



Original article

Bariatric surgery is safe and effective in Medicare patients regardless of age: an analysis of primary gastric bypass and sleeve gastrectomy outcomes

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Abstract

Background: Numerous studies have shown that bariatric surgery in older patients is safe and effective. However, both the Agency for Healthcare Research and Quality (AHRQ) and a Medicare Evidence Advisory Committee (MEDCAC) have cited gaps in the evidence for outcomes in Medicare patients undergoing bariatric surgery. These gaps are predominantly in the safety and outcomes evidence in Medicare patients younger than 65 years old (Centers for Medicare and Medicaid Services [CMS] < 65).

Objectives: The aim of our study was to review both the safety and efficacy of gastric bypass (RYGB) and sleeve gastrectomy (SG) in Medicare patients compared with other payers.

Setting: A single academic medical center.

Methods: A prospectively maintained database of 3300 patients who underwent bariatric surgery between January 2007 and December 2017 was utilized. The outcomes of Medicare patients undergoing RYGB and SG were analyzed and compared to those of similar patients covered by Medicaid or Commercial insurers.

Results: There were too few patients with commercial insurance older than 65 to compare to those with Medicare (CMS \geq 65). Mortality at 90 days for CMS \geq 65 was 1.3% and the overall complication rate was 20.1% (minor 15.6%; major 7.1%). Total weight loss (TWL) at 6 months and 1, 2, and 3 years was 25.3%, 30.0%, 29.9%, and 29.4% respectively. For any time after surgery, 23% of CMS \geq 65 had complete remission of diabetes and 45% had partial remission.

Demographic analysis of CMS < 65 found Medicare patients were significantly older with more diabetes, hypertension and hyperlipidemia than those with commercial payers. Mortality at 90 days for CMS < 65 was 0.6% and the overall complication rate was 18.3% (minor 14.3%; major 4.7%). Mortality was not significantly different between payers. After adjustment for baseline differences and comparing to the Medicare group, the commercial group was less likely to have minor complications ($P = .019$), any complications ($P = .007$), and extended length of stay ($P < .001$). The TWL for the entire cohort age < 65 at 6 months and 1, 2, and 3 years was 28.1%, 34.1%, 34.1%, and 31.8% respectively. After adjusting for differences, there was no significant difference in TWL between payers. For any time after surgery, complete remission of diabetes was 45% in CMS < 65 patients and partial remission was 59%. The comparison of remission between groups was then adjusted for DiaRem score and surgery type. CMS < 65 patients had significantly less partial remission of diabetes than commercial patients ($P = .034$) but no difference in complete remission.

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Conclusions: RYGB and SG are both safe and effective in Medicare patients of all ages. CMS ≥ 65 have acceptable mortality and complication rates with TWL and diabetes remission similar to younger patients. CMS < 65 patients are older than those with commercial insurance with more comorbid disease. While they have longer hospital stays after bariatric surgery, their weight loss and complete remission of diabetes are no different than patients with Medicaid or commercial insurance. This study helps fill an important evidence gap in bariatric surgical patients raised by both Agency for Healthcare Research and Quality, and a Medicare Evidence Advisory Committee. (*Surg Obes Relat Dis* 2019; ■:1–8.) © 2019 American Society for Bariatric Surgery. Published by Elsevier Inc. All rights reserved.

Key words: Bariatric surgery; Medicare; Gastric bypass; Sleeve gastrectomy; Health and human services; Obesity; Diabetes remission

On August 30, 2017, the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) convened a public hearing to review the available evidence for the “health outcomes after bariatric surgical therapies in the Medicare population.” The purpose of this hearing was to obtain public comment on the findings of an Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program study of evidence for “short- and long-term outcomes after bariatric surgery in the Medicare population.” The conclusion of the AHRQ study was that “very few studies exist that address clinically relevant outcomes in Medicare-eligible patients who undergo surgical or endoscopic bariatric procedures” [1].

