Bariatric Surgery Complications Before vs After Implementation of a National Policy Restricting Coverage to Centers of Excellence

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Prompted by concerns about perioperative safety with bariatric surgery, the Centers for Medicare & Medicaid Services (CMS) issued a national coverage decision in 2006 that limited coverage of weight loss surgery to centers of excellence (COEs).1-4 These COEs were accredited by 1 of 2 surgical professional organizations: the American College of Surgeons (ACS) or the American Society for Metabolic and Bariatric Surgery (ASMBS). In addition to other structural measures and processes of care, the accreditation was based on a hospital volume threshold (>125 cases/year).2,5

Whether the CMS restriction of bariatric surgery to COEs is associated with improved outcomes remains uncertain. Previous studies comparing COEs with non-COEs have largely failed to identify better outcomes at COEs.6,7 In contrast, studies examining outcomes before and after the CMS national coverage decision have suggested a beneficial effect of the CMS policy restricting bariatric surgery to COEs.8,9

However, because these latter studies lacked a control group, they were unable to isolate the effect of the CMS national coverage decision from the many other unrelated factors that may have improved bariatric surgery outcomes during the same period. For example, improved outcomes could have been due to the use of lower risk pro-

Importance Starting in 2006, the Centers for Medicare & Medicaid Services (CMS) has restricted coverage of bariatric surgery to hospitals designated as centers of excellence (COE) by 2 major professional organizations.

Objective To evaluate whether the implementation of the COE component of the national coverage decision was associated with improved bariatric surgery outcomes in Medicare patients.

Design, Setting, and Patients Retrospective, longitudinal study using 2004-2009 hospital discharge data from 12 states (n=321 464 patients) of changes in outcomes in Medicare patients undergoing bariatric surgery (n=6723 before and n=15 854 after implementation of the policy). A difference-in-differences analytic approach was used to evaluate whether the national coverage decision was associated with improved outcomes in Medicare patients above and beyond existing time trends in non-Medicare patients (n=95 558 before and n=155 117 after implementation of the policy).

Main Outcome Measures Risk-adjusted rates of any complication, serious complications, and reoperation.

Results Bariatric surgery outcomes improved during the study period in both Medicare and non-Medicare patients; however, this change was already under way prior to the CMS coverage decision. After accounting for patient factors, changes in procedure type, and preexisting time trends toward improved outcomes, there were no statistically significant improvements in outcomes after (vs before) implementation of the CMS national coverage decision for any complication (8.0% after vs 7.0% before; relative risk [RR], 1.14 [95% CI, 0.95-1.33]), serious complications (3.3% vs 3.6%, respectively; RR, 0.92 [95% CI, 0.62-1.22]), and reoperation (1.0% vs 1.1%; RR, 0.90 [95% CI, 0.64-1.17]). In a direct assessment comparing outcomes at hospitals designated as COEs (n=179) vs hospitals without the COE designation (n=519), no significant differences were found for any complication (5.5% vs 6.0%, respectively; RR, 0.98 [95% CI, 0.90-1.06]), serious complications (2.2% vs 2.5%; RR, 0.92 [95% CI, 0.84-1.00]), and reoperation (0.83% vs 0.96%; RR, 1.00 [95% CI, 0.86-1.17]).

Conclusions and Relevance Among Medicare patients undergoing bariatric surgery, there was no significant difference in the rates of complications and reoperation before vs after the CMS policy of restricting coverage to COEs. Combined with prior studies showing no association of COE designation and outcomes, these results suggest that Medicare should reconsider this policy.

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PROCEDURES (e.g., laparoscopic gastric banding), increasing surgeon experience, fellowships for advanced training in laparoscopic bariatric surgery, or healthier patients undergoing surgery due to broader acceptance of weight loss surgery.

In this study, we sought to evaluate whether the COE component of the national coverage decision was associated with improved bariatric surgery outcomes in Medicare patients. Our objective was to examine outcomes in Medicare patients before compared with after the implementation of the CMS policy that restricted coverage of bariatric surgery to hospitals designated as COEs. We controlled for secular trends using a control group of non-Medicare patients to better account for other factors that may have lead to improved outcomes with time, independent of the CMS policy.10-12

METHODS
Data Sources and Study Population
We used data from the State Inpatient Databases, which were created by the Agency for Healthcare Research and Quality as part of its Healthcare Cost and Utilization Project.13 Each State Inpatient Database includes all inpatient discharges from short-term, acute care, nonfederal, general, and other specialty hospitals in participating states. We used 2004-2009 hospital discharge data from the 12 states of Arizona, California, Florida, Iowa, Massachusetts, Maryland, North Carolina, Nebraska, New Jersey, New York, Washington, and Wisconsin.

