**REVIEW ARTICLE** 





# Sleeve Gastrectomy Weight Loss and the Preoperative and Postoperative Predictors: a Systematic Review

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#### Abstract

The sleeve gastrectomy (SG) is the most popular weight loss procedure in the USA. Despite its popularity, little is definitively known about the variables that correlate with weight loss. We performed a literature search to find studies that reported variables that correlated with weight loss following SG. Forty-eight articles were identified and included. These articles covered 36 different factors predictive of weight loss while only including five predictive models. Only 12.5% of multivariate analyses evaluated sufficiently reported their results. The factors that predict weight loss following SG cannot be concluded due to the inconsistency in reporting and the methodological flaws in analysis. Reporting factors that predict weight loss should be standardized, and methods should be changed to allow physicians to use the data presented.

Keywords Sleeve gastrectomy · Predictive modeling · Univariate · Multivariate · Multilinear regression · Weight loss

# Introduction

Bariatric surgery is rapidly gaining popularity across the USA and across the world. Despite this, there is a relative paucity of data showing what correlates with success and failure after surgery. This work has been previously done for Roux-en-Y gastric bypass but not for SG [1]. Personalized weight loss predictions are of utmost importance for bariatric surgeons due to the large unexplained variances observed in published studies. Weight loss outcomes, the primary outcome for most patients undergoing bariatric surgery, and weight loss predictions have the power to help surgeons educate the patients about procedures best suited for them or make better care plans for the specific patient. This can increase patient

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<sup>1</sup> Bariatric Medicine Institute, 1046 East 100 South, Salt Lake City, UT 84102, USA satisfaction following bariatric surgery and decrease revisional patients and non-responders.

## Methods

Articles were identified by searching PubMed, MEDLINE, and the Cochrane Library using the search query "Sleeve gastrectomy" AND (model OR influence OR mapping OR prediction OR predictive OR predicts OR predictor OR predict OR predictors) for PubMed and similar queries for MEDLINE and the Cochrane Library. Additionally, the references of each article were reviewed for inclusion.

Papers were identified for review by title and abstract. Articles underwent full-text review if they were done on human subjects and referenced, in the abstract, the effect of any variable on weight loss. After full-text review, studies were included if they presented factors that affected weight loss at or greater than 6 months. Studies with more than one bariatric surgery included in the analysis were included if independent statistical analysis was performed for each surgery or if at least 50% of subjects underwent SG.

Each study was independently reviewed twice to collect important information like authors, number of subjects, statistical test performed, significant variables, non-significant variables, and if presented a model to predict weight loss. Each study was also classified as univariate or multivariate depending on which statistical tests were performed and adequately reported. If both univariate and multivariate methods are reported, the significant factors are reported from the multivariate analysis.

## Results

Overall, 1487 studies were identified in our initial search. We eliminated 1373 articles because they did not meet our inclusion criteria, leaving 114 for full-text review. Additionally, from the references of these 114 studies, 6 studies were identified as meeting the criteria for full-text review.

Of the 120 papers that met criteria for full-text review, 72 were excluded because they did not meet inclusion criteria leaving 48 studies for this review. In these studies, eight different statistical methods of identifying variables that affected or were correlated with weight loss were used. Of all studies reviewed, only five presented a model (two multivariate and three univariate) with two other studies presenting only a graphical explanation of their model without any numerical representation and six others presenting an incomplete model for predicting weight loss. Of 14 studies that reported results of a multilinear regression, only two reported the entire mathematical model with coefficients and variables.

There were 16 studies that used multivariate models to find variables that affect weight loss and 32 that used univariate methods to find variables that affect weight loss. Details of all 48 studies can be found in Table 1. From the 48 studies included in this review, 36 different variables were found to correlate with weight loss. All 36 variables and the studies that found them to be significant and non-significant can be found in Table 2. The majority of these variables [45] were analyzed in five or fewer analysis. There were also numerous other variables that were not found to affect weight loss as seen in Table 1. Of the 16 multivariate analyses, only 2 fully reported their finding in a way that they could be verified by other researchers.

Of the variables that affect weight loss age, BMI, bougie size, DM, gender, HTN, short-term postoperative weight loss, preop weight loss, and sleep apnea (SA) were the only variables studied in more than five studies. Of these nine variables, only six were studied over five times in a multivariate analysis. All variables found to be significant in multivariate studies, and the studies that found them to be significant and non-significant can be found in Table 3.

