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Comparative Effectiveness and Safety of Bariatric Procedures for Weight Loss:

A PCORnet Cohort Study

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PCORnet Bariatric Study Collaborative*

Abstract

Background: There has been a dramatic shift in use of bariatric procedures, but little is known about their long-term comparative effectiveness.

Objective: To compare weight loss and safety among bariatric procedures.

Design: Retrospective observational cohort study, January 2005 to September 2015. (ClinicalTrials.gov:)

Setting: 41 health systems in the National Patient-Centered Clinical Research Network.

Participants: 65 093 patients aged 20 to 79 years with body mass index (BMI) of 35 kg/m^2 or greater who had bariatric procedures.

Intervention: 32 208 Roux-en-Y gastric bypass (RYGB), 29 693 sleeve gastrectomy (SG), and 3192 adjustable gastric banding (AGB) procedures.

Measurements: Estimated percent total weight loss (TWL) at 1, 3, and 5 years; 30-day rates of major adverse events.

Results: Total numbers of eligible patients with weight measures at 1, 3, and 5 years were 44 978 (84%), 20 783 (68%), and 7159 (69%), respectively. Thirty-day rates of major adverse events were 5.0% for RYGB, 2.6% for SG, and 2.9% for AGB. One-year mean TWLs were 31.2% (95% CI, 31.1% to 31.3%) for RYGB, 25.2% (CI, 25.1% to 25.4%) for SG, and 13.7% (CI, 13.3% to 14.0%) for AGB. At 1 year, RYGB patients lost 5.9 (CI, 5.8 to 6.1) percentage points more weight than SG patients and 17.7 (CI, 17.3 to 18.1) percentage points more than AGB patients, and SG patients lost 12.0 (CI, 11.6 to 12.5) percentage points more than AGB patients. Five-year mean TWLs were 25.5% (CI,25.1% to 25.9%) for RYGB, 18.8% (CI, 18.0% to 19.6%) for SG, and 11.7% (CI, 10.2% to 13.1%) for AGB. Patients with diabetes, those with BMI less than 50 kg/m^2, those aged 65 years or older, African American patients, and Hispanic patients lost less weight than patients without those characteristics.

Limitation: Potential unobserved confounding due to nonrandomized design; electronic health record databases had missing outcome data.

Conclusion: Adults lost more weight with RYGB than with SG or AGB at 1, 3, and 5 years; however, RYGB had the highest 30-day rate of major adverse events. Small subgroup differences in weight loss outcomes were observed.

Primary Funding Source: Patient-Centered Outcomes Research Institute.

In the past decade, there has been a dramatic shift in surgical procedures performed for weight loss in the United States (1). Although Roux-en-Y gastric bypass (RYGB) predominated through the late 2000s, sleeve gastrectomy (SG) has surpassed it in the number of procedures performed in the United States and worldwide (2, 3). The adjustable gastric banding (AGB) procedure was popular in the mid-to-late 2000s, but it now accounts for fewer than 10% of annual U.S. bariatric procedures (4).

Despite this rapid shift, long-term data comparing the efficacy and safety of SG versus RYGB and AGB are lacking. At least 66 randomized controlled trials or observational studies have directly compared RYGB (n = 88 672 total patients) and SG (n = 22 100 total patients) (5–11). However, just 16 involved U.S. samples, and only 5 had at least 5 years of follow-up (n = 845 total SG patients and 867 total RYGB patients) (5–11). Thus, the long-term comparative effectiveness of SG, RYGB, and AGB is largely unknown, and there is no consensus in the medical community about the clinical utility of these procedures for weight loss (12), leading to unwarranted variation in insurance coverage and use of these procedures in the United States (13–16). More data are needed in larger, more broadly representative samples with long-term follow-up to inform clinical and policy decisions about bariatric surgery.

In 2016, the Patient-Centered Outcomes Research Institute funded the National Patient-Centered Clinical Research Network (PCORnet) Bariatric Study (PBS) to demonstrate the utility of PCORnet in promoting evidence-based and patient-centered health care. The PBS aims to compare the safety and effectiveness of the most common bariatric procedures in the United States (16, 17) by examining electronic health record data from 11 geographically diverse PCORnet Clinical Data Research Networks (CDRNs) (18).

In this article, we present findings on the comparative effectiveness of SG, RYGB, and AGB for weight loss among adults at 1, 3, and 5 years after surgery. We hypothesized that the procedures would lead to significantly different weight loss trajectories over 5 years. In addition, we leveraged the large sample size enabled by PCORnet to explore the effects of bariatric procedures in clinical subpopulations. These results could help patients, providers, and payers better understand how different bariatric procedures affect health.

METHODS

Study Setting and Population

The PBS cohort and protocol were previously described (16). The study was approved by the Institutional Review Board (IRB) of Kaiser Permanente Washington Health Research Institute (lead site) and was approved or determined to be exempt from review by participating sites through individual IRB review or reliance agreements. The PBS is guided by a stakeholder advisory group (comprising patients, advocacy groups, adult and pediatric surgeons, obesity medicine providers, and payers) that helped identify relevant outcomes, prioritize analyses, advise on study design, and plan for dissemination of findings.

We identified patients who had a primary bariatric procedure at health systems affiliated with participating CDRNs (Appendix Table 1, available at Annals.org) from 1 January 2005 through 30 September 2015. PCORnet uses a common data model to facilitate queries of standardized data (18). The PBS team collaborated with the PCORnet Coordinating Center to develop a bariatric case definition and query program. The cohort was identified using codes from the International Classification of Diseases, Ninth Revision (ICD-9); Current Procedural Terminology (CPT-4); and the Healthcare Common Procedure Coding System (Appendix Tables 2 and 3, available at Annals.org), which were extracted from the PCORnet common data model at each site.

Bariatric procedures were identified from more than 100 million patient records in 41 health systems from the 11 CDRNs. The inclusion and exclusion criteria are shown in Figure 1. For each patient, the first observed bariatric procedure was considered the index procedure; these had to occur in inpatient or ambulatory care encounters. We then excluded patients who were younger than 20 years or aged 80 years or older at the index procedure (n = 1809); those with multiple conflicting bariatric procedure codes on the same day (n = 1113); those with any revisional bariatric procedure code (n = 4576), gastrointestinal cancer diagnosis code (n = 4027), or fundoplasty (n = 119) in the year before the index procedure; those with an emergency department encounter on the day of the index procedure (n = 485); and those with no body mass index (BMI) data (n = 12 510) or no BMI of 35 kg/m^2 or greater (n = 1918) in the year before the procedure. We then excluded 18 583 patients who did not have a BMI measurement at 1, 3, or 5 years after surgery, resulting in a final sample of 46 510 adults with baseline and follow-up BMI measurements.

Data Extraction

We used SAS queries developed by the PCORnet Coordinating Center to extract information on eligible patients from participating sites, including site identifier; year of surgery; age at the index procedure; sex; race/ethnicity; deidentified dates of all encounters; all measures of height, weight, BMI, and blood pressure; all repeated or revisional bariatric procedures; presence of relevant comorbidities (anxiety, deep venous thrombosis, depression, eating disorder, type 2 diabetes, dyslipidemia, gastroesophageal reflux disease, hypertension, infertility, kidney disease, nonalcoholic fatty liver disease, obstructive sleep apnea, lower-extremity osteoarthritis, polycystic ovarian syndrome, psychosis, pulmonary embolism, smoking, or substance use disorder); and all diagnoses and procedures related to pregnancy. We used information from the year before surgery to calculate the Charlson–Elixhauser comorbidity index score for each patient (19). The Charlson–Elixhauser index was developed to predict mortality in older adults, but we used it to help address potential confounding because patients with higher risk for death might be offered a lower-risk procedure. Diagnoses were identified through ICD-9-CM and Systematized Nomenclature of Medicine codes (available on request). Additional details on variable construction are provided in the Statistical Appendix section of the Supplement (available at Annals.org).

