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Comparative effectiveness of Roux-en-Y gastric bypass and sleeve gastrectomy in super obese patients

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Abstract

Background The disproportionate increase in the super obese (SO) is a hidden component of the current obesity pandemic. Data on the safety and efficacy of bariatric procedures in this specific patient population are limited. Our aim is to assess the comparative effectiveness of the two most common bariatric procedures in the SO.

Methods Using the Bariatric Outcomes Longitudinal Database from 2007 to 2012, we compared SO patients (BMI $\geq$ 50) undergoing laparoscopic Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG). Stepwise logistic regression modeling was used to calculate a propensity score to adjust for patient demographics and comorbidities.

Results We identified 50,987 SO patients who underwent RYGB (N = 42,119) or SG (N = 8868). There was no difference in adjusted overall 30-day complication rate comparing RYGB and SG patients (11.5 vs. 11.1 %, $p = 0.250$). RYGB patients had higher adjusted rates of 30-day mortality (0.3 vs. 0.2 %, $p = 0.042$), reoperation (4.0 vs. 2.4 %, $p < 0.001$), and readmission (6.9 vs. 5.5 %, $p < 0.001$) compared to SG patients. The percent of total weight loss (%TWL) was significantly higher for RYGB patients compared to SG at 3 months (14.1 vs. 13.1 %, $p < 0.001$), 6 months (25.2 vs. 22.4 %, $p < 0.001$), and 12 months (34.5 vs. 29.7 %, $p < 0.001$). RYGB patients had increased resolution of all measured comorbidities: diabetes mellitus (61.6 vs. 50.8 %, $p < 0.001$), hypertension (43.1 vs. 34.5 %, $p < 0.001$), gastroesophageal reflux disease (53.9 vs. 32.5 %, $p < 0.001$), hyperlipidemia (39.7 vs. 32.5 %, $p < 0.001$), and obstructive sleep apnea (42.8 vs. 40.6 %, $p = 0.058$) at 12 months compared to SG patients.

Conclusions There are significant differences in comorbidity improvement and resolution as well as weight loss between RYGB and SG in the SO population. There was no difference in overall 30-day complications, but more RYGB patients required readmission and reoperation. However, RYGB was considerably more effective in controlling obesity-related comorbidities. Our results favor performance of RYGB in SO patients of appropriate risk.

Keywords Super obese · Bariatric surgery · Gastric bypass · Sleeve gastrectomy · BOLD

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Within the growing obesity pandemic over the last several decades, there has been a substantial increase in the prevalence of super obese (SO; BMI $\geq$ 50) individuals in the USA [1–3]. Bariatric surgery has proven to be the most effective long-term treatment for obesity [4–7]. In addition to weight loss, multiple studies have shown a reduction in long-term mortality, an improvement or resolution in a wide range of medical conditions including diabetes, hypertension, hyperlipidemia, a reduction in the prevalence of solid cancers, and substantial quality of life improvement after bariatric surgery [8–10].

SO patients present unique challenges to the healthcare system. There are considerable differences in obesity-related healthcare costs by degree of obesity [11]. Historically, SO patients have been associated with increased perioperative risk due to their greater incidence of comorbidities [12], although more recent data seem to be less clear [13–15]. Furthermore, these patients commonly have thicker abdominal walls, greater amounts of visceral fat in the abdominal cavity, and hepatomegaly [16]. These factors contribute to decreased visualization, the common need of specialized instrumentation, and pose technical challenges which can lead to increased operative times and surgeon fatigue [17].

Choosing the appropriate bariatric operation for the SO population is controversial. Both the laparoscopic Roux-en-Y gastric bypass (RYGB) and laparoscopic sleeve gastrectomy (SG) have been shown to result in significant weight loss and comorbidity reduction in the morbidly obese [17, 18]. The development of SG was based on the premise that biliopancreatic diversion and duodenal switch were potentially associated with significantly higher perioperative risk in the SO patients [19]. Therefore, patients wound undergo staged intervention with SG first followed by another second stage procedure at a later time. However, the second stage is uncommonly done, and SG is offered as a final treatment [20]. In addition, SG has recently supplanted the RYGB as the most commonly performed bariatric operation [21, 22]. There are few studies directly comparing RYGB and SG outcomes specifically within SO patients. The aim of this study is to assess the comparative effectiveness of the two most common bariatric procedures in the SO.