BMI was found to be a negative predictor of weight loss. Seventeen studies investigated BMI as a predictor of weight loss. Twelve of these studies used multivariate analysis to determine the effect of BMI on weight loss. Many methods were reported including the  $\beta$  coefficient from the regression analysis, the odds ratio of failing for every point BMI gained,

and viewing BMI as a categorical variable in a regression analysis.

Of the 12 multivariate studies that found BMI to be a significant predictor, 9 found it to be a negative predictor and 2 found it to be a positive predictor. In one of the two studies that BMI was a positive predictor, the model predicted BMI reduction instead of EWL% [23]. When predicting EWL%, the higher the BMI of the patient, the more weight they have to lose to achieve the same EWL%, and often even though larger patients are predicted to lose less EWL%, they often lose more weight.

Cottam et al. reported two models in their paper where they modeled both EWL% and BMI reduction on the same population and BMI was a strong negative predictor for EWL% and a strong positive predictor for BMI reduction [49]. The only other study where BMI was positively associated with weight had a sample size of seven sleeve patients and so is likely due to random error [3]. There was also one study that found that baseline BMI was not predictive of weight loss [27]. However, in this study, the authors included postoperative weight loss which was far more predictive of weight loss than baseline BMI, and so, BMI, while important, did not achieve statistical significance.

Bougie size was studied in 8 of the 49 papers with 3 papers finding that it did affect weight loss and 5 finding that it did not affect weight loss. The range of bougie size was fairly large (32–60) across the studies, and each study compared different sizes. In the three studies that found bougie size to be significant, the bougie size comparisons were 32 to 40, < 36 to > 44, and 32–36 to 38–60, and in the five that found it to not affect weight loss, the bougie comparisons were 32 to 36, 33 to 42, 32 to 42, 40 to 60, and 32 to 44 [7, 11, 18, 24–26, 40, 47].

However, these studies that found bougie size to be significant were somewhat misleading. Hady et al. compared bougie sizes 32 and 40 [7]. The initial BMI of the two groups was significantly different at the 0.001 level. Patients in the bougie size of 40 groups started with the mean BMI 5.46 points higher, and at 6 months, the patients with a bougie size of 40 have a mean BMI that is 5.05 higher. This shows that those in the larger bougie size group had a greater BMI reduction; however, since only %EWL, proportional measure, is reported, they appear to lose less weight even though they had a greater BMI reduction.

Discounting this study due to fault in their conclusion, there are two studies that found bougie size to be significant. However, Ellatif et al. only found bougie size to be significant 4 years after surgery. At every follow-up point before 4 years, it was non-significant. At 1 year, the p value was 0.3 [26]. So, during the typical postoperative weight loss period, only one study found bougie size to be significant and the difference was from 32 to 36, and 38–60. They did not report on how many patients received each specific bougie size [40].

