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# Evaluation of Care Management Intensity and Bariatric Surgical Weight Loss

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E ligibility criteria for bariatric surgery, defined by body mass index (BMI) and weight-related comorbidities, are nationally recognized.<sup>1</sup> However, while pre- and postoperative care management processes are strongly recommended, they are not standardized, and the effect of varying intensities of pre- and postoperative multidisciplinary care processes on outcomes is unclear.

Bariatric surgical guidelines recommend a multidisciplinary team that includes medical, nutritional, and behavioral consultants and a detailed preoperative evaluation.<sup>1,2</sup> Designation as a bariatric surgical "Center of Excellence" requires multidisciplinary staff, pre- and postoperative patient education and counseling, and relevant long-term followup.<sup>3,4</sup> However, recommendations on specific components of pre- and postoperative care management are not well defined and may include support groups, mental healthcare, nutritional support, and medical management of specific comorbidities.<sup>1,5</sup> The lack of specific recommendations is due in part to an absence of evidence on effective components and intensity of care management for bariatric surgical patients.6 One descriptive review of 123 centers of excellence found great variation in staffing and services provided, with notably fewer services during the postoperative period.<sup>7</sup>

Because levels of pre- and postoperative care management intensity (CMI) have different implications for healthcare resources and for patient preferences, there is a need to better define and systematically evaluate the types of care management processes that are associated with successful long-term surgical weight loss. The intensity of nonsurgical weight loss programs has been previously quantified based on the number of sessions, frequency of contacts, length of contacts, use of educational materials, and presence of specific behavioral and ancillary components.<sup>8-10</sup> Based on these assessments originally developed under the auspices of the US Preventive Services Task Force—we sought to determine how different levels of CMI affect long-term weight loss outcomes among bariatric surgery patients.

# ABSTRACT

**Objectives:** To examine the effect of pre- and postoperative care management on weight loss following bariatric surgery. **Study Design:** We conducted a retrospective cohort study supplemented by cross-sectional surveys across 9 bariatric surgery centers.

**Methods:** Based on the intensity of patient contact, care management intensity (CMI) was defined as high, moderate, or low for preoperative programs, and high or low for postoperative programs. Multivariable linear regression assessed 1- and 2-year post operative weight loss as a function of CMI.

**Results:** In the 9 centers, 4433 individuals underwent Roux-en-Y gastric bypass or adjustable gastric band placement between 2005 and 2009. Two sites had low, 5 had moderate, and 2 had high preoperative CMI; 5 sites had low and 4 had high postoperative CMI. In analyses stratified by procedure and adjusted for multiple covariates including site, we found no statistically significant associations between either preoperative or postoperative CMI and post operative change in body mass index at year 1 or year 2. Results were limited by heterogeneity of care management across sites and an inability to assess adherence to care management programs.

**Conclusions:** Prospective investigations that incorporate quantifiable measures of CMI and measure individual adherence to components of care management programs are needed to more accurately determine the effect of care management on weight loss. Additional investigations should examine the effect of CMI on other relevant outcomes, such as nutritional status and quality of life, that may be more directly affected by care management.

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The aim of our investigation was to assess 1- and 2-year weight loss following bariatric surgical procedures as a function of pre- and postoperative CMI across 9 health plans and care delivery systems participating in the "Scalable PArtnering Network" (SPAN), a distributed research network.<sup>11</sup> We hypothesized that high preand postoperative CMI would be associated with the most weight loss, low CMI with the least amount of weight loss, and

moderate intensity programs with intermediate weight loss 1 and 2 years postoperatively.

# **METHODS**

## **Study Setting and Design**

We conducted a retrospective cohort study supplemented by cross-sectional surveys in 9 sites participating in the SPAN Network for comparative effectiveness research (see Acknowledgments). This study was conducted in accordance with the Declaration of Helsinki, and was approved by the Kaiser Permanente Colorado (KPCO) Institutional Review Board (IRB); the requirement for informed consent was waived. Participating sites either ceded IRB oversight to the KPCO IRB or obtained IRB approval from their sites' IRBs.

