

Early Mortality Among Medicare Beneficiaries Undergoing Bariatric Surgical Procedures

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IN THE UNITED STATES, MOST ADULTS are overweight or obese,¹ and obesity is soon to become the leading cause of death. Bariatric surgical procedures are the only interventions² that consistently help patients achieve significant and sustained weight loss and improvements in comorbid medical conditions.³⁻⁵ As a result, there has been dramatic growth in bariatric surgery over the last decade, with interest in applying it to those at high risk based on associated medical conditions and the growing population of older, obese patients.⁶ Balanced against these beneficial effects, however, are the risks of perioperative death and short-term adverse outcomes. These risks have been poorly defined in the community at large, with the expected rates largely derived from case series.⁴ Several high-profile reports of death after bariatric surgery have challenged these estimates and have triggered a critical reappraisal of bariatric surgical safety.

Medicare, the United States' largest health care insurer, currently reimburses for bariatric procedures on a regional basis and is the primary payer for approximately 20% of all procedures performed in at least 1 state.⁷ However, Medicare policy in this area is at a crossroads: there is no national

See also pp 1909, 1918, 1957, and 1960, and Patient Page.

Context Case series demonstrate that bariatric surgery can be performed with a low rate of perioperative mortality (0.5%), but the rate among high-risk patients and the community at large is unknown.

Objectives To evaluate the risk of early mortality among Medicare beneficiaries and to determine the relative risk of death among older patients.

Design Retrospective cohort study.

Setting and Patients All fee-for-service Medicare beneficiaries, 1997-2002.

Main Outcome Measures Thirty-day, 90-day, and 1-year postsurgical all-cause mortality among patients undergoing bariatric procedures.

Results A total of 16 155 patients underwent bariatric procedures (mean age, 47.7 years [SD, 11.3 years]; 75.8% women). The rates of 30-day, 90-day, and 1-year mortality were 2.0%, 2.8%, and 4.6%, respectively. Men had higher rates of early death than women (3.7% vs 1.5%, 4.8% vs 2.1%, and 7.5% vs 3.7% at 30 days, 90 days, and 1 year, respectively; $P < .001$). Mortality rates were greater for those aged 65 years or older compared with younger patients (4.8% vs 1.7% at 30 days, 6.9% vs 2.3% at 90 days, and 11.1% vs 3.9% at 1 year; $P < .001$). After adjustment for sex and comorbidity index, the odds of death within 90 days were 5-fold greater for older Medicare beneficiaries (aged ≥ 75 years; $n = 136$) than for those aged 65 to 74 years ($n = 1381$; odds ratio, 5.0; 95% confidence interval, 3.1-8.0). The odds of death at 90 days were 1.6 times higher (95% confidence interval, 1.3-2.0) for patients of surgeons with less than the median surgical volume of bariatric procedures (among Medicare beneficiaries during the study period) after adjusting for age, sex, and comorbidity index.

Conclusions Among Medicare beneficiaries, the risk of early death after bariatric surgery is considerably higher than previously suggested and associated with advancing age, male sex, and lower surgeon volume of bariatric procedures. Patients aged 65 years or older had a substantially higher risk of death within the early postoperative period than younger patients.

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coverage decision and no consensus regarding the efficacy and safety of bariatric surgery in older patients. The purpose of this study was to determine the risk of all-cause early postsurgical mortality among Medicare beneficiaries undergoing open bariatric surgery to help inform patients, clinicians, insurers, and other stakeholders who are involved in medical decision making. A secondary goal was to determine the risk of adverse outcomes among older Medicare beneficiaries undergoing these procedures compared with that of younger patients.

METHODS

Study Design

We used a retrospective cohort design, using Medicare National Claims History Part B data from January 1, 1996, through December 31, 2002, that con-

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tained *Current Procedural Terminology* (CPT) codes pertaining to bariatric surgery. The University of Washington (Seattle) Human Subjects Review Committee (04-3527-X) approved this study.

Data Sources and Setting

The Medicare Part B database, maintained by the Centers for Medicare & Medicaid Services (CMS), contains all the payment claims for the professional component of services delivered to Medicare beneficiaries in either an inpatient or an outpatient setting. Dates of death were obtained from the Enrollment Database, which is obtainable from the Social Security Administration's database, the Master Beneficiary Record.

