Observed Variability in Sleeve Gastrectomy Volume and Compliance Does Not Correlate to Postoperative Outcomes

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Background: Restrictive bariatric procedures reduce gastric capacity as a primary mechanism of action. Intraoperatively, surgeons observe variability in size and compliance of specimens. We hypothesized that higher gastric specimen volume or tissue compliance would respond better to restrictive procedures.

Materials and Methods: Consecutive patients undergoing laparoscopic sleeve gastrectomy between September 2012 and September 2013 were enrolled. Specimens were insufflated at graduated pressure points creating pressure volume curves, and compliance was calculated. Postoperative weight loss and a hunger scores were recorded. Correlations were determined by Spearman correlation.

Results: Eighty-four patients consented to enrollment. Mean age, weight, and body mass index (BMI) were 45 ± 12 years, 126 ± 23 kg, and 45.4 ± 6 m/kg^2, respectively. The resected specimens varied in insufflated capacity from 0.3 to 1.8 (0.71 ± 0.32) L and compliance varied from 14.3 to 85.7 (36.1 ± 14.7) cc/mm Hg. Male patients had a larger greater curvature length (GCL) ($P < 0.001$), staple line length (SLL) ($P = 0.03$), gastric volume (GV) ($P = 0.002$), and gastric compliance (GC) ($P < 0.001$). Neither GV nor GC correlated to excess body weight loss (EBWL%) as hypothesized. There was an inverse correlation between hunger score and GV ($P = 0.010$). The mean 1-month, 3-month, 6-month, and 12-month EBWL was 17.4%, 33.2%, 43.7%, and 54.1%, respectively. Follow-up was 71.4% at 1 month, 39.3% at 3 months, 54.8% at 6 months, and 42.9% at 12 months.

Conclusions: Sleeve gastrectomy specimens exhibit nearly 6-fold variability in both volume and compliance. A large GC is anticipated in male and tall subjects. These observations do not appear to be correlated to %EBWL.

Key Words: laparoscopic sleeve gastrectomy, stomach size, gastric capacity, weight loss, hunger score, bariatric surgery, bariatric surgical outcomes, hunger score

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INTRODUCTION/PURPOSE

Bariatric surgery volumes have increased in recent decades with the rise of the obesity epidemic. A recent study showed that 68.8% of Americans have a body mass index (BMI) ≥ 25 and the overall age-adjusted prevalence of obesity is 35.7%, as compared with 12.8% in 1962.[1] Obesity may result in life-threatening comorbidities and increased risk of premature death.[2] With increasing bariatric surgical volumes, efforts toward operative standardization and optimization will hopefully lead to better patient outcomes.

The etiology of obesity is multifactorial and contributing causes like genetics, endocrine disorders, and lifestyle factors are well recognized. The role of the stomach in the control of food intake has been of interest for many years. Some authors suggest that greater capacity for gastric distension in extremely obese people may be an etiologic factor in the development of obesity or an adaptation to the normal eating pattern.[3] In fact, studies have shown significantly larger gastric capacity in obese than in lean subjects.[4,5]

Previous reports highlight the role of gastric stretch receptors in satiety control. Distention of the stomach activates mechanoreceptors that transmit satiety signals to the central nervous system through vagal afferent fibers.[6] It is hypothesized that the stomach capacity should reach certain level of distension before these receptors activate. Hence, a stomach with a large capacity or higher compliance may require a larger meal to induce the same level of subjective fullness as a stomach with a smaller capacity or lower compliance.[7] Others have argued that the stomach size is not always a determinant for obesity development, citing morbidly obese patients who have previously undergone total gastrectomy.[8]

Despite the likelihood of multiple and complex mechanisms governing satiety, it has been demonstrated that procedures reducing the gastric capacity (GC) result in early satiety and weight loss.[5,9,10] Early on in the development of bariatric surgery, some authors observed that mechanical distension of the stomach with a balloon could elicit a feeling of fullness.[9,10] Geliebter et al[5] confirmed that food intake was decreased significantly by gastric distension by > 400 mL, mediated by gastric stretch receptors. These physiologic experiments are the basis for the incorporation of restrictive procedures in the management of morbid obesity.

