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SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Long-term success and failure with SG is predictable by 3 months: a multivariate model using simple office markers

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Abstract

Introduction: Despite being the most common surgery in the United States, little is known about predicting weight loss success and failure with sleeve gastrectomy (SG). Papers that have been published are inconclusive. We decided to use multivariate analysis from 2 practices to design a model to predict weight loss outcomes using data widely available to any surgical practice at 3 months to determine weight loss outcomes at 1 year.

Setting: Two private practices in the United States.

Methods: A retrospective review of 613 patients from 2 bariatric institutions were included in this study. Co-morbidities and other preoperative characteristics were gathered, and %EWL was calculated for 1, 3, and 12 months. Excess weight loss (%EWL) $<55\%$ at 1 year was defined as weight loss failure. Multiple variate analysis was used to find factors that affect %EWL at 12 months.

Results: Preoperative sleep apnea, preoperative diabetes, %EWL at 1 month, and %EWL at 3 months all affect %EWL at 1 year. The positive predictive value and negative predictive value of our model was 72% and 91%, respectively. Sensitivity and specificity were 71% and 91%, respectively.

Conclusion: One-year results of the SG can be predicted by diabetes, sleep apnea, and weight loss velocity at 3 months postoperatively. This can help surgeons direct surgical or medical interventions for patients at 3 months rather than at 1 year or beyond. (Surg Obes Relat Dis 2017;13:1266–1271.)

Keywords: Sleeve gastrectomy failure; Sleeve gastrectomy; Sleeve gastrectomy model; Weight loss model; Obesity surgery; Obesity

Sleeve gastrectomy (SG) has become the most popular bariatric procedure in the country [1]. It has found high amounts of weight loss early while reaching weight loss nadir at approximately a year from surgery [2]. In the next 12 months, SG patients tend to regain approximately 5% to 10% of their excess weight loss (%EWL) [3,4]. The ability to reliably predict which patient will be successful and who will fail would help practitioners and patients make appropriate surgical and medical decisions.

The most common definition of failure in bariatric surgery is a failure to lose 50% EWL or regain $>50\%$ of their %EWL [5–7]. In a review of the literature, we found that the %EWL in the first 3 months after Roux-en-Y gastric bypass accurately predicted 3-year outcomes [8].

A similar model has not been attempted with a sleeve gastrectomy.

Methods

A retrospective data analysis of prospectively kept databases of all SG performed at 2 private practice institutions from 2013 to 2015 was completed. All patients in this study

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were operated on by 3 different surgeons at 1 institution and by 5 different surgeons at the other institution. Each patient who had surgery had similar preoperative and postoperative follow-up regimens, which included dietary and exercise counseling at both institutions.

The sleeve gastrectomy was created similarly at both institutions. Briefly, the SG was created by stapling alongside a 38 or 40 French bougie from 4 to 6 cm from the pylorus. There was no over-sewing or staple line reinforcement. The bougie was merely a guide and none of the surgeons involved stapled tight against the bougie. Additionally, the amount of stomach removed was not measured. All hiatal hernias identified at surgery were repaired.

Co-morbidities and demographic data were gathered for each patient. These co-morbidities included type 2 diabetes (T2D), hypertension (HTN), sleep apnea, and gastroesophageal reflux disease (GERD). However, these co-morbidities were only diagnosed if the patient was on medication or was diagnosed with sleep apnea from a sleep study. These co-morbidities were chosen because their presence or absence was gathered at both institutions equally.

Statistical analysis

To be included in the study, the patient needed to be beyond 1 year and have at least 3 follow-up appointments during the first year. The follow-up requirement was needed to allow accurate statistical interpolation of weight loss. Those 3 dates allowed nonlinear regression analysis to be performed separately for each patient. Patients were removed from the study if their regression analysis had an r^2 value of <95. (This simply means that at most 5% of the weight loss cannot be explained by the passage of time but is due to extraneous variables.)

Exclusion criteria for this study were patients who had not made it to a year and patients who did not follow up at least 3 times within the first year. A demographic comparison was then made between the patients who were excluded/lost to follow-up using *t* tests and chi squared tests.

Multiple logistical regression analysis was then used to identify factors that affect weight loss failure at 1 year. Factors looked at included preoperative body mass index (BMI), T2D, sleep apnea, HTN, GERD, %EWL at 1 month, %EWL at 3 months, gender, age, and surgical location. After identifying factors that affect weight loss failure, these factors were optimized using receiver operator curves (ROC).

All statistical analysis was done through SigmaPlot software. This study was approved by the Quorum IRB.

