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Original article

Comparative effectiveness of bariatric procedures among adolescents: the PCORnet bariatric study[☆]

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Abstract

Background: Bariatric surgery has been used for treatment of severe obesity in adolescents but most studies have been small and limited in follow-up.

Objectives: We hypothesized that electronic health record data could be used to compare effectiveness of bariatric procedures in adolescents.

Setting: Data were obtained from clinical research networks using a common data model to extract data from each site.

Methods: Adolescents who underwent a primary bariatric procedure from 2005 through 2015 were identified. The percent change in body mass index (BMI) at 1, 3, and 5 years was estimated using random effects linear regression for patients undergoing all operations. Propensity score adjusted estimates and 95% confidence intervals were estimated for procedures with >25 patients at each time period.

Results: This cohort of 544 adolescents was predominantly female (79%) and White (66%), with mean (±standard deviation) age of 17.3 (±1.6) years and mean BMI of 49.8 (± 7.8)

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kg/m². Procedures included Roux-en-Y gastric bypass (RYGB; n=177), sleeve gastrectomy (SG; n=306), and laparoscopic adjustable gastric banding (n=61). For those undergoing RYGB, SG, and laparoscopic adjustable gastric banding, mean (95% confidence interval) BMI changes of −31% (−30% to −33%), −28% (−27% to −29%), and −10% (−8% to −12%), were estimated at 1 year. For RYGB and SG, BMI changes of −29% (−26% to −33%) and −25% (−22% to −28%) were estimated at 3 years.

Conclusions: Adolescents undergoing SG and RYGB experienced greater declines in BMI at 1- and 3-year follow-up time points, while laparoscopic adjustable gastric banding was significantly less effective for BMI reduction. (*Surg Obes Relat Dis* 2018;000:1–13.) © 2018 American Society for Bariatric Surgery. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license. (<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

Keywords:

Adolescent; Bariatric; Gastric bypass; Sleeve gastrectomy; Adjustable gastric band; Outcome

Severe adolescent obesity (defined as a body mass index [BMI] ≥ 35 kg/m² or BMI $\geq 120\%$ of the 95th percentile for age and sex) [1] now affects an estimated 4% to 7% of youth in the United States [2] and is associated with multiple adverse health consequences [3–6]. Lifestyle modifications, including diet and exercise, have been minimally effective, and pharmacologic treatment options are quite limited for adolescents with severe obesity [2]. These factors have driven increasing interest in bariatric surgery for adolescents and increasing annual case volumes [7,8]. While short- and long-term studies (1- to 8-yr outcomes) of Roux-en-Y gastric bypass (RYGB) show significant and sustained weight loss in most adolescents, there are fewer studies of sleeve gastrectomy (SG) and adjustable gastric banding (AGB) in adolescents [9–15].

To address this knowledge gap, the PCORnet Bariatric Study (PBS) is using the National Patient Centered Clinical Research Network (PCORnet) to aggregate and analyze data from de-identified electronic health records of 11 Clinical Data Research Networks (CDRN) representing up to 56 participating healthcare systems [16].

The purpose of the current analysis was to compare weight loss associated with RYGB, SG, and AGB in the largest study of adolescents undergoing bariatric surgery to date. These data will enable patients, families, and healthcare providers to better understand trends in the use of specific bariatric procedures and how they impact weight loss in adolescents.

Methods

Study setting and population

A detailed description of the PBS cohort and protocol has been published recently [17] and is also registered at ClinicalTrials.gov (NCT02741674). The study was approved by the institutional review board of Kaiser Permanente Washington Health Research Institute (lead site) and approved or determined to be exempt from review by

all participating sites' institutional review boards. For this analysis, we identified adolescents (age 12–19 yr) who underwent a primary (first) bariatric procedure at health systems affiliated with 11 CDRN (see Supplementary Table 1) from January 1, 2005 through September 30, 2015. The cohort was identified using the International Classification of Diseases, Ninth Revision (ICD-9), Current Procedure Terminology-4, and Healthcare Common Procedure Coding System procedure codes (Supplementary Tables 2 and 3) extracted from the PCORnet common data model from each site [16]. Analyses focused on the most common bariatric procedures in the United States (RYGB, SG, and AGB).

Bariatric procedures were identified from approximately 100 million patient records in PCORnet data-contributing sites, using queries that were distributed from the PCORnet Coordinating Center (Fig. 1). The index procedure was defined as the first observed bariatric procedure associated with an inpatient or ambulatory care encounter. Patients <12 years of age (n=184) and ≥ 20 years of age (n=80,188) at the time of procedure were excluded. Those with multiple conflicting bariatric procedure codes on same day, patients with a prior revisional bariatric procedure, gastrointestinal cancer diagnosis, a fundoplasty procedure within 1 year leading up to the index procedure, and all who had an emergency room encounter on the same day as their index procedure were also excluded. Those for whom BMI was not available (n=127) and those who did not have a BMI ≥ 35 kg/m² (n=54) in the year before surgery were also excluded. To accomplish this, height, weight, and BMI data were first cleaned to remove biologically implausible values (height <4 or ≥ 8 ft; weight <70 or ≥ 700 lbs; BMI <15 or ≥ 90 kg/m²). All weight measurements that occurred during a pregnancy (9 mo before and 3 mo after any ICD-9 or Current Procedure Terminology-4 code indicating a full-term delivery, preterm delivery, miscarriage, or abortion procedure) were excluded. Our final analytic sample included 544 adolescents who met eligibility criteria and had at least 1 BMI measurement at 1,

Table 1
Descriptive statistics for the adolescent PCORnet Bariatric Study (PBS) cohort at baseline*

