, congestive heart failure, asthma, poor functional status, DVT/PE, sleep apnea, pulmonary hypertension, and venous edema). Due to relatively small sample size, infrequency of events and limits of claims-based datasets, prior studies evaluating BMI and risk have been unable to sort out which factors linked to higher BMI account for this finding, and it is therefore possible that BMI is serving as a surrogate metric of risk. Controlling for potentially confounding variables is important in assessing risk of adverse outcomes considering the higher prevalence of comorbid conditions in this population.

Several studies have suggested that male patients [4,13,15,16] have more adverse outcomes, increased healthcare utilization, and less weight loss than female patients following bariatric surgery. In addition, a few studies have found that Black/African-American patients lose less weight compared to others [17–19]. However, these studies have not adequately controlled for the relationship between race and sex and other factors such as BMI. In contrast, a retrospective case series found the relationship between male sex and morbidity persisted even after adjusting for patient weight, suggesting that factors other than weight links males and poor outcome [20]. A recent study also identified male sex as a risk factor for major complications, even after controlling for patient age, type of surgery, history of diabetes, BMI, and surgeon experience [21]. In the present analysis we found that the proportions of males and of Black/African-American patients were higher as BMI category increased. It is possible that there are differences in the timing of the decision to undergo on operation by both sex and race (i.e. males and of Black/African-American wait until they are more obese before considering bariatric surgery). However, in this analysis we could not tease out the factors, such as socioeconomic status and access to healthcare versus disease burden, that affect this decision process. We did find the odds of having several co-morbidities (i.e. hypertension, diabetes mellitus, congestive heart failure, sleep apnea, ischemic heart disease, and venous edema) was significantly higher for males compared to females, even after adjusting for BMI, which may reflect true differences in disease burden between the sexes and/or differences in the timing of the decision to undergo an operation. Since LABS1 relies on self-report of health conditions and receipt of healthcare interventions (such as polysomnography and CPAP machines) the findings of less obstructive sleep apnea in Black/African-American patients may also relate to access to care/diagnosis issues rather than a lack of pathology. No matter the reason for these differences, incorporating race and sex into risk stratification models requires that BMI and co-morbidities also be considered.

Interestingly, although older age has been associated with an increased likelihood of adverse outcomes in many studies [4,15,22,23], in this study the highest BMI strata included the smallest proportion of older patients. Patient selection may contribute to this finding such that surgeons who believe older patients and heavier patients are at greatest risk may be less likely to select patients who are both the heaviest (BMI ≥60 kg/m^2) and oldest (≥60 years) to minimize risk of poor outcome. Additional explanations are that the heaviest patients may not wait as many years to undergo surgery, patients may lose weight in later years, and the heaviest patients may not live to be as old. While outcomes analysis is still needed to fully understand risk, our data suggest that older age may not exert its effect on risk through the mechanism of increased BMI.

In conclusion, this analysis reveals associations between BMI and factors commonly considered to be important in risk assessment including sex, race, age and comorbid conditions. Ongoing and future LABS consortium studies will attempt to determine the relative contributions of these factors on the risks and benefits of bariatric surgical procedures.

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Table 1

Demographic and clinical characteristics by BMI (kg/m^2) group

	BMI (kg/m^2) Group				
	Total	**40 to < 50**	**50 to < 60**	**60+**	
Demographics	(N=2559)	(N=1490)	(N=751)	(N=318)	**p value***
Patient age, %					
<30	11.7	11.4	13.2	9.7	.0254
30–39	26.0	25.8	24.2	31.1	
40–49	29.8	28.5	31.6	31.4	
50–59	24.0	24.4	23.3	23.3	
60+	8.6	9.9	7.7	4.4	
Sex, %					
Male	22.7	20.3	25.3	28.0	.0004
Race, %					
Black/African American # missing	9.7 39	7.9 26	11.1 9	15.3 4	<.0001
Ethnicity, %					
Hispanic	7.2	7.7	5.9	7.9	.5340
History of Comorbid Conditions					
Hypertension, %	54.6	51.7	58.3	58.8	.0018
Diabetes mellitus, %	33.3	31.0	34.2	41.8	.0003
Congestive heart failure, %	2.6	1.4	3.6	5.7	<.0001
Asthma, %	24.0	21.2	26.0	32.7	<.0001
History of intubation, %	7.2	5.9	6.2	12.8	.0447
Functional Status, %					
Able to walk 200 ft unassisted	92.5	96.3	91.3	77.0	<.0001
Assistance need to walk 200 ft.**	5.4	3.1	6.9	12.3	