We chose these 12 states because they (1) were geographically dispersed across the United States (allowing for diversity in our sample), (2) were available for the period we were studying, and (3) had relatively large sample sizes. Discharge records from these databases contain information collected from billing records, including patient demographics, International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedures, diagnoses, expected payer, admission and discharge dates, and discharge disposition.

We identified all patients undergoing bariatric surgery using a previously validated coding algorithm reliant on a combination of ICD-9-CM and diagnosis related group (DRG) codes.3,7,14 To optimize the clinical specificity of these algorithms, we further validated the algorithm using the more clinically precise Current Procedural Terminology codes in a cohort of Medicare beneficiaries whose data we had.1,8

To be included in the study population, patients had to have a procedure code for bariatric surgery (ICD-9-CM codes 43.89, 44.3, 44.31, 44.38, 44.39, 44.68, 44.95, 44.96, 44.97, 44.99, 44.5, 45.51, and 45.9) with a confirmatory primary or secondary diagnosis code for morbid obesity (ICD-9-CM codes 278.0, 278.00, 278.01, and V77.8) and a DRG code for weight loss surgery (DRG code 288 through October 1, 2007, and MS-DRG code 619-621 after October 1, 2007).

We excluded patients with a diagnosis code for abdominal cancer (ICD-9-CM codes 150.0-159.9 or 230.1-230.9) to ensure that our cohort represented only patients undergoing bariatric surgery. For certain analyses, we subdivided our cohort into 4 categories according to primary procedure codes: open Roux-en-Y gastric bypass surgery (ICD-9-CM codes 44.39 and 44.31), laparoscopic Roux-en-Y gastric bypass surgery (ICD-9-CM code 44.38), laparoscopic adjustable gastric banding surgery (ICD-9-CM code 44.95), and other (the remaining procedure codes other than the above 3 categories). Because the specific ICD-9 procedure code for a laparoscopic gastric bypass surgical procedure was not available before October 1, 2004, we considered patients with an ICD-9-CM code for diagnostic laparoscopy, laparoscopic lysis of adhesions, or laparoscopic cholecystectomy (ICD-9-CM codes 54.21, 54.51, or 51.23) in addition to a gastric bypass ICD-9-CM code as having laparoscopic gastric bypass.

We did not include sleeve gastrectomy in this study because it was infrequently performed (<1% of cases in this cohort).

Outcome Variables
We investigated whether the restriction of surgery to COEs as part of the 2006 Medicare national coverage decision was associated with improved outcomes of bariatric surgery. Because mortality after bariatric surgery is so rare, we used any complication, serious complications, and reoperation as our main outcome variables.6,13 Complications were ascertained from primary and secondary ICD-9-CM diagnostic and procedure codes from the index hospitalization. We chose a subset of codes used in prior studies of bariatric surgery outcomes (the full list appears in the eTable at http://www.jama.com).14,16,17

We defined serious complications as the presence of a coded complication and an extended length of hospital stay (≥5 days). Because most patients without complications are discharged within 2 or 3 days of surgery,6 the addition of the extended length-of-stay criterion increased the specificity of the outcome variable.18 We ascertained any reoperation using ICD-9-CM procedure codes indicating secondary procedures during the index hospitalization.10,17 Reoperation is relatively common after bariatric surgery, including interventions for leaks, bleeding, and bowel obstructions.

Statistical Analysis
The goal of this analysis was to examine whether the CMS national coverage decision was associated with improved outcomes after fully taking into account temporal trends toward lower complication rates in bariatric surgery. We used an econometric technique, the difference-in-differences approach, which is commonly used to evaluate the effect of policy changes.10-12 This approach isolates changes in outcomes associated with a policy change above and beyond any secular changes observed in a control group not exposed to the policy change.
We chose non-Medicare patients undergoing bariatric surgery as the control group because they were exposed to all other factors driving improved outcomes over time except the Medicare coverage decision. For our main analysis, we included patients undergoing all bariatric surgery procedures (ie, gastric bypass and laparoscopic adjustable gastric banding).