Evidence for the mechanisms, safety, and efficacy of bariatric surgery was presented to the MEDCAC by Dr. Eric DeMaria. Drs. Orestis Panagiotou and Thomas Trikalinos described their methodology and findings reported in the short- and long-term outcomes after bariatric surgery in the Medicare population, AHRQ Technology Assessment Program Study. Mr. Joseph Nadglowski offered an advocacy position of the importance of bariatric surgery in patients suffering from obesity, while Drs. Kimberly Marschhauser and David Arterburn presented the research evidence of physiologic mechanisms for the efficacy of bariatric surgery. These presentations were followed by a period of expert commentary and open public commentary.

The MEDCAC panel concluded the meeting with a vote indicating a high level of confidence that research studies demonstrate meaningful primary health outcomes after bariatric surgery (including weight loss, diabetic, cardiovascular, and musculoskeletal) as well as an acceptable risk profile and improved quality of life. However, when considering whether “the predictors of success in the Medicare population (such as patient characteristics and pre- and post-procedure standards of care) for any bariatric therapy is known,” the panel reported a low level of confidence.

Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) made up 89.5% of primary bariatric procedures performed in the United States in 2017 [2]. The aim of

our study was to review both the safety and efficacy of these 2 most common primary bariatric procedures in Medicare patients compared with other payors.

Methods

Data were collected prospectively; however, this study was an observational, retrospective review of 3300 patients who underwent bariatric surgery within a single health system and met all the following criteria:

1. Preoperative body mass index (BMI) >35 kg/m²
2. Primary open or laparoscopic RYGB or primary laparoscopic SG occurring between January 1, 2007 and December 31, 2017
3. Signed consent for study (institutional review board 2004-0255).

Prospective collection of patient data began in 2004, and no patients during this period underwent open SG. All patients undergoing initial RYGB or SG (bariatric surgery) after April 2008 were treated with an evidence-based care pathway for preoperative evaluations, perioperative care, and postoperative follow-up. Adherence to this pathway (ProvenCare Bariatric) was routinely measured and optimized. The program has been found to provide both significantly reduced length of stay and complications after bariatric surgery [3].

Medicare patients were stratified into the following 2 groups: age ≥ 65 and age < 65 years. Age ≥ 65 outcomes were reported with no payor comparison because of the very small number of patients without Medicare insurance. Age < 65 were compared with patients who underwent bariatric surgery with coverage by either private commercial payors or Medicaid.

Demographic analysis of payors for each group was done by analysis of variance and X^2 test. Perioperative outcomes were analyzed, including length of stay >2 days (extended length of stay [XLOS]), readmissions within 30 days of discharge, death within 90 days of discharge,

and complications within 30 days of discharge. Major and minor complications were defined by Clavien-Dindo score [4]. In unadjusted analysis, the percentage with each type of perioperative outcome was compared between insurance types using X^2 tests and Fisher's exact test. Time until death after surgery was also evaluated using Kaplan-Meier analysis, log rank tests, and Cox regression (with hazard ratios).

To account for baseline differences between groups in age <65, multiple logistic regression was used to compare perioperative outcomes between the insurance groups while adjusting for age, sex, race, BMI, presence of metabolic disease (diabetes, treatment for hypertension, treatment for hyperlipidemia), and surgery type. This analysis was not done for 90-day death because few deaths occurred.

Differences in the weight loss measures over the 3 years after surgery were compared between insurance groups using longitudinal linear regression models. These were adjusted for age, sex, race, BMI, presence of metabolic disease (diabetes, treatment for hypertension, treatment for hyperlipidemia), and surgery type in the age <65 group.

Remission of diabetes was analyzed for each group using a previously established algorithm (DiaRem score) [5]. Remission of diabetes was defined using American Diabetes Association criteria [6] as follows: (1) Complete remission was defined as normal labs (hemoglobin A1C <5.7%) without use of antidiabetic medications for a consecutive 365 days; and (2) partial or complete remission was defined as absence of abnormal labs (hemoglobin A1C <6.5%) without use of antidiabetic medications for a consecutive 365 days.