Outcomes

Our primary outcome was percent total weight loss (TWL) at 1, 3, and 5 years, calculated as follows: (weight in kilograms at each time point – weight in kilograms at surgery)/weight in

kilograms at surgery × 100 (20). We used pairwise comparisons of percent TWL between procedures (RYGB vs. SG, SG vs. AGB, and RYGB vs. AGB) among patients with at least 1 weight measurement at 1 year (6 to 18 months), 3 years (30 to 42 months), and 5 years (54 to 66 months) after surgery. Follow-up for weight measurements began at the index procedure date and ceased at the end of the study period (30 September 2015) or when the patient switched to a different bariatric procedure. Because pregnancy affects body weight, we ignored anthropometric measurements during pregnancy, defined as the 9 months before and the 3 months after any code indicating full-term delivery, preterm delivery, miscarriage, or abortion. Data were cleaned to remove biologically implausible values for height (<4 or ≥8 ft), weight (<70 or ≥700 lb), and BMI (<15 or ≥90 kg/m^2) (21). Secondary analyses examined the proportion of patients achieving TWL greater than 5%, 10%, 20%, and 30% at each time point.

We also examined 30-day rates of major adverse events, defined as any death, reoperation, percutaneous or endoscopic intervention, venous thromboembolism, or failure to be discharged from the hospital within 30 days (22, 23), among 65 093 patients who had complete information at baseline. Longer-term data on adverse events were not available.

Statistical Analysis

Weight Loss Outcomes—Mean adjusted weight at 1, 3, and 5 years with each procedure was estimated using a linear mixed-effects (random-effects) model framework (24). For patients included in each pairwise comparison at each time point, all available postsurgery weight measures were used. Each model estimated a mean population-level time-varying curve for the trend in weight from the time of surgery to the end of the study and included random-effects terms for patient (intercept) and follow-up time (slope). For clinical relevance in presentation, we transformed mean adjusted weight to mean percent TWL and mean weight change, but all inferences were made on the mean weight estimates (including *P* values) and 95% CIs were transformed from those for mean weight. Additional details are provided in the Statistical Appendix section of the Supplement.

Confounding—To control for potential confounding variables, a propensity score model was constructed for each pairwise analysis and time point cohort. The propensity score estimated the probability of having a specific bariatric procedure given baseline (presurgery) covariates. In each cohort, variables were selected and parameters were estimated simultaneously using maximum penalized likelihood estimation and the LASSO (least absolute shrinkage and selection operator) method (see the Statistical Appendix section of the Supplement for details) (25). In addition to adjusting for deciles of predicted propensity score, we included main effects for weight, sex, age, and all other baseline covariates in the outcome model (Table 1).

Subgroup Analyses—We examined potential variability in treatment effects across baseline patient characteristics (aged ≥65 or <65 years, sex, race/ethnicity, presence or absence of diabetes, and BMI ≥50 or <50 kg/m^2) by including an interaction term between procedure type and each characteristic of interest in the random-effects model framework.

Subgroups were chosen on the basis of consensus among study stakeholders, including patients and providers.

Sensitivity Analyses—To assess the effects of dropout and missing baseline data on our results, we compared the results of our primary analysis with those from a simple covariate-adjusted model (no propensity scores) run on a single data set that included all longitudinal data among patients with at least 1 postsurgery measurement (n = 56 156) and excluded the race, ethnicity, and blood pressure variables, which were the primary sources of missing baseline data. To address concerns about lack of overlap of the propensity scores, we compared our primary results with those we obtained after trimming the propensity scores for each pairwise analysis and refitting the propensity score and outcome models (further details are provided in the Statistical Appendix section of the Supplement). In addition, we examined how the results of each analysis changed if we removed follow-up censoring due to switching to a different procedure. Finally, because the SG technique evolved rapidly during the study period (26, 27), we examined whether 1-year weight loss for SG patients differed by year of surgery.

Role of the Funding Source

The Patient-Centered Outcomes Research Institute had no role in the design or conduct of the study or the reporting of the results.

RESULTS

Characteristics of the PBS Cohort

The PBS analytic sample included 46 510 patients (24 982 RYGB patients, 18 961 SG patients, and 2567 AGB patients) (Table 1) with at least 1 weight measurement at 1, 3, or 5 years after surgery. The total numbers of patients with at least 1 BMI measurement at 1, 3, and 5 years were 44 978, 20 783, and 7159, respectively, representing 84%, 68%, and 69% of the 53 351, 30 521, and 10 442 patients who were eligible to be observed at those time points (Table 2 of the Supplement). Five-year follow-up rates differed by procedure, with 86% of SG patients, 67% of RYGB patients, and 55% of AGB patients having a weight measure in this period (Table 2 of the Supplement).

Patients were predominantly white (74%); 21% were African American, and 21% were Hispanic. At baseline, RYGB patients had higher mean BMI (49.6 kg/m^2), were more often white (80%), and had greater prevalence of most comorbid conditions than SG or AGB patients. The frequency of procedure types differed across study years, with a sharp decrease in AGB, a sharp increase in SG, and a gradual decrease in RYGB (16).

We compared characteristics of patients in our analytic cohort with those who were excluded due to missing BMI data at baseline and during follow-up (Table 3 of the Supplement). Those without follow-up BMI data were younger (44 vs. 46 years), were less often white (67% vs. 74%), had more recent procedures, and had fewer comorbid conditions. Baseline BMI was more often missing for AGB patients (49%) than RYGB (17%) or SG (9%) patients.

Thirty-Day Rates of Major Adverse Events

Thirty-day rates of major adverse events (Table 4 of the Supplement) were 5.0% for RYGB patients (n = 32 208), 2.6% for SG patients (n = 29 693), and 2.9% for AGB patients (n = 3192). More adverse events were seen with RYGB than with SG (odds ratio [OR], 1.57 [95% CI, 1.40 to 1.77]) or AGB (OR, 1.66 [CI, 1.28 to 2.16]); however, rates did not differ significantly between AGB and SG (OR, 0.99 [CI, 0.72 to 1.36]).

Comparative Effectiveness for Weight Loss

Patients having RYGB had the greatest percent TWL at each time point, and AGB patients had the lowest (Table 2 and Figure 2). At 1 year, average TWL was 31.2% (CI, 31.1% to 31.3%; mean weight loss, 39.6 kg) for RYGB patients, 25.2% (CI, 25.1% to 25.4%; mean weight loss, 32.0 kg) for SG patients, and 13.7% (CI,13.3% to 14.0%; mean weight loss, 17.3 kg) for AGB patients. Patients having RYGB lost 5.9 (CI, 5.8 to 6.1) percentage points (7.6 kg) more of their baseline weight at 1 year than SG patients and 17.7 (CI, 17.3 to 18.1) percentage points (22.5 kg) more than AGB patients. Patients having SG lost 12.0 (CI, 11.6 to 12.5) percentage points (15.3 kg) more of their baseline weight at 1 year than AGB patients (Table 2).