Patients and Surgeons

Patients were defined as having had bariatric surgery if they had a claim for any of the following procedures: (1) CPT code 43842: gastric restrictive procedure without gastric bypass for morbid obesity; vertical-banded gastroplasty; (2) CPT code 43843: gastric restrictive procedure without gastric bypass for morbid obesity; other than vertical-banded gastroplasty; (3) CPT code 43846: gastric restrictive procedure with gastric bypass for morbid obesity, with short-limbed (<100-cm) Roux-en-Y gastroenterostomy (RYGB); (4) CPT code 43847: gastric restrictive procedure with gastric bypass for morbid obesity with small intestine reconstruction to limit absorption (including long-limbed [≥ 100 -cm] gastric bypass and distal bypasses such as biliopancreatic diversion); or (5) CPT code 43848: revision of gastric restrictive procedure for morbid obesity.

Individual surgeons were identified by their Unique Physician Identification Number. We calculated the total number of claims for bariatric procedures for each surgeon (1997-2002) and used this in analyses as a surrogate measure of surgeon volume. Surgeon volume was divided into quartiles of numbers of bariatric procedures. Surgeons with less than the median number of procedures are referred to as lower-volume surgeons.

To adjust for potential confounding based on comorbid conditions, a modified Charlson Comorbidity Index⁸ (score range, 0-3, with 3 indicating greatest comorbidity) was calculated for each patient based on all available claims.

The date of all-cause death was obtained from a cross-match with the Enrollment Database performed August 14, 2004, and reported at 30 days, 90 days, and 1 year after bariatric procedure. For multivariable analyses, the outcome of 90-day mortality was used to mark an "early" death.

Statistical Analysis

Descriptive and comparative statistics were applied to compare rates of death based on patient and surgeon characteristics. Categorical variables were compared using Pearson χ^2 statistics; continuous variables were compared using analysis of variance.

A multivariable logistic regression model was constructed to evaluate the odds of 90-day death based on age of 65 years or older or sex (models 1a and 1b), age of 65 years or older and sex (model 2), model 2 elements plus the Charlson Comorbidity Index (model 3), and model 3 elements plus surgeon volume (model 4), adjusting for clustering based on surgeon using generalized estimating equations. These models were developed using a nonparsimonious approach and including variables of clinical interest or those demonstrated in prior studies to be potentially important (eg, sex). Model fit was assessed using generalized Pearson residuals.⁹ A secondary logistic regression model was performed to assess the differential risk of 90-day mortality in patients older than 75 years compared with those aged 65 to 74 years, adjusting for model 3 correlates.

To estimate the probability of death over time, Kaplan-Meier curves were constructed. Survival was evaluated by age category (≥ 65 years), and log-rank and Wilcoxon tests were used to compare unadjusted survival estimates to determine the equality of survival curves. Rates of survival at all time points were also compared using χ^2 tests. The haz-

ard ratio of survival for patients aged 65 years or older compared with younger patients was compared using multivariable Cox proportional hazard regression analyses adjusted for clustering based on surgeon. The median follow-up was 3.4 years, with 25% of patients followed up for 5 years or more. The longest follow-up time was 7.7 years. Survival time was measured as the time from the index procedure until death or August 15, 2004. The proportional hazards assumption was confirmed by inspection of Schoenfeld residuals and log-log plotting.

Surgeon identifiers were present in 89% of cases, and analyses that involved surgeon volume, based on number of procedures, were performed using only complete cases. Missing data on surgeon identifiers were handled first by assessing the degree to which the data were missing at random. Serial comparisons of known variables were performed to determine if records missing surgeon identifier data were measurably different from those that contained the identifiers. We failed to identify any systematic way in which the physician identification variable was missing, so we assumed it to be missing at random and, therefore, we conducted a "complete case only" evaluation for multivariable analyses and tabular evaluations of this issue. We also performed a multiple imputation procedure for the missing surgeon volume data point and found that this did not change our results. We also performed a sensitivity analysis recategorizing cases with missing data as performed by surgeons with either lower or higher volume of bariatric procedures, and this did not change the results of the analysis.

This analysis was essentially a descriptive evaluation of mortality rates after bariatric procedures among different groups within the Medicare beneficiary cohort, and no a priori power calculations were performed. To evaluate the possibility of a type II error, we determined the number of patients needed in a 2-group evaluation of 30-day mortality rates between those

younger than 65 years and those aged at least 65 years (based on a baseline rate of 2%). Eight hundred seventy-four patients in each group of a 2-group trial would be needed to identify a doubling of this rate (with an α level of .05 and power of 90%).

