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

Justin B. Dimick, MD, MPH, **Lauren H. Nicholas, PhD**, **Andrew M. Ryan, PhD**, **Jyothi R. Thumma, MPH**, and **John D. Birkmeyer, MD**
From the Center for Healthcare Outcomes and Policy (JD, LN, JB), University of Michigan, Ann Arbor, MI; Division of Outcomes and Effectiveness Research (AR), Weill Cornell Medical College, New York, NY

Abstract

Importance—Starting in 2006, the Center for Medicare and Medicaid Services (CMS) has restricted coverage of bariatric surgery to hospitals designated as “Centers of Excellence” (COE) by two major professional organizations.

Objectives—We sought 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—Using 2004–09 hospital discharge data from 12 states (n=321,464 patients), we studied changes in outcomes in Medicare patients undergoing bariatric surgery. Using a difference-in-difference analytic approach, we evaluated whether the national coverage decision was associated with improved outcomes in Medicare patients above and beyond existing time trends in non-Medicare patients.

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

Results—Over the study period, bariatric surgery outcomes improved in both Medicare and non-Medicare patients and this change was underway prior to the CMS coverage decision. After accounting for patient factors, changes in procedure type, and pre-existing time trends toward improved outcomes, there were no statistically significant improvements in outcomes after (vs. before) implementation of the CMS national coverage decision: any complications (8.0% after vs. 7.0% before; Relative Risk [RR], 1.14, 95% Confidence Interval [CI], 0.95 to 1.33), serious complications (3.3% vs. 3.6%; RR 0.92, 95% CI, 0.62 to 1.22), and reoperation (1.0% vs. 1.1%; RR 0.90, 95% CI, 0.64 to 1.17). In a direct assessment comparing outcomes at hospitals designated as COEs vs. hospitals without COE designation, we found no significant difference in any of the three outcomes: any complications (5.5% vs. 6.0%; RR, 0.98, 95%, 0.90 to 1.06), serious complications (2.2% vs. 2.5%; RR 0.92, 95%CI, 0.84 to 1.00), and reoperations (0.83% vs. 0.96%; RR, 1.00, 95% CI, 0.86 to 1.17).

Corresponding author: Justin B. Dimick, MD, MPH, Center for Healthcare Outcomes & Policy, 2800 Plymouth Road, Building 520, Office 3144, Ann Arbor, MI 48109, Phone: (734) 998-7470, Fax: (734) 998-7473, jdimick@umich.edu.

Access to Data: Dr. Dimick and Mrs. Thumma had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Conflict of Interest Disclosures: Dr. Dimick and Dr. Birkmeyer are consultants and have an equity interest in ArborMetrix, Inc, which provides software and analytics for measuring hospital quality and efficiency. The company had no role in the study herein.

Conclusions and Relevance—Restricting bariatric surgery to hospitals designated as COEs has not improved surgical outcomes for Medicare beneficiaries. Eliminating this component of the CMS national coverage decision could enhance access without jeopardizing patient safety.

INTRODUCTION

Prompted by concerns about perioperative safety with bariatric surgery, the Center for Medicare and 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 one of two surgical professional organizations, the American College of Surgeons (ACS) or 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 per year).[2,5]

Whether the CMS restriction of bariatric surgery to COEs is associated with improved outcomes remains uncertain, however. Previous studies comparing COEs and 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 time period. For example, improved outcomes could have been due to the use of lower risk procedures (e.g., laparoscopic gastric banding), growing 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 versus after the implementation of the CMS policy compared to a control group of non-Medicare patients. This control group of non-Medicare patients will allow us better account for other factors that may have improved over time independent of the CMS policy.[10–12]

METHODS

Data Source and Study Population

We used data from the State Inpatient Databases (SID) which are created by the Agency for Healthcare Research and Quality (AHRQ) as part of their Healthcare Cost and Utilization Project (HCUP).[13] The SID includes all inpatient discharges from short-term, acute-care, nonfederal, general, and other specialty hospitals in participating states. We used data from 12 states (2004 to 2009): 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 time periods we were studying (i.e., as far back as 2004), and 3) were relatively large in terms of sample size. The discharge records from these databases contain information collected as part of 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 disposition.