At 5 years, patients in each group had, on average, regained some weight. The AGB group regained the least (11.7% TWL at 5 years vs. 13.7% at 1 year; mean weight regained, 2.5 kg), followed by the RYGB (25.5% at 5 years vs. 31.2% at 1 year; mean weight regained, 7.2 kg) and SG (18.8% at 5 years vs. 25.2% at 1 year; mean weight regained, 8.2 kg) groups. Despite these patterns, RYGB patients still had significantly greater TWL after 5 years than SG (difference, 6.7 [CI, 5.8 to 7.7] percentage points; $P < 0.001$) and AGB (difference, 13.9 [CI, 12.4 to 15.4] percentage points; $P < 0.001$) patients, and the SG group had significantly greater TWL than the AGB group (difference, 7.3 [CI, 5.2 to 9.3] percentage points; $P < 0.001$).

Figure 2 illustrates the rapid weight loss with all procedures. After 1.5 years, each group had a slow and steady weight regain through 5.5 years of follow-up.

Nearly all patients who had RYGB and SG achieved an estimated TWL greater than 5% at 1, 3, and 5 years (Figure 3). Patients having RYGB were more likely to achieve TWL greater than 10%, 20%, and 30% at all time points. Patients having AGB were less likely to achieve TWL greater than 5%, 10%, 20%, or 30% at all time points compared with RYGB and SG patients.

Weight Loss in Patient Subgroups

Patients with diabetes lost less weight than those without diabetes at all time points for all procedures (Table 5 of the Supplement). Patients with a BMI less than 50 kg/m^2 at the time of surgery lost less weight than those with a BMI of 50 kg/m^2 or greater at all time points for RYGB and SG. This difference was seen at 1 and 3 years in AGB patients, but by 5 years there was no significant difference (Table 6 of the Supplement). Patients aged 65 years or older at the time of surgery lost less weight than younger patients with RYGB and SG at all time points; however, there was no difference by age for AGB at any time point (Table 7 of

the Supplement). Men lost less weight with AGB than women at all time points. Men lost more weight with RYGB and SG at 1 year, but there were no differences at 3 and 5 years (Table 8 of the Supplement). African American patients lost less weight with RYGB and SG than white patients at all time points. Hispanic patients lost less weight with RYGB than white patients at all time points. This difference was also seen with SG and AGB at 1 and 3 years, but there were no significant differences at 5 years (Table 9 of the Supplement).

Sensitivity Analyses

Findings did not change when we removed follow-up censoring due to switching to a different bariatric procedure or when we examined whether 1-year weight loss for SG patients differed by year of surgery. Our sensitivity analysis model, which was run on a single data set that included all longitudinal data (n = 56 156), estimated lower TWL for AGB (8.1%), similar TWL for SG (18.7%), and slightly greater TWL for RYGB (26.3%) at 5 years compared with our main model estimates; other estimates were qualitatively similar (Table 10 of the Supplement). Estimates from the trimmed propensity score sensitivity analyses were similar to those from our primary analysis (Table 11 of the Supplement), except that the 5-year comparison between SG and AGB was attenuated and no longer statistically significant, although the number of AGB patients was small (n = 41) and the 95% CI still included our primary analysis estimate.

Comparisons of results by data mart and numbers of patients by site and procedure are provided in Table 1 of the Supplement.

DISCUSSION

In this large multicenter study, we examined the comparative effectiveness of the 3 most common bariatric procedures in the United States and demonstrated clear and clinically important differences in weight loss outcomes at 1, 3, and 5 years. Patients who had RYGB lost 5.9 percentage points more weight at 1 year and 6.7 percentage points more at 5 years than SG patients. The proportion of patients achieving 5% weight loss was similar for RYGB and SG, and the proportions losing more than 10% and especially more than 20% or 30% were much larger with RYGB than SG. These findings are compelling because recent smaller studies have suggested little or no difference in short-term weight loss between RYGB and SG (10, 11, 28–33). Other studies have found that RYGB results in greater weight loss than SG at 1 to 4 years of follow-up (5–8, 34–36). Bariatric surgical outcomes can vary widely across surgical centers (37), but the data presented here are probably more broadly representative of the typical experience of patients having bariatric surgery in most major surgical centers in the United States. The magnitude of the weight loss differences we observed will likely be meaningful to patients and providers as they consider treatment options for severe obesity.

When this new information is applied to clinical decision making, the expected magnitude of weight loss with each procedure needs to be tailored to the patient's specific clinical situation. The large PBS sample enabled subgroup analyses, which aimed to provide data that are relevant for individualized decisions. For example, we found that patients aged 65 years or older, those with diabetes, those with a preoperative BMI less than 50 kg/m^2, and

racial minority patients generally lost less weight with RYGB and SG than younger, nondiabetic, more severely obese, and non-Hispanic white patients. However, across all of the subgroups we examined, the magnitudes of the differences in TWL were clinically small and generally less than 3%. In contrast, the differences in weight loss between RYGB and SG were larger, and we did not identify any subgroup in which SG outperformed RYGB.

The magnitude of weight loss is not the only factor that patients and providers should consider when discussing bariatric procedure options, and the shared decision-making conversation should include information on risk for adverse events (such as reoperation, death, hypoglycemia, or micronutrient deficiencies) and expected changes in comorbid conditions with each procedure (38). We found that RYGB patients had a higher 30-day rate of major adverse events (5.0%) than SG (2.6%) or AGB (2.9%) patients. To better inform these discussions, future studies should examine longer-term differences in safety outcomes across procedures.

The PBS demonstrates that PCORnet is a valuable new resource for rapidly conducting patient-centered comparative effectiveness research. Its infrastructure enabled standardization of health record data across diverse health systems and analysis of a sufficiently large cohort to identify differences in outcomes across clinically relevant patient subgroups. The engagement of stakeholders throughout the PCORnet research process may also increase the likelihood that the findings are relevant to the decision-making process as patients and providers contemplate the best weight management option (39).

This study has several limitations. First, patients were not randomly assigned, so there was risk for unobserved confounding that may have persisted despite covariate and propensity score adjustment in our pairwise comparisons. Second, a sizable proportion of our cohort was missing BMI data in the electronic health record at baseline or during follow-up, and rates of missingness at baseline and 5 years varied across procedures. This may have introduced bias, although the magnitude and direction of that bias are uncertain. Third, weight data were not systematically collected as part of a prospective data collection effort, as in the Longitudinal Assessment of Bariatric Surgery (40), so weights at specific time points were model-estimated predictions. Fourth, comorbid conditions were assessed and Charlson–Elixhauser scores were calculated using ICD-9 diagnosis codes, which may underestimate prevalence of comorbidities (such as osteoarthritis), can be inaccurately coded, and do not account for disease severity. Fifth, comparing the effect of bariatric procedures on obesity-related chronic conditions was beyond the scope of this work. Sixth, because this study used deidentified data, we were only able to determine the timing of procedures by year, which prevented us from identifying patients who had missing follow-up data due to administrative censoring. Seventh, we were unable to examine heterogeneity of treatment effects by site because of resource constraints. Finally, the AGB procedure may be underrepresented in this cohort because PCORnet does not include small ambulatory surgical centers.