Statistical analysis was performed using Stata statistical analysis software, version 7 (Stata Corp, College Station, Tex).

RESULTS

A total of 16 155 patients underwent bariatric surgical procedures (mean age, 47.7 years [SD, 11.3 years]; 75.8% women), with 90.6% younger than 65 years (TABLE 1). A total of 61.2% of cases were claims for RYGB and 19.9% were for RYGB with small intestine reconstruction to limit absorption (distal bypass). There was more than a 3-fold increase in the number of procedures performed from 1997 (n=1464) to 2002 (n=4814). The median number of bariatric procedures performed per surgeon (among Medicare beneficiaries over the 6-year period) was 35 (interquartile range, 14-70).

Among all patients, the rates of 30-day, 90-day, and 1-year mortality were 2.0%, 2.8%, and 4.6%, respectively. Advancing age and male sex were associated with early death after bariatric surgery (TABLE 2), with the highest rates of early mortality identified among older men. Overall, men were much more likely to die after bariatric surgery than women (3.7% vs 1.5%, 4.8% vs 2.1%, and 7.5% vs 3.7% for men and women at 30 days, 90 days, and 1 year, respectively; $P < .001$ for all time points). Mortality rates were greater for those aged 65 years or older (n=1517) compared with younger patients (4.8% vs 1.7%, 6.9% vs 2.3%, and 11.1% vs 3.9% at 30 days, 90 days, and 1 year, respectively; $P < .001$ for all time points). We found no differences in early mortality rates between patients who had primary vs revision surgery (2.0% vs 1.5%, 2.8% vs 2.2%, and 4.6% vs 4.3% at 30 days, 90 days, and 1 year, respectively; all $P > .10$).

Higher Charlson Comorbidity Index score was associated with early death

(2.6%, 3.5%, 18.8%, and 24.7% for a Charlson score of 0-3, respectively; $P < .001$). Patients aged 65 years or older had a higher Charlson Comorbidity Index score than younger patients (0.13 vs 0.06; $P < .001$) but there were no significant differences in the sex distribution between these groups. After controlling for patient sex and Charlson Comorbidity Index score (TABLE 3), the odds of a 90-day death were 2.8 times higher (95% confidence interval [CI], 2.3-3.6) for patients aged 65 years or older compared with younger patients. Similarly, after controlling for patient age and Charlson Comorbidity Index score, the odds of death at 90 days were 2.3 times higher (95% CI, 1.9-2.7) for men than for women. The relationship of age and adverse outcome was stronger among older beneficiaries. The odds of death within 90 days of the operation were 5 times greater for patients aged 75 years or older than for those aged 65 to 74 years (95% CI, 3.1-8.0) after adjustment for sex, Charlson Comorbidity Index score, and surgeon volume.

Patients undergoing procedures by surgeons with lower volume of bariatric procedures (less than the median of surgical volume among Medicare beneficiaries between 1997-2003) had a higher rate of mortality than those with at least median experience (3.3% vs 2.0%; $P < .001$). Patients aged 65 years or older had much higher rates of early death when undergoing surgery by surgeons within the lowest quartile of volume (TABLE 4) compared with those in the highest quartile (9% vs 1.1% at 30 days and 13.8% vs 1.1% at 90 days; $P < .001$). Surgeons in the highest quartile of bariatric procedure volume had similar rates of early mortality in both younger and older patients (1.8% 90-day mortality in patients <65 years and 1.1% mortality in patients ≥ 65 years; $P = .40$). The higher overall rates of death among older patients were attributable in part to a higher proportion (36%) of older patients undergoing surgery by surgeons within the lowest quartile of bariatric surgery volume compared with younger patients. The odds of a 90-day death were 1.6

Table 1. Description of Study Population (N = 16 155)

Characteristics	No. (%)
Sex	
Male	3912 (24.2)
Female	12 243 (75.8)
Age category, y	
<25	203 (1.3)
25-34	1827 (11.3)
35-44	4409 (27.3)
45-54	5405 (33.5)
55-64	2794 (17.3)
65-74	1381 (8.6)
≥ 75	136 (0.8)
Cases performed per y	
1997	1464 (9.0)
1998	1791 (11.1)
1999	2091 (12.9)
2000	2503 (15.5)
2001	3526 (21.8)
2002	4780 (29.6)
Operation type	
Proximal gastric bypass*	9906 (61.2)
Distal gastric bypass†	3234 (20.0)
Vertical banded gastroplasty‡	1445 (8.9)
Revisional bariatric surgery§	1225 (7.6)
Other	345 (2.1)
Charlson Comorbidity Index score	
0	15 120 (93.6)
1	934 (5.8)
2	85 (0.5)
3	16 (0.1)

*Current Procedural Terminology (CPT) code 43846: gastric restrictive procedure with gastric bypass for morbid obesity, with short-limbed (<100-cm) Roux-en-Y gastroenterostomy.