Materials and methods

The Bariatric Outcomes Longitudinal Database [BOLD, Surgical Review Corporation (SRC); Raleigh, NC] from 2007 to 2012 was used for this study. This database was developed for the assessment of the early and long-term outcomes of bariatric surgery. It captured demographics, clinical and surgical characteristics, details of perioperative care, and outcomes. Data were collected by trained clinical reviewers for all patients undergoing bariatric surgery at accredited centers while SRC was the accrediting body. The database has been studied to ensure high data quality [23].

Baseline patient information assessed for this study included patient age, race, gender, BMI, insurance status, comorbidities, history of prior bariatric surgery, and American Society of Anesthesiologists (ASA) score. Patient comorbidities [history of congestive heart failure (CHF), angina, deep venous thrombosis (DVT) or pulmonary embolism (PE), impaired functional status, ischemic heart disease, obstructive sleep apnea (OSA), pulmonary hypertension, and tobacco use] are recorded on a 6-point scoring system (0–5) according to the relative severity of the condition with a score of 0 indicating absence of disease. These were used to assess for severity of baseline disease. Additionally, comorbidities were used to assess for surgery efficacy: diabetes mellitus (DM), hypertension (HTN), gastroesophageal reflux disease (GERD), hyperlipidemia (HLD), and obstructive sleep apnea (OSA). These were recorded in the same scoring system, at baseline and each follow-up visit. Comorbidity improvement was defined as a lower score on follow-up assessments compared to preoperative. Similarly, comorbidity resolution was defined as a change from any preoperative score $\geq$1–0 on follow-up assessment.

Information specific to the surgical procedure was assessed including adverse events and readmissions. Complications in BOLD include all deaths and unfavorable occurrences (anastomotic leakage, anastomotic stricture, DVT, myocardial infarction, pneumothorax, PE, organ system failure, sepsis, cerebrovascular accident, and bleeding requiring transfusion) that prolonged hospitalization, required return to the emergency department or hospital, or treatment outside of standard postoperative care. Reoperation is defined as any surgical intervention after the index operation as the result of a complication. Follow-up information was aggregated: The 3 month postoperative assessment included all visits from 0 to 3 months, the 6-month postoperative assessment included all visits from 4 to 6 months, and the 12-month assessment included all visits from 7 to 12 months after the index procedure. When multiple visits were recorded during each interval, data were only assessed from the visit closest to the time point of interest.

We limited our study population to patients with BMI $\geq$ 50 that underwent RYGB or SG within the study period. Additionally, we excluded all revisional bariatric procedures as well as cases that were not performed laparoscopically. The primary endpoint was percentage of total weight loss (%TWL) at 12 months. The weight loss indices among RYGB and SG patients within BOLD have been studied previously; %TWL was determined to be the most accurate and least influenced by initial weight and was suggested to be used for the expression of weight loss after surgery [24]. The secondary endpoints were disease resolution for DM, HTN, GERD, HLD, and OSA at 12 months, as well as 30-day postoperative safety. Further, we examined all the

Table 1 Unadjusted and adjusted preoperative characteristics and comorbidities of the entire cohort of RYGB (laparoscopic Roux-en-Y gastric bypass) and SG (laparoscopic sleeve gastrectomy) patients

	Unadjusted values			Adjusted values		
	RYGB $N = 42{,}119$	SG $N = 8868$	p value	RYGB $N = 42{,}119$	SG $N = 8868$	p value
Age	43.8 (43.6–43.9)	43.1 (42.9–43.4)	<0.001	43.7 (43.5–43.8)	43.9 (43.7–44.2)	0.036
BMI	56.4 (55.7–56.4)	56.8 (56.7–57.0)	<0.001	57.3 (57.2–57.4)	57.8 (57.6–57.9)	<0.001
Male gender	25.7 %	32.3 %	<0.001	27.1 %	29.1 %	<0.001
ASA > 2	82.4 %	76.3 %	<0.001	81.4 %	80.9 %	0.124
Caucasian	82.4 %	76.3 %	<0.001	70.6 %	70.7 %	0.767
Private insurance	69.7 %	69.7 %	0.983	69.4 %	70.2 %	0.053
CHF	3.5 %	2.6 %	<0.001	3.4 %	3.2 %	0.105
Angina	3.1 %	2.8 %	0.127	3.0 %	2.6 %	0.090
DVT/PE	3.7 %	3.2 %	0.031	3.6 %	3.9 %	<0.001
Functional status impairment	6.0 %	4.7 %	<0.001	5.8 %	6.3 %	0.002
Ischemic heart disease	4.0 %	3.5 %	0.052	3.9 %	4.1 %	0.817
OSA	56.1 %	55.3 %	<0.001	55.7 %	56.3 %	0.358
Pulmonary hypertension	5.9 %	4.7 %	<0.001	5.7 %	5.8 %	0.788
Tobacco use	6.5 %	6.8 %	0.272	6.4 %	6.6 %	0.586