These analyses demonstrate that RYGB is associated with greater weight loss than SG and that AGB is associated with the least weight loss in a large and geographically and racially diverse population. Health care providers, patients, and policymakers can use these data to

inform treatment and insurance coverage decisions. Not every patient with severe obesity will be interested in bariatric surgery (41), but all providers should incorporate a shared decision-making discussion of its potential role into their clinical practice.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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APPENDIX: PCORNET BARIATRIC STUDY COLLABORATIVE

The PCORnet Bariatric Study Collaborative includes the following key investigators and stakeholders who made substantial contributions to the manuscript as authors: Joseph Vitello, MD (Jesse Brown VA Medical Center); Elisha Malanga, BS (COPD Foundation); Corrigan L. McBride, MD, and James McClay, MD, MS (University of Nebraska Medical Center); Emily Harmata, MSN, and David Schlundt, PhD (Vanderbilt University); Tammy St. Clair, LMSW; Joe Nadglowski, BS (Obesity Action Coalition); Anita P. Courcoulas, MD, MPH, and Kathleen M. McTigue, MD, MS, MPH (University of Pittsburgh Medical Center); Marc Michalsky, MD (Nationwide Children's Hospital); Nirav Desai, MD (Boston Children's Hospital); Alberto Odor, MD (University of California, Davis); Rosalinde Saizan, RN, and William Richardson, MD (Ochsner Surgical Weight Loss Center); Caroline Apovian, MD, and William G. Adams, MD (Boston Medical Center/Boston University School of Medicine); Elizabeth Cirelli, MSN, RN (Brigham and Women's Hospital); Roni Zeiger, MD (Smart Patients, Inc.); Laura Rasmussen-Torvik, PhD (Northwestern Medicine); Jessica Sturtevant, MS, Casie E. Horgan, MPH, Gabrielle Purcell, MPH, Sengwee Toh, ScD, Jeffrey Brown, PhD, and Ali Tavakkoli, MD (Harvard Medical School and Harvard Pilgrim Health Care Institute); John H. Holmes, PhD (University of Pennsylvania); Rabih Nemr, MD (Lutheran Medical Center); Ana Emiliano, MD, and Jonathan N. Tobin, PhD (Rockefeller University); Jeanne Clark, PhD, and Wendy Bennett, MD, MPH (Johns Hopkins University); Thomas H. Inge, MD, PhD (University of Colorado, Denver, and Children's Hospital of Colorado); Stavra A. Xanthakos, MD (Cincinnati Children's Hospital Medical Center); Lydia Bazzano, MD, PhD (Tulane University School of Public Health); Elizabeth Nauman, MPH, PhD (Louisiana Public Health Research Institute); Denise M. Hynes, PhD, MPH, RN (University of Illinois); David Meltzer, MD, PhD (University of Chicago); Bipan Chand, MD (Loyola Medicine); Jeffrey J. VanWormer, PhD (Marshfield Clinic Research Institute); Lemuel Russell Waitman, PhD (Kansas University Medical Center); Lindsay G. Cowell, PhD (University of Texas Southwestern); Lawrence P. Hanrahan, PhD, MS (University of Wisconsin–Madison); Meredith Duke, MBA, MD (University of North Carolina); Daniel M. Herron, MD (Mount Sinai Health System); Sameer Malhotra, MD, MA (Weill Cornell Medical College); Jenny Choi, MD (Montefiore Medical Center); Jiang Bian, PhD (University of Florida Health); Michelle R. Lent, PhD (Geisinger Health); Jennifer L. Kraschnewski, MD, MPH, and Julie Tice, MS (Pennsylvania State University); Michael A. Edwards, MD (Temple University); Molly Conroy, MD, MPH (University of Utah); Matthew F. Daley, MD (Kaiser Permanente Colorado); Michael Horberg, MD (Kaiser Permanente Mid-Atlantic); Jay R. Desai, PhD, MPH (Health Partners); Stephanie L. Fitzpatrick, PhD (Kaiser Permanente Northwest); Douglas S. Bell, MD, PhD (University of California, Los Angeles); Erin Roe, MD (Baylor Scott & White); Xiaobo Zhou, MD (Wake Forest School of Medicine); Christina C. Wee, MD, MPH (Beth Israel Deaconess Medical Center); David E. Arterburn, MD, MPH, Robert D. Wellman, MS,R. Yates Coley, PhD, Jane Anau, BS, Roy Pardee, JD, MA, and Andrea Cook, PhD (Kaiser Permanente Washington Health Research Institute); Steven R. Smith, MD (Florida Hospital); Andrew O. Odegaard, MPH, PhD (University of California, Irvine); Cheri D. Janning, RN, BSN, MS (Duke

Clinical & Translational Science Institute); Neely A. Williams, MDiv (Community Partners' Network); Karen J. Coleman, PhD; and Sameer Murali, MD (Kaiser Permanente Southern California).

Appendix Table 1.

Participating PCORnet CDRNs and Sites Contributing Data

CDRN	Sites Contributing Data
Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN)	Loyola Medicine
	Northwestern Medicine
	University of Chicago Medical Center
	University of Illinois Hospital & Health Science System
Greater Plains Collaborative (GPC)	Marshfield Clinic
	University of Texas Southwestern Medical Center
	University of Iowa Healthcare
	University of Kansas Medical Center
	University of Wisconsin – Madison
Kaiser Permanente & Strategic Partners Patient Outcomes Research To Advance Learning (PORTAL)	Kaiser Permanente Washington Health Research Institute (formerly Group Health Research Institute)
	HealthPartners Research Foundation
	Kaiser Permanente Colorado
	Kaiser Permanente Mid-Atlantic States
	Kaiser Permanente Northwest
	Kaiser Permanente Southern California
Mid-South	Greenway
	University of North Carolina
	Vanderbilt University Medical Center
New York City Clinical Data Research Network (NYC-CDRN)	Mount Sinai
	New York University
	Weill Cornell
	Montefiore/Einstein
OneFlorida Clinical Research Consortium	University of Florida Health
	Orlando Health
	Tallahassee Memorial Health System
PaTH Towards a Learning Health System Clinical Data Research Network (PaTH)	Geisinger Health System
	Johns Hopkins University and Health System *
	Penn State College of Medicine, Penn State Milton S. Hershey Medical Center
	Temple Health System, Lewis Katz School of Medicine at Temple University
	University of Pittsburgh and UPMC
	UPMC Health Plan *

CDRN	Sites Contributing Data
A Pediatric Learning Health System (PEDSnet)	University of Utah and University of Utah Health Care
	Cincinnati Children's Hospital Medical Center
	Nemours
	Nationwide Children's Hospital
Patient-Centered SCAlable National Network for Effectiveness Research (pSCANNER)	University of California, Irvine
	University of California, Los Angeles
Research Action for Health Network (REACHnet)	Baylor Scott & White Health
	Ochsner Health System
	Tulane University
Scalable Collaborative Infrastructure for a Learning Healthcare System (SCILHS)	Beth Israel Deaconess Medical Center
	Boston HealthNet *
	Partners Health
	Wake Forest Baptist Hospital

CDRN = Clinical Data Research Network; PCORnet = National Patient-Centered Clinical Research Network; UPMC = University of Pittsburgh Medical Center.

* Johns Hopkins University and Health System, UPMC Health Plan, and Boston HealthNet did not contribute data for this article but will for future analyses.

Appendix Table 2.