## **Study Cohort**

We included individuals who met the following criteria: 1) primary bariatric surgical procedure between 2005 and 2009; 2) procedure was a Roux-en-Y gastric bypass (RYGB) or adjustable gastric band (AGB) placement; 3) aged at least 21 years old at the time of surgery; 4) at least 1 preoperative BMI ≥30 kg/m<sup>2</sup> in the year prior to surgery; and 5) 1 year of preoperative and 1 year of postoperative health plan enrollment. We excluded individuals who had a bariatric surgical adjustment, revision, sleeve gastrectomy, or bariatric surgery status code (V45.86) prior to the bariatric surgery procedure. The few sleeve gastrectomy patients were eliminated due to inconsistencies with procedure coding during the cohort period.

# **Data Collection**

We collected site-level care management information through 2 cross-sectional surveys: 1) an open-ended survey covering eligibility criteria for surgery, surgical procedures performed, preoperative surgical programs, patient education curricula, weight management counseling, postoperative programs, and program variation; and 2) a

#### **Take-Away Points**

This retrospective cohort study examined the effect of preoperative and postoperative care management intensity on weight loss outcomes 1 and 2 years after bariatric surgery.

- There is substantial variation in care management intensity across practices.
- Care management intensity did not affect weight loss in 4433 individuals who underwent Roux-en-Y gastric bypass and adjustable gastric band placement.

• Care management intensity is a multidimensional process that is difficult to quantify.

Prospective studies are needed to assess the effect of bariatric surgical care management on outcomes other than weight change.

close-ended survey covering duration, type, and frequency of pre- and postoperative counseling, including weight management and other medical visits with clinicians; behavioral, dietary, and physical activity counseling; and mental health evaluations. Both surveys covered the time period from 2004 to 2010.

Individual-level data were extracted from site-specific obesity data marts with standardized data structures populated by data from electronic medical records at each site.

#### **Determination of Program Intensities**

We used a modified Delphi method to assign intensity ratings to preoperative and postoperative care management processes at each site. Based on published criteria that quantify CMI for nonsurgical weight-loss programs, we based assessments of site-level CMI on frequency, duration, and overall components of care management.<sup>10</sup> We also considered length of preoperative and postoperative program enrollment, number and type of participating clinical staff, educational curricula and materials, requirements for preoperative participation, number and frequency of counseling sessions (covering issues related to weight management, surgery, medical visits, behavior, diet, physical activity, and mental health), and postoperative tasks for weight management and for surgical care. Two independent reviewers (SP and WTD) scored each of the sites as low, moderate, or high preoperative CMI. Due to less variability across sites, postoperative CMI was dichotomized into low and high. If there was no consensus, a third reviewer (EB) scored the site, and the overall rating was determined by agreement between at least 2 of the 3 reviewers.

#### **Data Analysis**

All statistical analyses were performed utilizing SAS version 9.2 software (SAS, Cary, North Carolina). The independent variables of interest were level of preoperative CMI and level of postoperative CMI. We used the

Program Intensity Ratings		Surgeries Performed, N (%)				
Preoperative	Postoperative	RYGB	AGB	Total		
Highª	High <sup>a</sup>	626 (89.3)	75 (10.7)	701		
Moderate	High	897 (87.3)	131 (12.7)	1028		
Moderate	Low	1275 (68.6)	583 (31.4)	1858		
Low <sup>b</sup>	Low <sup>b</sup>	728 (86.1)	118 (13.9)	846		
All		3526 (79.5)	907 (20.5)	4433		
ACR indicates adjustable gastric band: RVCR. Boux on V gastric bypass						

**Table 1.** Surgical Procedures by Pre- and Postoperative Intensity Ratings

<sup>a</sup>Sites with high preoperative intensity ratings also had high postoperative ratings.

<sup>b</sup>Sites with low preoperative intensity ratings also had low postoperative ratings.

bariatric procedure date as the index date in defining the pre- and postoperative time periods. The primary dependent variable of interest was the change in BMI at 1 and 2 years post bariatric procedure as separate functions of pre- and postoperative CMI. We calculated the change in BMI as the difference between the BMI closest to the surgery in the preoperative period and the furthest measured BMI 1 year and 2 years postoperatively.