	BMI (kg/m²) Group				
	Total	**40 to < 50**	**50 to < 60**	**60+**	
Unable to walk 200 ft.**	2.2	0.6	1.7	10.7	
# missing	1	1	0	0	
History of Comorbid Conditions	(N=2559)	(N=1490)	(N=751)	(N=318)	
DVT/PE, %	4.1	3.0	4.4	8.5	<.0001
Sleep apnea, %	48.3	41.5	53.7	67.6	<.0001
Use of CPAP/BiPAP, %	80.3	76.2	83.5	86.0	.0002
Supplemental oxygen dependent, %	3.9	2.2	4.2	7.7	.0007
Ischemic heart disease, %	4.2	4.0	4.3	5.0	.4461
Pulmonary hypertension, %	1.6	0.7	2.0	4.4	<.0001
Venous edema with ulcerations, %	4.6	1.8	6.3	14.1	<.0001
# missing	359	198	112	49	
Number of comorbid conditions, %					
None	17.4	21.8	13.6	6.3	<.0001
1	27.9	30.2	26.0	22.0	
2	26.5	25.4	29.6	24.2	
3	16.0	14.1	17.0	22.3	
4 or more	12.2	8.6	13.8	25.2	

* Mantel-Haenszel test for trend

** These categories combined was considered to be a comorbidity

Table 2

Unadjusted and adjusted odds ratios (OR)s and 95% confidence intervals (CI)s of having specific comorbid conditions for the higher BMI stratums (BMI 50–<60 kg/m^2 and BMI 60+ kg/m^2) compared to BMI 40–<50 kg/m^2.

Co-morbidity	BMI group	Unadjusted OR (95% CI)	*Adjusted OR (95% CI)
Hypertension	50–<60 kg/m^2	1.31 (1.09, 1.56)	1.37 (1.13, 1.66)
	60 + kg/m^2	1.33 (1.04, 1.70)	1.42 (1.09, 1.85)
Diabetes Mellitus	50–<60 kg/m^2	1.16 (.96, 1.40)	1.20 (.98, 1.45)
	60 + kg/m^2	1.60 (1.25, 2.05)	1.73 (1.34, 2.24)
Congestive Heart Failure	50–<60 kg/m^2	2.61 (1.47, 4.65)	2.79 (1.55, 5.01)
	60 + kg/m^2	4.20 (2.21, 7.97)	4.96 (2.56, 9.62)
Asthma	50–<60 kg/m^2	1.30 (1.06, 1.60)	1.36 (1.11, 1.68)
	60 + kg/m^2	1.81 (1.39, 2.36)	1.92 (1.46, 2.51)
Poor Functional Status**	50–<60 kg/m^2	2.47 (1.71, 3.58)	3.03 (2.05, 4.47)
	60 + kg/m^2	7.77 (5.34, 11.31)	13.49 (8.83, 20.61)
DVT/PE***	50–<60 kg/m^2	1.48 (.93, 2.33)	1.55 (.98, 2.47)
	60 + kg/m^2	2.98 (1.82, 4.88)	3.34 (2.02, 5.53)
Sleep Apnea	50–<60 kg/m^2	1.63 (1.37, 1.94)	1.69 (1.41, 2.03)
	60 + kg/m^2	2.94 (2.27, 3.80)	3.24 (2.48, 4.23)
Ischemic Heart Disease	50–<60 kg/m^2	1.06 (.68, 1.64)	1.15 (.73, 1.82)
	60 + kg/m^2	1.26 (.72, 2.22)	1.62 (.89, 2.95)
Pulmonary Hypertension	50–<60 kg/m^2	2.74 (1.25, 6.00)	2.80 (1.27, 6.15)
	60 + kg/m^2	6.19 (2.79, 3.77)	6.78 (3.01, 15.28)
Venous Edema	50–<60 kg/m^2	3.68 (2.19, 6.21)	3.69 (2.18, 6.24)
	60 + kg/m^2	9.08 (5.31, 15.52)	9.49 (5.51, 16.36)

*Adjusted for age, sex, race, and ethnicity

**Inability to walk at least 200 ft. unassisted

**Deep Vein Thrombosis or Pulmonary Embolism