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Impaired Weight Loss in Laparoscopic Adjustable Gastric Banding Patients Over 50 Years of Age: Diabetes Mellitus as an Independent Risk Factor

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Abstract

Introduction—Laparoscopic Adjustable Gastric Banding (LAGB) represents a safe and effective bariatric procedure, particularly for patients over 50. Preoperative risk factors for impaired post-LAGB excess weight loss are not well characterized for this population. This study aimed to identify demographics, characteristics or comorbidities associated with excess weight loss at 6 and 12 months postoperatively (EWL180 and EWL365, respectively) for these patients.

Methods—117 LAGB patients > 50 years of age from 2005-2014 were retrospectively reviewed for factors potentially associated with EWL180 and EWL365. Rationally selected variables chosen for analysis included age, race, gender, initial body-mass index and preoperative weight loss; comorbidities assessed included hypertension, psychiatric disorders and diabetes mellitus (DM). Variables correlated with EWL180 or EWL365 on bivariate linear regression analysis ($P < .05$) were input into multivariate linear regression analysis to confirm independent association.

Results—Preoperative DM ($B = -9.1\%$ EWL; 95% CI -13.6% , -4.5% ; $P < .001$) and African-American race ($B = -8.8\%$ EWL; 95% CI -17.3% , -0.3% ; $P = .05$) were independent risk factors for impaired EWL180. Only DM was a risk factor for impaired EWL365 ($B = -9.7\%$ EWL; 95% CI -17.7% , -1.8% ; $P = .02$).

Conclusions—LAGB is a successful operation in patients > 50 years of age. Preoperative DM is an independent risk factor for impaired EWL in this cohort.

Keywords

bariatric; obesity; laparoscopy; gastric banding

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Introduction

The incidence of morbid obesity is rising in the United States, and patients are increasingly turning to surgical means of weight loss. After deciding on surgical intervention, the bariatric surgeon and patient are tasked with deciding which operation to perform. While laparoscopic sleeve gastrectomy (LSG) is rapidly gaining popularity[1], two of the most common procedures are the laparoscopic Roux-en-Y gastric bypass (LRYGB) and laparoscopic adjustable gastric banding (LAGB). Both have demonstrated efficacy not only in reducing excess body weight, but also alleviating comorbidities such as hypertension (HTN), obstructive sleep apnea, hyperlipidemia and diabetes mellitus (DM). Despite the fact that LRYGB leads to superior weight loss of LAGB in the first three years, patients often elect LAGB or LSG for a variety of reasons [2, 3]. Unlike LSG and LRYGB, LAGB is adjustable and reversible, not associated with nutritional deficiencies, generally performed in under an hour, and does not leave staple lines. Compared to LSG, long-term outcomes for LAGB are well known, while the surgeon learning curve and severity of complications are also lower [4]; therefore, it represents an attractive option for older patients with serious comorbidities.

Patients over 60 years old now comprise 10% of those undergoing bariatric surgery in US academic centers, albeit with higher morbidity and in-hospital mortality than the non-elderly [5]. Some centers are reluctant to perform LRYGB on patients older than 65. As such, the availability of a less-invasive, outpatient surgical option such as LAGB is critical [6]. In experienced hands, LAGB has been well tolerated in patients over 70 years old, and has led to moderate resolution of comorbidities as well, with few complications [6]. Non-elderly older patients (age over 50) are an increasingly larger proportion of operative candidates, but there are few studies that specifically examine this demographic.

Greater initial postoperative weight loss has been associated with more successful long-term outcomes. Variation in post-surgical weight loss depends primarily on preoperative patient variables, but also on technical aspects of the operation, intraoperative and postoperative concerns, and socioeconomic factors. Multiple patient variables have been associated with excess weight loss (EWL) after LRYGB: sex, race, age, preoperative BMI (BMI_0), preoperative weight loss and diagnoses of HTN, DM, and psychiatric disorders. Many of these factors have been shown to also impact EWL for LAGB; however, validation has been lacking [7-9]. Compared to LRYGB outcomes, there is a dearth of data investigating preoperative patient factors that may portend worse outcomes for LAGB, especially for older patients for whom this procedure may be more desirable. We hypothesized that patients above the age of 50 have a higher incidence of comorbid conditions that inhibit postoperative weight loss after LAGB. We examined the influence of selected preoperative variables in this cohort to determine independent preoperative predictors of EWL at six and twelve months after LAGB.