## Table 1 All 48 studies and collected information

Ref. no.	Number	Туре	Follow-up time	Success	Significant variables	Non-significant variables	Was a model presented
[2]	308	Uni	2 years	NA	Age	NA	NA
[3]	7	Multi	1 year	%EWL > 50%	BMI (+), surgery (RYGB vs SG), caloric intake capacity (-)	Anxiety, depression, eat, reduction in intake capacity, gender, age, height, weight	NA
[4] [5]	228 713	Multi Uni	1 year 18 months	NA NA	Age (-), HTN (?) DM, employment status	Surgery, DM, DL Gender, race, SA, insurance status	NA NA
[6]	64	Uni	1 year	NA	Years of education, psychotherapy, active coping	Age, gender, marital status, employment status, DM, depression, eating disorders, stress, anxiety, other coping styles, motivation to lose weight	NA
[7] [8]	120 152	Uni Multi	6 months 1 year	NA NA	Bougie size BMI (-), age (-)	NA Gender, HTN, DM, DL, OSA	NA BMI = $-3.597 + 0.621 \times$ presurgery
							BMI + $0.135 \times age$
[9]	141	Uni	l year	NA	NA	Preop weight loss	NA
[10]	1309	Uni	6 months	NA	NA	Previous abdominal surgery	NA
	131	Uni	l year	NA NH cí 20cí	NA	Bougie size	NA
[12]	538	Multi	WL < 2 years	WL%>20%	3–6 months (+), BMI (-), age (-), ethnicity (?), center	Gender, DM	Partial model
[13]	272	Uni	1 year	%EWL>50%	Weight loss at 1 month, weight loss at 3 months	NA	%EWL > 35% at 3 months predicts success
[14]	190	Multi	1 year	%EWL>50%	Age (-), BMI (-), 1 month %EWL (+)	Gender, DM	%EWL > 15.7% at 1 month predicts success, partial model
[15]	106	Multi	6 months	%EWL>40%	Emotional food cravings after surgery (-)	Intentions, lack of control, positive reinforcement, negative reinforcement, thoughts, guilt, cues, hunger	NA
[ <mark>16</mark> ]	242	Uni	2 years	%EWL>50%	Excess BMI loss at 3 months	NA	%EWL>20.1% predicts success
[17]	162	Uni	5 years	NA	Gender	NA	NA
[18]	36	Uni	1 year	NA	None	Bougie size, antrum size	NA
[ <mark>19</mark> ]	133	Uni	3 months-3 years	NA	Postoperative eating pattern	Preoperative eating pattern	NA
[20]	287	Uni	1 year	%EWL > 50%	BMI	Resected gastric volume, gender	NA
[21]	203	Uni	1 year	NA	NA	Retained fundus	NA
[22]	55	Multi	6 months	%EWL>50%	BMI (-)	DM, ASA score, age, gender, number of comorbidities, HTN, OSA, HL	Graph
[23]	204	Multi	1 year	NA	Preoperative weight loss (+), age (-), BMI group (+), DM (-), arthritis (+), follow-up time (3, 6, 12 months)	Gender, OSA, HTN, HL, GERD, depression, work	Partial model
[24]	120	Uni	1 year	NA	NA	Bougie size (32–42)	NA
[25]	120	Uni	2 years	NA	NA	Bougie size (44–32)	NA
[26]	1419	Multi	4 years	%EWL > 50%	Bougie size (-)	Distance from the pylorus	NA
[27]	1169	Multi	1 year	%EWL>55%	%EWL 1–3 months (+), DM (-), SA (-)	Age, gender, hypertension, GERD, BMI, bougie size	Graph
[28]	118	Multi	6 months	%EWL>50%	Childhood obesity (-), university education (+)	Age, gender, family history, marital status, smoking, income	NA
[ <mark>29</mark> ]	20	Uni	1 year	NA	Baseline Nacc brain activity	Other brain activity	NA
[30]	201	Multi	3 years	NA	BMI (-), age (-), number of medications (-), physical activity (+)	NA	NA

#### Table 1 (continued)

Ref. no.	Number	Туре	Follow-up time	Success	Significant variables	Non-significant variables	Was a model presented
[31] [32]	99 127	Uni Uni	3 years 1 year	NA NA	Stomach transit time Preoperative weight loss, %EWL at 4 months	NA Preoperative diet weight loss, BMI	NA NA
[33]	292	Multi	2 years	NA	BMI (-), HTN (-), total clinic visits in 2 years (+)	Gender, baseline weight, presurgery weight loss, DM, SA. age	Partial model
[34]	160	Multi	2 years	NA	Gender (W-), BMI (-), smoking (+)	Age, relationship status, education years, employment, waiting time, mental disorder, musculoskeletal pain, preoperative weight loss	Partial model
[35]	100	Uni	7 months (average)	NA	Preoperative 6-min walking distance change	Preoperative to postoperative 6-min walking distance change	NA
[36]	247	Uni	1 year	NA	Preoperative weight loss	NA	NA
[37]	71	Uni	1 year	NA	Anger/frustration eating	Anxiety, depression, food addiction	NA
[38]	53	Uni	1 year	%EWL>50%	BMI, resected gastric volume/BMI/weigh- t)	Age, gender, weight, height, WC, resected gastric volume	NA
[ <mark>39</mark> ]	45	Uni	1 year	NA	Gastric reservoir volume	NA	NA
[40]	540	Uni	2 years	NA	BMI, age, distance of first staple line to pylorus, bougie caliber	NA	NA
[41]	157	Uni	1 vear	%EWL > 50%	NA	Sweet eating	NA
[42]	64	Uni	1 year	NA	Family also having surgery	NA	NA
[43]	65	Uni	4 years	NA	EDI-2 score	BIS-15, PHQ-9	NA
[44]	64	Uni	1 year	NA	Resected gastric weight (+)	NA	NA
[45]	90	Multi	1 year	NA	BMI (-), gender (W-), volume resected stomach (+)	Age, DM, HTN, HL	Partial model
[46]	178	Uni	1 year	NA	BMI, 6-month excess BMI lost%	Food addiction	NA
[47]	135	Uni	1 year	NA	NA	Bougie size	NA
[48]	125	Uni	2 years	NA	Antrum size	NA	NA
[49]	1026	Multi	1 year	NA	DM (-), HTN (-), DM with HTN (-), age (-), BMI (-)	SA, GERD, gender, weight, height, BMI <sup>2</sup> , BMI × age, age <sup>2</sup> , HTN with DM, HTN with GERD, HTN with SA, GERD with DM, GERD with SA, SA with DM	%EWL at 1 year = 140.9 - (0.731 × DM) - (1.53 × HTN) - (0.304 × Age) - (1.22 × BMI) - (12.5 × HTN and DM)