Baseline characteristics were reported as means, medians, and standard deviations for continuous variables, and proportions for nominal- and ordinal-level data. We assessed the differences in means for continuous variables using t tests and Wilcoxen rank-sum tests, and differences in proportions for categorical variables using 2 tests of association. We used 2 separate linear mixed effects regression models with sites as a random effect to analyze the change in BMI as a function of pre- and postoperative CMI at years 1 and 2; we also ran the same models stratified by bariatric procedure. The demographic characteristics, insurance type, year of procedure, comorbidity history variables, and Charlson Comorbidity Index scores were entered as covariates.<sup>12,13</sup>

# RESULTS

A total of 13,821 individuals across the 9 sites underwent bariatric surgery between 2005 and 2009. After inclusion and exclusion criteria were applied, the final cohort was composed of 4433 individuals. There were 2 primary reasons for exclusion from the final cohort: 1) receipt of care in nonintegrated settings, which affected 70% of enrollees at 1 site and 88% of enrollees at a second site and prevented capture of BMI data from electronic medical records; and 2) insufficient preoperative enrollment across sites preventing capture of temporally comparable baseline BMI data. Relative to eligible cohort members, the 5717 individuals excluded for these 2 reasons were slightly more likely to undergo AGB (25% vs 20%) than

RYGB (71% vs 77%), were less likely to be female (77% vs 80%), were younger (aged 44.7 years vs 47.4 years), had slightly lower rates of diabetes (33% vs 37%) and hypertension (60% vs 64%), and were more likely to have commercial insurance (93% vs 73%).

Clinicians with knowledge of bariatric surgical programs at all sites responded to both surveys. Preoperative CMI was rated as low for 2 sites, moderate for 5 sites, and high for 2 sites. Postoperative CMI was rated as low for 5 sites and high for 4 sites. Program ratings and bariatric surgical procedures performed at each site are presented in Table 1. Table 2 describes the spectrum of pre- and postoperative care management components within each category of program intensity. Although there was substantial heterogeneity of CMI across sites, in general, sites with higher preoperative CMI engaged patients in higher frequency and more multidimensional interactions over a longer time period than those with moderate CMI. A similar pattern was observed for those with moderate to low CMI. All sites incorporated behavioral, dietary, and mental health counseling into preoperative care management, and all but 1 included physical activity counseling. Likewise, sites rated as having higher intensity postoperative care management in general had a longer duration of follow-up and more frequent and more varied interactions with patients than sites with lower intensity postoperative care management.

Cohort characteristics by preoperative program intensity are presented in Table 3. Individuals in moderate intensity programs were less likely to have commercial health insurance (65% moderate vs 83% high and 90% low), had a lower modified Charlson Comorbidity Index score, and had a marginally higher preoperative BMI (46.6 kg/m<sup>2</sup> moderate vs 45.8 kg/m<sup>2</sup> high and 45.7  $kg/m^2 low$ ).

The mean (95% CI) unadjusted decrease in BMI for the overall cohort was 12.7 (12.5-12.9) kg/m<sup>2</sup> at year 1 and

# **Table 2.** Pre- and Postoperative Care Management Intensity Components

# PREOPERATIVE CARE MANAGEMENT INTENSITY

Intensity	Enroll- ment Length (months)	No. of Clinicians (besides surgeon)	Education	Participation Requirements	Weight Manage- ment Counseling Required	Months of Operative Counseling	Clinician Visit Frequency	BC	Diet	PA	МН
High	6 to 12	3 to 7	Support groups, physical activity sessions, visits with primary care provider, educational courses, mul- tiple nutrition classes, multiple behavioral class- es, orientation program, book and binder	Demonstration of failed weight loss, evaluation process, support group sessions, patient education classes, orienta- tion, information packet, maintain or decrease orienta- tion weight	Yes	5 to 10	At least once per month	Yes	Yes	Yes	Yes
Moderate	2 to 12	3 to 4	Orientation class, weight management program support groups, behavioral and dietary education	Weight manage- ment program, orientation, demonstrated 5% body weight loss, support group visits, physical activity practice, attend classes, patient-reported motivation, medical and behavioral evaluations	Variable	3 to 12	Less than once per month to greater than once per month	Yes	Yes	V	Yes
Low	2 to 6	4 to 5	Weight program, information from dietician, support group, NIH literature	Demonstration of failed weight loss, attend dietician education seminar, phone counseling sessions, contract to meet with dieti- cian and behavioral health providers postoperatively	Variable	1 to 4	Less than once a month to once a month	Yes	Yes	Yes	Yes