Methods

The fully de-identified Vanderbilt University Synthetic Derivative database was used to perform this retrospective study [10]. As no identifying information was available, informed consent was waived by the Vanderbilt University Institutional Review Board. All patients between 2005-2014 who underwent LAGB at age 50 or greater were identified by CPT code query (43770), with exclusion of those patients who required operative removal, replacement or adjustment procedures or conversion to open bypass due to complications, within the first year postoperatively (CPT codes 43644, 43771-43774). Patients were further excluded if they did not have record of an immediately preoperative weight, follow-up weight or BMI value at either 180 or 365 days postoperatively, or a height measurement for calculation of ideal body weight. The remaining patients underwent directed chart review for preoperative factors proposed to influence EWL after LAGB. All patient data was managed using the Research Electronic Data Capture (RedCAP) program hosted at Vanderbilt University [11].

LAGB procedures were done using the pars flaccida technique [12]. Adjustable banding system used was not considered; this has consistently shown no effect on postoperative EWL [13, 14]. Per institutional protocol, standard postoperative care consisted of a clinic visit at one-week, followed by assessments at every four to six weeks for the first postoperative year to make minor adjustments to band tightness via accession of the port.

Demographics including age, gender and race were recorded. Initial height, preoperative BMI (BMI_0), and the temporally closest BMI recorded between 3-24 months preoperatively were noted as well, to determine whether weight was lost in anticipation for surgery. All patients met established guidelines for bariatric surgical candidacy [15]. Select preoperative comorbidities were documented, using corresponding ICD-9 codes followed by manual chart verification as criteria for attribution. These comorbidities included hypertension (ICD-9 codes 401-405), depression (311), anxiety (300) and diabetes mellitus (250). No distinction was made between insulin- and non-insulin- dependent DM. The primary endpoints were EWL at 180 ± 30 days and 365 ± 45 days postoperatively (EWL180 and EWL365, respectively). EWL was defined as $100\% * (pre\ surgery\ weight - post\ surgery\ weight) / (pre\ surgery\ weight - ideal\ body\ weight)$, where ideal body weight (IBW) was estimated by the Lorentz formula, $IBW\ (kg) = height\ (cm) - 100 - (0.25\ for\ females, 0.5\ for\ males) * (height - 150)$ [16].

To determine those factors associated with EWL180 and EWL365, bivariate linear regression analysis was performed. Factors for which $P \leq 0.05$ were input into a multivariate linear regression model to confirm independent association. Continuous data was expressed as mean $\pm$ standard deviation, and categorical data was expressed as a percentage. Statistical analysis was performed with IBM SPSS Statistical Data Editor 21 (IBM, Somers, NY) and GraphPad Prism (La Jolla, CA). Graphical illustration was performed with the Vanderbilt Dot Plot Maker (Tatsuki Koyama and Will Gray, Nashville, TN. Available: <http://data.vanderbilt.edu/~graywh/dotplot/>). $P \leq .05$ was the criterion used for statistical significance.

Results

141 patients met initial eligibility criteria, but 24 were either lost to follow-up or had incomplete data in their medical charts. The remaining 117 patients were ultimately included. Institutionally, LAGB procedures have declined since 2008 (Figure 1), ostensibly due to the emergence of LSG, although it remains common both nationally and worldwide. Upon linear regression analysis, there were no significant trends in EWL180 and EWL365 ($B = -0.07\%$ per year, $P = .94$, and $B = 0.05\%$ per year, $P = .97$, respectively) over the ten year period.