The CMS national coverage decision implemented 2 major changes: (1) the restriction of bariatric surgery in Medicare beneficiaries to COEs and (2) provided universal coverage for laparoscopic banding procedures for Medicare patients. The use of laparoscopic banding operations increased in non-Medicare patients around the time the national coverage decision was implemented. Inclusion of patients receiving either laparoscopic banding or gastric bypass in our analysis allowed us to account for the potential change in outcomes due to increased use of laparoscopic banding.

Prior to using non-Medicare patients as a control group, we empirically assessed whether they were subject to spillover effects. In the context of policy evaluation, spillover effects occur when a group that is not directly exposed to the policy is indirectly effected. For example, the restriction of surgery to COEs for Medicare patients could change patterns of referral for all patients (including non-Medicare patients). If non-Medicare patients are more likely to have surgery at COEs due to this indirect effect, they could potentially have better outcomes as a result. If these spillover effects are present (analogous to contamination in a randomized clinical trial), non-Medicare patients would not be an ideal control group.

To assess for spillover effects in our study, we created logistic regression models limited to non-Medicare patients for each outcome variable. The predecision-postdecision indicator variable for the onset of the policy change was the variable of interest. We also adjusted for linear time trends (each quarter of a year during the study period), patient characteristics, and procedure type. If the predecision-postdecision indicator is not significantly different from an odds ratio of 1.0, then there are no significant improvements in outcomes due to the policy (ie, no spillover effects in non-Medicare patients).

In preliminary analyses, we found no evidence of spillover effects for any complication (relative risk [RR], 1.00 [95% CI, 0.91-1.10]), serious complications (RR, 1.10 [95% CI, 0.89-1.10]), or reoperation (RR, 1.00 [95% CI, 0.80-1.20]). Therefore, we believe that non-Medicare patients undergoing bariatric surgery were the best- available control group.

To perform the difference-in-differences analysis, we used logistic regression models to evaluate the relationship between each dependent variable (any complication, serious complications, and reoperation) and the implementation of the coverage decision (the full details appear in the eFigure and the eStatistical Methods). We included a dummy variable indicating whether the patient had surgery before or after (ie, predecision-postdecision) the coverage decision. Because the State Inpatient Databases do not have the dates of surgery, we used admission quarter to define whether patients had surgery before or after the CMS coverage decision (defined as the first quarter of 2006).

To adjust for secular trends, we included a continuous time variable that accounted for linear time trends. Because 2 of the outcomes (any complication and serious complications) were improving faster in Medicare patients than non-Medicare patients prior to the coverage decision, we also included the interaction term Medicare × quarter to account for this difference in the models.

In addition, we added an interaction term of Medicare × predecision-postdecision to account for the Medicare (vs non-Medicare) variable and the before-and-after policy implementation variable. The coefficient from this interaction term (ie, the difference-in-differences estimator) can be interpreted as the independent relationship between the CMS national coverage decision and improved outcomes for Medicare patients.

In all models, we adjusted for patient characteristics by entering the 29 Elixhauser comorbid diseases as individual covariates, which is a widely used and previously validated approach for risk adjustment of administrative data. The models were also adjusted for procedure type by including a categorical dummy variable for the 4 main categories of bariatric procedures: open gastric bypass, laparoscopic gastric bypass, laparoscopic gastric banding, and other procedures.

We conducted several sensitivity analyses to test the robustness of our evaluation of the effect of the CMS national coverage decision for Medicare. Our main analysis included all bariatric procedures. Because most adverse events occur after gastric bypass surgery, we performed an analysis limiting our cohort to patients undergoing gastric bypass surgery.

Because the time trends in outcomes may not be linear, we tested several nonlinear approaches. Using nonlinear time trends had no effect on our results. Due to the hierarchical nature of our data, we repeated our analysis using a hierarchical modeling strategy (ie, using hospital random effects). The use of random-effects models had no effect on our results. Consequently, we report the results using standard logistic regression models with robust standard errors to account for patient clustering.