Age was studied in 18 different papers. Of these 18 papers, 14 used multivariate analysis to look at the impact of age on weight loss. Of these 14, there was an even split with 7 finding age to affect weight loss and 7 finding that it does not affect weight loss. The studies that did find that age affects weight loss were consistent in reporting age as a negative predictor.

Diabetes was studied in 12 different papers, 10 of which used a form of multivariate analysis. It was found to be a negative predictor in the three multivariate analysis where it was significant and it was not found to be significant in 7 multivariate analysis.

Gender was studied in 16 different papers, 12 of which used a form of multivariate analysis. It was found to be predictive twice out of the 12 studies, and in both of the studies, female gender was found to be predictive of lower weight loss.

Hypertension was studied in eight different papers, all of which were multivariate analysis. It was found to be predictive three times out of the eight studies and in the two studies which reported whether it was a positive or negative predictor;

Table 2 All 36 variables found to be significant in univariate and multivariate analysis and which studies found them to be significant

Variable	Significant	Total	Not significant	Total
Number of medications	14	1		0
Active coping	21	1		0
Age	2, 3, 8, 14, 15, 17, 18, 19, 20	9	4, 5, 21, 22, 23, 24, 25, 26, 27	9
Anger/frustration eating	37	1		0
Antrum size	38	1		0
Arthritis	2	1		0
Baseline Nacc brain activity	39	1		0
BMI	2, 3, 4, 8, 14, 15, 19, 20, 22, 24, 25, 26, 27, 28, 31	15	5, 29	2
Bougie size	6, 7, 8	3	9, 10, 11, 12	4
Caloric intake capacity	4	1		0
Center	19	1		0
Childhood obesity	23	1		0
Distance of first staple from pylorus	8	1	7	1
DM	2, 3, 5, 30	4	15, 18, 19, 20, 21, 22, 24, 31	8
EDI-2 score	40	1		0
Education	21, 23	2	25	1
Emotional food cravings (after surgery)	41	1		0
Employment status	30	1	21, 25	2
Ethnicity	19	1	30	1
Family member also having bariatric surgery	42	1		0
Gastric reservoir volume	43	1		0
Gender	25, 27, 32	3	3, 4, 5, 15, 19, 20, 21, 22, 23, 24, 26, 28, 30	13
HTN	3, 18, 24	3	2, 5, 15, 22, 27	5
Physical activity	14	1		0
Postoperative weight loss	5, 19, 20, 29, 31, 33, 34	7		0
Postoperative eating pattern	44	1		0
Preoperative weight loss	2, 29, 35	3	24, 25, 29, 36	4
Preoperative 6-min walking distance change	45	1		0
Psychotherapy	21	1		0
Resected gastric weight	46	1		0
RGV	26	1	26, 28	2
SA	5	1	3, 15, 22, 24, 30	5
Smoking	25	1	23	1
Stomach transit time	47	1		0
Total clinic visits in first 2 postoperative years	24	1		0
Volume resected stomach	27	1		0

it was a negative predictor. The other study never specified the effect (positive or negative) of HTN on weight loss.