Values represent mean (95 % Confidence Interval) or proportion

weight loss indices and disease resolution or improvement at earlier time points (3 and 6 months). The entire cohort was used for assessment of early 30-day complications, while long-term outcomes evaluation was limited to patients that had follow-up within each time frame (3, 6, and 12 months). This study was deemed exempt by the East Carolina University and Medical Center Institutional Review Board. Using SAS (Cary, NC) version 9.4, a stepwise logistic regression model was used to calculate a propensity score and adjust for patient demographics and comorbidities. Covariates used in the model were age, preoperative BMI, ASA score, race, insurance type, CHF, angina, DVT or PE, ischemic heart disease, OSA, pulmonary hypertension, and tobacco use. The adjusted data are presented as weighted percentage or mean (95 % Confidence Interval) where the weights are defined as the inverse of the propensity score of the actual group assigned. Nominal values were compared using Chi-squared or Fisher's exact test. Continuous variables were compared using Student's t test. Results are reported as mean (95 % Confidence Interval) for continuous variables and frequency for nominal variables. Any p value < 0.05 was considered statistically significant.

Results

We identified 50,987 SO patients, of which 42,119 underwent RYGB and 8868 underwent SG procedures. The mean age and BMI for the entire cohort were 43.6 (43.5–43.7) years and 57.1 (57.0–57.2) kg/m^2, respectively. The majority were females (73.1 %). The stepwise logistic regression model resulted in very similar cohorts, with small differences in some variables that were statistically significant but unlikely to have a significant clinical impact. Nevertheless, there was a small difference in age [43.7 (43.5–43.8) vs. 43.9 (43.7–44.2), $p = 0.036$], BMI [57.3 (57.2–57.4) vs. 57.8 (57.6–57.9), $p < 0.001$], and male gender [27.1 % (26.5–27.6) vs. 29.1 % (28.5–29.7), $p < 0.001$] when comparing the RYGB and SG groups (Table 1). Patient comorbidities were also very similar with small differences in DVT/PE history (3.6 vs. 3.9 %, $p < 0.001$) and functional status impairment (5.8 vs. 6.3 %, $p = 0.002$) but without any statistically significant differences in other comorbidities.

The analysis of 30-day outcomes showed no difference in overall complications (11.5 vs. 11.1 %, $p = 0.250$) between RYGB and SG, respectively. However, RYGB patients had higher adjusted rates of mortality (0.3 vs. 0.2 %, $p = 0.042$), reoperation (4.0 vs. 2.4 %, $p < 0.001$), and readmission (6.9 vs. 5.5 %, $p < 0.001$) compared to SG patients. The 90-day adjusted outcomes showed no difference in mortality (0.4 vs. 0.3 %, $p = 0.697$) or anastomotic leak (0.8 vs. 1.0 %, $p = 0.129$) among RYGB and SG patients. RYGB patients had higher rates of 90-day readmission (9.2 vs. 6.6 %, $p < 0.001$), morbidity (16.0, 13.7 %, $p < 0.001$), and reoperation (6.7 vs. 3.2 %, $p < 0.001$) compared to SG patients.