†CPT code 43847: gastric restrictive procedure with gastric bypass for morbid obesity with small intestine reconstruction to limit absorption (including long-limbed [>100 -cm] gastric bypass and distal bypasses such as biliopancreatic diversion).

‡CPT 43842: gastric restrictive procedure without gastric bypass for morbid obesity; vertical-banded gastroplasty.

§CPT code 43848: revision of gastric restrictive procedure for morbid obesity.

||CPT code 43843: gastric restrictive procedure without gastric bypass for morbid obesity; other than vertical-banded gastroplasty.

times higher for patients of surgeons with lower volume (less than the median) after adjusting for age, sex, and Charlson Comorbidity Index score (95% CI, 1.3-2.0).

The hazard ratio for death (FIGURE) at any time after the procedure was 2.3 times greater for patients aged 65 years or older compared with younger patients (95% CI, 2.0-2.7), with 9.5% 5-year mortality in younger patients compared with 21.6% mortality in the older cohort ($P < .001$). The odds of 90-day death did not change significantly based on the year the procedure was performed, even after controlling for patient age, sex, and Charlson Comorbidity Index score (odds ratio, 1.0; 95% CI, 0.9-1.0).

COMMENT

This study of the complete, nationwide fee-for-service Medicare population undergoing bariatric surgery from

1997 through 2002 found that the early risk of postsurgical death in this population was higher than suggested by prior series. We also identified strong

associations between the risk of early death and advancing age, male sex, and surgeon procedural volume.

While at least 1 case series¹⁰ has reported no early deaths following bariatric procedures among elderly patients, most have found higher mortality rates compared with younger patients.¹¹⁻¹⁴ Our study demonstrates that in the community at large, patients aged 65 years or older face a nearly 3-fold increase in the risk of early mortality. This absolute mortality risk (4.8% within 30 days) is more than double the risk of mortality associated with coronary revascularization ($\approx 2\%$)¹⁵ or hip replacement ($\approx 1\%$),¹⁶ 2 procedures commonly performed in older patients. There may be several reasons for these findings. Older patients do not tolerate surgical stress as well as younger patients¹⁷ and may also have less benefit after surgery than younger patients because much of the impact of obesity on organ systems, such as the heart,¹⁸ may have occurred by the time of the operation. It also remains to be seen if surgical weight loss in older patients decreases utilization of health care resources,¹⁹ improves functional status and quality of life,²⁰ or extends survival^{7,21,22} as has been suggested in studies of younger patients.

Other studies have demonstrated that men have a higher rate of death and adverse outcome^{7,12,23} following bariatric surgery. In 1 retrospective series¹² of 1067 patients undergoing RYGB, men had more than a 3-fold higher mortality rate than women, even after controlling for body mass index differences. In our previous study of nearly 3000 patients undergoing RYGB in the state of Washington, men had a 2.3-fold increased odds of death, even after adjustment for comorbid conditions.⁷ Further studies are necessary to better understand why postoperative mortality rates are significantly higher in men. The fact that this effect persists even after controlling for body mass index and comorbid conditions suggests that unmeasured characteristics associated with men (eg, body composition, occult heart disease, diminished physiologic tolerance to stress) may be involved. Among the youngest subgroup of patients evaluated in our study (<25

Table 2. Mortality Rate After Bariatric Surgery, by Age and Sex

Age Category (y) and Sex	No.	Mortality Rate, %		
		30 Days	90 Days	1 Year
<25				
Women	150	0.7	1.3	2.0
Men	53	0.0	1.9	1.9
Subtotal	203	0.7	1.5	2.0
25-34				
Women	1341	0.8	1.3	2.5
Men	486	2.1	3.3	4.3
Subtotal	1827	1.1	1.8	3.0
35-44				
Women	3288	1.0	1.5	2.7
Men	1121	3.2	3.7	5.6
Subtotal	4409	1.5	2.0	3.4
45-54				
Women	4214	1.1	1.8	3.1
Men	1191	4.5	5.4	7.7
Subtotal	5405	1.9	2.6	4.1
55-64				
Women	2126	2.0	2.5	4.7
Men	668	2.1	3.1	6.9
Subtotal	2794	2.0	2.7	5.2
65-74				
Women	1039	2.6	3.4	6.2
Men	342	5.8	8.2	12.9
Subtotal	1381	3.4	4.6	7.8
≥ 75				
Women	85	18.8	28.2	40.0
Men	51	19.6	35.3	51.0
Subtotal	136	19.1	30.9	44.1
Total	16 155	2.0	2.8	4.6

