



The Use of Predictive Markers for the Development of a Model to Predict Weight Loss Following Vertical Sleeve Gastrectomy

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Abstract

Background Average percent excess weight loss data is commonly discussed preoperatively to guide patient expectations following surgery. However, there is a wide range and variation in weight loss following vertical sleeve gastrectomy (SG). Unfortunately, most surgeons and even fewer patients have heard of using predictive models to help guide their decisions on procedure choice. We have developed a predictive model for SG to help patient choice prior to this major life-changing decision. **Objective** Predict weight loss results for SG patients at 1 year using preoperative data. **Setting** Private practice.

Methods Three hundred and seventy-one SG patients met the criteria for our study. These patients underwent surgery between October 2008 and June 2016. Non-linear regressions were performed to interpolate individual patient weights at 1 year. Multivariate analysis was used to find factors that affected weight loss. A model was constructed to predict weight loss performance.

Results Variables that affect weight loss were found to be preoperative body mass index (BMI), age, hypertension, and diabetes. Diabetes and hypertension together were found to significantly affect weight loss.

Conclusion Patient weight loss can be accurately predicted by simple preoperative factors. These findings should be used to help patients and surgeons decide if the SG is an appropriate surgery for each patient. Using this model, most patients can avoid failure by choosing an appropriate surgical approach for their personal circumstances.

Keywords Sleeve gastrectomy · Predictive modeling · Hypertension · BMI · Age · Diabetes

Introduction

The vertical sleeve gastrectomy (VSG) has become the most popular weight loss surgery in the USA and worldwide [1]. Comparative studies of VSG and Roux-en-Y gastric bypass (RYGB) have shown variable results. However, the majority of these investigations show that the VSG has slightly lower average weight loss than RYGB. In addition, there is a much wider standard deviation in VSG patients. A patients' understanding of the likely results with a given procedure would allow them a realistic opportunity to make an informed decision regarding a weight loss procedure. Selection of bariatric procedure has always been an area of active debate. Prior to the laparoscopic era, arguments were common between advocates of vertical banded gastroplasty (VBG) and RYGB. Proponents of VBG stated that there was no reason to bypass the proximal intestine and risk anemia and bone loss. Supporters of RYGB countered with the stomach and intestinal combination offered better weight loss, lower chance of weight loss failure, and reduced recidivism. Following a 10-year report that showed poor long-term results following VBG, this operation has disappeared.

Another gastric-only stapling procedure has risen in popularity, the VSG. With the large numbers of VSG being done, there are more reports of patients that have not had weight loss results that meet their expectations. In addition, many patients have weight regain or recidivism. For these reasons, identification of markers and a model that would allow stratification of patients would be most helpful. The purpose of this paper is to make a preoperative predictive model so that patients and their surgeons can make an informed decision about which procedure is right for them.

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Methods

One thousand and twenty-six patients who underwent primary VSG at a single private practice institution from October 2009 through June 2016 were evaluated. This study was approved by Quorum IRB number 31353. Demographic data and comorbid condition were collected. All revision patients were excluded from this study. Data was gathered retrospectively on a prospectively kept data base. Patients were diagnosed with type 2 diabetes mellitus (DM), hypertension (HTN), or gastroesophageal reflux disease (GERD) if they were on medications for these disease processes. Sleep apnea (SA) was only counted as positive if they had the diagnosis of sleep apnea on a sleep study. Severity of any of the disease processes es was not assessed.

Patients were included in the study if they had a follow-up point at or greater than 1 year with at least two other follow-up points. Using this data, the individual patient could be modeled with regression analysis to interpolate weight loss at specific time points. The shortest follow-up point considered acceptable as a 1-year follow-up was 330 days. Patients needed to be able to be modeled with a $R^2 > 0.95$. (This coefficient of determination is a type of measure of the correlation between time since surgery and weight. At this level, 95% of the variability in weight can be explained by the time since surgery. This high explanatory rate allows us to accurately interpolate data.)

This left 371 patients of 1026 patients for data analysis. A comparison between the 371 patients that followed up and the whole population was performed for age, sex, body mass index (BMI), and the presence of common comorbid conditions to confirm that the 371 patients were a representative sample.

Each patient weight was calculated at 1 year and their percentage excess weight loss (%EWL) and BMI reduction was calculated. Multilinear regression analysis was performed using SA, DM, GERD, HTN, and gender as simple binary variables. Age, weight, height, BMI, BMI2, BMI × age, and age2 were used as simple sliding variables. Combination binary variables include the presence of only HTN and DM, HTN and GERD, HTN and SA, GERD and DM, GERD and SA, DM and SA and all four comorbidities. Variables were taken out based upon collinearity and standardized pvalues. From the remaining variables, weight loss predictions could be made. Assessment of the average error of the model was then calculated.