Variable		All			AGB			RYGB			SG		
		Total = 544			Total = 61			Total = 177			Total = 306		
		N	%	Mean (SD)	N	%	Mean (SD)	N	%	Mean (SD)	N	%	Mean (SD)
Procedure	AGB	61	11.2		61	100		177	100		306	100	
	RYGB	177	32.5										
	SG	306	56.3										
Procedure yr	2005–2009	52	9.6		21	34.4		24	13.6		7	2.3	
	2010	78	14.3		17	27.9		30	17		31	10.1	
	2011	98	18		9	14.8		44	24.9		45	14.7	
	2012	106	19.5		8	13.1		27	15.3		71	23.2	
	2013	105	19.3		6	9.8		34	19.2		65	21.2	
	2014	101	18.6		0	0		17	9.6		84	27.5	
	2015	4	.7		0	0		1	.6		3	1	
Sex	Female	428	78.7		48	78.7		145	81.9		235	76.8	
	Male	116	21.3		13	21.3		32	18.1		71	23.2	
Race	Asian	5	1		0	0		2	1.2		3	1.1	
	Black	122	24.6		10	17.2		29	17.8		83	30.1	
	Multiple	12	2.4		3	5.2		3	1.8		6	2.2	
	Native American	3	.6		0	0		0	0		3	1.1	
	Other	25	5		7	12.1		7	4.3		11	4	
	White	330	66.4		38	65.5		122	74.9		170	61.6	
	N/A	47	8.6		3	4.9		14	7.9		30	9.8	
Ethnicity	Non- Hispanic	401	83.2		52	92.9		111	79.3		238	83.2	
	Hispanic	81	16.8		4	7.1		29	20.7		48	16.8	
	N/A	62	11.4		5	8.2		37	20.9		20	6.5	
Age, yr		544		17.3 (1.6)	61		17.3 (1.3)	177		17.7 (1.5)	306		17.1 (1.7)
Age categories, yr	12	2	.4		0	0		0	0		2	.7	
	13–15	75	13.8		6	9.8		17	9.6		52	17	
	16–17	157	28.9		26	42.6		40	22.6		91	29.7	
	18–19	310	57		29	47.5		120	67.8		161	52.6	
Maximum BMI (kg/m ²)	≥35, <40	5	.9		1	1.6		2	1.1		2	.7	
in year before surgery	≥40, <50	249	45.8		27	44.3		77	43.5		145	47.4	
	≥50, <60	192	35.3		27	44.3		62	35		103	33.7	
	≥60	98	18		6	9.8		36	20.3		56	18.3	
BMI (kg/m ²) at baseline		544		49.8 (7.8)	61		48.7 (7.1)	177		51.4 (8.5)	306		49.2 (7.4)
BMI (kg/m ²) categories	<35	1	.2		0	0		1	.6		0	0	
At baseline	35–39	26	4.8		4	6.6		4	2.3		18	5.9	
	40–49	283	52		32	52.5		85	48		166	54.3	
	50–59	172	31.6		21	34.4		61	34.5		90	29.4	
	>60	62	11.4		4	6.6		26	14.7		32	10.5	
Blood pressure [†] , mm Hg													
Systolic		532		128.5 (16.7)	61		126.5 (16.6)	170		127.6 (15.8)	301		129.4 (17.2)
Diastolic		532		71.3 (12)	61		75.0 (11.7)	170		73.6 (12.2)	301		69.2 (11.6)
Charlson-Elixhauser co-morbidity index	<0	46	8.5		1	1.6		14	7.9		31	10.1	
	>0	133	24.5		2	3.3		62	35		69	22.6	
	0	365	67.1		58	95.1		101	57.1		206	67.3	
Co-morbidities [‡]													
Anxiety		87	16		8	13.1		32	18.1		47	15.4	
Depression		151	27.8		18	29.5		54	30.5		79	25.8	
Diabetes		88	16.2		4	6.6		38	21.5		46	15	
Dyslipidemia		192	35.3		27	44.3		51	28.8		114	37.3	
Eating disorder		25	4.6		1	1.6		18	10.2		6	2	
GERD		137	25.2		11	18		56	31.6		70	22.9	
Hypertension		175	32.2		28	45.9		55	31.1		92	30.1	
Infertility		4	.7		0	0		3	1.7		1	.3	

(continued on next page)

Table 1 (continued)

Variable	All			AGB			RYGB			SG		
	Total = 544			Total = 61			Total = 177			Total = 306		
	N	%	Mean (SD)	N	%	Mean (SD)	N	%	Mean (SD)	N	%	Mean (SD)
Kidney disease	7	1.3		0	0		3	1.7		4	1.3	
NAFLD	103	18.9		2	3.3		63	35.6		38	12.4	
Osteoarthritis, lower limb	0	0		0	0		0	0		0	0	
PCOS	120	22.1		12	19.7		49	27.7		59	19.3	
Psychotic disorder	14	2.6		0	0		5	2.8		9	2.9	
Pulmonary embolus	1	.2		0	0		0	0		1	.3	
Sleep apnea	198	36.4		9	14.8		85	48		104	34	
Smoker	25	4.6		1	1.6		8	4.5		16	5.2	
Substance use disorder	2	.4		1	1.6		1	.6		0	0	

Baseline = measured in the year prior to surgery; AGB=adjustable gastric banding; RYGB=Roux-en-Y gastric bypass; SG=sleeve gastrectomy; SD=standard deviation; N/A=not applicable; BMI=body mass index (kg/m^2); GERD=gastroesophageal reflux disease; NAFLD=nonalcoholic fatty liver disease; PCOS=polycystic ovarian syndrome; DVT/PE = deep vein thrombosis or pulmonary embolism.

*This table includes only patients who were eligible at baseline and had at least 1 follow-up BMI measurement at 1, 3, or 5 years after surgery.