Intraoperatively, we observed significant variability in size of resected specimens despite standard surgical technique. There also appeared to be variability in tissue thickness and, thus, perhaps tissue compliance. This could also be seen during the endoscopy done for leak test, when some patients appeared to have more compliant stomachs. Very few reports in the literature describe the anatomic and volumetric characteristics of the stomach of patients undergoing sleeve gastrectomy (SG). Obeidat et al,[11] reported correlation of sleeve gastrectomy specimen size to weight loss when divided into large (> 1100 mL) and small (< 1100 mL) specimen groups. No studies address the potential correlation between the stomach size and compliance and clinical outcomes such as weight loss and satiety control. For these reasons, study questions have been raised by the authors: does the size or compliance of

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the stomach matter? Is the volume of the resected stomach important? Are the outcomes different in patients with large resected stomachs, or more distensible stomachs, compared with patients with small or nondistensible resected stomachs? The aim of this study was to describe this observed variability in characteristics of resected sleeve gastrectomy specimens and to assess potential correlations to weight loss outcomes over time.

MATERIALS AND METHODS

Patient Population

We performed a prospective analysis of morbidly obese patients referred for bariatric surgical treatment. After approval by the Institutional Review Board, 84 patients consented to the study and underwent SG in our institution between September 2012 and September 2013. Patients who had a previous gastric operation (ie, gastric band, fundoplication) and patients with large paraesophageal hernias were excluded from this analysis because it was anticipated they might have different gastric tissue characteristics and compliance. We also excluded patients whose specimen was lacerated during the retrieval. Preoperative and postoperative variables including demographics, comorbidities, and anthropometric data were obtained from electronic medical records.

Sleeve Gastrectomy Technique

The same standardized surgical technique was used in all patients. All cases were either laparoscopic or robot-assisted procedures and performed by 2 surgeons (S.D., E.L.). The patient is placed in supine position; the surgeon stands at the patient's right. We use a 4-trocar approach and a liver retractor. The procedure proceeds using an endoscope (32 F) as a calibration device, with the staple line starting 5 cm proximal to the pylorus. The gastroscope is hugged loosely to approximate a target sleeve of 40 F. Staple loads are reinforced with buttress material (Gore Seamguard), and small sliding hiatal hernias are sought and repaired if present.

Specimen Measurements

Characteristics of the resected stomach were recorded for each case. The Gastric volume (GV) of the specimen was measured by inserting a Veress needle through a purse string suture into the antrum. A standard laparoscopic insufflator was used to insufflate the specimen with CO_2 (mL) at graduated pressure points from 3 mmHg up to a maximum of 21 mmHg (Fig. 1). To avoid equipment variability in the volume measurements, the same insufflation device was used for nearly all cases. A pressure versus volume curve was then generated for each specimen to calculate the gastric compliance (GC). Using the curve, the plateau pressure at which point maximal volume was measured was identified. The gastric compliance was defined as the GC (mL) divided by the observed plateau pressure (mm Hg). The insufflated specimen was then measured for greater curve length (GCL) and staple line length (SLL). The measured GV and calculated GV were compared with preoperative variables collected, including weight, BMI, and sex.

Outcomes Evaluation

Postoperative weight loss data was collected at 1, 3, 6, and 12 months and expressed as percentage of excess body weight loss (EBWL) and absolute weight loss. All patients were asked to complete the modified hunger score scale to assess satiety control. This is a reliable and valid questionnaire for satiety evaluation in obese and lean individuals.[12] The scale contains 7 questions to assess the overall feeling of hunger or satiety for different kinds of foods. Each question has a scale range of 0 to 100. According to the ratings, 0 is the minimum score indicating complete satiety and 700 is the maximum indicating an extreme feeling of hunger.

Postoperative weight loss outcomes were then correlated to preoperative variables including sex, weight, and BMI, as well as the GV and GC collected from specimen measurement.

FIGURE 1. Measurement of the gastric volume. The readings from the CO_2 laparoscopic insufflators used to calculate gastric volume. The picture shows one of the biggest specimens fully distended.

Statistical Analysis

Results are reported as mean ± SD for continuous variables. Correlations between continuous variables were determined by the Spearman test, as some of the measures were not distributed normally. A P-value < 0.05 was considered significant. All statistical calculations were generated using Microsoft Excel 2007 (Microsoft) and SAS/STATS (SAS Institute).