We identified all patients undergoing bariatric surgery using a previously validated coding algorithm that use a combination of ICD-9-CM and Diagnostic Related Groups (DRG)

codes.[4,7,14] To optimize the clinical specificity of these algorithms, we further validated the algorithm using the more clinically precise Current Procedure Terminology (CPT) codes in a cohort of Medicare beneficiaries in which we had this data available.[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 diagnosis code for morbid obesity (ICD-9-CM codes 278.0, 278.00, 278.01, and V77.8) and a diagnosis related group (DRG) code for weight loss surgery (DRG 288 through October 1, 2007 and MS-DRG 619–621 after October 1, 2007). We excluded all patients with a diagnostic code for abdominal cancer (ICD-9 diagnosis codes: 150.0 to 159.9 or 230.1 to 230.9) to further ensure that our cohort represented only patients undergoing bariatric surgery.

For certain analyses, we subdivided our cohort into four categories according to primary procedure codes: Open roux-en-y gastric bypass (ICD-9-CM codes 44.39, 44.31), laparoscopic roux-en-y gastric bypass (44.38), laparoscopic adjustable gastric banding (44.95), and other (remaining procedures codes other than the above three categories). Because the specific ICD-9 procedure code for a laparoscopic gastric bypass procedure was not available before October 1, 2004, we considered patients with ICD-9-CM code for diagnostic laparoscopy, laparoscopic lysis of adhesions, or laparoscopic cholecystectomy (54.21, 54.51, or 51.23) in addition to a gastric bypass ICD-9-CM code as having laparoscopic gastric bypass. Because sleeve gastrectomy was infrequently performed (<1% of cases in this cohort) as a stand-alone bariatric surgical procedure during the time of this study, especially in Medicare patients, we do not include it as a separate procedure in this evaluation.

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 in the modern era, we used complications, serious complications, and reoperations as our main outcome variables.[6,15] Complications were ascertained primary and secondary ICD-9-CM diagnostic and procedure codes from the index hospitalization. We chose a subset of codes that have been used in several prior studies of bariatric surgery outcomes (See **Appendix** for full list).[14,16,17] We defined serious complications as the presence of a coded complication and an extended length of stay (greater than or equal to 5 days). Since most patients without complications are discharged within 2 or 3 days of surgery[6], the addition of the extended length of stay criterion was intended to increase the specificity of the outcome variable.[18] Finally, we ascertained reoperations using ICD-9-CM procedure codes indicating secondary procedures during the index hospitalization.[16,17] Reoperations are relative common after bariatric surgery, including interventions for leaks, bleeding, and bowel obstructions.

Statistical Analysis

The goal of this analysis was to examine whether Medicare's national coverage decision was associated with improved outcomes after fully taking into account temporal trends towards in bariatric surgery. We used an econometric technique, the difference-in-difference approach, which is commonly used to evaluate the impact of policy changes.[10–12] This approach isolates changes in outcomes associated with the policy change above and beyond any changes over time seen in a control group that were not exposed to the policy change. In our analysis, we chose non-Medicare patients undergoing bariatric surgery as the control group because they are exposed to all other factors driving improved outcomes over time except the Medicare coverage decision. For our main analysis, we include patients undergoing all bariatric surgery procedures (i.e., gastric bypass and laparoscopic adjustable

gastric banding). Although adverse outcomes are much more common after gastric bypass, we chose to include patients undergoing all procedures because of the possibility of selection bias from changes over time in patients having gastric bypass, i.e., higher risk patients may be shifted to laparoscopic banding irrespective of Medicare status.

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 are when a group that is not directly exposed to the policy is indirectly impacted. 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.[12] 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 spillovers in our study, we created logistic regression models limited to non-Medicare patients for each outcome variable. The variable of interest was the pre-post indicator variable for the onset of the policy change. We also adjusted for linear time trends (each quarter of a year during the study period), patient characteristics, and procedure type. If the pre-post indicator is not significantly different from an odds ratio of "1.0" then there are no significant improvements in outcomes due to the policy (i.e., no spillover effects in non-Medicare patients). In preliminary analyses, we found no evidence of spillover effects in any outcomes: Any complications (Relative Risk [RR], 1.0; 95% Confidence Interval [CI], 0.91 to 1.10); serious complications (RR, 1.1; 95% CI, 0.89 to 1.10); reoperations (RR, 1.0; 95% CI, 0.80 to 1.20). We therefore believe that non-Medicare patients undergoing bariatric surgery would be the best available control group.