†Blood pressure is most recent measurement in year before surgery.

‡Health Conditions were identified by ≥ 1 of the International Classification of Diseases, Ninth Revision or Systematized Nomenclature of Medicine diagnosis code in the year before surgery.

3, or 5 years after surgery. Patients included in the analysis cohort were more likely to be younger and female and have fewer co-morbidities than patients missing baseline or follow-up BMI (data not shown).

Data extraction

Once the cohort was identified, SAS ((Statistical Analysis Software) Institute, Cary, NC) queries extracted detailed de-identified information on each case during the study period. These data included site, year of surgery, subject age at the index procedure, sex, race/ethnicity, inpatient and ambulatory encounters, all measures of height, weight, BMI, and blood pressure, all repeat or revisional bariatric procedures, major gastrointestinal operative reinterventions, occurrence of specific health conditions (i.e., type 2 diabetes, hypertension, dyslipidemia, obstructive sleep apnea, osteoarthritis of the lower extremity, cardiovascular disease, cerebrovascular disease, nonalcoholic fatty liver disease, cancer, gastroesophageal reflux disease, atherosclerotic or hypertensive kidney disease, infertility, polycystic ovarian syndrome, deep vein thrombosis, pulmonary embolism, depression, anxiety disorders, eating disorders, substance use disorders, smoking, and psychoses), and all diagnoses and procedures related to pregnancy. We calculated a combined Charlson/Elixhauser co-morbidity index score for each case following the methods by Gagne et al. [18] using diagnosis information available in the year before the index procedure. All diagnoses were identified through a combination of ICD-9 and Systematized Nomenclature of Medicine–Clinical Terms codes (available on request).

Statistical analysis

The primary outcome was percentage change in BMI from baseline among the patients who had at least 1 valid measurement during the following defined follow-up windows: 1 year after surgery (6–18 mo); 3 years after surgery (30–42 mo); and 5 years after surgery (54–66 mo). Follow-up for measurements commenced at the index procedure date and was censored at the end of the study period on September 30, 2015.

Pair-wise comparisons were conducted for the primary analyses and consisted of comparing AGB versus RYGB, SG versus RYGB, and AGB versus SG at 1, 3, and 5 years. Because these exposures were not randomly assigned, propensity score and covariate adjustment were used to address potential confounding bias in each comparison [19]. Propensity scores for RYGB versus SG and RYGB versus AGB comparisons were estimated via logistic regression with a lasso penalty using potential confounding covariates [20] (Supplementary Table 4). Propensity score adjustment was ultimately not used for AGB versus SG comparisons because available covariate data were not predictive of procedure selection.

Linear mixed-effects models [21] were used to estimate the average percent change in BMI for patients undergoing each comparison procedure at 1, 3, and 5 years. Each analysis included all postsurgery BMI measurements on patients with the comparison procedure and at least 1 BMI measurement in the time period of interest. Time since surgery was included in the model using a B-spline representation with 5 degrees of freedom, and an interaction between procedure type and time was included to accom-

Table 2

Comparative effectiveness of Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and adjustable gastric banding (AGB) for percent change in BMI among adolescents at 1-, 3-, and 5-years follow-up

Time	Comparing SG versus RYGB				Comparing AGB versus RYGB				Comparing AGB versus SG*			
	Groups	N	Mean % change BMI	95% CI	Groups	N	Mean % change BMI	95% CI	Groups	N	Mean % change BMI	95% CI
1 yr	SG	301	−28.07	−29.02 to −27.12	AGB	58	−9.95	−12.1 to −7.8	AGB	58	−9.39	−11.67 to −7.12
	RYGB	165	−31.38	−32.59 to −30.17	RYGB	165	−31.82	−33.12 to −30.52	SG	301	−27.74	−28.75 to −26.72
	Difference		−3.2	1.58–4.82			−21.87	−24.45 to −19.28			−18.34	−20.89 to −15.8
	P value			<.001				<.001				<.0001
3 yr	SG	84	−24.67	−27.8 to −21.54	AGB [†]	21	−2.86	−9.11 to 3.4	AGB [†]	21	−3.27	−10.21 to 3.68
	RYGB	69	−29.39	−32.82 to −25.96	RYGB	69	−29.46	−32.9 to −26.02	SG	84	−24.44	−27.92 to −20.97
	Difference		−4.72	−.01 to 9.45			−26.6	−33.75 to −19.46			−21.18	−28.94 to −13.41
	P value			.051				n/a				n/a
5 yr [†]	SG	16	−20.66	−29.34 to −11.98	AGB [†]	6	1.78	−13.86 to 17.42	AGB [†]	6	2.73	−11.81 to 17.27
	RYGB	25	−23.99	−30.89 to −17.08	RYGB	25	−24.56	−32.21 to −16.9	SG	16	−20.65	−29.56 to −11.74
	Difference		−3.32	−7.77 to 14.41			−26.33	−43.74 to −8.93			−23.38	−40.43 to −6.32
	P value			n/a				n/a				n/a

AGB = adjustable gastric banding; RYGB = Roux-en-Y gastric bypass; SG = sleeve gastrectomy; CI=confidence interval; BMI=body mass index (kg/m²); n/a=not applicable.

Estimates are adjusted for propensity scores and baseline covariates (see Supplementary Table 4) unless otherwise indicated.

* Estimates comparing change in BMI between AGB and SG are not adjusted for propensity scores as available covariate information was not predictive of procedure received.

[†] Unadjusted estimates are given when 1 comparator arm has <25 patients at the time point of interest.