Cox regression was used to compare time until remission between insurance groups while adjusting for DiaRem score and surgery type.

Results

Demographic characteristics

A total of 3300 patients were analyzed. The mean follow-up for the entire population was 4.7 years. There were 154 patients age ≥ 65 years (RYGB = 136; SG = 18). Only 11 patients in this group had primary commercial insurance and 7 in this group had Medicare supplemental insurance. Medicaid was the primary insurance in 4 of these patients. The small number of patients without Medicare coverage precluded meaningful comparison of payor groups. There were 3146 patients in the age <65 group; 16% of these patients had Medicare coverage ($n = 505$), while 22% had Medicaid coverage ($n = 686$) and 62% had commercial payors ($n = 1965$). There were many baseline demographic and characteristic differences when comparing Medicare, Medicaid, and commercial insurance types for those age <65 (Table 1). Demographic analysis of age <65 found Medicare patients tended to older with more diabetes as well as treated hypertension and hyperlipidemia. Medicaid patients had the highest percentage of females, lowest percentage of white race, and the highest mean BMI.

Age ≥ 65

The mean follow-up for the age ≥ 65 group was 5.1 years. The mortality at 90 days was 1.3% ($n = 2$). The overall complication rate was 20.1% (minor 15.6%, $n = 24$; major 7.1%; $n = 11$). The 30-day readmission rate was 3.1% ($n = 6$). Complications and readmissions were unknown for 6 patients. XLOS for this group was 26.0% ($n = 40$).

The total weight loss (TWL) at 6 months and 1, 2, and 3 years was 25.3% (standard deviation [SD] = 7.0), 30.0% (8.5), 29.9% (8.9), and 29.4% (8.4), respectively (Fig. 1). The excess weight loss (EWL) at 6 months and 1, 2, and 3 years was 57.5% (SD = 24.3), 68.1% (25.5), 68.6% (25.0), and 68.5% (23.6), respectively.

Table 1
Age <65: baseline demographic characteristics and characteristics compared between insurance payor types ($n = 3146$)

	Medicare $n = 505$	Medicaid $n = 686$	Commercial $n = 1955$	<i>P</i> value
Age, mean (SD)	50.1 (9.3)	40.2 (10.0)	44.3 (10.3)	<.0001*
Female, % (n)	77 (387)	87 (597)	79 (1546)	<.0001†
White race, % (n)	94 (477)	87 (600)	97% (1889)	<.0001†
Baseline BMI, mean (SD)	49.5 (9.6)	50.8 (9.4)	48.1 (7.9)	<.0001*
Diabetes, % (n)	53 (268)	39 (265)	33 (641)	<.0001†
Treated hypertension, % (n)	81 (409)	62 (424)	60 (1176)	<.0001†
Treated hyperlipidemia, % (n)	55 (279)	33 (229)	31 (601)	<.0001†
Surgery type				.210*
RYGB, % (n)	92 (466)	91 (621)	90 (1753)	
LSG, % (n)	8 (39)	9 (65)	10 (202)	

SD = standard deviation; BMI = body mass index; RYGB = Roux-en-Y gastric bypass; LSG = laparoscopic sleeve gastrectomy.

* Analysis of variance.

† X^2 test.

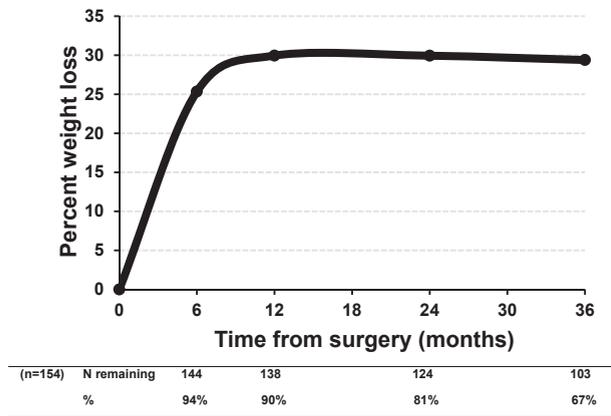


Fig. 1. Age >65: total weight loss.