Bariatric Surgery Procedure Codes Used as Inclusion Criteria *

Description	Code	Code Type	Procedure Assignment
Gastric restrictive procedure, without gastric bypass, for morbid obesity; other than vertical-banded gastroplasty	43843	CPT-4	AGB
Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy	43846	CPT-4	RYGB
Laparoscopy, surgical; gastric restrictive procedure, adjustable gastric band includes placement of subcutaneous port	S2082	HCPCS	AGB
Gastrectomy, partial, distal; with Roux-en-Y reconstruction	43633	CPT-4	RYGB
Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)	43770	CPT-4	AGB
Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption	43645	CPT-4	RYGB
Laparoscopy, gastric restrictive procedure, with gastric bypass for morbid obesity, with short limb (less than 100 cm) Roux-en-Y gastroenterostomy	S2085	HCPCS	RYGB
Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)	43775	CPT-4	SG
Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (Roux limb 150 cm or less)	43644	CPT-4	RYGB
Gastric restrictive procedure, with gastric bypass for morbid obesity; with small intestine reconstruction to limit absorption	43847	CPT-4	RYGB
High gastric bypass	44.31	ICD-9	RYGB

Description	Code	Code Type	Procedure Assignment
Laparoscopic vertical (sleeve) gastrectomy	43.82	ICD-9	SG
Laparoscopic gastric restrictive procedure	44.95	ICD-9	AGB
Open and other partial gastrectomy	43.89	ICD-9	SG
Laparoscopic gastroenterostomy	44.38	ICD-9	RYGB
Other gastroenterostomy without gastrectomy	44.39	ICD-9	RYGB
Laparoscopic gastric restrictive procedure with gastric bypass and Roux-en-Y gastroenterostomy	43844	CPT-4	RYGB

AGB = adjustable gastric banding; CPT = Current Procedural Terminology; HCPCS = Healthcare Common Procedure Coding System; ICD-9 = International Classification of Diseases, Ninth Revision; PCORnet = National Patient-Centered Clinical Research Network; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy.

* Patients who had one of these procedure codes during the study period were considered to be potentially eligible for the PCORnet Bariatric Study. Additional inclusion and exclusion criteria and codes are provided in the text and Appendix Table 3.

Appendix Table 3.

Codes Used as Exclusion Criteria *

Description	Code	Code Type
Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	43772	CPT-4
Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy	43865	CPT-4
Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty	43842	CPT-4
Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; without vagotomy	43850	CPT-4
Revision of gastroduodenal anastomosis (gastroduodenostomy) with reconstruction; with vagotomy	43855	CPT-4
Laparoscopy, surgical, gastric restrictive procedure; revision of adjustable gastric restrictive device component only	43771	CPT-4
Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	43773	CPT-4
Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)	43845	CPT-4
Gastric restrictive procedure, open; removal of subcutaneous port component only	43887	CPT-4
Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy	43860	CPT-4
Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)	43848	CPT-4
Gastric restrictive procedure, open; revision of subcutaneous port component only	43886	CPT-4
Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components	43774	CPT-4
Gastric restrictive procedure, open; removal and replacement of subcutaneous port component only	43888	CPT-4
Laparoscopic gastroplasty	44.68	ICD-9
Laparoscopic removal of gastric restrictive device(s)	44.97	ICD-9
Laparoscopic revision of gastric restrictive procedure	44.96	ICD-9

Description	Code	Code Type
Gastrectomy, total; with Roux-en-Y reconstruction	43621	CPT-4
Gastrectomy, partial, proximal, thoracic or abdominal approach including esophagogastrostomy, with vagotomy; with pyloroplasty or pyloromyotomy	43639	CPT-4
Gastrectomy, partial, distal; with formation of intestinal pouch	43634	CPT-4
Gastrectomy, partial, distal; with gastrojejunostomy	43632	CPT-4
Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty	43842	CPT-4
Gastrectomy, partial, proximal, thoracic or abdominal approach including esophagogastrostomy, with vagotomy;	43638	CPT-4
Gastrectomy, partial, distal; with gastroduodenostomy	43631	CPT-4
Gastrectomy, total; with esophagoenterostomy	43620	CPT-4
Gastrectomy, total; with formation of intestinal pouch, any type	43622	CPT-4
Gastroenterostomy without gastrectomy	44.3	ICD-9
Partial gastrectomy with anastomosis to esophagus	43.5	ICD-9
Other partial gastrectomy	43.8	ICD-9
Total gastrectomy	43.9	ICD-9
Partial gastrectomy with anastomosis to duodenum	43.6	ICD-9
Other total gastrectomy	43.99	ICD-9
Partial gastrectomy with anastomosis to jejunum	43.7	ICD-9
Total gastrectomy with intestinal interposition	43.91	ICD-9
Partial gastrectomy with jejunal transposition	43.81	ICD-9
Laparoscopic procedures for creation of esophagogastric sphincteric competence	44.67	ICD-9
Esophagogastroplasty	44.65	ICD-9
Other procedures for creation of esophagogastric sphincteric competence	44.66	ICD-9
Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed	43279	CPT-4
Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; without implantation of mesh or other prosthesis	43332	CPT-4
Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	43281	CPT-4
Laparoscopy, surgical, esophagogastric fundoplasty (e.g., Nissen, Toupet procedures)	43280	CPT-4
Laparoscopy, surgical, esophageal lengthening procedure (e.g., Collis gastroplasty or wedge gastroplasty) (List separately in addition to code for primary procedure)	43283	CPT-4
Esophageal lengthening procedure (e.g., Collis gastroplasty or wedge gastroplasty) (List separately in addition to code for primary procedure)	43338	CPT-4
Esophagogastric fundoplasty partial or complete; laparotomy	43327	CPT-4
Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; without implantation of mesh or other prosthesis	43334	CPT-4
Repair, paraesophageal hiatal hernia (including fundoplication), via laparotomy, except neonatal; with implantation of mesh or other prosthesis	43333	CPT-4
Esophagogastric fundoplasty (e.g., Nissen, Belsey IV, Hill procedures)	43324	CPT-4

Description	Code	Code Type
Esophagogastric fundoplasty; with gastroplasty (e.g., Collis)	43326	CPT-4
Repair, paraesophageal hiatal hernia (including fundoplication), via thoracotomy, except neonatal; with implantation of mesh or other prosthesis	43335	CPT-4
Esophagogastric fundoplasty; with fundic patch (Thal-Nissen procedure)	43325	CPT-4
Repair, paraesophageal hiatal hernia (including fundoplication), via thoracoabdominal incision, except neonatal; without implantation of mesh or other prosthesis	43336	CPT-4
Repair, paraesophageal hiatal hernia (including fundoplication), via thoracoabdominal incision, except neonatal; with implantation of mesh or other prosthesis	43337	CPT-4
Esophagogastric fundoplasty partial or complete; thoracotomy	43328	CPT-4
Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	43282	CPT-4

CPT = Current Procedural Terminology; ICD-9 = International Classification of Diseases, Ninth Revision.

* Patients who had any of these codes identified in the year before their first observed primary bariatric procedure were excluded.