Overall weight loss metrics at follow-up intervals of 3, 6, and 12 months were greater for RYGB patients

Table 2 Adjusted postoperative weight loss per procedure type at 12-month follow-up

	3-month follow-up			6-month follow-up			12-month follow-up		
	RYGB $N = 38{,}035$	SG $N = 7752$	p value	RYGB $N = 20{,}821$	SG $N = 3398$	p value	RYGB $N = 12{,}896$	SG $N = 1487$	p value
% TWL	14.1 (14.0–14.2)	13.1 (12.9–13.2)	<0.001	25.2 (25.0–25.3)	22.4 (22.1–25.3)	<0.001	34.5 (34.3–34.6)	29.7 (29.2–30.2)	<0.001
% EBWL	24.9 (24.8–25.0)	22.8 (22.6–23.0)	<0.001	42.9 (42.8–43.1)	38.0 (37.6–38.4)	<0.001	58.0 (57.7–58.2)	49.0 (48.3–49.9)	<0.001
BMIL	8.1 (8.0–8.2)	7.6 (7.5–7.7)	<0.001	15.0 (14.9–15.0)	13.5 (13.4–13.7)	<0.001	20.2 (20.2–20.3)	17.9 (17.6–18.2)	<0.001

Values represent mean (95 % Confidence Interval)

LRYGB laparoscopic Roux-en-Y gastric bypass, *LSG* laparoscopic sleeve gastrectomy, *%TWL* percent total weight loss, *%EBWL* percent excess body weight loss, *BMIL* BMI loss

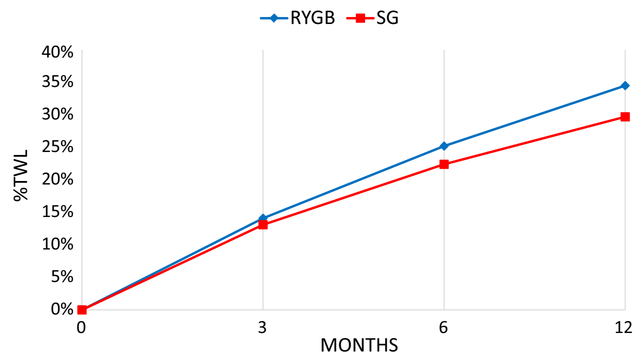

Fig. 1 Percent total weight loss of RYGB (laparoscopic Roux-en-Y gastric bypass) and SG (laparoscopic sleeve gastrectomy) at 3, 6, and 12-month follow-up

(Table 2). There was significantly higher %TWL for SO patients who underwent RYGB compared to SG at 3 months (14.1 vs. 13.1 %, $p < 0.001$), 6 months (25.2 vs. 22.4 %, $p < 0.001$), and 12 months (34.5 vs. 29.7 %, $p < 0.001$; Fig. 1). Additionally, percent of excess body weight loss (%EBWL) was significantly higher for patients undergoing RYGB compared to SG at 3 months (24.9 vs. 22.8 %, $p < 0.001$), 6 months (42.9 vs. 38.0 %, $p < 0.001$), and 12 months (58.0 vs. 49.0 %, $p < 0.001$). At 12 months, there was a higher rate of patients with %EBWL $\geq$ 50 % [71.9 % (70.8–72.9) vs. 47.4 % (46.1–48.7), $p < 0.001$], TWL $\geq$ 25 % [88.3 % (CI 87.6–89.1) vs. 69.4 % (CI 68.1–70.6), $p < 0.001$], and TWL $\geq$ 30 % [72.0 % (71.0–73.0) vs. 48.0 % (46.7–49.3), $p < 0.001$] following RYGB compared to SG.

Comorbidity resolution at 3, 6, and 12 months is shown in Fig. 2. RYGB patients had a higher resolution of all measured comorbidities—DM, HTN, GERD, HLD, and OSA at 3, 6, and 12 months compared to SG patients. All differences in comorbidity resolution are statistically significant except OSA resolution at 12-month follow-up. RYGB patients displayed a higher rate of improvement of all examined comorbidities (Fig. 3).

Discussion

We found significant differences in weight loss as well as comorbidity improvement and resolution between RYGB and SG in the SO population. Few studies have previously compared SG and RYGB in this patient population, but small sample size and single institution design limit the applicability of results.