Preoperative variables deemed most likely to contribute to EWL were examined for these patients. Mean age at surgery was 59.3 ± 5.7 years, and BMI_0 was 43.6 ± 6.2 kg/m². The mean EWL180 and EWL365 were $27.2\% \pm 12.6\%$ and $30.2\% \pm 19.2\%$, respectively. The majority of patients were female (77.8%), and the overall prevalence of comorbidities including HTN (89.7%) and DM (47.0%) was high. Demographics and patient characteristics are fully summarized in Table 1.

A bivariate association of each preoperative variable and EWL was performed (Table 2). Reduced EWL180 was associated with African-American race ($B = -11.6\%$, $P = .01$) and DM ($B = -9.9\%$, $P < .001$). Only DM was associated with a reduced EWL365 ($B = -9.7\%$, $P = .02$). On multivariate analysis of EWL180, African-American race ($B = -8.8\%$ EWL; 95% CI $-17.3, -0.3$; $P = .04$) and DM ($B = -9.1\%$ EWL; $-13.6, -4.5$; $P < .001$) were independently associated with impaired EWL180 (Table 3). DM was the greatest risk factor for impaired EWL in the cohort, contributing to an adjusted decrement of 8.8% EWL180 and 9.1% EWL365. Stratified by DM status, EWL180 and EWL365 are illustrated in dot-plot format in Figure 2A and Figure 2B, respectively.

Discussion

We report the novel finding of DM status as an independent risk factor for decreased postoperative weight loss in older patients who underwent LAGB. DM was associated with an 8.8% and 9.1% decrease in EWL at six and twelve months, respectively. DM has been validated as a risk factor for decreased postoperative weight loss after LRYGB, particularly in patients with initial glycated hemoglobin (HbA1c) values greater than 9% [17]. Our data suggests that this effect translates to LAGB, particularly in older bariatric patients for whom DM is a more prevalent comorbidity.

Patient age in this study (mean 59.3 years) was considerably higher than in other large LAGB-only series (38-42 years) [18, 19], as we elected to exclusively examine the > 50-year age group. We chose age 50 because these patients define a booming proportion of today's patient population and have a well-documented greater burden of comorbidities than their younger counterparts, a trend exacerbated in the obese. Additionally, patients of advanced age may lose less weight postoperatively, yet see a similar benefit in reduction of comorbidities [20, 21]. As such, bariatric surgery is quickly emerging as an excellent weight loss option for older patients, with LAGB recognized as the simplest and least morbid of the options.

Obesity is highly associated with development of Type 2 DM, as a BMI > 35 kg/m² confers a 40-90 times greater relative risk of DM compared to a BMI < 23 kg/m² [22, 23]. Weight loss is the single most important tenet of Type 2 DM management, and surgical weight loss is more effective than medical therapies at inducing long-term remission and mitigating DM-associated morbidity and mortality [24]. After bariatric surgery, the most rapid decline in DM severity occurs within the first six months, coinciding with the period of greatest weight loss [25]. Mechanisms of glucose intolerance and insulin resistance depend on a complex coordination of nutrient signals, energy metabolism, and gastrointestinal hormones [26, 27]. Further insight into how insulin resistance in turn affects these processes may provide a physiological explanation as to why DM is associated with decreased postoperative EWL.

Obesity-related insulin resistance and Type 2 DM are more likely to develop in African-American rather than white adult patients [28]. We thus evaluated African-American race as a risk factor for poor EWL and found it to be an independent predictor of impaired EWL180 but not EWL360. We did not see this impairment beyond six months, but had an admittedly low proportion of African-American patients. In contrast, Parikh *et al.* showed in 2006 that control-matched African-Americans had impaired EWL after LAGB at one, two and three years postoperatively [8].

HTN is also a common comorbid condition and has been previously associated with lower post-LAGB weight loss [9]. Psychiatric and personality disorders are associated with poor eating behaviors, and have been routinely associated with impaired postoperative weight loss in LAGB cohorts [29, 30]. Interestingly, neither psychiatric conditions nor HTN were associated with EWL after LAGB in our study.