All data was analyzed using SigmaPlot.

Results

Three hundred and seventy-one patients met the inclusion criteria of this study. Of these 371, 277 were female and 94 were male. The average %EWL for the cohort at 1 year was

 $70\% \pm 22\%$ and the BMI reduction at 1 year was 13.19 ± 4.48 (mean \pm standard deviation). Our group studied was demographically statistically equal to general VSG patient population. Demographic data and comparisons are found on Table 1.

Of the variables tested for only BMI, age, HTN, DM, and HTN and DM were found to be significant. These variables created the model:

$$140.9-(0.731 \times DM)-(1.53 \times HTN)-(0.304 \times Age)$$

-(1.22 × BMI)-(12.5 × HTN&DM) = %EWL at 1 year

The equation had an *R* value of 0.521 and an R^2 of 0.272. This means that 27.2% of the variation of weight loss at 1 year can be explained by the variables in the model. Predictions for %EWL at 1 year based upon the model can be found in Table 2.

This equation was used to predict patient weight loss with an average error of the prediction being $14.9\% \pm 11.6\%$. This means that on average we are within 15% of the actual weight loss of the patient. Additionally, predictions were found to be within 20.3% on 75% of patients giving them an accurate window of how much weight they are going to lose.

For BMI reduction, similar variables were found to affect the total BMI reduction. BMI, age, and HTN with DM were found to affect BMI reduction. These variables created the model

 $0.73-(0.0581 \times Age) + (.343 \times BMI)-(2.31 \times HTN\&DM)$ = BMI reduction at 1 year

The equation had an *R* value of 0.626 and an R^2 of 0.391. This means that 39.1% of the variation of weight loss at 1 year

 Table 1
 Comparison of preoperative characteristics of our sample group to our center's sleeve patients

N	Study patients 371	All patients 1026	p value
BMI	44.78 ± 7.54	44.1 ± 7.6	0.132
Weight	285.83 ± 58.31	281.7 ± 57.6	0.320
Height (inches)	66.8 ± 3.6	66.8 ± 4.2	0.709
Age	43.97 ± 10.68	43.1 ± 11.1	0.206
Male/female	94/277	323/761	0.535
Diabetes	91 (25%)	284 (26%)	0.672
Sleep apnea	139 (37%)	419 (38%)	0.830
GERD	158 (43%)	432 (40%)	0.587
Hypertension	151 (41%)	478 (44%)	0.505

BMI body mass index

GERD gastroesophageal reflux disease

*Data presented as either mean \pm STDEV, male/female, or total and percentage of patients with comorbidity

Table 2%EWL predictions at 1year for patients with different BMIsand ages separated by those with and without DM and HTN

Age BMI	20	30	40	50	60
Patient	without DM a	nd HTN			
38	88.46	85.42	82.38	79.34	76.3
40	86.02	82.98	79.94	76.9	73.86
42	83.58	80.54	77.5	74.46	71.42
44	81.14	78.1	75.06	72.02	68.98
46	78.7	75.66	72.62	69.58	66.54
48	76.26	73.22	70.18	67.14	64.1
50	73.82	70.78	67.74	64.7	61.66
52	71.38	68.34	65.3	62.26	59.22
54	68.94	65.9	62.86	59.82	56.78
56	66.5	63.46	60.42	57.38	54.34
58	64.06	61.02	57.98	54.94	51.9
60	61.62	58.58	55.54	52.5	49.46
Patient	with DM and	HTN			
38	73.699	70.659	67.619	64.579	61.539
40	71.259	68.219	65.179	62.139	59.099
42	68.819	65.779	62.739	59.699	56.659
44	66.379	63.339	60.299	57.259	54.219
46	63.939	60.899	57.859	54.819	51.779
48	61.499	58.459	55.419	52.379	49.339
50	59.059	56.019	52.979	49.939	46.899
52	56.619	53.579	50.539	47.499	44.459
54	54.179	51.139	48.099	45.059	42.019
56	51.739	48.699	45.659	42.619	39.579
58	49.299	46.259	43.219	40.179	37.139

can be explained by the variables in the model. Predictions for %EWL at 1 year based upon the model can be found in Table 3.

This equation was used to predict patient weight loss with an average error of the prediction being 2.75 ± 2.14 . This means that on average we are within 2.75 BMI points of the actual BMI reduction of the patient. Additionally, predictions were found to be within 3.8 BMI points on 75% of patients giving them an accurate window of how much weight they are going to lose.

Discussion

The purpose of our study was to determine whether we could use simple readily available preoperative data points to develop a mathematical model that could predict 1-year outcomes for VSG, the ultimate goal being a dose response curve like that seen for medications. Our primary reason for doing so is due to VSG prevalence increasing rapidly and the lack of predictive models for success.