Diabetes analysis was limited to the subset of patients with diabetes ($n = 93$) and enough follow-up to determine remission status ($n = 78$ of 93). The mean DiaRem score was 11.9 (SD = 5.8). For any time after surgery, the percent with complete remission was 23% (18/78). The percent with partial remission was 45% (35/78).

Age <65

The mean follow-up in the age <65 group was 4.7 years. In unadjusted analysis, the Medicare group followed by Medicaid had the highest percentage perioperative complications, XLOS, and readmissions (Table 2). After adjustment for baseline differences and comparing to the Medicare group, the commercial group was less likely to have minor complications, any complications, and XLOS. There were no significant differences between the Medicare and Medicaid groups (Table 3).

There was no significant difference in the risk of death at 90 days between groups (Table 2). The differences in time until death between insurance type group was significant (log rank P value < .0001). The Medicare group had the highest percentage of deaths (1-yr estimate of 1.0% and 3-yr estimate of 3.0%), followed by the commercial group (1-yr estimate of .5% and 3-yr estimate of 1.1%), and the

Medicaid group (1-yr estimate of .5% and 3-yr estimate of 1.0%). Using Cox regression adjusted for age, sex, race, BMI, presence of metabolic disease (diabetes, treatment for hypertension, treatment for hyperlipidemia), and surgery type had the following results:

1. The chance of death remained significantly higher in the Medicare group versus the commercial group (hazard ratio = 1.91, 95% confidence interval = [1.26–2.92], $P = .0026$).
2. The chance of death in the Medicare group versus the Medicaid group was not significant (hazard ratio = 1.57, 95% confidence interval = [.87–2.85], $P = .133$).

The TWL for the CMS age <65 at 6 months and 1, 2, and 3 years was 28.1% (SD = 6.6), 34.1% (8.5), 34.1% (10.4), and 31.8% (11.0), respectively. The EWL for the entire cohort at 6 months and 1, 2, and 3 years was 61.0% (SD = 17.4), 73.8% (21.2), 73.7% (24.2), and 68.7% (24.6), respectively. After adjusting for age, sex, race, BMI, presence of metabolic disease (diabetes, treatment for hypertension, treatment for hyperlipidemia), and surgery type, longitudinal linear regression revealed that the difference in %TWL was not significant when comparing Medicare with Medicaid ($P = .088$) or when comparing Medicare with commercial ($P = .310$) (Fig. 2). Longitudinal linear regression analysis of %EWL using the same adjustments revealed no significant differences when comparing Medicare with Medicaid ($P = .216$) or when comparing Medicare with commercial ($P = .560$).

The analysis of DiaRem score in age <65 was again limited to the subset of patients with diabetes ($n = 1174$) and enough follow-up to determine remission status ($n = 904$ of 1174). To evaluate the probability of remission within each group, the mean DiaRem score was compared between groups. The Medicare group had a significantly higher mean DiaRem score, suggesting that the chance of diabetes remission would be lowest within this subgroup (Table 4).

Table 2
Age <65: unadjusted comparison of perioperative outcomes

	Medicare n = 505	Medicaid n = 686	Commercial n = 1955	P value
Any minor complication*, % (n)	14.3 (64)	13.6 (85)	8.9 (152)	.0002 [†]
Any major complication*, % (n)	4.7 (21)	2.9 (18)	2.8 (48)	.119 [†]
Any complication* (minor/major), % (n)	18.3 (82)	16.2 (101)	11.5 (196)	.0001 [†]
Length of stay >2 d, % (n)	26.1 (132)	17.1 (117)	12.8 (251)	<.0001 [†]
Readmission*, % (n)	5.6 (25)	5.5 (34)	3.6 (61)	.053 [†]
90-d death, % (n)	.6 (3)	.0 (0)	.3 (5)	.084 [‡]

* 30-d complications and readmissions were unknown for 376 patients ($n = 58$ Medicare, $n = 63$ Medicaid, and $n = 255$ commercial).