Results

Of 1169 patients, 613 met the qualifications for the studies. A total of 556 patients were lost to follow-up and not included in this study. Demographic similarities and differences between the 2 groups are found in Table 1. Demographic similarities and differences between included patients and those who were lost to follow-up are found in Table 2. Of the independent risk factors analyzed, only preoperative sleep apnea, preoperative T2D, %EWL at 1 month, and %EWL at 3 months were shown to be predictive of weight loss failure at 1 year (Table 3). Once these factors were identified, their outcomes were optimized using ROC curves. ROC curves found that sleep apnea and T2D were found to affect weight loss negatively, whereas % EWL at 1 and 3 months were found to be variable factors instead of binary factors. This model is presented in Fig. 1.

This model had a sensitivity and specificity of 71% and 91%, respectively. The positive and negative predictive values were 72% and 91%, respectively, meaning that of those who had weight loss failure or lost $<55\%$ EWL, 71% were caught by the model. When the model predicts weight loss failure at 3 months, it is right 72% of the time. Of those who achieve weight loss success or lost $>55\%$ EWL, this model catches 91% of them. When the model predicts weight loss success at 3 months, it is right 91% of the time.

Table 1
Pre-operative Center Comparisons

	Center 1	Center 2	*P* value
N	122	491	
BMI	44.0 ± 7.0	44.1 ± 6.9	.886
Age	44.5 ± 10.1	47.9 ± 11.6	.003
Male/Female	21/101	107/384	.504
Diabetes	28 (23%)	130 (26%)	.496
Sleep apnea	52 (43%)	213 (43%)	.961
GERD	61 (50%)	151 (31%)	<.001
Hypertension	51 (42%)	248 (51%)	.105

BMI = body mass index; GERD = gastroesophageal reflux disease.

This shows the preoperative characteristics of the patients from both centers. Data are presented as averages plus or minus the standard deviation or the amount of patients that have the respective co-morbidity. The difference between the two is measured by *P* values.

Table 2
Lost to Follow-Up vs Included Patients Pre-operative Statistics

	Included patients	Lost to follow-up	*P* value
N	613	556	
BMI	44.1 ± 6.9	43.9 ± 7.2	.628
Age	47.2 ± 11.5	43.2 ± 11.4	<.001
Male/Female	129/484	191/365	<.001
Diabetes	158 (26%)	146 (26%)	.903
Sleep apnea	265 (43%)	240 (43%)	.971
GERD	212 (35%)	196 (35%)	.859
Hypertension	299 (49%)	256 (46%)	.381

BMI = body mass index; GERD = gastroesophageal reflux disease.

This shows the preoperative characteristics of the patients who were lost to follow-up versus those that were included. Data are presented as averages plus or minus the standard deviation or the number of patients with the respective co-morbidity. The difference between the two is measured by *P* values.

Table 3
Variable Impact on Weight Loss

Factor	*P* value	Wald statistic
%EWL 1 mo	<.001	71.79
%EWL 3 mo	<.001	110.4
Diabetes	.028	4.182
Sleep apnea	.004	8.189
Age	.176	1.831
Gender	.841	.040
Center	.967	.002
Hypertension	.659	.195
GERD	.833	.045
BMI	.951	.004

%EWL = percentage of excess weight loss; BMI = body mass index; GERD = gastroesophageal reflux disease.

This table is comparing the effect each variable has on whether a person will achieve 55%EWL. The higher the Wald statistic and the lower the *P* value, the more it affects weight loss.

Discussion

Most surgeons today quote average %EWL to patients as a guide for expected weight loss results. However, this type of presentation is not individualized and is not a realistic guide for a large number of bariatric patients who have sleep apnea, T2D, or who have a high BMI. If these patients have not lost significant amounts of weight at 3 months, they are likely to lose <55% %EWL (Table 1; Fig. 1). The purpose of this study was to identify patients who fail SG in terms of weight loss early, so timely intervention can be made. Based on this data, the time for intervention is at 3 months, and the standard course of waiting for 1 year to propose intervention, whether it is surgical or medical, will result in a delay in diagnosis in >70% of weight loss failures.

There has been a similar study to this study with gastric bypass analysis. Mor et al. found that patients' weight loss results at 3 months after gastric bypass accurately predicted weight loss failure at 3 and 5 years [8]. This study is one of the first of its type using short-term markers for 1-year success in sleeve gastrectomy patients. We chose 1 year since that is statistically the highest point of weight loss. It is also the point that most people start to consider intervention for weight loss failure. There have been other predictive papers for long-term success of sleeve; however, they have focused on things such as grip strength, 6-minute walk distance, caloric intake, racial background, osteoarthritis, and disability status. However, these outcomes were not gathered at either location of the study and are not routinely gathered in most practice locations around the country [9–13].