Table 3 BMI reduction predictions at 1 year for patients withdifferent BMIs and ages separated by those with and without DM andHTN

Age BMI	20	30	40	50	60
Patient	without DM a	nd HTN			
38	12.602	12.021	11.44	10.859	10.278
40	13.288	12.707	12.126	11.545	10.964
42	13.974	13.393	12.812	12.231	11.65
44	14.66	14.079	13.498	12.917	12.336
46	15.346	14.765	14.184	13.603	13.022
48	16.032	15.451	14.87	14.289	13.708
50	16.718	16.137	15.556	14.975	14.394
52	17.404	16.823	16.242	15.661	15.08
54	18.09	17.509	16.928	16.347	15.766
56	18.776	18.195	17.614	17.033	16.452
58	19.462	18.881	18.3	17.719	17.138
60	20.148	19.567	18.986	18.405	17.824
Patient	with DM and	HTN			
38	10.292	9.711	9.13	8.549	7.968
40	10.978	10.397	9.816	9.235	8.654
42	11.664	11.083	10.502	9.921	9.34
44	12.35	11.769	11.188	10.607	10.026
46	13.036	12.455	11.874	11.293	10.712
48	13.722	13.141	12.56	11.979	11.398
50	14.408	13.827	13.246	12.665	12.084
52	15.094	14.513	13.932	13.351	12.77
54	15.78	15.199	14.618	14.037	13.456
56	16.466	15.885	15.304	14.723	14.142
58	17.152	16.571	15.99	15.409	14.828

Theoretic advantages of VSG include no anastomosis, faster and better short-term weight loss than laparoscopic gastric banding, and fewer long-term vitamin and micronutrient needs than RYGB. However, with all of these benefits, it is increasingly being questioned whether weight loss is adequate or enduring. Furthermore, with multiple procedures now available, there is no reason why it should be one procedure for all. A better approach would be to match objectives with likely outcomes. To date, most quote average %EWL results. Yet, this is vastly inaccurate as standard deviations are high and this is not personalized to an individual patient.

Using our model, a patient who is 35 years old, has a BMI of 50, and has no comorbidities would be expected to lose 69% of their excess weight. This means this patient would be predicted to have a BMI of 32.69 at 1 year. However, a patient who is 35 years old and has a BMI of 50, hypertension, and diabetes would be expected to lose 54% of their excess weight. This means this patient would be predicted to have a BMI of 36.38 at 1 year. With the use of this formula, surgeons could inform patients of an expected outcome specifically for

them. If this predicted outcome was not in line with the patient's desired outcome, then a more invasive surgery could be suggested based upon their personal weight loss goals, thus, improving overall patient care.

We chose to predict 1-year weight loss because studies have shown that the average VSG patient stops losing statistically significant amounts of weight at 1 year [2]. The 1-year follow-up point also has less patients lost to follow-up compared to 18 months or 2 years. This improves the accuracy of the model and it also allows the prediction of expected maximum weight loss after the sleeve gastrectomy. This prediction of maximum weight loss allows patients to judge if they will ever meet their weight loss goals. The model does not account for weight regain after 1 year which occurs in some patients. This means that the model is not predictive of final weight following sleeve gastrectomy but maximal weight loss. This should be explained to the patient as well as their role in weight maintenance following the sleeve gastrectomy. In this way, it is a useful tool to gauge if the VSG will help a patient achieve their weight loss goals.

Should the model prove to be translatable to other practices, there are many uses. Although it has been shown that 1-year weight loss for the sleeve can be more accurately predicted after 1–3 months after surgery [2, 3], we believe that a preoperative model should also be used. If some people can be predicted to lose less than their desired weight before they even have surgery, they will be better able to choose a more invasive better weight loss procedure such as the duodenal switch or the gastric bypass. This change in procedures and frustration from failing to achieve their lose weight goals. This will improve the overall bariatric quality of care and help patients succeed following bariatric surgery.

Also, it could be said that this model is too simple to be truly predictive. It does not take into account many parts of patient personality and life choices. While this could be argued, the purpose of this study was to make an easy prediction model where the average practice would not have to collect more data than they already collect. Also, it does not limit people in their choices as many people did much better than predicted even up to 70% more EWL than the model predicted. While this model cannot account for all factors, it does address the average bariatric patient and their expected weight loss.

There have been many variables that have been suggested to correlate with outcomes following VSG. They include 6min walk distance and handgrip strength, the theory being that those who are most fit or strongest will lose the most weight. While these metrics may be predictive of weight loss, these metrics are not commonly recorded. Another variable mentioned is waist circumference as a marker for central obesity. Some postulate that those with central obesity lose less weight than those with a gynoid or peripheral distribution. Other markers suggested are appearance on postoperative swallow study, weight of the resected specimen, genetics, and bougie size. Again, the majority of these metrics would not be readily available for the development of a simple mathematical model [4-14].