In a separate analysis, we evaluated whether hospitals designated as COEs by the ACS and the ASMBS had better outcomes than non-COEs. We identified hospitals with the COE designation for each quarter using the CMS list of COE hospitals. We conducted a patient-level analysis comparing each of the adverse outcomes in hospitals designated as COEs vs non-COEs at the time the patient underwent surgery. In these analyses, we adjusted for patient characteristics, procedure type, and the period (quarter and year of surgery).
Given the strong secular trend toward improved outcomes, and the increasing number of COEs over time, accounting for the period in which the patient had surgery proved to be important. Because Medicare patients no longer underwent bariatric surgery in non-COEs after the coverage decision, we performed our main analysis combining Medicare and non-Medicare patients together. However, we also performed a sensitivity analysis comparing outcomes at COEs with non-COEs for Medicare and non-Medicare patients separately, which demonstrated similar findings. Given the possibility of unmeasured differences in patient characteristics between those treated at COEs and non-COEs, we conducted a sensitivity analysis comparing these 2 groups using an instrumental variable approach. In this analysis, we used the national coverage decision as an instrument to pseudorandomize patients to COEs and non-COEs. The results of this analysis also demonstrated no difference between COEs and non-COEs, enabling us to report our results using standard logistic regression.

We present our main analyses as RRs instead of odds ratios because the latter may not be an accurate representation of the risk ratio when an outcome variable is relatively common.23 We used logistic regression models to estimate marginal effects, which were then used to calculate the RRs and 95% confidence intervals. We used a P value of less than .05 as the threshold for statistical significance and all reported P values are 2-sided. All statistical analyses were conducted using Stata version 11.0 (StataCorp).