This study had a large sample size of 613 patients. This helped to control for variability in patient co-morbidities and weight loss outcomes. This allowed us to have a statistically more random set of patients to identify which factors actually affect weight loss results. That being said any model benefits from more patients to bring up the sensitivity and positive predictive rates. This is mainly because only 25.1% or 154 of the patients looked at in this study actually had <55% %EWL. This number would need to be higher to bring up that sensitivity rate.

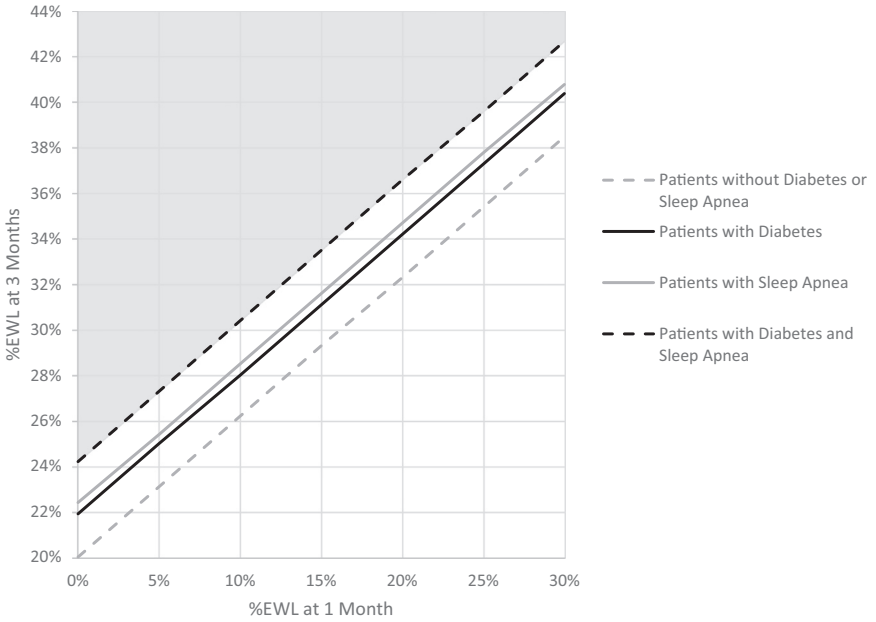

Fig. 1. This model is a simple way to manage patient expectations. The model works by plotting a patient's percentage of excess weight loss (%EWL) at 1 month against their %EWL at 3 months. If they are above the line in the shaded region for their particular combination of comorbidities at 1 and 3 months, then they will achieve at least 55%EWL. If they are below, they will fail to reach 55%EWL. For example, if a patient with diabetes and sleep apnea preoperatively achieved 15%EWL at 1 month and 28% at 3 months then they would be predicted to reach <55%EWL at 1 year. Similar procedures work if or if not the patient has sleep apnea or diabetes.

One of the interesting facts of this study is the fact that sleep apnea is a significant factor in weight loss results at 1 year as measured in the multiple variable analysis of a *P* value of .004, which is quite statistically significant. This would contradict the current literature about sleep apnea, which is found to not affect weight loss in the Roux-en-Y gastric bypass [11]. This finding prompts future studies that look into the severity of sleep apnea and weight loss results, which the authors of this paper are currently working on.

Another weakness of this study is the strict inclusion criteria. If patients did not adhere to the strict follow-up criteria, they had to be excluded. This could possibly alter the results associated with the study, but this was corrected by having a large number of patients meet the strict criteria. This eliminates most, but not all, of the pitfalls that may arise from smaller sample sizes and erroneous data.

The cohort had an average of 70% EWL at 1 year. This is well within the range of published %EWL values at 1 year [14–18]. As a result, we are confident that these findings correlate with data for other practices and international centers.

This model revealed that bougie size, HTN, GERD, surgeon, and practice make no difference in outcomes. These finding are consistent with other studies about predicting weight loss [19–21].

This model shows that early weight loss is the most important predictive factor to consider when looking at overall weight loss success or failure of each patient. This stresses the importance attached to these early postoperative visits. This would suggest that follow-up past 3 months may not be important to patients' weight loss success. A greater focus on early postoperative visits needs to be made.