RESULTS

Perioperative Variables

Eighty-four patients were included in this study. Table 1 summarizes the preoperative and operative

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TABLE 1. Patient Demographics and Operative Characteristics

Characteristics	
Age (y)	
Mean (SD)	45.2 ± 12
Range	20-71
Sex	
Male	18%
Female	82%
Preoperative weight (kg)	
Mean (SD)	126 ± 23
Range	94-188
Height (cm)	
Mean (SD)	167 ± 8
Range	152-198
BMI (kg/m^2)	
Mean (SD)	45.4 ± 6
Range	33.6-64.5
Comorbidities (%)	
Hypertension	75
GERD	48
Joint disease	46
Diabetes	36
Obstructive sleep apnea	36
Psychiatric disorders	22
Hyperlipidemia	17
Hypothyroidism	16
Chronic kidney disease	10
Asthma	7
Polycystic ovarian syndrome	5
Hiatal hernia	4
Others	< 4
OR time (min)	
Mean (SD)	92 ± 25
Range	49-160
Blood loss (mL)	
Mean (SD)	38 ± 35
Range	5-200
Conversion rate (%)	0
Length of stay (days)	
Mean (SD)	2.3 ± 0.9
Range	2-7
30-day readmission rate (%)	7
Morbidity (%)	11%
Mortality (%)	0

BMI indicates body mass index; GERD, gastroesophageal reflux disease; OR, operating room.

data collected. 82% of the patients were female and 18% were male. The mean age, preoperative weight, and preoperative BMI were 45.2 ± 12 years, 126 ± 23 kg, and 45.4 ± 6 kg/m^2, respectively. The main comorbidities in decreasing order were hypertension 75%, gastroesophageal reflux disease 48%, joint disease 46%, diabetes 36%, and obstructive sleep apnea 36%. All cases were completed either laparoscopically (62 patients) or robot-assisted (22 patients) with no intraoperative complications or conversions to open technique. The mean operative time and estimated blood loss were 92 ± 25 min and 38 ± 35 mL, respectively. Patients had a mean length of stay of 2.3 ± 0.9 days. The readmission rate in the first 30 days following the procedure was 7%. Combined early and late morbidity was 11% and there was no mortality. There were no staple line leaks in this series. 4/84 (95%) had no follow-up data obtained at any time point after surgery. In the rest, follow-up data was available at the corresponding time points as follows: 1-month 60/84 patients (71.2%), 3-month 33/84 patients, 46/84 patients (39.3%), 6-months 46/84 patients (54.8%), and 12-months 36/84 patients (42.9%). Some patients had missing data at a given time point and others came at time points variant from our specifications (ie, 9 mo), and thus the data was not used in these instances. Four patients did not return for any postoperative follow-up despite contact by mail and phone. The median obtained follow-up length was 8.8 months (1 to 12 mo).

Preoperative weight and BMI were compared with postoperative weight loss (Fig. 3). There was a significant correlation between both of these variables at all measured time points, indicating that larger patients lose more weight as expressed in %EWBL.

Gastric Measurements

All 84 specimens were used to calculate the stomach size and gastric capacity. Table 2 summarizes the measurements obtained on the resected specimens. Insufflated gastric capacity from 0.3 to 1.8 (0.71 ± 0.32) L (6-fold variability) and the compliance varied from 14.3 to 85.7 (36.1 ± 14.7) cc/mm Hg (6-fold variability). Mean GCL and SLL of insufflated specimens were 46 ± 5 cm and 24 ± 3 cm, respectively. Male patients had a significantly longer GCL and SLL, as well as greater GV and GC than female patients. Regarding patient anthropometrics, and not portrayed in the figures, patient height was highly correlated with GCL ($P < 0.001$) and GV ($P < 0.001$). GV and GC were also correlated with preoperative weight ($P < 0.001$) but not with preoperative BMI ($P = 0.05$).

Gastric Volume, Compliance, and Weight Loss

The mean 1-month, 3-month, 6-month, and 12-month excess body weight loss (EBWL) was 17.4%, 33.2%, 43.7%, and 54.1%, respectively. The mean 1-month, 3-month, 6-month, and 12-month total body weight loss (TBW) was 7.5%, 14.1%, 18.9%, and 23.3%. The mean BMI change was -3.5 kg/m^2, -6.4 kg/m^2, -8.7 kg/m^2, and -12.5 kg/m^2. There was no difference in weight loss between the 2 operating surgeons.

Statistical comparisons were made between preoperative weight and BMI and measured GC and GV (Fig. 2). Logically, a higher compliance correlated strongly with high measured gastric volumes and also in patients with a high preoperative weight, although it was not correlated to a high preoperative BMI. Likewise, a high gastric volume correlated to a high preoperative weight but not preoperative BMI.