To perform the difference-in-difference analysis, we used logistic regression models to evaluate the relationship between each dependent variable (complications, serious complications, and reoperations) and the implementation of the coverage decision (See Statistical Appendix for full details). We included a dummy variable indicating whether the patient had surgery before or after (i.e., pre-post) the coverage decision. Because the SID does not have dates of surgery, we used admission quarter to define whether patients had surgery before or after the CMS coverage decision, defined as the 1st quarter of 2006. To adjust for secular trends, we included a continuous time variable which effectively takes into account linear time trends. Because two of the outcomes (any complications and serious complications) were improving faster in Medicare patients than non-Medicare patients prior to the coverage decision we also included an interaction term (Medicare*quarter) to account for this difference in these models. Finally, we added an interaction term of the Medicare (vs. non-Medicare) variable and the pre-post policy implementation variable (Medicare*pre-post$_1$). The coefficient from this interaction term, i.e., the difference-in-difference estimator, can be interpreted as the independent relationship between the CMS national coverage decision and improved outcomes for Medicare patients.[11,19,20]. In all models we adjusted for patient characteristics by entering the 29 Elixhauser comborbid diseases as individual covariates, a widely used and previously validated approach for risk-adjustment in administrative data.[21,22] These models are also adjusted for procedure type in all analyses by including a categorical variable for the four 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 Medicare's national coverage decision. First, as discussed above our main analysis included all bariatric procedures. Because most adverse events occur after gastric bypass, we performed an analysis limited our cohort to patients undergoing open and laparoscopic gastric bypass. The results from this analysis are reported in Table 3. Second, because the

time trends in outcomes may not be linear we tested several non-linear approaches. Using non-linear time trends had no effect on our results and we therefore do not report them herein. Third, because of the hierarchical nature of our data, we repeated our analysis using a hierarchical modeling strategy, i.e., using hospital random effects. The use of random effects models had no impact on our results and we therefore 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 ACS and ASMBS had better outcomes than non-COEs. We identified hospitals with COE designation for each quarter using the list of COE hospitals from CMS. For this analysis, 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 time period (quarter and year of surgery). Given the strong secular trend towards improved outcomes, and the increasing number of COEs over time, it was important to account for the time period in which the patient had surgery. Because Medicare patients were no longer having surgery in non-COEs after the coverage decision, we performed our main analysis combining Medicare and non-Medicare patients together. However, we performed a sensitivity analysis dividing Medicare and non-Medicare patients into separate groups which demonstrated similar findings. Given the possibility of unmeasured differences in patient characteristics between COEs and non-COEs, conducted a sensitivity analysis comparing these two groups using an instrumental approach. In this analysis, we used the national coverage decision as an instrument to pseudo-randomize patients to COEs and non-COEs. The results of this analysis also demonstrated no difference between COEs and non-COEs and we therefore report our results using standard logistic regression herein.

We present our main analyses as relative risks 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 $P<.05$ as the threshold for statistical significance and all reported P-values are two-sided. All statistical analyses were conducted using STATA 11.0 (College Station, Texas).

RESULTS

Characteristics of Medicare and non-Medicare patients before and after the national coverage decision are show in Table 1. 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 is less than 65 because a majority of patients undergoing bariatric surgery qualified for Medicare due to disability rather than age. With respect to the CMS national coverage decision, Medicare patients were slightly older after the policy was implemented but were generally similar with respect to other demographics and comorbid diseases (Table 1).

There were large shifts in procedure use in the time 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 (45% before and 10% after, $P<.001$) and non-Medicare patients (40% before and 9% after, $P<.001$). Although there was a dramatic increase in the use of laparoscopic gastric banding for all patients (Table 1), the increase was larger in Medicare patients (6% before and 35% after, $P<.001$) compared to non-Medicare patients (6% before and 24% after, $P<.001$), $P<.001$ for the difference between Medicare and non-Medicare patients.

As seen in Table 2, rates of any complication, serious complications, and reoperations fell substantially after the CMS coverage decision in both Medicare and non-Medicare patients. As noted in the Figure, trends towards improving outcomes were well underway before the implementation of the CMS policy. A large proportion of the improvement in 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 relative risk (RR) of 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 pre-existing trends toward improved outcomes, there were no measurable improvements in outcomes after (vs. before) implementation of the CMS national coverage decision: any complications (8.0% after vs. 7.0% before; Relative Risk [RR], 1.14, 95% Confidence Interval [CI], 0.95 to 1.33), serious complications (3.3% vs. 3.6%; RR 0.92, 95% CI, 0.62 to 1.22), and reoperation (1.0% vs. 1.1%; RR 0.90, 95% CI, 0.64 to 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 vs. non-COEs. We found that COEs as defined by the CMS coverage decision did not have better outcomes than non-COEs. After accounting for patient factors, procedure type, and the year of operation, patients undergoing bariatric surgery at hospitals with COE designation did not have significantly different rates of any complications (5.5% vs. 6.0%; RR, 0.98, 95%, 0.90 to 1.06), serious complications (2.2% vs. 2.5%; RR 0.92, 95%CI, 0.84 to 1.00), and reoperations (0.83% vs. 0.96%; RR, 1.00, 95% CI, 0.86 to 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 over the past decade. As described in our analysis, much of this improvement can be attributed to evolving surgical technique and the use of different types of procedures, including the transition from open to laparoscopic approaches and the increased use of laparoscopic adjustable gastric banding. Beyond changes in procedure use, there was a strong underlying time trend toward better outcomes for bariatric surgery in both Medicare and non-Medicare patients. However, the analysis in our study could not attribute any of this improvement in outcomes to the CMS policy restricting coverage of Medicare patients to COEs.