Some may classify the definition of 55% EWL loss as a weakness of this study. Currently there is no widely accepted standard for what constitutes weight loss failure in bariatric surgery and patient's failure to reach this point is rarely ever mentioned. However, some studies have used $<50\%$ EWL as constituting failure [5–7]. We also realize that this number did not tell the whole story of sleeve weight loss failures as co-morbidity resolution and psychological improvement can also constitute success or failure. Yet we strongly believe that patients who do not achieve this number in the short term will fail to keep adequate weight off in the long term [3,4]. Because this data is based on 1-year outcomes, we had to assume weight regain in the model, so we revised the weight loss failure point upward to 55% EWL to account for this fact.

Once a patient is identified as possibly failing the procedure, the practitioner has several options. The first of the options would be an intensive dietary and exercise follow-up appointment. This step corrects the dietary and exercise mistakes that patients so often make. The second step is medication intervention. There currently are many FDA-approved drugs to help if patients have problems with impulse control or hunger. Both practices have medical interventionalists to address this need. The last option would be revisional surgery. The decision to resleeve or convert to gastric bypass or duodenal switch depends on the individual patient's needs. We actively use all 3 methods for weight regain, and the nuances of each are beyond the scope of this paper.

Perhaps the biggest question of this study relates to why some patients fail and succeed so early, long before most patients are even eating normally. We cannot be sure; however, we believe that metabolism may be genetically controlled and the patients' weight, diabetes, and sleep apnea reflect metabolic derangements and not failures of willpower.

One weakness of this study is the number of patients lost to follow-up. Their data was not able to be used to optimize the model's findings. We tried to rectify this weakness by studying the differences in demographic data between those who were lost to follow-up and those who were included. The most surprising fact is how similar the groups are. They have statistically similar rates of co-morbidities and BMIs. However, age and gender proportions were the only statistically significant differences. We cannot be sure if age or gender would have been a factor if all the patients had kept up with their follow-ups. This is an area we plan to address by creating a model that uses even more patients to account for more statistically random sets of patients. This would allow us to have an even more accurate and applicable model moving forward.

One of the other weaknesses of this study is the use of co-morbidity data from T2D, HTN, GERD, and sleep apnea. The databases did not account for severity and accurately judging severity in hindsight was impossible. We acknowledge that length and amount of insulin and severity of sleep apnea might affect weight loss but this proved impossible retrospectively. As such, the approach of only looking at diagnosed disorders where medications were needed, at least opens up the possibility of future prospective studies into certain disorders and their effect on weight loss.

Conclusion

Every patient who has factors for weight loss failure (diabetes, sleep apnea, and high BMI) should have a discussion preoperatively to help them choose a procedure that will work for them. This discussion should be continued at 1 and 3 months postoperatively when weight loss velocity curves are known to better guide therapeutic decisions and expectations of future weight loss.

Statement of human and animal rights

I certify that the manuscript did not involve the use of animal or human patients.

Since this is a retrospective study the formal consent is not required for this type of study.

Disclosures

The authors have no commercial associations that might be a conflict of interest in relation to this article.

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Editorial comment

Comment on: Long-term success and failure with sleeve gastrectomy is predictable by 3 months: a multivariate model using simple office markers

What determines success and failure after metabolic and bariatric surgery? Traditionally, weight loss metrics have been the primary outcomes for determining success after bariatric surgery. However, weight loss alone can often be a one-dimensional view of the effectiveness of metabolic surgery. Weight loss metrics may not reflect other important outcomes, including co-morbidity resolution, quality of life, and disease prevention [1,2]. Nevertheless, clinicians and patients alike often focus on a difficult question to answer: "How much weight should I be losing?"

This question is not easy to answer because weight loss after bariatric surgery is extremely variable. Historically, this variability has been attributed to patient behavior, dietary choices, lifestyle, activity level, and degree of patient compliance. However, variability in weight loss may rely more on the multifactorial causes of morbid obesity and a diverse pathophysiology. With a multitude of known and unknown confounding factors, are weight loss outcomes from bariatric surgery predictable? If so, how early in the process can this occur?

In this issue of the Journal, Daniel Cottam et al. derived a model for predicting 12-month weight loss success, defined by greater than 55% excess weight loss (EWL), after sleeve gastrectomy based on 1- and 3-month postoperative weight loss results [3]. The model has impressive sensitivity and specificity of 71% and 91%, respectively. The model was derived from a retrospective review of 613 patients who underwent laparoscopic sleeve gastrectomy in 2 separate bariatric practices among 8 bariatric surgeons who used similar surgical techniques. Limitations of the study include having 556 patients (48%) from an initial patient population of 1169 excluded from the model creation secondary to