Our study shows no difference in 30-day postoperative morbidity between RYGB and SG. However, RYGB had higher rates of 30- and 90-day rates of reoperation and readmission. Our results are consistent with prior analyses comparing these procedures in the SO. In a single- center

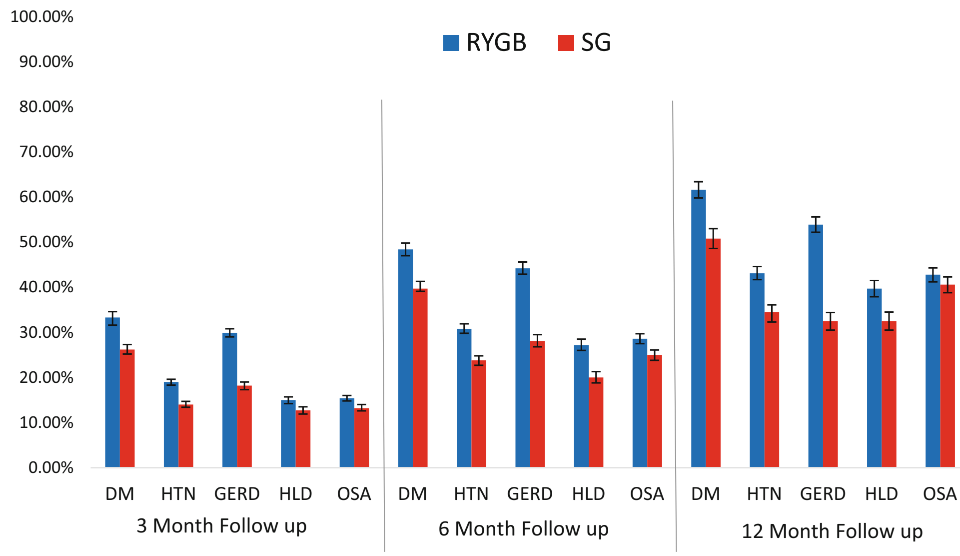

Fig. 2 Comparison of comorbidity resolution between RYGB (laparoscopic Roux-en-Y gastric bypass) and SG (laparoscopic sleeve gastrectomy) at 3, 6, and 12-month follow-up. *Error bars* represent 95 % Confidence Interval. DM (type 2 diabetes), HTN (hypertension), GERD (gastroesophageal reflux disease), HLD (hyperlipidemia), and OSA (obstructive sleep apnea)

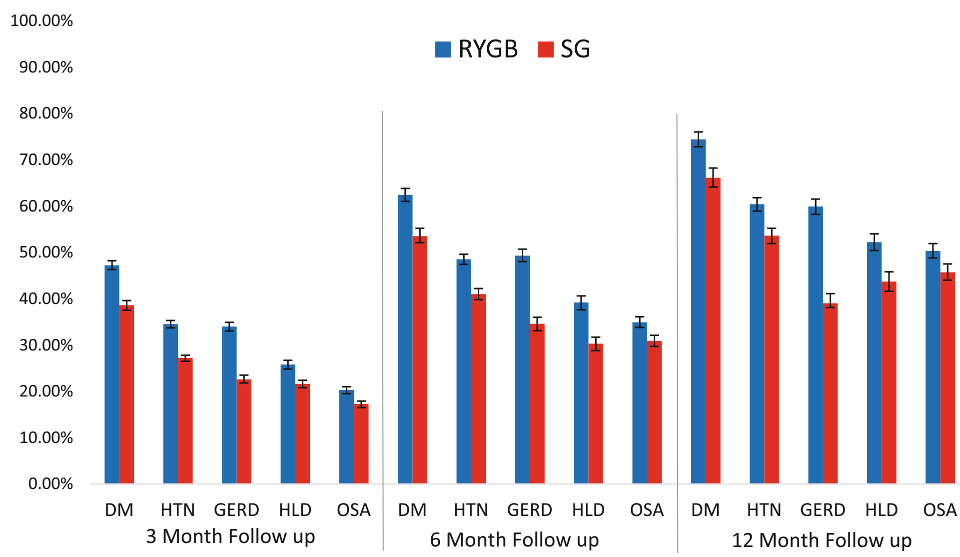

Fig. 3 Comparison of comorbidity improvement between RYGB (laparoscopic Roux-en-Y gastric bypass) and SG (laparoscopic sleeve gastrectomy) at 3, 6, and 12-month follow-up. *Error bars* represent 95 % Confidence Interval. DM (Type 2 diabetes), HTN (hypertension), GERD (gastroesophageal reflux disease), HLD (hyperlipidemia), and OSA (obstructive sleep apnea)