#### **POSTOPERATIVE CARE MANAGEMENT INTENSITY** Weight Frequency Months of Frequency Manage-Months of of Regular of ment Follow-up Follow-up Operative Postop-Medical Clinician Visits Intensity Tasks Length Counseling erative Visits MH Length BC Diet PA Counseling High 6 to 24 Regular sup-2 years to 1 to 12 Less than Greater Less than Yes Yes Yes Yes than 12 months port group lifelong once a month once a sessions, to greater months month regular than once a physical activmonth ity sessions, postoperative interview, evaluate dietary adherence Low No Variable No require-1 to 12+ 5 to 12+ Less than V V V V Less than once a requirenutrition and ment once a month months to 1 year month to ment physical to once a activity month once a counseling month

BC indicates behavioral counseling; Diet, dietary counseling; MH, mental health evaluation; NIH, National Institutes of Health; PA, physical activity counseling; V, variable.

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# **Table 3.** Cohort Characteristics by Preoperative Program Intensity

	Program Intensity Rating			
Characteristic	High (n = 701)	Moderate (n = 2886)	Low (n = 846)	Total (n = 4433)
Age (years): mean (SD)ª	46.8 (10.9)	47.8 (10.9)	45.7 (10.6)	47.2 (10.9)
Female (n, %)	570 (81.3)	2325 (80.5)	682 (80.6)	3577 (80.7)
Race (n, %) <sup>a</sup>				
Caucasian	462 (65.9)	2105 (72.9)	604 (71.4)	3171 (71.5)
Black/African American	12 (1.7)	129 (4.5)	191 (22.6)	332 (7.5)
Hispanic/Latino	28 (4.0)	168 (5.8)	6 (0.7)	202 (4.6)
Other	195 (27.8)	70 (2.4)	8 (1.0)	273 (6.2)
Not available	4 (0.6)	414 (14.4)	37 (4.4)	455 (10.3)
BMI (kg/m²) <sup>a,b</sup>	45.8 (7.1)	46.6 (6.9)	45.7 (6.9)	46.3 (7.0)
Smoking (n, %)ª				
Ever	343 (48.9)	1176 (40.8)	384 (45.4)	1903 (42.9)
Never	333 (47.5)	1189 (41.2)	407 (48.1)	1929 (43.5)
Not available	25 (3.6)	521 (18.1)	55 (6.5)	601 (13.6)
Modified Charlson Comorbidity Index score (n, %)^a				
0	174 (24.8)	1122 (38.9)	341 (40.3)	1637 (36.9)
1	232 (33.1)	870 (30.2)	274 (32.4)	1376 (31.0)
2	167 (23.8)	523 (18.1)	123 (14.5)	813 (18.3)
3 or more	128 (18.3)	371 (12.8)	108 (12.8)	604 (13.8)
Comorbidities (n, %)				
Diabetes	286 (40.8)	1075 (37.3)	288 (34.1)	1649 (37.3)
Hypertension	466 (66.5)	1828 (63.7)	507 (59.9)	2811 (63.4)
GERD <sup>a</sup>	230 (32.8)	1185 (41.1)	378 (44.7)	1793 (40.5)
OSAª	288 (41.1)	1442 (50.0)	423 (50.0)	2153 (48.6)
Health Insurance Type (n, %) <sup>a</sup>				
Medicaid	19 (2.7)	1 (0.0)	19 (2.3)	39 (0.9)
Medicare	56 (8.0)	249 (8.6)	27 (3.2)	332 (7.5)
Commercial	586 (83.4)	1865 (64.6)	766 (90.5)	3217 (72.6)
Other	40 (5.7)	771 (26.7)	34 (4.0)	845 (19.1)
Median Family Income <sup>a,c</sup>	\$49,097	\$56,534	\$59,993	\$56,172

BMI indicates body mass index; GERD, gastroesophageal reflux disease; OSA, obstructive sleep apnea.

<sup>a</sup>Significant at P <.0001.

<sup>b</sup>BMI preoperatively closest to surgery.

<sup>c</sup>Derived from census data.