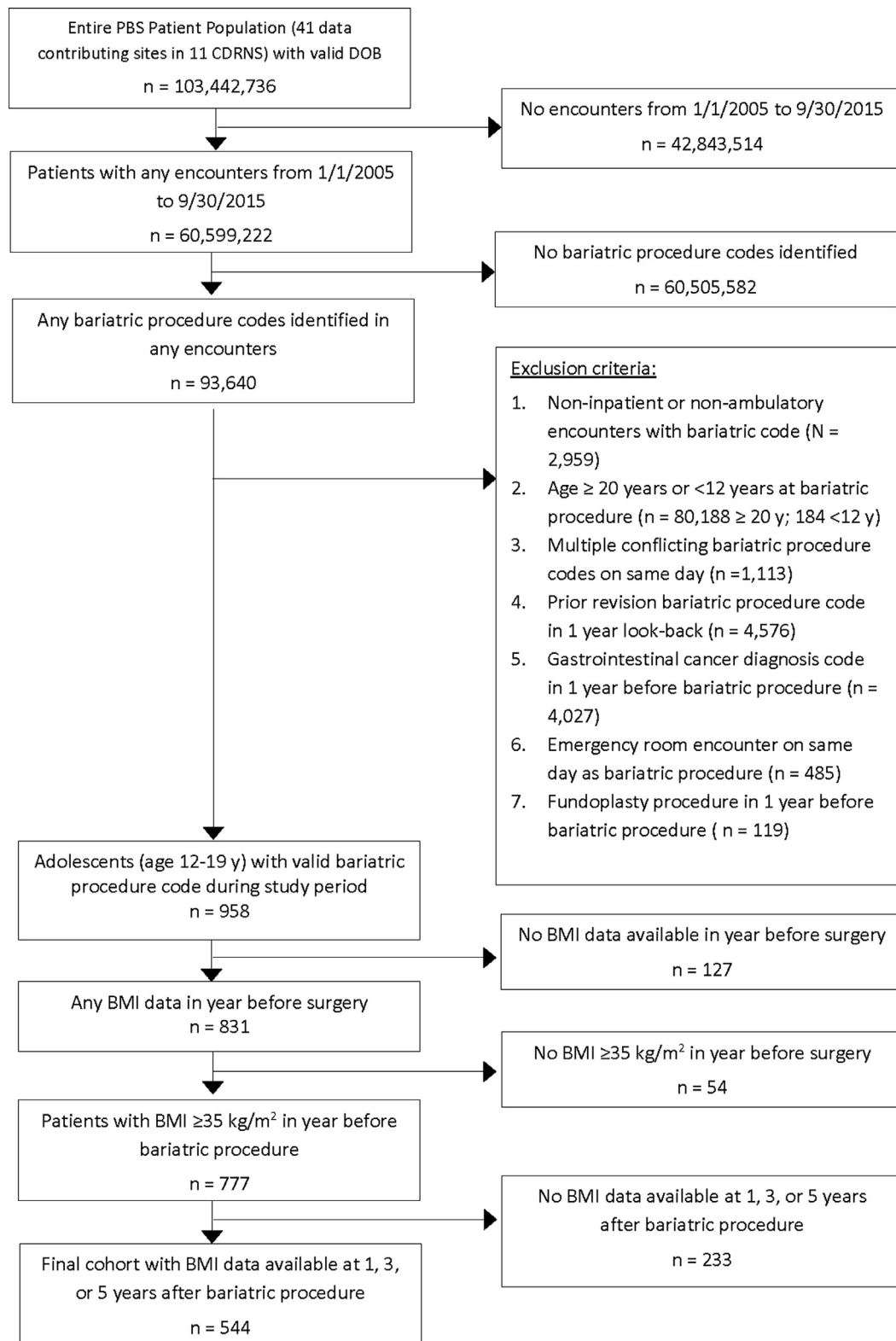


Fig. 1. Flow diagram for identification of the adolescent PCORnet bariatric study cohort in 11 Clinical Data Research Networks.

Table 3

Perioperative complications in the first 30 days after surgery

	All		AGB		RYGB		VSG	
	Total = 544		Total = 61		Total = 177		Total = 306	
	n	%	n	%	n	%	n	%
Death	0	0	0	0	0	0	0	0
Percutaneous, endoscopic, or subsequent operative intervention	18	3.31	0	0	8	4.52	10	3.27
Venous thromboembolic event	2	.37	0	0	1	0.56	1	.33
Failure to discharge	4	.74	1	1.64	1	0.56	2	.65
Any 30-d adverse event	24	4.41	1	1.64	10	5.65	13	4.25

AGB = adjustable gastric band; RYGB = Roux-en-Y gastric bypass; VSG = vertical sleeve gastrectomy.

moderate possible effect modification [22]. Random effects for intercept and change over time were used to model within-patient BMI trends, and an autoregressive correlation structure was specified for random effects. Regression models were further adjusted for covariates (including age, sex, baseline BMI, race, ethnicity, year, and site) and for propensity score deciles (for RYGB versus SG and RYGB versus AGB comparisons).

Ninety-five percent confidence intervals (CI) and *P* values were calculated for the average percent difference in BMI loss between comparison procedures at time points with follow-up BMI observations available on at least 25 patients in each arm. Secondary analyses summarized the proportion of patients having >5%, >10%, >20%, and >30% loss in BMI for each procedure. When <25 patients in each arm had BMI measurements in the time period of interest, descriptive estimates of the mean percent difference and 95% CI were calculated without adjusting for propensity scores or covariates.

To assess the sensitivity of model estimates to differential follow-up, we fit a linear mixed-effects regression model for each procedure comparison that included all eligible patients regardless of the availability of follow-up BMI measurements [23]. This approach assumes that loss to follow-up is associated with patients' covariate data (not outcome data) and mean estimates of percent change in BMI are weighted to reflect BMI trajectories in the baseline population rather than the subset with follow-up data available.