RESULTS

Characteristics of Medicare and non-Medicare patients before and after the national coverage decision appear in Table 1. There were 6723 Medicare patients who received bariatric operations in the State Inpatient Databases before and 15,854 patients after the national coverage decision was issued. There were 95,558 non-Medicare patients in the State Inpatient Databases before and 155,117 patients after the national coverage decision policy.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Medicare Predecision</th>
<th>Medicare Postdecision</th>
<th>Non-Medicare Predecision</th>
<th>Non-Medicare Postdecision</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean (SD), y)</td>
<td>51.6 (11.4)</td>
<td>55.0 (11.7)</td>
<td>42.1 (10.5)</td>
<td>43.0 (11.0)</td>
</tr>
<tr>
<td>Female sex</td>
<td>5138 (76.7)</td>
<td>11,626 (73.5)</td>
<td>77,304 (82.0)</td>
<td>122,264 (79.4)</td>
</tr>
<tr>
<td>White race</td>
<td>4123 (72.9)</td>
<td>10,441 (74.3)</td>
<td>62,253 (74.3)</td>
<td>100,074 (71.7)</td>
</tr>
<tr>
<td>Procedure type</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Open gastric bypass</td>
<td>3023 (45.0)</td>
<td>1525 (9.6)</td>
<td>37,967 (39.7)</td>
<td>13,113 (8.5)</td>
</tr>
<tr>
<td>Laparoscopic gastric bypass</td>
<td>2957 (44.0)</td>
<td>8232 (51.9)</td>
<td>47,854 (50.1)</td>
<td>98,584 (63.6)</td>
</tr>
<tr>
<td>Laparoscopic gastric banding</td>
<td>424 (6.3)</td>
<td>5467 (34.5)</td>
<td>6148 (6.4)</td>
<td>37,323 (24.1)</td>
</tr>
<tr>
<td>Other bariatric procedure</td>
<td>319 (4.7)</td>
<td>630 (4.0)</td>
<td>3589 (3.8)</td>
<td>6097 (3.9)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>4365 (64.9)</td>
<td>10,902 (68.8)</td>
<td>45,739 (47.9)</td>
<td>78,891 (50.9)</td>
</tr>
<tr>
<td>Diabetes</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Without chronic complications</td>
<td>2693 (40.1)</td>
<td>6911 (43.6)</td>
<td>22,824 (23.9)</td>
<td>41,474 (26.7)</td>
</tr>
<tr>
<td>With chronic complications</td>
<td>260 (3.9)</td>
<td>617 (3.9)</td>
<td>871 (0.9)</td>
<td>1737 (1.1)</td>
</tr>
<tr>
<td>Chronic pulmonary disease</td>
<td>1763 (26.2)</td>
<td>3772 (23.8)</td>
<td>16,109 (16.9)</td>
<td>26,377 (17.0)</td>
</tr>
<tr>
<td>Depression</td>
<td>1401 (20.8)</td>
<td>3241 (20.4)</td>
<td>15,519 (16.2)</td>
<td>27,188 (17.5)</td>
</tr>
<tr>
<td>Liver disease</td>
<td>681 (10.1)</td>
<td>1439 (9.1)</td>
<td>8456 (8.9)</td>
<td>15,373 (9.9)</td>
</tr>
<tr>
<td>Hypothyroidism</td>
<td>866 (12.9)</td>
<td>2041 (12.9)</td>
<td>8451 (8.8)</td>
<td>14,218 (9.2)</td>
</tr>
<tr>
<td>Psychoses</td>
<td>329 (4.9)</td>
<td>870 (5.5)</td>
<td>957 (1.0)</td>
<td>2021 (1.3)</td>
</tr>
<tr>
<td>Fluid and electrolyte disorders</td>
<td>309 (4.6)</td>
<td>499 (3.2)</td>
<td>2187 (2.3)</td>
<td>3017 (1.9)</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>290 (4.3)</td>
<td>583 (3.7)</td>
<td>764 (0.8)</td>
<td>1106 (0.7)</td>
</tr>
<tr>
<td>Anemia</td>
<td>194 (2.9)</td>
<td>510 (3.2)</td>
<td>2338 (2.5)</td>
<td>4625 (3.0)</td>
</tr>
<tr>
<td>Other neurological disorders</td>
<td>153 (2.3)</td>
<td>470 (3.0)</td>
<td>595 (0.6)</td>
<td>1767 (1.1)</td>
</tr>
<tr>
<td>Renal failure</td>
<td>84 (1.3)</td>
<td>487 (3.1)</td>
<td>169 (0.2)</td>
<td>824 (0.5)</td>
</tr>
<tr>
<td>Pulmonary circulation disease</td>
<td>79 (1.2)</td>
<td>173 (1.1)</td>
<td>322 (0.3)</td>
<td>504 (0.3)</td>
</tr>
<tr>
<td>Coagulopathy</td>
<td>29 (0.4)</td>
<td>72 (0.5)</td>
<td>300 (0.3)</td>
<td>490 (0.3)</td>
</tr>
<tr>
<td>Paralysis</td>
<td>30 (0.5)</td>
<td>40 (0.3)</td>
<td>47 (0.1)</td>
<td>70 (0.1)</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>65 (1.0)</td>
<td>162 (1.0)</td>
<td>405 (0.4)</td>
<td>477 (0.3)</td>
</tr>
</tbody>
</table>

aAge is expressed as mean (SD) but all of the other variables in this table are expressed as number (percentage).
As expected, Medicare patients were older than non-Medicare patients and had more comorbid conditions (Table 1). The average age of Medicare patients in this cohort was younger than 65 years because a majority of patients undergoing bariatric surgery qualified for Medicare due to disability rather than age. After the national coverage decision, the average age for patients increased. Rates of other demographics and comorbid conditions were similar before and after the national coverage decision (Table 1).

There were large shifts in procedure use during the periods surrounding the coverage decision (Table 1). The use of laparoscopic surgery increased for all patients undergoing bariatric surgery, whereas the use of open gastric bypass decreased for both Medicare (6% before and 35% after the coverage decision; \( P < .001 \)) compared with non-Medicare patients (6% before and 24% after the coverage decision; \( P < .001 \)).

Rates of any complication, serious complications, and reoperation decreased substantially after the CMS coverage decision in both Medicare and non-Medicare patients (Table 2). Trends toward improved outcomes were well under way before the implementation of the CMS restriction of care to COEs (Figure). A large proportion of the improved outcomes over time for both Medicare and non-Medicare patients could be attributed to the changes in procedure mix. After adjusting for the type of bariatric procedure performed, the RR for adverse outcomes after (vs before) the CMS policy was much lower (Table 2). In contrast, none of the improvement could be attributed to the CMS policy.