It is also apparent that there are many other variables that can affect weight loss that are not easily measurable or are not measurable. These may include eating habits, educational status, support, impulsivity, and even coping habits. This limits the predictive power of any model. Some patients simply do better with their diet and leaving behind their bad eating habits. This probably could not be known before the surgery; however, most patients behave in a similar way and therefore can be generalized and their weight loss predicted [15-19]. These reasons however are why any model can only be so accurate. There are many variables that affect weight loss and their interactions are not fully understood nor can they truly be. This is why the model only achieved an R value of 0.521 for EWL and an R value of 0.626 for BMI reduction. This may just be the limit of the explanatory value of preoperative predictors as there are many other factors at play in weight loss.

Our cohort has an average %EWL of $70\% \pm 22\%$ and an average BMI reduction of 13.19 ± 4.48 at 1 year. This is within previously published large sample studies and suggests that our results are consistent with those achieved around the world. As a result, we are confident that our findings will correlate with data from other practices and international centers [20–24].

BMI was found to affect weight loss (p < 0.001). The reason for this can be easily explained. Those that have a higher BMI have more weight to lose and because of this, they often fail to lose as much %EWL as their slightly thinner counterparts. The effect of BMI amounts to a predicted decrease of 1.2 %EWL for every point of BMI heavier a patient is. In terms of BMI reduction, this effect is the opposite. Since larger patients have more weight to lose even though they lose less of their excess weight, they lose more weight. The effect of BMI amounts to an increase of 0.343 points of BMI reduction for every 1 BMI point heavier they are.

Age was also found to influence weight loss (p < 0.001). This has been debated in literature but has been shown in the past to affect weight loss [22–24]. The amount that age affects weight loss is about a predicted 1% decrease in the %EWL for every 3 years older a patient is. Age effects BMI reduction in a similar manner amounting to a 1-point decrease in expected BMI reduction for every 20 years older a patient is.

DM and HTN were the only comorbidities that were found to affect weight loss (p = 0.009). They were mainly shown to affect weight loss when both are present. When both were present, patients could expect about 14% less %EWL and 2.31 BMI points less. These two comorbidities seem to have some interaction that affects weight loss. There are different possible mechanisms for this; however, the authors cannot say to the cause. This study is not meant to show how DM and HTN affect weight loss, but only to show that it affects weight loss. DM and HTN have been shown in other studies to have an effect on weight loss after bariatric surgery [25–27].

GERD was not found to influence %EWL (p = 0.525). Only one study has suggested that GERD impacts weight loss [27, 28].

Gender was not found to influence %EWL (p = 0.266); this is debated in literature however with studies publishing conflicting reports [25, 29]. However, in our model this was not found to be significant.

Sleep apnea was not found to influence %EWL (p = 0.491). Previous literature has never shown sleep apnea to be a factor in weight loss; however, some studies have shown it to affect complication rates in RYGB [30, 31].

Another fault with this study is the low follow-up rate. While it is true that we only achieved 36% follow-up at 1 year, our sample group is statistically the same to our general VSG patient population. J. Hunter Mehaffey et al. did a study on the continued follow-up versus lost to follow-up patients in 10 years following the gastric bypass. They compared 151 patients who continued to follow up vs 500 found patients who they contacted. They found that these patients who had been lost to follow-up were statistically similar in terms of preoperative characteristics and that they had lost almost identical weight following the procedure at each time point during the 10 years of follow-up [32]. Goldenshluger et al. also found that mid-term weight loss (less than 3 years) was not predictive of adherence to postoperative follow-up [33]. For these reasons, we believe that it is due to the large sample size and the patients who actually followed up being statistically similar in terms of all demographic data that they are representative of the overall population.

Our model will have to be tested at other centers to know if the model is transferable. We postulate that bougie size, starting point from pylorus and distance from angle, postoperative care standards, and many other general variables can affect weight loss. These factors cannot be tested for in a single center due to our standard of care. Despite these shortcomings, we believe that this model is generally applicable to other centers despite these missing variables [11, 34].

Conclusion

The sleeve gastrectomy is a powerful tool when used with the right patient. Our model allows surgeons to accurately predict how much weight each individual patient is likely to lose with VSG. This model allows surgeons to recommend procedures that are more aligned with a patient's weight loss goals.

Compliance with Ethical Standards

Conflict of Interest Author one has no conflicts of interest to declare. Author two, the corresponding author, reports personal fees from Medtronic, outside the submitted work.

Author three has no conflict of interest to declare.

Author four has no conflicts of interest to declare.

Author five has no conflicts of interest to declare.

Author six has no conflicts of interest to declare.

Statement of Human and Animal Rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Since this is a retrospective study, formal consent is not required.

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