Figure 3 shows GV and GC correlations to observed weight loss at the measured time points following the operation. It has already been discussed that preoperative weight and BMI were significantly correlated to weight loss outcomes at all measured time points. Interestingly, neither GV nor GC correlate significantly to weight loss as a proportion of EBWL (P = NS), at any of the measured time points.

Gastric Volume and Satiety Control

Seventy-two patients (85%) completed the hunger score. We found a mean hunger score of 211 ± 100 (0 to 260) in this series indicating good satiety control after the procedure. There was a significant correlation between the recorded postoperative Hunger scores and measured GV and GC (Fig. 2). The recorded Hunger score did not appear to correlate to postoperative weight loss; however, at any time point except the 6-month time period (Fig. 3).

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TABLE 2. Overall and Sex-related Gastric Measurements*

Measurement	Overall Mean (Range)	Female Mean (Range)	Male Mean (Range)	*P*
Greater curvature length (cm)	46 ± 5 (33-65)	44 ± 4 (33-55)	52 ± 6 (42-65)	< 0.001
Staple line length (cm)	24 ± 3 (17-32)	24 ± 3 (17-32)	26 ± 3 (20-32)	0.030
Gastric volume (mL)	715 ± 317 (300-1800)	666 ± 276 (300-1800)	940 ± 403 (600-1800)	0.002
Gastric compliance (mL/mmHg)	36 ± 14 (14-85)	33 ± 12 (14-85)	47 ± 17 (28-85)	< 0.001

P-value < 0.05 was considered significant (female vs. male).
*Results are shown in mean ± SD.

DISCUSSION

Sleeve gastrectomy originally began in the late 1980s as the "Magenstrasse and Mill" procedure, which restricted food intake by excluding the gastric fundus and body but preserving the antrum.[13] Later, the procedure was performed by Marceau et al[14] in the early 1990s as the restrictive component and first stage of the biliopancreatic diversion with duodenal switch (BPD/DS) operation. The authors observed that many of these patients lost enough weight with the gastric sleeve only and the secondary procedure was often not pursued. Subsequent modifications have simplified the technique and the laparoscopic approach has become the standard.[2] As a standalone procedure, sleeve gastrectomy has become more popular in the last decade due to fewer technical and nutritional considerations than a malabsorptive procedure, minimal morbidity, and the fact that it avoids foreign materials used in vertical banded gastroplasty (VBG) or gastric band.[15]

To date, the early findings of prospective and retrospective studies about SG have demonstrated excellent