retrospective study of 359 SO patients, there was no significant difference in the 30-day complication rates of RYGB and SG [25]. A similar study by Zerrweck et al. [12] involved 77 SO patients and also found no difference in the 30-day complication rate between RYGB and SG. Although these studies did not provide a detailed breakdown of individual complications, our results show a higher rate of readmission and reoperation for the RYGB, suggesting higher resource utilization compared to the SG. The 30-day mortality in our study was slightly higher among RYGB patients. This finding barely reached statistical significance and was not retained when 90-day outcomes were examined. Furthermore, our observed mortality rates are similar to current published rates, demonstrating low mortality among all bariatric patients [26].

RYGB SO patients had significantly higher %TWL at each time point (3, 6, and 12 months), and significantly, more RYGB SO patients achieved commonly used benchmarks for successful weight loss compared to SG SO patients. This is in accordance with other studies comparing RYGB and SG in this specific patient population [12, 25].

It is noteworthy that the RYGB patients in our study displayed higher rates of improvement of all examined comorbidities and higher rates of resolution of all but obstructive sleep apnea. This finding verifies what Thereaux's study has suggested in this patient population [25]. A recent meta-analysis on the treatment of obesity-related comorbidities after RYGB and SG in the general bariatric population, using 62 studies with over 18,000 patients favored the RYGB in resolution of all measured comorbidities [27]. There was a significantly higher resolution rate after RYGB for HTN, HLD, and GERD, while procedural effect for DM and OSA was not statistically significant [27].

The SG and RYGB were recently compared in a randomized trial among general bariatric population patients in the Swiss Multicentre Bypass or Sleeve Study (SM-BOSS) [28]. The results showed that among the general bariatric population, SG and RYGB have similar outcomes. The investigators found no significant difference in 30-day complication rates, comorbidity improvement, or weight loss between the two procedures. However, the results from this important study may not be applicable to the SO. A greater prevalence and severity of metabolic comorbidities including diabetes, hypertension, and dyslipidemia are seen in the SO compared to the morbidly obese [3, 29]. Furthermore, SO patients have historically demonstrated different weight loss patterns compared to non-SO patients, following both vertical banded gastroplasty and more recently with RYGB [3, 30, 31]. Additionally, SO patients can pose a technical challenge as they typically have more visceral fat and hepatomegaly resulting in longer operative times and surgeon fatigue compared to non-SO patients [17, 32]. Thus, while SM-BOSS showed comparable outcomes after RYGB and SG in morbidly obese, it should not be surprising that our results among the SO differ. Future studies are needed to further examine the effects of procedure type on this bariatric patient population.

We recognize that the present study has several limitations. While BOLD uses prospectively collected data from trained clinical reviewers, it was not designed to answer the aims of this study, and it is inherent to selection bias. To account for this, at least in part, we used propensity matching to apply weights to the outcomes examined. We chose the endpoint of 12 months after surgery as it represents a milestone for the postoperative bariatric care and provides a good understanding of weight loss. The lost to follow-up rate increases dramatically in the dataset after 12 months, and selection bias would greatly impact longer time points. However, up to 12-month follow-up, we observed a low rate of attrition that further validates our results. Although the longer-term risks may be less with SG (anastomotic ulcer, internal hernia, micronutrient deficiencies), our study was not designed to assess for these since it is limited to 12 months. Additionally, we were not able to evaluate weight maintenance or weight regain using this dataset. The SG was still a relatively new operation for much of the time period studied, and some of the perioperative complications could be attributed to a learning curve of the procedure.

We have shown that there are considerable differences in comorbidity improvement and resolution as well as weight loss after RYGB and SG in the SO population. Overall, perioperative complications are similar between the two groups, but RYGB patients require increased healthcare utilization in terms of reoperation and readmission. The RYGB was considerably more effective in controlling obesity-related comorbidities within the first year from surgery. Although bariatric procedure selection needs to be individualized based on patient risk tolerance and long-term goals, our results favor the performance of RYGB in SO patients of appropriate risk.

Compliance with ethical standards

Disclosures Drs. Celio, Wu, Kasten, Manwaring, Pories, and Spaniolas have no conflicts of interest or financial ties to disclose.

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