[†] χ^2 test.

[‡] Fisher's exact test.

Table 3
Age <65: multiple logistic regression for comparing perioperative outcomes between insurance groups while adjusting for age, sex, race, BMI, presence of metabolic disease, and surgery type

	Medicare n = 505	Medicaid n = 686	Commercial n = 1955
Any minor complication*, % (n)			
OR	Ref	1.12	0.68
[95% CI]		[.70, 1.47]	[.49, .94]
P value		.940	.019
Any major complication*, % (n)			
OR	Ref	.82	.68
[95% CI]		[.42, 1.62]	[.40, 1.18]
P value		.569	.176
Any complication* (minor/major), % (n)			
OR	Ref	.98	.67
[95% CI]		[.70, 1.38]	[.50, .90]
P value		.914	.0072
Length of stay >2 d, % (n)			
OR	Ref	.75	.52
[95% CI]		[.55, 1.01]	[.40, .66]
P value		.058	<.0001
Readmission*, % (n)			
OR	Ref	1.02	.72
[95% CI]		[.58, 1.80]	[.44, 1.18]
P value		.943	.187

BMI = body mass index; OR = odds ratio; CI = confidence interval.

* Complications and readmissions were unknown for 376 patients (n = 58 Medicare, n = 63 Medicaid, and n = 255 Commercial).

For any time after surgery, the percentage of patients with complete remission was 46% (231/501) for commercial, 55% for Medicaid (104/190), and 45% (94/209) in Medicare. The percentage of patients with partial remission was 70% (352/503) for commercial, 70% for Medicaid (133/191), and 59% (123/210) in Medicare.

The comparison of remission between groups was then adjusted for DiaRem score and surgery type. The overall test for differences in diabetes remission was significant ($P = .034$) for partial/complete remission but not for complete remission ($P = .478$). The hazard ratios adjusted for DiaRem score and surgery type using Medicare as the reference group showed no significant difference between complete remission for either payor compared with Medicare. There was significantly more partial/complete remission in commercial versus Medicare (odds ratio = 1.31, $P = .011$); however, there was no significant difference between Medicaid and Medicare patients (Table 4).

Discussion

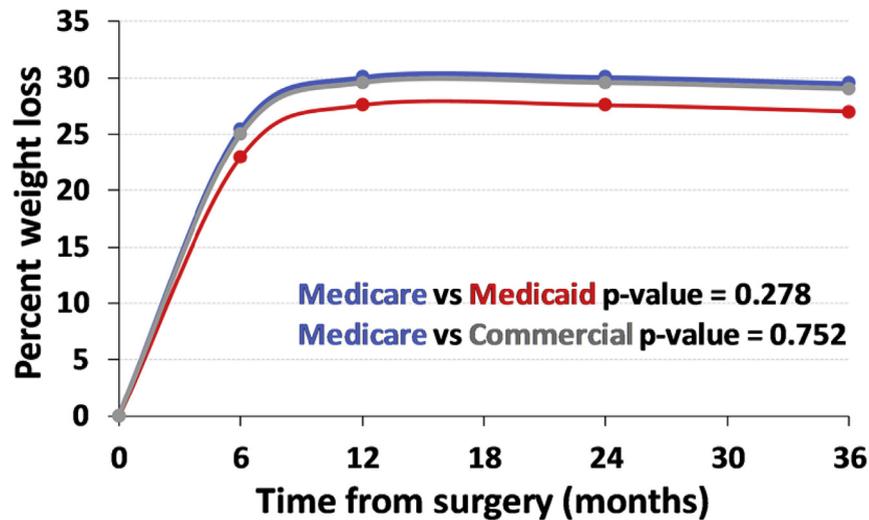
The prevalence, morbidity, and cost of obesity prompted the American Medical Association to classify obesity as a