Results

Characteristics of the PCORnet bariatric study adolescent cohort

The final PBS adolescent cohort included a total of 544 (306 SG, 177 RYGB, 61 AGB) individuals (age 12–19 yr) with at least 1 BMI ≥ 35 kg/m² available in the year before surgery and at least 1 BMI at follow-up years 1, 3, or 5 (Table 1, Fig. 1). Between 2005 and 2009, only 52 cases met inclusion criteria. This number increased to 78 per year in 2010, and by 2012 more than 100 cases per

year. A major shift in procedure type was observed over the study period. SG represented only 13% of cases (7/52) from 2005 to 2009, increasing to 83% of cases (87/105) in the years 2014 to 2015 (Table 1, Fig. 2). The PBS adolescent cohort is predominantly female (79%) and White (66%), with 25% Black, and 17% Hispanic. The mean (\pm standard deviation) age before surgery was 17.3 (± 1.6) years, with most patients between ages 16 and 19. Mean BMI at baseline was 49.8 (± 7.8) kg/m². Co-morbid health conditions are shown in Table 1. The most commonly documented co-morbidities include obstructive sleep apnea (36%), dyslipidemia (35%), hypertension (32%), depression (28%), gastroesophageal reflux disease (25%), polycystic ovary syndrome (22%), nonalcoholic fatty liver disease (19%), and type 2 diabetes (16%). The number of individuals with sufficient follow-up weight data for inclusion in 1-, 3-, and 5-year analyses was 524, 174, and 47, respectively, which represents 82%, 50%, and 39% of the adolescents who were eligible to be observed at those time points.

Comparative effectiveness for BMI change

Preoperative weights used in this analysis were measured on the day of operation or the closest weight available. For 319 (59%) patients, a BMI was available for the day of operation, while for 179 (33%), the baseline BMI measurement was within a month of surgery. Only 46 patients (8.5%) had a baseline BMI measurement more than a month before operation. Adolescents undergoing RYGB, SG, and AGB procedures had comparable baseline BMI (51, 49, 49 kg/m², respectively; Table 1). Those undergoing RYGB and SG experienced the greatest reduction in BMI at each time point during follow-up (Table 2; Fig. 3). Comparing BMI change at year 1 for those undergoing RYGB and SG, RYGB was associated with BMI loss of 31.4% (95% CI: –30% to –33%), and SG was associated with BMI loss of 28% (95% CI: –27% to –29%). Thus, at 1 year, patients undergoing RYGB lost 3 percentage points (95% CI: –2% to –5%; *P* < .001) more than those undergoing SG. At 3 years, those undergoing RYGB experienced

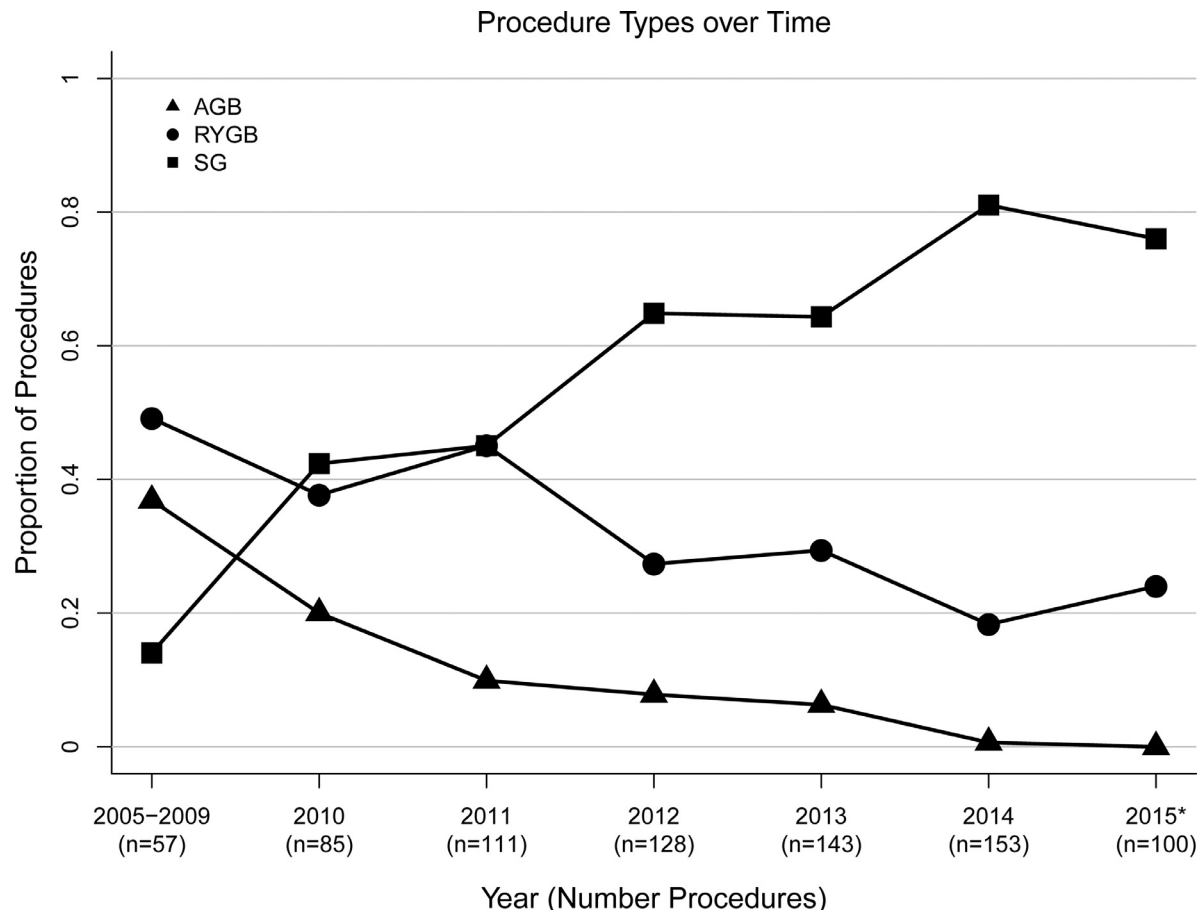


Fig. 2. Procedure prevalence over time. *Number and proportion of procedures observed through September 30, 2015.