Table 3. Odds of Death at 90 Days Based on Patient Characteristics

Model	Odds Ratio (95% Confidence Interval)
Model 1a (age ≥ 65 y)	3.0 (2.3-3.9)
Model 1b (male sex)	2.4 (1.9-2.8)
Model 2 (adjusted for age and sex)*	
Age ≥ 65 y	3.1 (2.5-3.9)
Male sex	2.3 (1.9-2.8)
Model 3 (adjusted for age, sex, and Charlson Comorbidity Index)*	
Age ≥ 65 y	2.8 (2.3-3.6)
Male sex	2.3 (1.9-2.7)
Charlson Comorbidity Index†	1.9 (1.6-2.4)
Model 4 (adjusted for age, sex, Charlson Comorbidity Index, and surgeon volume)*	
Age ≥ 65 y	2.7 (2.1-3.4)
Male sex	2.3 (1.9-2.8)
Charlson Comorbidity Index†	1.9 (1.6-2.3)
Surgeon volume‡	0.8 (0.8-0.9)

*Each variable adjusting for the other.

†For each unit increase in Charlson Comorbidity Index.

‡For each increase in quartile of surgical volume with bariatric surgery among Medicare beneficiaries, 1997-2002.

years), we found fewer differences in death rates between men and women.

Another important factor linked to early postoperative death and adverse outcomes following bariatric surgery is surgeon⁷ and hospital procedural volume.^{24,25} In the state of Washington, patients whose surgeons had performed fewer than 20 procedures had a 4.7-fold increased risk of death at 30 days.⁷ Among a large, multistate collaborative of teaching hospitals, institutions where fewer than 50 procedures were performed per year had the highest rates of in-hospital mortality (1.2% compared with 0.3% in higher-volume [>100 cases] hospitals).²⁵ In the state of Pennsylvania, patients of surgeons who performed fewer than 50 cases per year in low-volume (<50 cases per year) hospitals had the highest rates of adverse outcomes. This suggests an additive effect of surgeon and institutional volumes.²⁴

The interaction of advanced age of the patient and surgical volumes may be a particularly important influence on the risk of adverse outcomes. In the teaching hospital series,²⁵ mortality rates among patients older than 55 years were 3 times greater at low-volume hospitals. Despite finding higher-than-expected rates of overall mortality among older patients, our study clearly demonstrates similarly low mortality rates for older and younger Medicare beneficiaries who undergo procedures by surgeons with the highest procedural volume. This study helps to demonstrate that bariatric surgery is not necessarily a higher-risk procedure among those aged 65 years or older. The specific processes of care, elements of surgical training, or patient selection used by surgeons who perform higher volumes of bariatric procedures should be further investigated.

This study has several limitations. While a proportion of the cases included in this analysis may have been performed laparoscopically, we cannot be certain when the laparoscopic procedure was performed or if laparoscopic procedures were excluded by this analysis. While all procedural codes that explicitly describe surgical procedures for the treatment of morbid obesity were used to de-

fine this cohort, until January 2005 there was no discrete code for laparoscopic bariatric procedures. Until this new code was activated, billing personnel variably used the code 43659 (“unlisted laparoscopic procedure stomach”) or “open” codes for those procedures. Unfortunately, the unlisted code was not exclusively used for the purposes of laparoscopic bariatric procedures and included procedures such as laparoscopic excision of a gastric mass and laparoscopic repair of a perforated ulcer. Given the possibility that this code might not refer to bariatric surgical procedures (and an inability to absolutely distinguish it from other procedures), we elected to exclude this claim from the cohort definition. We considered the possibility that patients undergoing laparoscopic pro-

cedures were at lower risk of death than those undergoing the open procedure as a result of patient, surgeon, or hospital selection. In that case, excluding laparoscopic cases from the analysis might have created a cohort of patients at progressively greater risk for death as the study period advanced and the proportion of all procedures performed laparoscopically increased. However, we found no differences in mortality rates over time, and, barring a countervailing trend of outcome improvement with open bariatric surgery, we would have expected to see the mortality rate increase if the cohort was becoming progressively higher-risk over time.