13.9 (13.7-14.0) kg/m<sup>2</sup> at year 2. Mean decrease in unadjusted BMI ranged from 14.2 (14.1-14.4) kg/m<sup>2</sup> for bypass patients to 6.7 (6.4-7.0) kg/m<sup>2</sup> for band patients at year 1, and 15.6 (15.4-15.8) kg/m<sup>2</sup> to 7.6 (7.2-7.9) kg/m<sup>2</sup> for bypass and band patients, respectively, at year 2. Table 4 presents adjusted associations between preoperative CMI and change in BMI for the whole cohort and stratified by bariatric procedure. We found no statistically signifi-

cant change in BMI across CMI categories either for the overall cohort or when stratified by procedure. Sensitivity analyses, in which we re-categorized preoperative moderate intensity programs into high or low intensity, did not change the postoperative BMI results. Likewise, we found no significant associations between postoperative CMI and change in BMI either for the overall cohort or stratified by procedure (**Table 5**).

**Table 4.** Associations of Preoperative Program Intensity Ratings on Change in Body Mass Index Stratified by Procedure

		Mean Change in Body Mass Index (kg/m <sup>2</sup> )		
		Gastric Bypass	Gastric Band	
Care Management Intensity <sup>a</sup>	Total Adjusted <sup>a,b</sup>	Adjusted <sup>a,b</sup>	Adjusted <sup>a,b</sup>	
Year 1	(n = 4310)	(n = 3436 )	(n = 874)	
High	-12.7 (-14.7 to -10.6)	-13.9 (-15.4 to -12.5)	-5.2 (-7.3 to -3.1)	
Moderate	-11.9 (-13.3 to -10.6)	-13.8 (-14.7 to -12.8)	-6.7 (-8.0 to -5.3)	
Low	-12.3 (-14.4 to -10.2)	-13.5 (-15.0 to -12.1)	-5.8 (-7.8 to -3.9)	
P°	.8825	.9254	.3454	
Year 2	(n = 3846)	(n = 3055)	(n = 791)	
High	-13.5 (- 15.7 to -11.3)	-14.7 (-16.0 to -13.4)	-7.3 (-9.3 to -5.3)	
Moderate	-13.2 (-14.6 to -11.7)	-15.2 (-16.1 to -14.3)	-8.1 (-9.5 to -6.7)	
Low	-14.1 (-16.4 to -11.9)	-15.4 (-16.8 to -14.1)	-7.2 (-9.0 to -5.3)	
P°	.7637	.6841	.5190	

<sup>a</sup>Least squared means, 95% Cl.

<sup>b</sup>Model adjusted for gender, age, insurance type, year of procedure, smoking status, Charlson Comorbidity Index score, and 14 clinical history variables (atrial fibrillation, diabetes, gastrointestinal reflux, hypertension, sleep apnea, asthma, deep venous thrombosis, pulmonary embolus, congestive heart failure, hyperlipidemia, stroke, cardiovascular composite, and myocardial infarction).

<sup>c</sup>P values represent the overall significance of the model and not necessarily a trend.

# CONCLUSIONS

In this exploratory retrospective cohort analysis of 4433 individuals who underwent RYGB and AGB at 9 bariatric surgery centers across the United States, we found substantial heterogeneity of pre- and postoperative care management practices surrounding bariatric surgical procedures at the different centers. Although we did not demonstrate an association between CMI and change in BMI at 1 or 2 years postoperatively, this investigation should serve as a call for more research on the effect of care management on bariatric surgical outcomes.

There is extensive literature demonstrating the effectiveness of behavioral interventions for moderate nonsurgical weight loss.<sup>10,14</sup> There is much less evidence detailing the role of behavioral support for surgical weight loss patients. Limited studies suggest that behavioral factors are associated with weight regain, and poor uptake of support services is associated with less weight loss.<sup>15-17</sup> One recent study specifically showed that more dietary counseling sessions during the postoperative period was associated with better weight loss, whereas additional nondietitian expert counseling sessions were not associated with better postoperative weight loss.<sup>18</sup> This suggests that appropriate bariatric care management has the potential to optimize patient outcomes, but more evidence is needed. Generating this evidence will require studies that: 1) incorporate standardized components of care management that can be more easily quantified, and

2) examine a range of outcomes meaningful to bariatric surgical patients.