Preoperative weight loss was studied in seven different papers, three of which were multivariate analysis. It was found to be predictive only once out of the three multivariate studies. It was found to be a positive predictor of weight loss in that study. However, in the other two univariate analysis that found it to significantly affect weight loss, it was found to be a positive predictor in one and a negative predictor in the other. Short-term postoperative weight loss was studied in seven different papers, three of which were multivariate analysis. In all seven studies, it was found to be predictive of weight loss following surgery. The correlation was found as early as 1 month, but the exact best time following surgery varied from paper to paper.

SA was studied in six different papers, all of which were multivariate analysis. It was found to be predictive only once and was a negative predictor. However, all other times, SA

Variable	Significant (positive or negative predictor)	Total	Not significant	Total
Number of medications	14 (-)	1 (-)		0
Age	2 (-), 3 (-), 14 (-), 15 (-), 18 (-), 19 (-), 20 (-)	7 (-)	4, 5, 22, 23, 24, 25, 27	7
Arthritis	2 (+)	1 (+)		0
BMI	2 (+BMIR), 3 (-), 4 (+), 14 (-), 15 (-), 19 (-), 20 (-), 22 (-), 24 (-), 25 (-), 27 (-)	9 (-), 2 (+)	5	1
Bougie size	7 (-)	1 (-)		0
Caloric intake capacity	4 (-)	1 (-)		0
Childhood obesity	23 (-)	1 (-)		0
Diabetes	2 (-), 3 (-), 5 (-)	3 (-)	15, 16, 17, 18, 22, 24, 27	7
Education	23 (+)	1 (+)	25	1
Emotional food cravings	41 (-)	1 (-)		0
Ethnicity	19 (?)	1 (?)		0
Gender	25 (F-), 27 (F-)	2 (F-)	2, 3, 4, 5, 15, 19, 20, 22, 23, 24	10
Hypertension	3 (-), 18 (?), 24 (-)	2 (-), 1 (?)	2, 5, 15, 22, 27	5
Physical activity	14 (+)	1 (+)		0
Postoperative weight loss	5 (+), 19 (+), 20 (+)	3 (+)		0
Preoperative weight loss	2 (+)	1 (+)	24, 25	2
Sleep apnea	5 (-)	1 ()	2, 3, 15, 22, 24	5
Smoking	25 (+)	1 (+)	23	1
Total clinic visits in 2 years	24 (+)	1 (+)		0
Volume resected stomach	27 (+)	1 (+)		0

Table 3 All variables found to be significant in multivariate analysis and which studies found them to be significant

was not found to be a predictor of weight loss. A more detailed explanation of why SA is unlikely to be truly predictive of weight loss can be found in Supplementary Materials File 2.

## Discussion

While bariatric surgery is not a new field and the sleeve gastrectomy is a well-established procedure within the specialty, there is little known about why patients fail to achieve adequate weight loss after the surgery. Predictive modeling can help to mediate this problem by finding correlation between variables and future weight loss. Alarmingly, only two papers give us enough information to replicate their studies.

This foreknowledge gained through predictive modeling can help doctors immensely as once these problem patients are identified, doctors can start a more targeted approach and warn the patient of the risks of inadequate weight loss. There are two general times to make predictions: the first is presurgery based on the patient's baseline demographics, and the other is in the short term following the procedure based on the patient's weight loss curve and the patient's demographics.

Preoperative predictions regarding the SG are particularly useful since the SG has been shown on average to be a less effective procedure in terms of weight loss when compared to the Roux-en-Y gastric bypass or the duodenal switch. This information is also of use if the surgeon or patient still feels that the SG is the right procedure for them. If they know that the patient has a high likelihood of not completing their goals, they can make a more targeted care plan for the patient. This could include many things such as more follow-up visits, more recommended exercise, phone calls to check up on them, and their nutrition. If a patient and surgeon know before the surgery how much weight the patient is expected to lose, they can consider other surgeries or make a more targeted approach to follow up care so that the patient can succeed.

Postoperative predictions are somewhat less useful as a patient has already undergone the procedure and so cannot choose to start with a more invasive procedure, or with a more targeted care plan. However, they allow surgeons to identify non-responders early in the postoperative treatment and change the individual treatment to better suit the patient. This information can help the surgeon make a targeted care program for the patient still within the typical weight loss window of about the first year.