The mean BMI₀ in our cohort (43.6 ± 6.2 kg/m²) was lower compared to other reports of LAGB in the aged population (46-48 kg/m²) [18, 19]. Higher preoperative BMI₀ has been among the most consistently validated factors associated with impaired postoperative weight loss for all bariatric operations [7, 17, 31]. The largest of these studies was an analysis of 1,791 consecutive LAGB patients by Favretti *et al.* in 2007, which demonstrated that patients classified as super-obese (BMI > 50) had significantly less EWL than those who were morbidly-obese (BMI > 40) at 1, 2, 3, 4 and 6 years postoperatively [18]. To this effect, the need to control for BMI₀ was anticipated; however, in our study preoperative BMI only trended with EWL180 ($P = .06$) and did not demonstrate an association with EWL365 ($P = .87$).

Weight loss outcomes from our institutional cohort were slightly inferior to those reported in existing literature. EWL180 in our cohort was 27.2% ± 12.6%, compared to an estimated EWL180 of 30% reported in a recent meta-analysis of bariatric outcomes of older patients by Lynch and colleagues [32], while EWL365 was 30.2% ± 19.2%, on the lower end of the reported EWL365 range of 28-40% [18, 19, 32]. A higher burden of preoperative comorbidities and limited sample size may contribute to these findings, as our patient population had a significantly higher rate of DM (47%) and HTN (89.7%) than in the cohort of Favretti and colleagues (11.2% and 32.2%, respectively [18]) and the general bariatric population (15.3% and 35.4%, respectively [33]). However, these findings are more likely

due to our use of the Lorentz formula, a common and validated algorithm[16] that generates a smaller IBW than the 1983 Metropolitan height and weight tables more frequently cited in existing analyses [18, 19, 32, 34].

This study had several limitations. Though Vanderbilt University is a major bariatric referral center, the demographics of our cohort represent a regional profile including only 7% African-Americans, potentially limiting external validity. To this effect, the finding of African-American race as a risk factor for impaired EWL180 must be considered in the context of a small cohort. This study was also limited by its retrospective nature and inclusion of patients from a single institution. There may have been selection bias from excluding patients lost to follow-up and from the decline of LAGB operations in recent years due to the emergence of LSG. Patients who chose LAGB over LSG indicated a desire for a non-permanent intervention and required an added commitment to success. Thus, these more recent patients may have “self-selected” in a manner distinct from earlier LAGB patients, who may not have had LSG as an option. Additionally, we did not examine other factors that could have contributed to impaired EWL, such as socioeconomic, intraoperative, postoperative concerns such as the impact of routine outpatient band adjustments. Finally, our study only measured weight loss at six and 12 months, while weight loss after LAGB continues well beyond one year, and is subject to plateau and regain [3]. Future, prospective studies are needed to investigate the influence of DM severity and perioperative glycemic control on EWL, as well as the effect of DM on longer term EWL (>1 year) and long-term weight re-gain in older vs. younger patients.

With rates of obesity increasing within a rapidly aging population, bariatric surgery is a valuable tool to reduce BMI and associated comorbidities. While LRYGB may represent the gold standard, older patients selected for LAGB often were those with a severe comorbidity such as congestive heart failure, obstructive pulmonary disease or end stage renal disease necessitating the least stressful procedure. Alternatively, a sub-cohort of LAGB patients requested the procedure, with the success of LAGB in an acquaintance or desire for a temporary intervention often cited as reasons. Particularly since it became an option for Medicare patients in 2012, LSG has been progressively replacing LAGB as the less strenuous alternative to LRYGB in older patients [35]. Nonetheless, LAGB remains a safe and effective surgical weight loss modality important to the armamentarium of treatment options for the bariatric surgeon. It is important to recognize clinical predictors of success or failure so that the surgeon and patient hold realistic expectations of postoperative outcomes. Because patients > 50 years of age have a higher rate of comorbidities and less robust response to bariatric surgery, more aggressive preoperative control of DM may optimize postoperative weight loss after LAGB and identify those patients who would benefit from more rigorous long-term care and follow-up.