disease in 2013 [7], and it remains one of the most serious public health problems in the United States. The estimated annual medical cost of obesity in the United States was \$147 billion in 2008 U.S. dollars. The medical costs for people with a BMI >30 kg/m² was approximately \$1400 higher than those with a normal BMI (18.5–24.9 kg/m²) [8]. This disease burden is of particular concern for the Centers for Medicare and Medicaid Services as they consider healthcare policy. Based on the U.S. National Health and Nutrition Examination Survey in 2012, the obesity epidemic affects people ≥60 years with a BMI prevalence of ≥30 (35%), ≥35 (14%), and ≥40 (6%) kg/m² [9]. However, the Centers for Medicare and Medicaid Services responsibility for obesity care is not confined to older patients; they provide funding for bariatric surgery in eligible patients <65 with disabilities.

In their AHRQ Technology Assessment Program Study, Panagiotou et al. [1] concluded that there was evidence for the benefits of bariatric surgery for both weight loss and nonweight loss outcomes. This group [1] used a mean age of 55 to qualify eligible studies for review because they found no eligible studies specifically for bariatric surgery in Medicare patients age <65. They found only 3 studies eligible for review with a mean age of ≥65 that reported weight loss and/or nonweight loss outcomes [1]. The age ≥65 studies included that by Perry et al. [10], who used a Medicare database of patients undergoing bariatric surgery between 2001 and 2004. This was the only study to report outcomes in patient subgroups older and younger than 65. Studies by Casillas et al. [11] reported from a data registry of 14 hospitals and 200 medical offices and Spaniolas et al. [12] reviewed the National Surgical Quality Improvement Database for 2010 and 2011. Both studies compared outcomes in patients undergoing laparoscopic SG and RYGB.

Our single-center study found that nearly all age ≥65 patients were covered by Medicare as either a primary or supplemental insurer (95%). There was a lack of statistical power for comparison of payor groups in this population due to small Medicaid and commercial sample sizes. The mean follow-up of 5.1 years was longer than any of the eligible studies in the Panagiotou et al. AHRQ study [1]. Our results confirmed both the safety and efficacy of bariatric surgery for weight loss and non-weight loss outcomes in age ≥65 patients with results similar to those reported in other eligible studies (Table 5). The difference in mortality and complications reported in the Casillas et al. [11] study is likely due to the preponderance of SG patients (58.7%) compared with our study (11.7%).

Most age <65 patients were covered by commercial payors (62%). Medicare patients in this group were significantly older with more co-morbid diseases than other payor groups, which may skew direct analysis. Therefore, adjusted logistic regression analysis of perioperative outcomes was completed. This demonstrated a significantly higher risk of XLOS and minor complications (but not major



Medicare (n=505)	N remaining	474	447	382	325
	%	94%	89%	76%	64%
Medicaid (n=686)	N remaining	609	555	471	386
	%	89%	81%	69%	56%
Commercial (n=1955)	N remaining	1819	1684	1463	1281
	%	93%	86%	75%	66%

Fig. 2. Age <65: total weight loss compared between insurance types.

complications) for patients with Medicare compared with commercial payors. There were no significant differences between Medicare and Medicaid age <65 patients.

The risk of death at 90 days was not significantly higher for age <65 Medicare patients than for other payors. However, approximately 1% of Medicare patients died within 1 year of surgery and approximately 3% within 3 years. This rate was higher than the death rates for other age <65 payors of approximately .5% at 1 year and 1% at 3 years.