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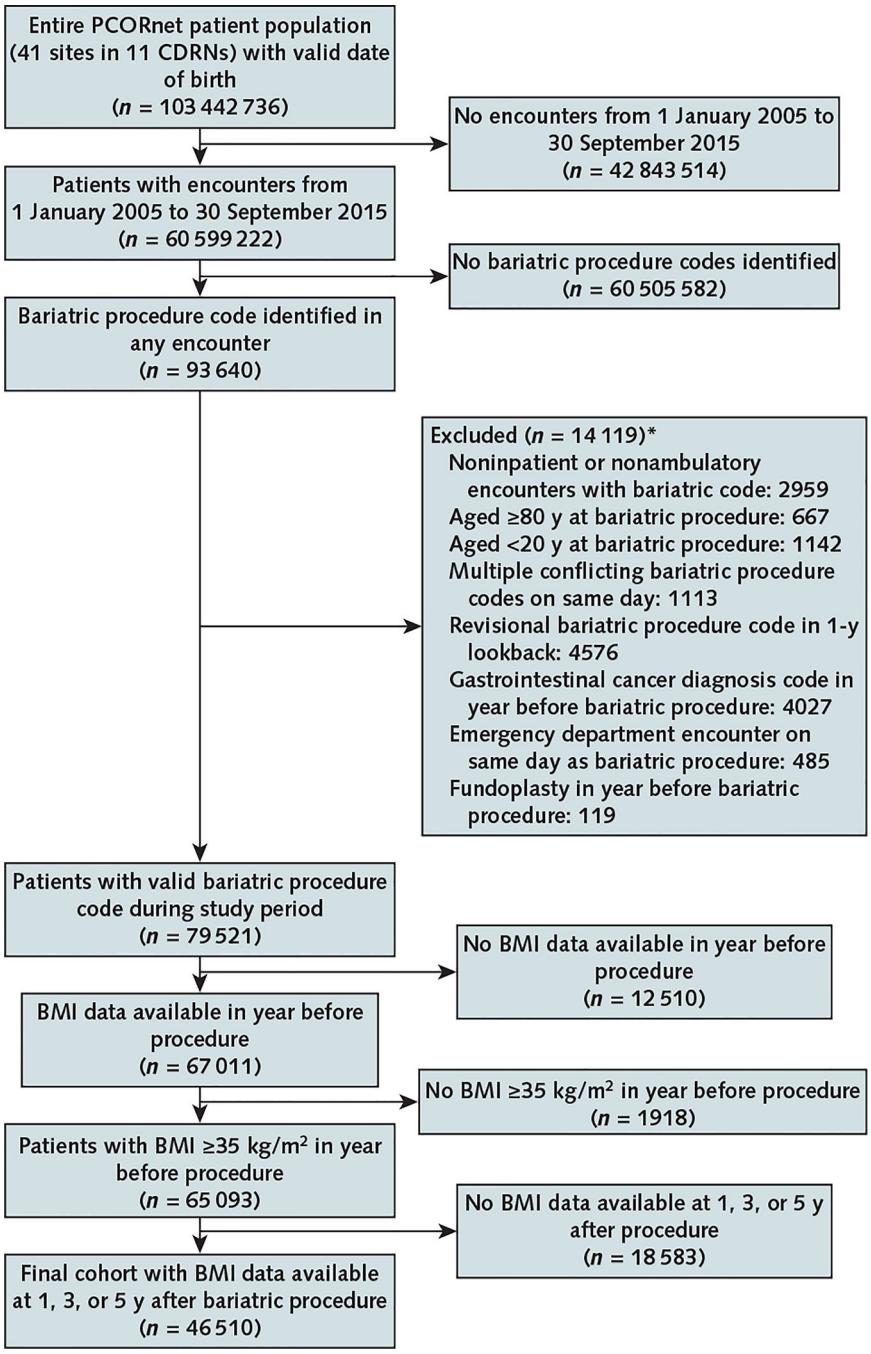

Figure 1. Flow diagram for identification of the adult PCORnet Bariatric Study cohort in 11 CDRNs.

BMI = body mass index; CDRN = Clinical Data Research Network; PCORnet = National Patient-Centered Clinical Research Network.

* Patients could be excluded for >1 reason.

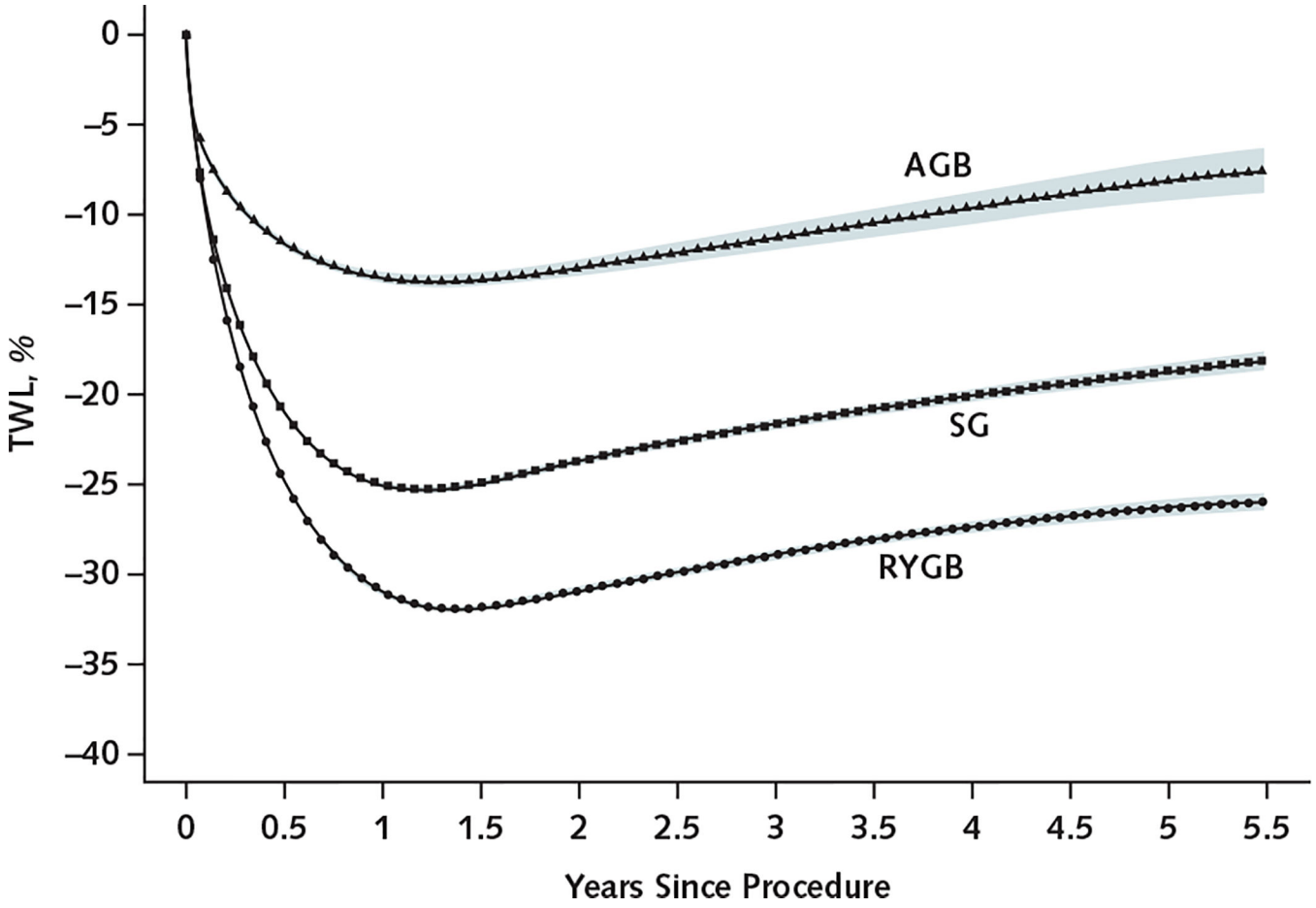

Figure 2. Estimated percentage of TWL through 5 y after bariatric surgery, by procedure type.
This plot shows the estimated percentage of TWL for a patient with the average baseline covariate profile using results from our sensitivity analysis, which included all follow-up weight measurements from 56 156 patients with any postsurgery weight observations. Additional details are provided in the Methods section of the text and the Statistical Appendix section of the Supplement. Shaded areas indicate pointwise 95% CIs. AGB = adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; TWL = total weight loss.