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Figure 1.
Institutional distribution of LAGB patients by year

Figure 2.

EWL vs. DM status.

A- EWL180; $n = 103$, $*P < .001$; **B-** EWL365; $n = 88$, $*P = .02$

Dots represent EWL for each individual case. Boxes represent interquartile range, dashed lines represent distances to non-outlying extremes, thin horizontal line represents median value, and thick horizontal line represents mean value. P values calculated via the Student's unpaired t -test.

Table 1

Patient Demographics and Characteristics

Variable	Patients with Trait (categorical) Mean $\pm$ SD (continuous)
Age At Surgery	59.3 $\pm$ 5.7 years
Male Gender	26/117 (22.2%)
African-American race	8/117 (6.8%)
BMI ₀	43.6 kg/m ² $\pm$ 6.2 kg/m ²
Preoperative Weight Loss	61/117 (52.1%)
Hypertension (HTN)	105/117 (89.7%)
Depression	35/117 (29.9%)
Anxiety	17/117 (14.5%)
EWL180	27.2% $\pm$ 12.6% (n = 103)
EWL365	30.3% $\pm$ 19.2% (n = 88)

Continuous variables are expressed as mean $\pm$ standard deviation. Categorical variables expressed as number out of cases for which data point was available, (percentage). For continuous measures, the number of cases with available data for each variable is indicated in parentheses.

Table 2

Bivariate Association of Variables with EWL180 and EWL365

Variable	<u>EWL180</u>		<u>EWL365</u>	
	B (95% CI)	P	B (95% CI)	P
Age At Surgery (years)	−0.01%/year (−0.45%, 0.43%)	.96	−0.1%/year (−0.8%, 0.6%)	.76
Male Gender	0.5% (−5.7%, 6.6%)	.88	−5.4% (−15.3%, 4.5%)	.23
African-American race	−11.6% (−20.6%, −2.6%)	.01	−12.0% (−28.1%, 4.1%)	.14
BMI ₀ (kg/m ²)	−0.4%/unit BMI (−0.8%, 0.0%)	.06	0.06%/unit BMI (−0.6%, 0.8%)	.87
Preoperative Weight Loss	−2.5% (−7.8%, 2.9%)	.36	−6.2% (−15.2%, 2.8%)	.17
Hypertension (HTN)	−3.1% (−11.5%, 5.2%)	.46	−8.8% (−21.6%, 4.0%)	.18
Depression	1.3% (−4.0%, 6.6%)	.63	3.0% (−6.0%, 12.1%)	.51
Anxiety	−1.5% (−8.2%, 5.1%)	.65	−6.7% (−18.6%, 5.1%)	.26
Diabetes Mellitus (DM)	−9.9% (−14.4%, −5.3%)	<.001	−9.7% (−17.7%, −1.8%)	.02

Table 3

Multivariate Association of Variables with EWL180 and EWL365

Variable	EWL 180			EWL 365		
	B	(95% CI)	P	B	(95% CI)	P
Age At Surgery (years)	-	-	-	-	-	-
Male Gender	-	-	-	-	-	-
African-American race	-8.8%	(-17.3% , -0.3%)	.04	-	-	-
BMI ₀ (kg/m ²)	-	-	-	-	-	-
Preoperative Weight Loss	-	-	-	-	-	-
Hypertension (HTN)	-	-	-	-	-	-
Depression	-	-	-	-	-	-
Anxiety	-	-	-	-	-	-
Diabetes Mellitus (DM)	-9.1%	(-13.6% , -4.5%)	<.001	-9.7%	(-17.7% , -1.8%)	.02

EWL180: Constant = 32.1%, $r^2 = .189$, $F = 11.6$, $P < .001$ EWL365: Constant = 35.1%, $r^2 = .065$, $F = 6.0$, $P = .02$ (bivariate statistics; only one factor)

Dash indicates the variable was not included in multivariate analysis.