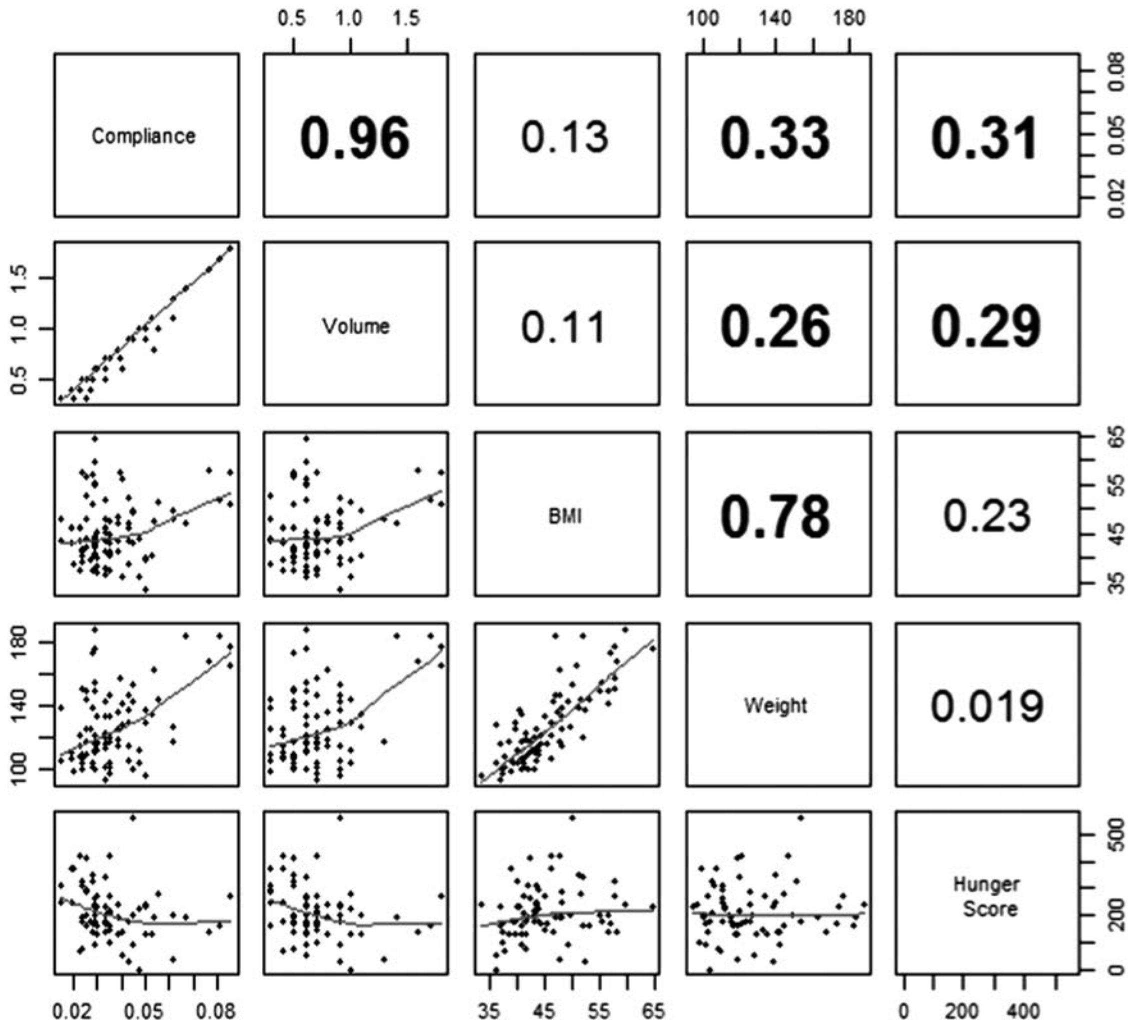

FIGURE 2. Correlation matrix between baseline characteristics. Lower half of the plot is scatter plots between each 2-way combination of variables. Lines show smoothed trend lines through the data. Upper half of the plot shows Spearman correlation coefficients; those in bold were statistically significant correlations at a 0.05 alpha level.