a 5 percentage point greater BMI loss ($P = .051$) compared with those undergoing SG. At 5 years, insufficient numbers of records were available for statistical comparison; however, data suggested some stabilization of BMI in those who underwent RYGB or SG. At year 5, patients who underwent RYGB maintained an average (unadjusted) loss of 24% of their baseline BMI (95% CI: -17% to -31%), while patients who had undergone SG maintained a loss of 21% (95% CI: -12% to -29%).

Patients undergoing AGB lost an estimated 10% of baseline BMI (95% CI: -8% to -12%). Thus, at 1 year, patients undergoing RYGB experienced a 22 percentage point ($P < .0001$) greater decrease in BMI than those undergoing AGB, while those undergoing SG had an 18 percentage point ($P < .0001$) greater decrease in BMI (Table 2; Fig. 3). There were insufficient observations beyond 1 year to make meaningful comparisons between AGB and other procedures; however, trends suggested no further reduction in BMI among those who underwent AGB (Table 2).

Fig. 4 (and Supplementary Table 5) depicts the proportion of individuals who experienced estimated BMI loss $>5\%$, $>10\%$, $>20\%$, and $>30\%$ at each time point, by

procedure. Within the first year of the procedure, the proportion of individuals who underwent RYGB, SG, and AGB who had at least a 10% BMI decrease was 99%, 100%, and 50%, respectively. The proportion who had at least a 30% BMI decrease was 61%, 57%, and 1.7%, respectively. At 3 years, the proportions undergoing RYGB and SG experiencing 5%, 10%, and 20% BMI loss were comparable; however 49% of RYGB and 37% of SG patients had experienced $>30\%$ BMI loss.

Perioperative (30-d postoperative) morbidity

Perioperative major adverse events data were also available for this cohort. In Table 3, we show the prevalence of any of the following events occurring within 30 days of surgery for all 544 patients in this sample: death, venous thromboembolism, percutaneous, endoscopic or subsequent operative interventions, and failure to discharge from the hospital within 30 days of the procedure. These data show that a minority of patients experienced perioperative morbidity, and the numbers were so small that no procedural comparisons were possible. There were no periopera-

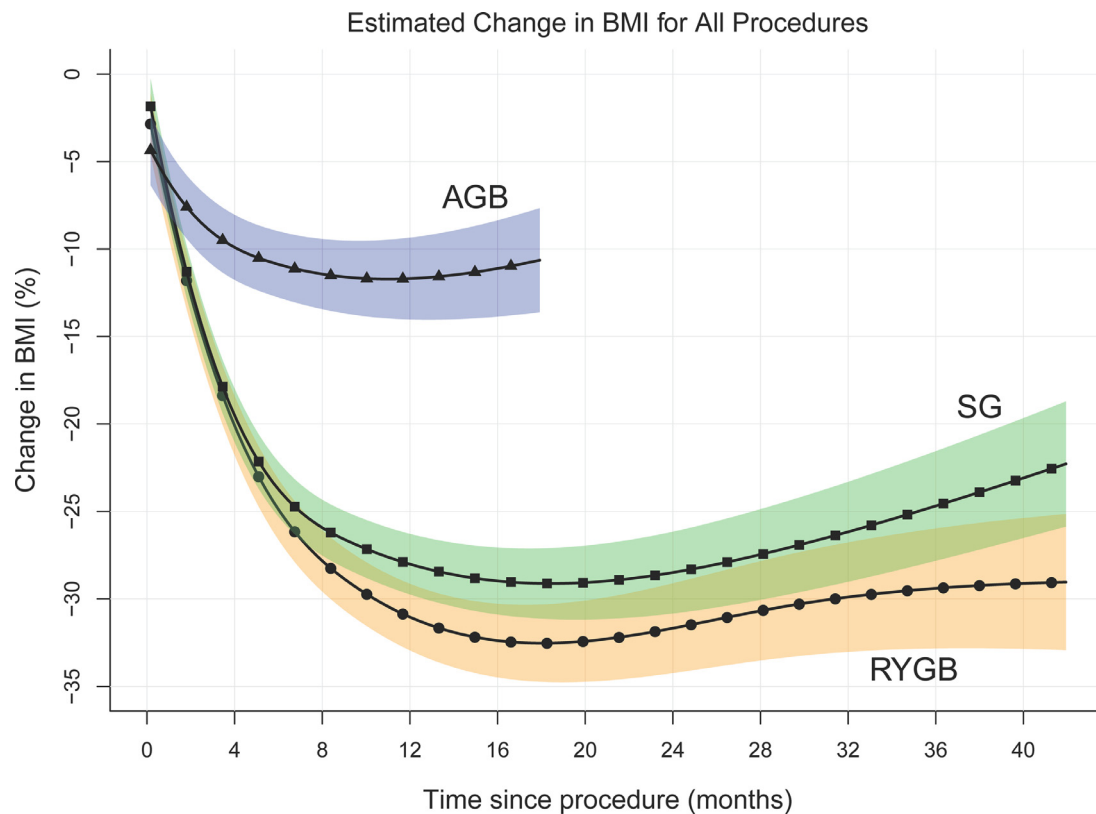


Fig. 3. Percentage change in body mass index through 3 years after bariatric surgery, by procedure type.* *Sample sizes were insufficient for AGB to model 3 years of follow-up. This plot shows the estimated change in body mass index for the average patient. The intervals for RYGB and SG overlap here even though the difference was significant at 1 year because these curves also take into account uncertainty in the effect of other variables. AGB=adjustable gastric banding; RYGB=Roux-en-Y gastric bypass; and SG=sleeve gastrectomy.

tive deaths. Percutaneous, endoscopic, or subsequent operative procedures were seen in only 3.3% of patients. VTEs (Venous thromboembolic events) were observed in only .4%, and failure to discharge in 30 days was observed in only .7%.