After accounting for patient factors, changes in procedure type and preexisting trends toward improved outcomes, there were no measurable improvements in outcomes after (vs before) implementation of the CMS national coverage decision for any complication (8.0% vs 7.0%; RR, 1.14 [95% CI, 0.95–1.33]), serious complications (3.3% vs 3.6%, respectively; RR, 0.92 [95% CI, 0.62–1.22]), and reoperation (1.0% vs 1.1%; RR, 0.90 [95% CI, 0.64–1.17]; Table 2). In a sensitivity analysis limited to only gastric bypass procedures, we found similar findings for all adverse outcomes (Table 2).

In an analysis to further explore the null effect of the CMS national coverage decision, we directly compared outcomes at COEs (n = 179) vs non-COEs (n = 519). We found that COEs (as de-

### Table 2. Rates of Adverse Outcomes Before and After the Implementation of the Centers for Medicare & Medicaid Services Policy Restricting Bariatric Surgery to Centers of Excellence

<table>
<thead>
<tr>
<th>No./Total (%) of Patients With Adverse Outcome After Bariatric Surgery by National Coverage Decision Period</th>
<th>Relative Risk (95% CI) of Adverse Outcomea</th>
<th>Simple Before vs After Comparison</th>
<th>Adjusted for Patient Factors Only</th>
<th>Adjusted for Patient Factors and Procedure Type</th>
<th>Independent Effect of the Policyb</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predecision January 2004 to March 2006</td>
<td>Postdecision April 2006 to December 2009</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Any complication</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>829/6723 (12.3)</td>
<td>1252/15854 (7.9)</td>
<td>0.67 (0.60–0.74)</td>
<td>0.89 (0.77–1.00)</td>
<td>1.14 (0.95–1.33)</td>
</tr>
<tr>
<td>Non-Medicare</td>
<td>6203/9558 (6.5)</td>
<td>7467/155117 (4.8)</td>
<td>0.79 (0.75–0.84)</td>
<td>0.92 (0.84–0.90)</td>
<td>1 [Reference]</td>
</tr>
<tr>
<td><strong>Serious complications</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>501/6723 (7.5)</td>
<td>539/15854 (3.4)</td>
<td>0.48 (0.42–0.55)</td>
<td>0.64 (0.44–0.83)</td>
<td>0.92 (0.62–1.22)</td>
</tr>
<tr>
<td>Non-Medicare</td>
<td>2786/9558 (2.9)</td>
<td>2675/155117 (1.7)</td>
<td>0.66 (0.61–0.70)</td>
<td>0.81 (0.70–0.92)</td>
<td>1 [Reference]</td>
</tr>
<tr>
<td><strong>Reoperation</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>127/6723 (1.9)</td>
<td>162/15854 (1.0)</td>
<td>0.58 (0.46–0.73)</td>
<td>0.85 (0.58–1.12)</td>
<td>0.90 (0.64–1.17)</td>
</tr>
<tr>
<td>Non-Medicare</td>
<td>1067/9558 (1.1)</td>
<td>1123/155117 (0.7)</td>
<td>0.66 (0.59–0.75)</td>
<td>0.87 (0.71–1.03)</td>
<td>1 [Reference]</td>
</tr>
</tbody>
</table>

**Gastric bypass surgery**

| Any complication | | | | | |
| Medicare | 773/5980 (12.9) | 1004/9757 (10.3) | 0.79 (0.72–0.88) | 0.88 (0.75–1.00) | 1.19 (1.01–1.38) |
| Non-Medicare | 5918/85821 (6.9) | 6483/111697 (5.8) | 0.89 (0.85–0.93) | 0.91 (0.83–0.99) | 1 [Reference] |
| **Serious complications** | | | | | |
| Medicare | 457/5980 (7.6) | 448/9757 (4.6) | 0.59 (0.51–0.68) | 0.66 (0.46–0.87) | 0.98 (0.69–1.28) |
| Non-Medicare | 2647/85821 (3.1) | 2383/111697 (2.1) | 0.76 (0.72–0.80) | 0.81 (0.70–0.92) | 1 [Reference] |
| **Reoperation** | | | | | |
| Medicare | 115/5980 (1.9) | 126/9757 (1.3) | 0.69 (0.54–0.88) | 0.89 (0.61–1.17) | 0.90 (0.62–1.18) |
| Non-Medicare | 997/85821 (1.2) | 965/111697 (0.9) | 0.74 (0.66–0.84) | 0.91 (0.75–1.06) | 1 [Reference] |

aThe logistic regression models also control for patient characteristics, changes in procedure type, and any differences in preimplementation trends in outcomes between Medicare and non-Medicare patients.