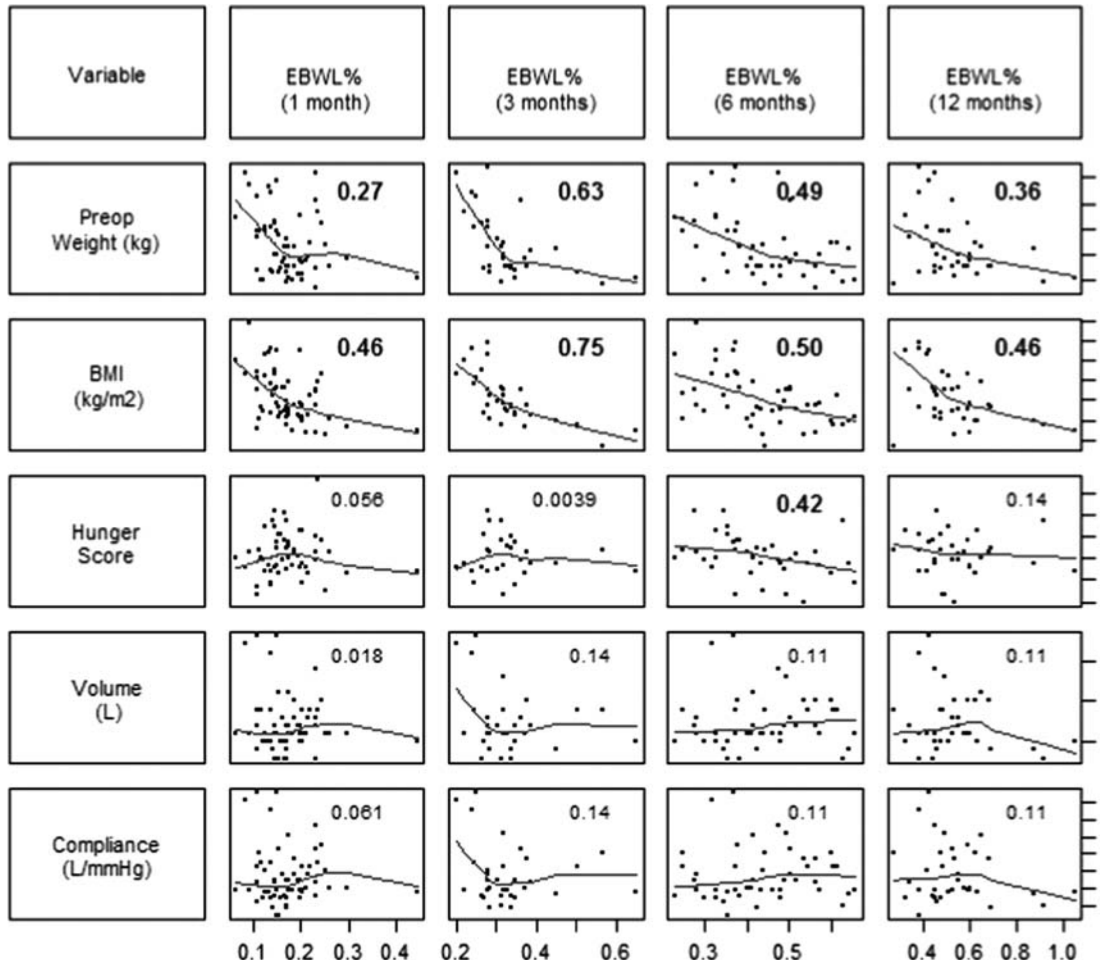

FIGURE 3. Correlation Matrix between Baseline Characteristics and Weight Loss. Scatterplots show relationship between each baseline variable and weight loss. Lines show smoothed trend lines through the data. The numbers in each scatterplot are Spearman correlation coefficients; those in bold were statistically significant at a 0.05 alpha level.

weight loss outcomes and comorbidity resolution. Furthermore, many of the technical details of the procedure have been agreed upon by consensus of experienced bariatric surgeons.[16,17] Nuances such as ideal Bougie size and extent of antral resection are currently mainstays of ongoing research, with ongoing efforts to optimize the balance of restrictions versus staple line leaks. Resecting the gastric fundus and creating a narrow gastric tube for decreasing the caloric intake are believed to be the chief mechanisms of weight loss after the procedure. However, some evidence suggests that the procedure also produces metabolic changes through not well defined pathways.[18] In addition, the mechanism of early satiety after the procedure is still unclear and a number of factors such as alterations in hormonal levels, modifications in gastric emptying, or elevated intragastric pressure may be involved.[19]

Complete resection of the gastric fundus provides optimal restriction but also effectively reduces ghrelin production, an important orexigenic hormone.[18,20] Different studies have documented a significant decrease in ghrelin levels and an increase in neuropeptide Y (NPY) levels after SG.[6,21] Although this is the most obvious hormonal impact of SG, of the hormonal effects on appetite become quite complex when it also needs to account for Agouti-related peptide (AgRP), NPY, and leptin.[6] Hence, the exact role of this hormonal interaction and its long-term effects on weight loss and satiety control remains to be explained.

Santoro[8] has pointed out the importance of gastric and intestinal satiety components. First, gastric satiety is reached through the stretch receptors mechanism previously mentioned. Second, in the postprandial status, there is initially rapid gastric emptying but as soon as the intestine is loaded, the distal gut hormones like glucagon-like peptide 1 (GLP-1), oxyntomodulin, and polypeptide (PYY) are produced to trigger a metabolic response that decreases gastric emptying and controls hunger; this is called intestinal satiety. However, if the individual follows a diet with highly refined/predigested foods, early absorption occurs in the proximal small bowel which delays intestinal satiety.[8,22] At this point, along with the kind of diet the patient will follow after surgery, the influence of SG in gastric emptying becomes a key issue, even more important than the gastric tube size itself. Two reports have showed that SG accelerates the gastric emptying time, suggesting a possible mechanism of early satiety.[23,24] However; it seems that when the procedure is performed with antrum preservation (starting the resection ≥ 6 cm from the pylorus) there is no

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effect on gastric emptying rates.[25] Whichever is the resultant effect of SG on gastric emptying, it would help to gain greater understanding of the interaction between gastric and intestinal satiety in obese patients.