Sensitivity analyses

Sensitivity analyses suggested that loss to follow-up did not have a meaningful impact on study conclusions. Estimates that accounted for the anticipated weight trajectories of all adolescent bariatric patients (regardless of follow-up) were similar to those obtained in the primary analysis (Supplementary Table 6).

Discussion

In this large, multisite analysis of adolescents who underwent bariatric surgery between 2005 and 2015, the use of RYGB and AGB declined markedly, while SG increased over time. We found that RYGB resulted in the greatest BMI loss at 1 year, although both RYGB and SG resulted in durable and generally comparable loss in BMI, as the

observed mean difference between their effects at 3 years was not significantly different, although the *P* value was .051 and a 5% difference may be considered clinically meaningful. As expected based on prior studies, BMI loss stabilized by 3 years after RYGB or SG. In contrast, AGB resulted in significantly less weight loss at 1 year, and the small sample size of adolescents undergoing AGB prevented analysis of longer-term outcomes. At 1 year, clinically meaningful (>10%) BMI reduction was observed in nearly all patients undergoing RYGB and SG, but was seen in only half of those undergoing AGB.

This work represents the largest retrospective U.S. study to date that directly compares outcomes of the most common weight loss procedures among adolescents. Another large adolescent bariatric outcome study based in the United States is the Teen-Longitudinal Assessment of Bariatric Surgery (Teen-LABS) study. Teen-LABS is a National Health Institute-funded, prospective, multicenter observational study of 242 teenagers and has reported 1- to 3-year weight loss after these same surgical procedures. In Teen-LABS, fewer adolescents underwent the SG (*n*=67) than RYGB (*n*=161), and unlike PCORnet, the