Table 4
Age <65: Cox regression results (adjusting for DiaRem score and surgery type) for time until remission compared between insurance groups

	Medicare n = 210	Medicaid n = 191	Commercial n = 503
DiaRem, mean (SD)	10.8 (6.6)	8.9 (6.9)	8.9 (6.4)
P value*		.0010*	
Complete remission			
HR	Ref	1.07	.93
95% CI		[.81, 1.41]	[.73, 1.18]
P value†		.650	.542
Partial/complete remission			
HR	Ref	1.16	1.31
95% CI		[.91, 1.48]	[1.07, 1.61]
P value†		.241	.011

SD = standard deviation; CI = confidence interval; HR = hazard ratio.

* Analysis of variance.

† P value is from comparing each insurance group versus the Medicare group (adjusted for DiaRem and surgery type).

When adjusted, Cox regression revealed that this risk of death was significant at 1 and 3 years when age <65 Medicare patients were compared with commercial, but not compared with Medicaid patients. We were not able to perform adjusted analysis for the disabilities that qualify patients under age 65 for Medicare coverage. Because there is no disability requirement for commercial payors, it is probable that these disabilities and their associated socioeconomic factors as well as age, have a significant influence on the both late mortality and the clinical outcome differences between the Medicare and commercial payor groups. This association requires further investigation.

The overall TWL in age <65 patients at 3 years was 28.1% and the EWL at 3 years was 61%. Neither TWL nor EWL in Medicare patients was significantly different from weight loss for commercial or Medicaid patients even when adjusted for age, sex, race, BMI, presence of metabolic disease (diabetes, treatment for hypertension, treatment for hyperlipidemia), and surgery type (Fig. 2).

The age <65 Medicare patients did have significantly higher baseline DiaRem scores, which are associated with lower rates of diabetes remission [5]. Despite this finding, there was no significant unadjusted or adjusted difference in complete remission between any of the age <65 payor groups. When Medicare patients were compared with commercial patients by linear regression adjusted for DiaRem score and type of surgery, the rate of partial/complete remission was significantly higher for commercial patients age <65.

Table 5
Age >65: comparative studies of bariatric surgery in the Medicare population

	Data source	Mean age ≥65 (n)	Mortality	30-d complications	Diabetes	TWL					
Petrick et al. [3]	Single center	Total	154	90 d	1.3%	Any	20.1%	Preoperative	60%	1 yr	25.3%
		SG	18	1 yr	2.2%	Major	7.1%	Partial remission	45%	2 yr	29.9%
		RYGB	136			Minor	15.6%	Complete remission	23%	3 yr	29.4%
AHRQ technology assessment project eligible studies (Panagiotou et al. [1])											
Casillas et al. [11]	Multicenter	Total	429	90 d	0.7%	Any	NR	Preoperative	55%	1 yr	9.7%
		SG	252	1 yr	1.4%	Major	4.0%	Partial remission	NR	2 yr	9.7%
		RYGB	177			Minor	5.8%	Complete remission	NR	3 yr	9.2%
Spaniolas et al. [12]	NSQIP	Total	1005	90 d	NR	Any	NR	Preoperative	54%	1 yr	NR
		SG	155	1 yr		Major		Partial remission	NR	2 yr	
		RYGB	850			Minor		Complete remission	NR	3 yr	
Perry et al. [10]	Medicare	Total	11,903	30 d	1.6%	Any	NR	Preoperative	52%	1 yr	NR
		SG	NR	1 yr	NR	Major		Partial remission	5.5%	2 yr	
		RYGB	NR	2 yr	8.0%	Minor		Complete remission	NR	3 yr	

TWL = total weight loss; SG = sleeve gastrectomy; RYGB = Roux-en-Y gastric bypass; NR = not reported.

Our study suffers from the known limitations of a retrospective, observational study. However, our patients were prospectively consented into a nonrandomized study of patient undergoing bariatric surgery and all demographic and outcomes data were collected prospectively. Furthermore, after 2008 the care of all patients was optimized using and evidence-care pathway with close monitoring of pathway adherence. There was no difference in any patient care determined by payor status.