bThe independent effect of the Centers for Medicare & Medicaid Services coverage decision is derived from a difference-in-differences model that represents improvement in outcomes before and after the policy change in Medicare patients compared with non-Medicare patients (the control group was not exposed to the policy).
After accounting for patient factors, procedure type, and the year of operation, patients undergoing bariatric surgery at hospitals with the COE designation (vs hospitals without the COE designation) did not have significantly different rates for any complication (5.5% vs 6.0%, respectively; RR, 0.98 [95% CI, 0.90-1.06]), serious complications (2.2% vs 2.5%; RR, 0.92 [95% CI, 0.84-1.00]), and reoperation (0.83% vs 0.96%; RR, 1.00 [95% CI, 0.86-1.17]). In a sensitivity analysis that evaluated Medicare and non-Medicare patients separately, we also found no relationship between hospital COE designation and adverse outcomes.

**COMMENT**

Perioperative outcomes of bariatric surgery have improved substantially during the past decade. These improved outcomes might have been attributable to evolving surgical technique and the use of different types of procedures. This included transitioning from open to laparoscopic procedures and the increased use of laparoscopic adjustable gastric banding.

Beyond changes in procedure use, a strong underlying time trend of better outcomes for bariatric surgery in both Medicare and non-Medicare patients was observed. We could not attribute any outcome improvement to the CMS policy restricting performance of bariatric operations on Medicare patients to COEs.

In the first study evaluating the influence of the national coverage decision, Nguyen et al9 evaluated outcomes before and after the coverage decision in Medicare patients undergoing bariatric surgery at academic health centers. The seemingly better outcomes after the coverage decision were misleading and based on a simple before vs after study design. When secular improvements in outcomes were controlled for in our study, we found no association with the CMS policy and outcomes.

In a subsequent study using national Medicare claims, Flum et al8 also found fewer deaths, complications, and readmissions after the coverage decision. The study by Flum et al8 did adjust for linear time trends but did not adjust for secular improvements in overall bariatric outcomes because there was no control group of non-Medicare patients. Because we included such a control group, our study more fully adjusted for other unrelated factors, fueling improved outcomes during this period.

Our study is consistent with prior studies directly comparing outcomes at COEs and non-COEs.6,7 In the earliest study evaluating bariatric surgery outcomes at COEs vs non-COEs, Livingston7 found no significant differences in a nationally representative sample of hospitals. This study used administrative data and lacked clinical detail. Birkmeyer et al10 used high-quality clinical registry data and confirmed these findings, demonstrating no difference in risk-adjusted rates of serious complications between COEs and non-COEs.

The absence of a COE effect could result from a lack of evidence-based COE criteria. The criteria for becoming a COE were established by expert opinion and clinical consensus.2,5 There were 3 primary criteria for COE designation: (1) hospital structure and process elements, (2) minimum hospital volume (>125 cases/year), and (3) mandate to submit data to the ACS or the ASMBS clinical registry.

The hospital structural requirements were mainly resources required for severely obese patients receiving any type of hospital care and did not substantially differ from existing Joint Commission standards. Although these measures had intuitive appeal, there was no evidence that they would lead to safer care. Hospital volume standards do not reliably discriminate hospital performance (ie, some high-volume centers have substandard outcomes and some low-volume centers have excellent outcomes). While numerous studies have demonstrated volume-
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outcome relationships with bariatric surgery, this effect is relatively small (compared with cancer surgery, for example) and has likely declined over time as the field has matured. In addition, whereas both professional societies (the ACS and the ASMBS) required that hospitals submit data to clinical registries, these data were not used to provide feedback on outcomes to surgeons and the outcomes themselves were not used as criteria for COE determination.

Rather than the CMS policy restricting bariatric surgery to COEs, we found that the improvement in outcomes over time could be explained in part by the evolution away from higher risk toward lower risk procedures. Procedure mix changed in 2 important ways. First, there was a general shift away from open to laparoscopic surgery, which is consistent with broader trends in surgery toward less invasive procedures with more favorable safety profiles. This change was similar for both Medicare and non-Medicare patients.