There are some reports addressing the role of the resected specimen in SG patients. Baraki et al,[26] showed that the amount of resected stomach is correlated to the height, sex, and preoperative weight. The authors also suggested what the amount of gastric tissue that should be resected is an average of 120 g in females and 160 g in males. This is equivalent to a gastric capacity reduction of approximately 1200 to 1600 mL. Those results agree with the findings in this study. Weiner et al[27] studied a prospective series of 120 SG patients in whom the investigators used different Bougie sizes and measured both the resected specimen and the sleeve volume. Interestingly, they found that 2-year weight loss was higher for those in the group using smaller calibration Bougies (44 and 32 Fr) and pointed out that a removed gastric volume < 500 mL to be a predictor for either treatment failure or early weight regain. In another study, the authors measured the volume and pressure for both the gastric specimen and the remaining sleeve in 20 patients. They demonstrated that the distensibility of the resected portion is 10-fold higher than the gastric sleeve with a significantly lower intraluminal pressure. They concluded the mechanism of restriction following the sleeve gastrectomy is the combination of the small capacity, low distensibility, and the resultant immediate high intraluminal pressure.[19] However, none of the above mentioned studies reported any data pertaining to satiety control following the operation.

Our study describes the characteristics of the resected stomach specimen and correlates them to clinical outcomes. These variances were observed by us as surgeons during conduction of the procedures. We found logical, and perhaps expected, differences in stomach size by comparing preoperative characteristics like sex and height. Male and tall obese patients in this series showed a significantly longer GCL and SLL, as well as greater GV and GC. This subgroup of patients had better satiety control and a greater absolute weight loss during follow-up. Interestingly, we found no significant correlation for the primary variables measured in this study, GV and GC, to postoperative weight loss measured at multiple time points after surgery up to 1 year. This finding does not support the findings of the one prior study looking into this hypothesis, were larger resected specimen size (> 1100 mL) was correlated to higher %EWBL after sleeve gastrectomy.[11] In that study, the measurements were done using a different methodology (instilling with saline vs. CO_2, and no compliance data were collected). The analysis was also done by dividing the groups into large and small specimens resected, but this does not take into account patient specific variables. We did confirm that patients at a higher weight preoperatively do have a correlation to higher %EBWL at each time point, but the correlation to the size of the specimen independent of preoperative variables was not significant in our data.

There are limitations in this study. First, we used the specimen measurement as a surrogate indicator of the remaining conduit stomach size and gastric capacity. This assumes those measurements are an objective representation of the sleeve size because the size calibration tube and surgical technique are standardized to ensure the same proportion of tissue resected every time. A method to determine the volume of the constructed sleeve itself would have provided valuable data to layer into our finding that increased compliance and volume do not correlate to reported %EBWL. The ways to measure this preoperatively are limited and imprecise. The sleeve volume was not measured because, to date, we do not know of a safe method to perform this task intraoperatively without risk of aspiration. Second, it is unclear if the gastric capacity is truly related to the size of ingested meals and, although this is also difficult to demonstrate, a preoperative "eating test" could be a strategy to differentiate the gastric capacity among patients. Long-term follow-up will contribute to the overall picture of which type of procedure may suit patients best on an individualized basis. However, we believe the real impact of a bariatric procedure is more important in the early months, because, later on, patient compliance in terms of diet and physical activity plays a critical role. Indeed, there was high correlation between observed weight loss outcomes at each ensuing time point to those seen as soon as the first postoperative visit. Recording of the Hunger score was done during the conduction of the study during collection of follow-up data. Thus, preoperative data was not available for the patients. The value of this score also needs to be studied over varying time points after sleeve gastrectomy so that the effect of time from operative date can be quantified on this value. Lastly, although patient follow-up data are available for nearly all patients, many were missing data at our given time points. Weight loss data collected at intervening time points was not used as it would be spurious in one direction or the other. As a Center of Excellence center, follow-up is important. All patients were contacted by email and phone for missed follow-up visits, with the most common reason for loss being distance of travel and requests for primary care physicians to complete these items locally. All patients were provided suggested laboratory follow-up information for use by the accepting primary care provider.

CONCLUSIONS

In summary, the stomach size is significantly related to sex, height, and also to preoperative weight. We also found a significant positive correlation between gastric volume and absolute weight loss and a negative correlation between gastric volume and hunger score. These variances did not, however, correlate to %EBWL outcomes as others have reported. Theoretical preoperative assessment of gastric compliance or volume would not appear to contribute significantly to choice of bariatric procedure.

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