MEDCAC

The conclusion of the short- and long-term outcomes after bariatric surgery in the Medicare-population technology-assessment program was that “in order for clinicians, patients, and payors to make informed decisions regarding the benefits and harms of bariatric surgery in the Medicare-eligible population, and the relative effectiveness of various surgical approaches, evidence from new randomized trials or high-quality comparative observational studies is needed.” The AHRQ’s *Methods Guide for Effectiveness and Comparative Effectiveness Reviews* recommends the use of observational studies because “it is unusual to find sufficient evidence from randomized controlled trials [RCTs] to answer all key questions concerning benefit or the balance of benefits and harms.” AHRQ comparative effectiveness reviewers are advised to routinely assess the appropriateness of observational studies for questions of benefit as follows: (1) when there are gaps in the evidence from randomized controlled trials, and (2) when observational studies provide valid and useful information, including refocusing the study questions on gaps in the evidence from randomized control trials, assessing the risk of bias in observational studies,

and assessing whether available observational studies address the gap review questions [13].

Both the MEDCAC panel and Panagiotou et al. [1] found studies providing evidence of the safety and benefits of bariatric surgery in Medicare patients age ≥65. These studies were judged to be generalizable to the Medicare population because a large proportion of age ≥65 patients undergoing bariatric surgery are covered by Medicare. This was confirmed in our study in which 95% of age ≥65 patients had Medicare coverage. However, an AHRQ analysis of Medicare Beneficiary data from 2006 to 2009 showed that only 34% of Medicare bariatric surgery recipients were age ≥65 and the mean age of Medicare-eligible bariatric patients was 56. Medicare patients under age 65 represent a unique population of disabled patients eligible for surgery under the Medicare benefit. Nearly half of these Medicare patients were <55 years old [14]. In the AHRQ Technology Assessment Program, Panagiotou et al. [1] concluded that “evidence from studies in younger populations is probably not directly generalizable to the broader group of Medicare-eligible patients because Medicare beneficiaries tend to have more and more severe comorbid conditions and are more often frail compared with the non-Medicare-eligible population.” MEDCAC panel members agreed with this conclusion.

Our study provides substantial evidence for the safety and medical benefits of bariatric surgery in Medicare patients age <65 undergoing bariatric surgery. It is one of the first to compare outcomes between payors in this unique group of Medicare patients. Diabetes, hypertension, and hyperlipidemia were more prevalent in Medicare patients age <65 than other payors and diabetes was more severe as determined by DiaRem scores. However, weight loss and

diabetes remission were similar between payors after bariatric surgery with the only significant difference being a higher partial/complete remission for commercial patients compared with Medicare patients. There was no difference in 90-day mortality between any payor groups. The age <65 group was a higher risk group than patients with commercial payors. Not only were they older with more co-morbid disease burden, but they also suffered from ≥ 1 of the 14 disabilities that define Medicare eligibility [15,16]. Further investigation is needed to understand how these factors affect short- and long-term clinical outcomes after bariatric surgery.

Conclusions

We believe that this work represents a high-quality observational study that adds to the evidence for the safety and efficacy of bariatric surgery in patients age ≥ 65 while addressing many of the gaps in the evidence for bariatric surgical benefits in Medicare-eligible patients age <65 cited by the AHRQ report on short- and long-term outcomes after bariatric surgery. Specific evidence gaps cited by the MED-CAC panel remain. One is the lack of studies comparing bariatric surgical outcomes to nonsurgical weight loss outcomes. However, a 2007 meta-analysis of interventions involving a reduced-energy diet and/or weight loss medication resulted in a TWL of only 5%–9% with weight plateaus at approximately 6 months [17]. TWL routinely exceeds 25%–30% at 1 to 3 years in studies of bariatric surgical patients [18,19]. These findings, confirmed in this study, make the feasibility of a comparative trial with nonsurgical interventions difficult. A better understanding of the causes of disability and the clinical implications of those disabilities on Medicare-eligible bariatric surgical patients represents a more pressing gap in our knowledge that will be important to investigate.

Disclosures

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

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