An additional limitation is that because the CMS cohort includes all patients aged 65 years or older but only

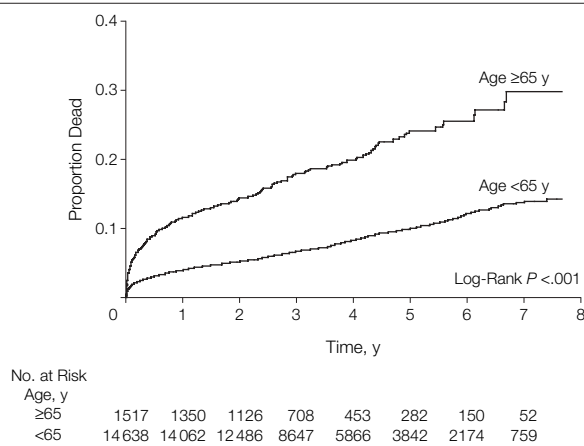
Table 4. Rate of Early Mortality After Bariatric Surgery, Stratified by Surgeon Volume*

Annual Surgeon Volume†	No.	Mortality Rate, %		
		30 Days	90 Days	1 Year
Patients aged <65 y				
<15	3200	2.2	3.0	5.0
15-35	3191	1.7	2.2	3.5
36-70	3295	1.7	2.3	4.2
71-268	3205	1.2	1.8	3.1
Total	12 891	1.7	2.3	4.0
Patients aged ≥ 65 y				
<15	480	9.0	13.8	21.0
15-35	282	3.2	4.6	6.4
36-70	284	1.8	2.1	4.2
71-268	274	1.1	1.1	3.6
Total	1320	4.5	6.7	10.7

*Numbers are adjusted to reflect complete-case-only analysis.

†Number of open bariatric procedures in Medicare beneficiaries, 1997-2002.

Figure. Survival After Bariatric Surgery by Age Group



medically disabled patients younger than 65 years, comparisons of outcome between those aged 65 years or older and younger patients may be biased. Medically disabled patients younger than 65 years may have a higher burden of comorbid conditions than older patients and this might be expected to act as a conservative bias in that we demonstrate a comparatively worse outcome in the older population.

Morbid obesity itself is not an indication for a disability claim in the CMS system; rather, a specific disabling condition is required for coverage. This data set does not provide information to help determine if obesity-related comorbid conditions were the reason patients were provided coverage based on disability. In practice, a group of conditions related to extreme obesity are often the justification for these disability claims. These conditions include debilitating osteoarthritis, depression, peripheral edema, and hypoventilation syndrome.

Another limitation of this analysis is that the measure for surgeon volume only counts procedures performed among CMS beneficiaries and begins after 1996. These would tend to underestimate surgeons' procedure volume if they had performed any procedures outside of CMS or before the study period. This might have acted as a conservative bias given our findings linking surgeon inexperience to adverse outcomes, but surgeons who perform more procedures among CMS beneficiaries may be different in other ways than other surgeons.

We also used number of bariatric procedures to evaluate the relationship of surgeon volume and outcome because in evaluations of other abdominal operations,²⁶ "hospital volume" effects are largely related to "surgeon volume" effects and, when available, surgeon volume may be the more direct and, therefore, appropriate measure of outcome that relates to technical factors. While multidisciplinary care and other hospital resources may play a role in adverse outcome, we did not assess this effect in these outcomes. Last, surgeon identifiers used to derive the volume variable

were missing in approximately 11% of cases and a complete-case-only analysis was performed for relevant evaluations. Complete and incomplete cases were compared and found in all other ways to be similar but the possibility that cases with missing data were different in other ways from cases with complete data cannot be excluded.

In conclusion, this study found that the risk of early postsurgical death among Medicare beneficiaries undergoing bariatric surgery was considerably higher than prior case series have suggested and was strongly associated with advancing age, male sex, and lower surgeon volume. Those considering the role of bariatric procedures in older patients should balance this population-level risk of adverse outcomes against the anticipated benefits of the procedure. Directing care of older patients to surgeons who perform higher volume of bariatric procedures in Medicare beneficiaries might be expected to improve outcomes in this high-risk population.

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