There are many different ways to predict weight loss following the SG. In simple terms, these tests can be broken into two categories: univariate and multivariate analysis. Univariate analysis like *t* tests are easily understood and easily misinterpreted. These types of tests very often look promising but are subject to underlying causes and differences in group demographics. Multivariate analysis on the other hand can be somewhat harder to interpret; however, they consider all variables at once which allows the effect of group demographic differences to be mitigated as long as the confounding variable is measured and entered into the model. Multivariate analyses also allow for interacting variables to be more fully studied.

While neither univariate or multivariate analysis will prove causation in SG weight loss prediction, multivariate analysis offers the tools to make prediction models which account for many measurable variables.

These prediction models while not based upon a causational relationship can be very useful in a bariatric center. Patients should be informed before surgery of a personalized weight loss expectation for each procedure that they consider. This will help them choose a procedure appropriate to them when balanced with complication rates or choose a more targeted care plan to help them succeed with the SG. Also, in the early postoperative period, these models can help surgeons identify patients who will not meet their weight loss goals and try preventative measures to help their patients succeed.

Overall, these studies add to the understanding about what variables may correlate with weight loss following the sleeve gastrectomy. There are many variables that are hard to judge if they truly correlate with weight loss because of reporting practice and statistical methods. To rectify this, we recommend a change in how variables are reported so that in future studies, this effect can be measured more accurately.

In some multivariate studies, such as the one reported by Goldenshluger et al., the results are reported as the variables that affect weight loss and an associated p value [30]. This, while useful, fails to tell the reader the true impact of the results. The real question that needs to be answered is to what extent does that variable affect weight loss and in which direction, positive or negative. Also, in six studies, a multilinear regression is reported with all of the variables and beta coefficients; however, they do not report the constant. Without this, the model cannot be validated by other researchers and the entirety of their results is ineffective in a clinical setting.

We recommend reporting the entire model as did Cottam et al. and Goulart et al. so that surgeons can apply these findings in their own practices to improve bariatric care [8, 49]. These studies reported their entire models in the form %EWL =  $c + B_1V_1 + B_2V_2 + ... + B_iV_i$  where c is a constant from linear regression output, i is the number of significant variables, each V is a different variable labeled 1-I, and each Bis the beta coefficient associated with that variable. Another way which would also be equally acceptable is to present the model in a table. An example of an acceptable table can be found in Supplementary Materials File 1. That value c in the equation above is not multiplied by any variable but is necessary for the model to be validated by others.

We also recommend a decrease in the amount of studies which make their final conclusion based upon univariate comparisons. While there are numerous reasons to make univariate comparisons, which are valid and sometimes necessary in bariatric surgery, chopping up the population into subsets over and over again reduces the ability to make accurate conclusions due to the increased likelihood of a type 1 error [50]. If five tests are performed, then there is a 22% chance that incorrectly reports a difference. If you run eight tests, there is a 33% chance that at least one is reported incorrectly reported as significant. A more detailed mathematical explanation can be found in the Supplementary Materials File 2. This high type 1 error rate is why there is need for repeated testing by independent studies to determine the likelihood of a variable affecting weight loss. While this error is present in both univariate and multivariate analysis, univariate comparisons often show differences that are better ascribed to other measured variables where multivariate analysis mitigates this effect.

We also recommend more studies to use interacting variables in their models. It often is true that one variable's effect on the outcome is mediated by another variable. An example of this would be temperature. The temperature outside does affect how hot people feel, but the degree of the response is affected by the humidity. The same thing can happen in weight loss predictions, for example, Cottam et al. found that DM and HTN were interacting variables in predicting weight loss. HTN and DM individually predicted some decrease in weight loss, but together, the effect was greater than the added effects of the individual comorbidities.

## Conclusion

Early postoperative weight loss and baseline BMI are highly correlated with long-term weight loss and should be considered in future weight loss prediction models. All predictive models should be completely reported so that they can be easily validated in other research settings. Current reporting practices are inadequate for continued collaborative research and must change to allow other researcher to use and validate their results.

## **Compliance with Ethical Standards**

**Conflict of Interest** Samuel Cottam has no conflict of interest to declare. Daniel Cottam, the corresponding author, reports personal fees from Medtronic, outside the submitted work. Austin Cottam has no conflict of interest to declare.

**Statement of Human and Animal Rights** This study did not involve performing any procedures. Thus, it was done in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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

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