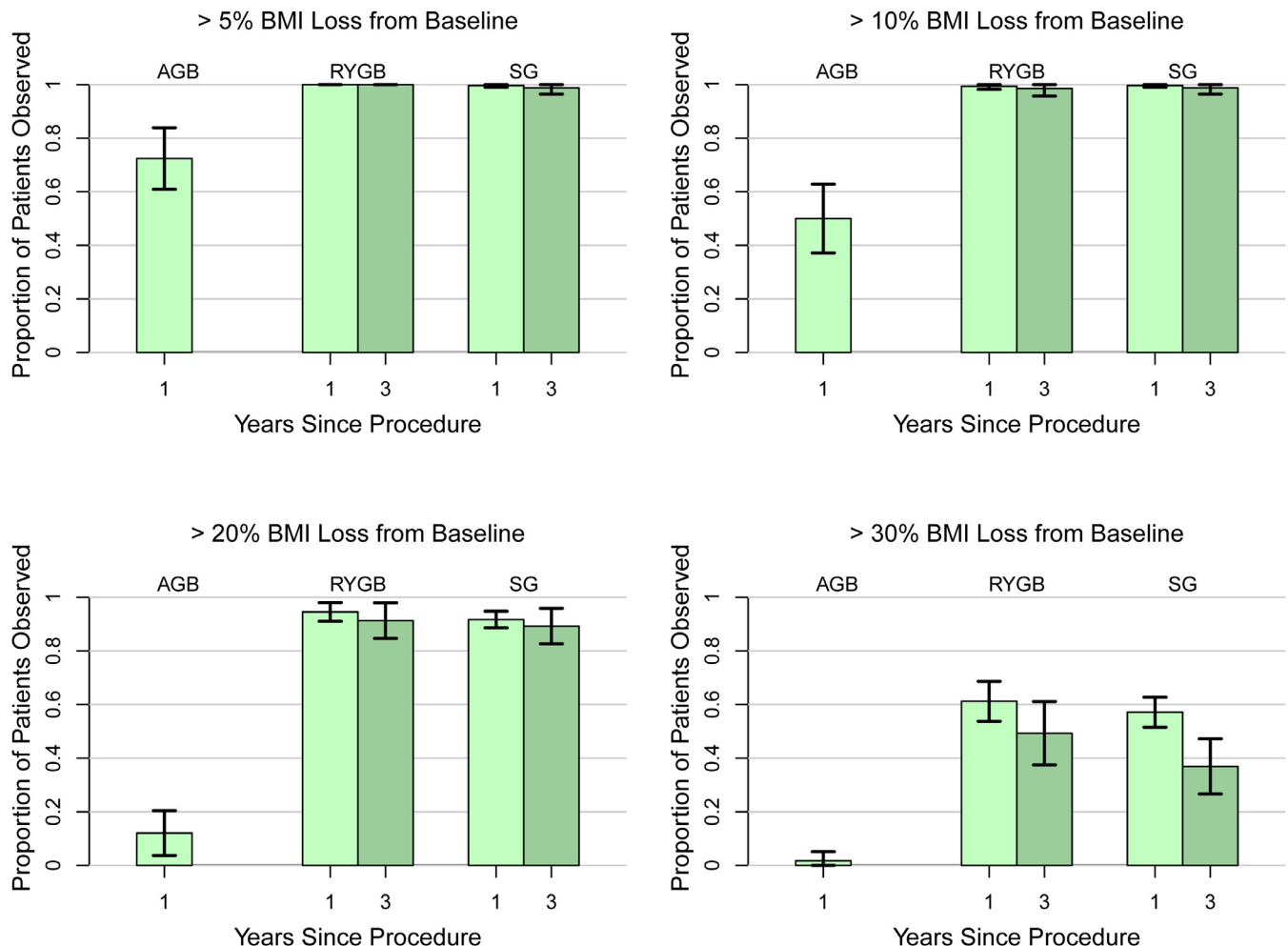


Fig. 4. Proportions of adolescent patients undergoing Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and adjustable gastric banding (AGB) with weight loss of >5%, >10%, >20%, and >30% at 1 and 3* years, by procedure. *Sample sizes were insufficient for AGB to model 3 years of follow-up.

study was not designed to compare outcomes between SG and RYGB. Notably, the 3-year weight loss in Teen-LABS was comparable to that seen with the PCORnet cohort; Teen-LABS found approximately 27% weight loss after RYGB or SG, compared with 29% and 25% after RYGB and SG in the current analysis. The similarities in BMI outcomes between the studies increases confidence in the estimates derived from PCORnet data, despite the magnitude of missing BMI data in this study (e.g., only 50% of eligible patients were observed at 3-yr follow-up).

Detailed assessments of co-morbid conditions were not conducted on this data set, which relied on the use of ICD-9 and Systematized Nomenclature of Medicine diagnosis codes to identify co-morbidities at baseline. Thus, we were unable to assess whether the differences in BMI change between RYGB and SG over time were associated with differential resolution or improvement in

co-morbid conditions. However, a weight loss of $\geq 10\%$ after lifestyle or medical intervention has been shown to result in clinically meaningful changes in weight-related co-morbidities [24]. It is likely that the sustained BMI loss of $\geq 20\%$ in approximately 90% of patients undergoing either SG or RYGB would be expected to result in significant degree of resolution of related clinical disease(s); including improvement in biological markers of disease risk [10]. However, this question requires further study, including more carefully phenotyped co-morbidity status at baseline and follow-up time points.

Due to a theoretically lower risk of nutritional deficiencies [10,25–29] and reduced surgical risk [10,25] associated with SG, this procedure has gained increasing acceptance in adults [30] and adolescents. Similar to other recent reports, our data suggest that SG is the predominant bariatric procedure used for adolescents in the United

States. While the estimated magnitude of weight loss after SG at 5 years remains substantial at 20%, the appearance of slow, steady weight regain between 1 and 5 years (Table 2; Fig. 3) highlights the need to follow adolescents over the long term to best characterize the durability of this procedure and to proactively monitor patients lifestyle habits associated with long-term weight loss maintenance. It is also important to consider that while very few adverse events were recorded for any of the procedures, the vertical SG is the only irreversible procedure of the 3 evaluated, and this fact should be weighed when comparing risks of each of these procedures. Furthermore, a greater proportion of RYGB than SG patients achieved 30% weight loss, suggesting that RYGB may be a superior procedure for patients with the most severe levels of obesity.

The use of AGB has declined precipitously in adults and is currently not indicated for individuals <18 years of age according to the U.S. Food and Drug Administration. This analysis and other data showing substantially less weight loss among patients who used AGB compared with SG and RYGB, as well as the lack of studies evaluating long-term outcomes related to AGB, suggest that AGB is unlikely to have a significant role in treatment of adolescent obesity in the future.

This study has several limitations. First, patients were not randomized, risking unobserved confounding that may have persisted after covariate and propensity score adjustment in our comparisons. Second, in this retrospective study using data collected during clinical care, the amount of missing weight data was substantial, particularly at 5 years after surgery, which could introduce bias into our outcome assessment. However, this concern is mitigated by our sensitivity analysis demonstrating that BMI loss trajectories for patients lost to follow-up is comparable to those with continued follow-up after conditioning on observed covariates. Additionally, the very similar estimates of percent weight loss compared with the Teen-LABS prospective cohort study, which has <20% missing data at 3 years, bolsters confidence in the current weight loss estimates. The AGB procedure may be underrepresented in this cohort as PCORnet does not include small ambulatory surgical centers. Another limitation is that co-morbid health conditions' baseline prevalence was based only on use of ICD-9 and Systematized Nomenclature of Medicine codes, which can be inaccurately applied and do not account for disease severity. Perhaps more importantly, co-morbidities were only captured from the electronic health records at the health system where the surgery was performed, and so co-morbidities diagnosed by doctors outside these systems would not be included. Clinical laboratory outcomes, such as insulin, lipid profiles, liver enzymes, and liver biopsies, were not available for defining co-morbid conditions. Finally, 9% of patients did not have baseline BMI measures within 30 days of operation. To the extent that there was major weight loss in this group between the baseline BMI

and the time of surgery, this unmeasured change would also represent a limitation in our study.

Conclusion

The PBS analyzed electronic health records of the largest sample of adolescents undergoing surgery to date and found that clinically significant and durable weight loss was achieved over a 3- to 5-year period. Adolescents undergoing RYGB and SG experienced the greatest decline in BMI and in large part maintained this weight loss over the 5-year follow-up time period, while patients undergoing AGB lost the least weight.

Understanding how these procedures impact long-term weight loss helps patients, families, and healthcare providers have more informed conversations about the potential benefits of surgical treatment of severe obesity in adolescents. Further long-term studies addressing how these bariatric procedures impact not only BMI but also nutrition, risk of adverse events, and obesity-related physical and mental health co-morbidities are needed.

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Disclosures

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

Supplementary materials

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