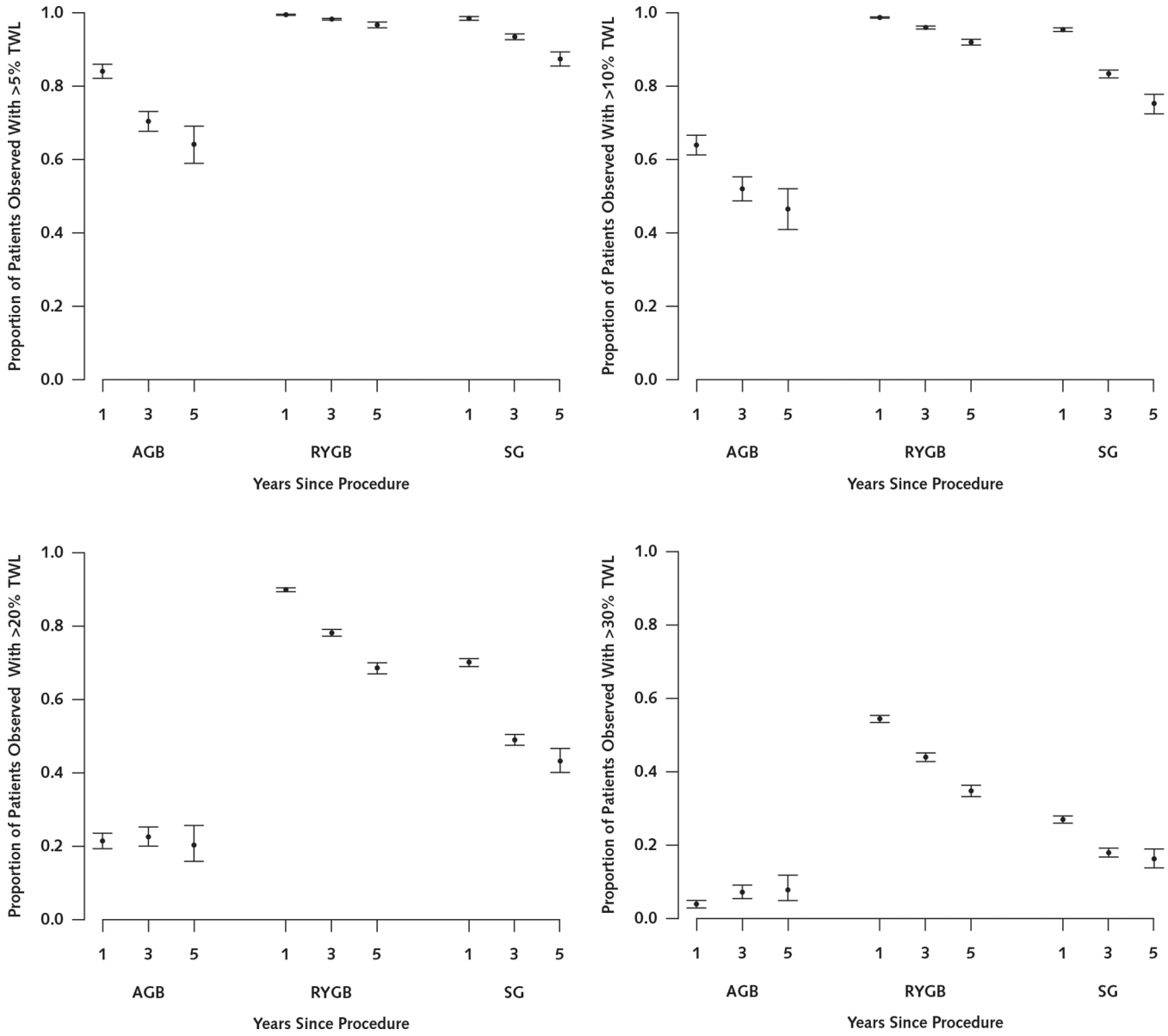

Figure 3. Proportions of AGB, RYGB, and SG patients with TWL >5%, >10%, >20%, and >30% at 1, 3, and 5 y.

AGB = adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; TWL = total weight loss.

Table 1.

Baseline Characteristics of the Adult PBS Cohort*

Characteristic	AGB (*n* = 2567 [5.5%])	RYGB (*n* = 24 982 [53.7%])	SG (*n* = 18 961 [40.8%])	Overall (*n* = 46 510 [100.0%])
Mean age (SD), *y*	46.0 (12.3)	46.0 (11.5)	44.8 (11.6)	45.5 (11.6)
Age, *n (%)*				
20–44 y	1194 (46.5)	11 343 (45.4)	9538 (50.3)	22 075 (47.5)
45–64 y	1198 (46.7)	12 326 (49.3)	8518 (44.9)	22 042 (47.4)
65–80 y	175 (6.8)	1313 (5.3)	905 (4.8)	2393 (5.2)
Female, *n (%)*	2046 (79.7)	20 022 (80.2)	15247 (80.4)	37 315 (80.2)
Mean BMI (SD), *kg/m²*	46.1 (6.7)	49.6 (8.2)	48.9 (8.2)	49.1 (8.2)
BMI, *n (%)*				
35–39 kg/m²	410 (16.0)	1904 (7.6)	1551 (8.2)	3865 (8.3)
40–49 kg/m²	1562 (60.9)	13 016 (52.1)	10 545 (55.6)	25 123 (54.0)
50–59 kg/m²	499 (19.4)	7379 (29.5)	4992 (26.3)	12 870 (27.7)
≥60 kg/m²	96 (3.7)	2683 (10.7)	1873 (9.9)	4652 (10.0)
Mean weight (SD), *kg*	121.0 (21.8)	128.0 (25.8)	124.8 (25.7)	126.3 (25.7)
Year of surgery, *n (%)*				
2005–2009	524 (20.4)	4207 (16.8)	452 (2.4)	5183 (11.1)
2010	621 (24.2)	3939 (15.8)	1259 (6.6)	5819 (12.5)
2011	654 (25.5)	5039 (20.2)	3322 (17.5)	9015 (19.4)
2012	443 (17.3)	4481 (17.9)	4053 (21.4)	8977 (19.3)
2013	223 (8.7)	3731 (14.9)	4602 (24.3)	8556 (18.4)
2014	94 (3.7)	3160 (12.7)	4697 (24.8)	7951 (17.1)
2015	8 (0.3)	425 (1.7)	576 (3.0)	1009 (2.2)
Ethnicity, *n (%)*				
Hispanic	286 (11.6)	4371 (17.8)	4955 (26.5)	9612 (21.0)
Missing	90 (3.5)	398 (1.6)	254 (1.3)	742 (1.6)
Race, *n (%)*				
Asian	10 (0.4)	194 (0.9)	218 (1.3)	422 (1.0)
African American	570 (24.3)	3415 (15.2)	4541 (27.9)	8526 (20.8)