We noted substantial variation in care management processes across sites. Preoperative enrollment requirements ranged from 2 to 12 months, and operative counseling ranged from 3 to 12 months. The education across sites included various combinations of support groups, individual appointments, and formal classes; written or digital materials were occasionally provided, and all sites provided information on diet and nutrition and behavioral counseling. Postoperative support was also highly variable, although it consistently included 6 to 12 months of clinical follow-up visits, and the majority of centers included dietary support and ongoing weight management support for 1 to 2 years. Factors influencing the elements of CMI available at each site may have included: available resources (eg, geography, staffing, funding), the ability to provide services internally as opposed to outsourcing, duration of program existence with concomitant evolving clinical experience over time, adaptations to local patient populations, prevalence of relevant health conditions to bariatric surgery, and changing accreditation standards over time. Further exploration of such influences is warranted. This information will be of interest to clinicians who can place their own programs within the context of a range of community practices.

The difficulty in classifying CMI, as well as an inability to measure adherence to care management, limits interpretation of our multivariate analyses of BMI as a function of CMI intensity levels. Nevertheless, the narrow range **Table 5.** Associations of Postoperative Care Management Intensity Ratings on Change in Body Mass Index Stratified by Procedure

		Mean Change in Body Mass Index (kg/m²)		
Care Management Intensity <sup>a</sup>	Total Adjusted <sup>a,b</sup>	Gastric Bypass Adjusted <sup>a,b</sup>	Gastric Band Adjusted <sup>a,b</sup>	
Year 1	(n = 4310)	(n = 3436 )	(n = 874)	
High	-12.8 (-14.1 to -11.5)	-13.9 (-14.9 to -12.8)	-6.3 (-8.1 to -4.7)	
Low	-11.7 (-12.8 to -10.5)	-13.7 (-14.6 to -12.8)	-6.2 (-7.6 to -4.8)	
P°	.1664	.7573	.8313	
Year 2	(n = 3846)	(n = 3055 )	(n = 791)	
High	-14.0 (-15.5 to -12.5)	-15.1 (-16.1 to -14.1)	-8.0 (-9.6 to -6.3)	
Low	-13.0 (-14.3 to -11.7)	-15.1 (-16.1 to -14.2)	-7.7 (-9.1 to -6.3)	
P°	.2694	.9702	.6936	

<sup>a</sup>Least squared means, 95% CI.

<sup>b</sup>Model adjusted for gender, age, insurance type, year of procedure, smoking status, Charlson Comorbidity Index score, and 14 clinical history variables (atrial fibrillation, diabetes, gastrointestinal reflux, hypertension, sleep apnea, asthma, deep venous thrombosis, pulmonary embolus, congestive heart failure, hyperlipidemia, stroke, cardiovascular composite, and myocardial infarction).
<sup>c</sup>P values represent the overall significance of the model and not necessarily a trend.

of decreases in BMI across as well as within CMI levels suggests that the effect of the procedures themselves likely overwhelms the potential impact of CMI on BMI as a surgical outcome. Our findings suggest that ancillary CMI may only modestly influence changes in BMI during the early postoperative years. However, more intensive CMI with good documentation of patient adherence could possibly influence early postoperative BMI—and more research is needed. Although our classification of CMI may have affected the final associations between CMI and BMI change, sensitivity analyses did not change our overall findings.

Bariatric surgical care management may be more likely to affect outcomes other than 2-year change in BMI. CMI may affect the trajectory of weight loss over a longer time frame—we limited follow-up to 2 years to maintain an adequate sample size. CMI may also be more likely to affect other outcomes such as nutritional status (ie, anemia, vitamin deficiencies); adherence to lifestyle changes with diet and physical activity; surgical reintervention; band adjustments; or quality of life. Unfortunately, none of these data were available to us in this study, but all of these outcomes are likely to be of importance to patients, so the bariatric care management team has a responsibility to help patients optimize these outcomes.

Despite our negative analytic findings, to our knowledge, this is the first attempt to define pre- and postoperative CMI for bariatric surgery. We did this in community settings with heterogeneous patient populations that included more men and racial/ethnic groups than in other studies.<sup>19,21</sup> Our results reflect a range of practice patterns and settings not seen in randomized trials, and our patient retention rates at postoperative year 1 (4310/4433, 97.2%) and year 2 (3846/4433, 86.8%) were high.

This study highlights the need for future research to determine how standardized elements of care management influence both long-term weight loss and other important parameters such as health outcomes of comorbid conditions, nutritional status, surgical reinterventions, and quality of life for bariatric surgical patients.

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