Second, there was a dramatic increase in the use of laparoscopic gastric banding, a safer but less effective procedure. The increased use of laparoscopic adjustable gastric banding around the time of the coverage decision was higher for Medicare than non-Medicare patients. Although this finding is no doubt in part attributable to the expanded coverage of laparoscopic adjustable gastric banding, the disproportionate increase in Medicare patients suggests that increased scrutiny of bariatric surgery in this population influenced physician decision making.

Our study found large improvements in bariatric surgery outcomes over time even after adjusting for changes in procedure use. These improved outcomes are likely due to numerous factors related to the maturing of bariatric surgery as a clinical specialty. During the past decade, surgeons practicing bariatric surgery have had a much greater cumulative experience and the techniques have been refined over time. Bariatric surgery is also dependent on technology, which has incrementally improved over time (eg, new surgical stapling devices and high-definition video equipment).

Bariatric surgeons also have much more exposure to bariatric surgery in general surgery residency training programs and many opportunities to participate in postresidency fellowship training in advanced laparoscopy and bariatric surgery. In addition, as bariatric surgery became more widely accepted, lower risk patients were choosing to pursue weight loss surgery.

Our study used administrative data, which have well-known limitations. Perhaps the best known limitation of administrative data is inadequate risk adjustment.24 Comorbid diseases are determined from discharge codes and are not as reliable as clinical data obtained directly from the medical record. However, the study design we used does account for unmeasured confounding factors.

Because we adjusted for time trends in all of our models, we account for any unmeasured differences in patient characteristics that change over time.12 This longitudinal study design is therefore much less prone to bias due to unmeasured variables than a cross-sectional study. Furthermore, based on studies from clinical registries, we have no reason to believe that patient mix has changed substantially for bariatric surgery during the period of this study.9,15 Complications ascertained from administrative data are also not as accurate as those determined from the medical record. To address this problem, we limited our complications to a subset of codes demonstrated to have the highest sensitivity and specificity.25 In addition, we have added prolonged length of stay (≥5 days) to our definition of serious complications. Length of stay is very accurate in administrative data and, because the vast majority of patients are discharged on day 2 or 3, prolonged hospitalization is a reliable marker of postoperative complications.18

The rates of any complication, serious complications, and reoperation in our present study track very well with published estimates from clinical registries.9,13 Moreover, the consistency of our findings across different outcomes—any complication, serious complications, and reoperation—substantiate our findings.

Our study was limited to perioperative safety. We were not able to examine the association of the CMS coverage decision with longer-term outcomes, including patient satisfaction, weight loss, and comorbidity resolution. However, laparoscopic gastric banding, which increased dramatically in Medicare patients after the coverage decision, has inferior long-term outcomes compared with other bariatric surgery procedures, such as gastric bypass.20,27

There is accumulating evidence that laparoscopic gastric banding also has much higher rates of long-term complications requiring reoperation for band removal due to erosion and slippage.28,30 For these reasons, the CMS coverage decision, which incentivized lower risk procedures, may have had the unintended consequence of sacrificing long-term effectiveness for improved short-term safety.

The most direct implications of this study are for Medicare patients. We found no association between the implementation of the COE component of the CMS national coverage decision and improved bariatric surgery outcomes. Consistent with prior studies, we also found no association between COE designation and better bariatric surgery outcomes.

However, there are concerns about the effect of the policy on patient access. For example, in a study of patients undergoing bariatric surgery in Texas, Livingston and Burchell31 found a markedly increased travel distance in Medicare patients after implementation of the CMS coverage decision. Therefore, the CMS policy restricting coverage to COEs has not been associated with improved outcomes for bariatric surgery, but may have had the unintended consequence of reducing access to care. These findings suggest...
that the CMS should reevaluate this policy.

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Study concept and design: Dimick, Nicholas, Ryan, Birkmeyer.

Acquisition of data: Dimick, Nicholas.

Analysis and interpretation of data: Dimick, Nicholas, Ryan, Thumma, Birkmeyer.

Drafting of the manuscript: Dimick, Nicholas, Thumma.

Critical revision of the manuscript for important intellectual content: Dimick, Nicholas, Ryan, Thumma, Birkmeyer.

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