Characteristic	AGB (*n* = 2567 [5.5%])	RYGB (*n* = 24 982 [53.7%])	SG (*n* = 18 961 [40.8%])	Overall (*n* = 46 510 [100.0%])
Multiple	32 (1.4)	281 (1.3)	152 (0.9)	465 (1.1)
White	1651 (70.4)	17 951 (79.9)	10 769 (66.2)	30 371 (74.0)
Pacific Islander	1 (0)	81 (0.4)	61 (0.4)	143 (0.4)
Native American	9 (0.4)	161 (0.7)	109 (0.7)	279 (0.7)
Other	72 (3.1)	382 (1.7)	412 (2.5)	866 (2.1)
Missing	222 (8.7)	2517 (10.1)	2699 (14.2)	5438 (11.7)
Mean blood pressure (SD), *mm Hg*				
Systolic	128.3 (16.1)	130.7 (17.4)	130.5 (16.8)	130.5 (17.1)
Diastolic	77.1 (10.9)	76.0 (11.3)	75.0 (11.9)	75.6 (11.6)
Missing blood pressure, *n (%)*	188 (7.3)	1114 (4.5)	499 (2.6)	1801 (3.9)
Charlson–Elixhauser comorbidity index score, *n (%)*				
≤−1	854 (33.3)	8431 (33.8)	6203 (32.7)	15 488 (33.3)
0	1387 (54.0)	12 426 (49.7)	10 066 (53.1)	23 879 (51.3)
≥1	326 (12.7)	4125 (16.5)	2692 (14.2)	7143 (15.4)
Mean days in hospital in year before surgery (SD)	0.34 (2.4)	0.42 (4.1)	0.45 (3.3)	0.43 (3.7)
Comorbid conditions, *n* (%) [†]				
Anxiety	477 (18.6)	5494 (22.0)	3946 (20.8)	9917 (21.3)
Depression	673 (26.2)	8346 (33.4)	5320 (28.1)	14 339 (30.8)
Diabetes	784 (30.5)	10 992 (44.0)	5544 (29.2)	17 320 (37.2)
Deep venous thrombosis	19 (0.7)	178 (0.7)	139 (0.7)	336 (0.7)
Dyslipidemia	1131 (44.1)	13 071 (52.3)	8621 (45.5)	22 823 (49.1)
Eating disorder	139 (5.4)	3801 (15.2)	1043 (5.5)	4983 (10.7)
Gastroesophageal reflux disease	986 (38.4)	11 381 (45.6)	6628 (35.0)	18 995 (40.8)
Hypertension	1499 (58.4)	15 979 (64.0)	10 539 (55.6)	28 017 (60.2)
Infertility	17 (0.7)	177 (0.7)	145 (0.8)	339 (0.7)
Kidney disease	144 (5.6)	2270 (9.1)	1410 (7.4)	3824 (8.2)
Nonalcoholic fatty liver disease	361 (14.1)	6486 (26.0)	2799 (14.8)	9646 (20.7)
Lower-extremity osteoarthritis	52 (2.0)	436 (1.8)	326 (1.7)	814 (1.8)
Polycystic ovarian syndrome	121 (4.7)	1317 (5.3)	907 (4.8)	2345 (5.0)
Pulmonary embolism	25 (1.0)	318 (1.3)	204 (1.1)	547 (1.2)

Characteristic	AGB (*n* = 2567 [5.5%])	RYGB (*n* = 24 982 [53.7%])	SG (*n* = 18 961 [40.8%])	Overall (*n* = 46 510 [100.0%])
Psychotic disorder	58 (2.3)	872 (3.5)	541 (2.9)	1471 (3.2)
Sleep apnea	1140 (44.4)	13 804 (55.3)	7950 (41.9)	22 894 (49.2)
Smoking	146 (5.7)	2346 (9.4)	1516 (8.0)	4008 (8.6)
Substance use disorder	27 (1.1)	523 (2.1)	434 (2.3)	984 (2.1)

AGB = adjustable gastric banding; BMI = body mass index; PBS = National Patient-Centered Clinical Research Network (PCORnet) Bariatric Study; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy.

*Baseline was defined as the year before surgery. Adults were defined as patients aged 20–79 y. Percentages may not sum to 100 due to rounding.

†Identified by International Classification of Diseases, Ninth Revision, or Systematized Nomenclature of Medicine diagnosis code.

Table 2.

Comparative Effectiveness of RYGB, SG, and AGB for TWL Among Adults at 1, 3, and 5 Years *

Comparison	Time Since Bariatric Procedure					
	1 Year		3 Years		5 Years	
	Patients, *n*	TWL (95% CI), %	Patients, *n*	TWL (95% CI), %	Patients, *n*	TWL (95% CI), %
SG vs. RYGB						
SG	14 929	−25.2 (−25.4 to −25.1)	5304	−21.0 (−21.3 to −20.7)	1088	−18.8 (−19.6 to −18.0)
RYGB	19 029	−31.2 (−31.3 to −31.1)	9225	−29.0 (−29.2 to −28.8)	3676	−25.5 (−25.9 to −25.1)
Difference	–	5.9 (5.8 to 6.1)	–	8.0 (7.6 to 8.4)	–	6.7 (5.8 to 7.7)
P value		<0.001		<0.001		<0.001
AGB vs. RYGB						
AGB	1681	−13.7 (−14.0 to −13.3)	943	−12.7 (−13.5 to −12.0)	337	−11.7 (−13.1 to −10.2)
RYGB	18 684	−31.4 (−31.5 to −31.3)	9152	−29.1 (−29.3 to −28.9)	3733	−25.6 (−26.0 to −25.2)
Difference	–	17.7 (17.3 to 18.1)	–	16.4 (15.6 to 17.2)	–	13.9 (12.4 to 15.4)
P value		<0.001		<0.001		<0.001
AGB vs. SG						
AGB	1681	−13.1 (−13.5 to −12.7)	933	−12.0 (−12.8 to −11.2)	306	−11.4 (−13.2 to −9.6)
SG	14 664	−25.1 (−25.3 to −25.0)	5270	−20.9 (−21.2 to −20.6)	1088	−18.7 (−19.5 to −17.8)
Difference	–	12.0 (11.6 to 12.5)	–	8.9 (8.0 to 9.8)	–	7.3 (5.2 to 9.3)
P value		<0.001		<0.001		<0.001

AGB = adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; TWL = total weight loss.

* TWL was calculated as follows: (weight in kilograms at 1, 3, and 5 y – weight in kilograms at baseline)/weight in kilograms at baseline × 100. A propensity score model was constructed for each pairwise analysis and time point. Age at index procedure, sex, race/ethnicity, year of index procedure, baseline body mass index, number of days from baseline weight to bariatric surgery, and baseline Charlson–Elixhauser comorbidity index score were forced into all propensity score models. Site, smoking status, inpatient hospitalizations in the year before surgery, baseline blood pressure, and comorbidities at baseline were included subject to the variable selection process. Further, to account for differing effects of confounders on propensity scores by site, interactions between site and all confounders were made available for selection. In addition to adjustment for deciles of the predicted propensity score, we included main effects for baseline weight, sex, age, and all other baseline covariates listed here in the outcome model. For each pairwise comparison, we restricted the analysis to sites that included ≥1 patient who had each procedure at each time point. See the Statistical Appendix section of the Supplement (available at Annals.org) for more details.