These conclusions should be considered in the context of prior studies. In the first study evaluating the impact of this policy, Nguyen and colleagues evaluated outcomes before and after the coverage decision in Medicare patients undergoing surgery at a subset of academic health centers.[9] Although the study found improved outcomes after the coverage decision, they used a simple “pre-post” design and therefore did not control for the strong time trends towards improved outcomes. In a subsequent study using national Medicare claims, Flum and colleagues similarly found fewer deaths, complications, and readmission after the coverage decision.[8] Although this study did adjust for time trends, it lacked a control group of non-Medicare patients. Because our analysis included non-Medicare patients, we could more fully adjust for other unrelated factors fueling improved outcomes during this time period and better isolate the independent effect of the CMS policy.

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, Livingston found no significant differences in a nationally representative sample of

hospitals.[7] Although this study used administrative data and lacked clinical detail, another recent study by Birkmeyer et al. used clinically rich registry data confirmed these findings, demonstrating no difference in risk-adjusted serious complication rates between COEs and non-COEs.[6] These findings could be due to the fact that the COE criteria were not evidence-based. Instead, they were largely based on expert opinion and clinical consensus. There were three primary criteria for COE designation: 1) a list of hospital structure and process elements, 2) a hospital volume standard (>125 cases per year), and 3) a mandate to submit data to a clinical registry. The hospital structural requirements were mainly resources required for severely obese patients receiving any type of hospital care. Although these measures have intuitive appeal, there was no evidence that they would lead to safer care. Hospital volume standards do not reliably discriminate hospital performance—i.e., some high volume centers have substandard outcomes and some low volume centers have excellent outcomes. While numerous studies have demonstrated volume-outcome relationships with bariatric surgery, this effect is relatively small (compared to cancer surgery, for example) and has likely declined over time as the field has matured. Finally, while both professional societies (ACS and ASMBS) required that hospitals submit data to clinical registries, these data have never been used to provide feedback on outcomes to surgeons and are not used as criteria for COE determinations.

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 towards lower procedures. Procedure mix changed in two important ways. First, there was a general shift away from open to laparoscopic surgery, which is consistent with broader trends in surgery towards 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. It appears that the increased use of laparoscopic adjustable gastric banding around the time of the coverage decision was much 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. Over the past decade, surgeons practicing bariatric surgery have 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 (e.g., new surgical stapling devices and high-definition video equipment). Finally, new surgeons have much more exposure to bariatric surgery in general surgery residency training programs and many opportunities to participate in post-residency fellowship training in advanced laparoscopy and bariatric surgery.

Our study uses administrative data which has well-known limitations. Perhaps the best known limitation of administrative data is risk-adjustment.[24] Comorbid diseases are derived from discharge codes and are not as reliable as those derived directly from the medical record. However, the study design we used is specifically designed to address such unmeasured variables. 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. Further, based on studies from clinical registries, we have no reason to believe that patient-mix has changed substantially for bariatric surgery over

time.[6,15] 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 (greater than or equal to 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. The rates of all complications, serious complications, and reoperations in our present study track very well with published estimates from clinical registries.[6,15] Moreover, The consistency of our findings across different outcomes—all complications, serious complications, and reoperations—reinforce the credibility of our findings.

Perhaps most importantly, 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 to other bariatric surgery procedures, such as gastric bypass.[26,27] There is accumulating evidence that laparoscopic gastric banding also has much higher rates of downstream 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 CMS. As highlighted herein, 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, our study also found no association between COE designation and better bariatric surgery outcomes. However, there are very real concerns about the effect the policy on patient access. For example, in a study of patients undergoing bariatric surgery in Texas, Livingston and Burchell found a markedly increased travel distance in Medicare patients after implementation of the CMS coverage decision.[31] In this context, we believe CMS should reconsider its national coverage decision and eliminate the restriction of coverage to COE hospitals. Aside from being fairer to hospitals, revising the national coverage decision in this way would enhance patient access without compromising safety.

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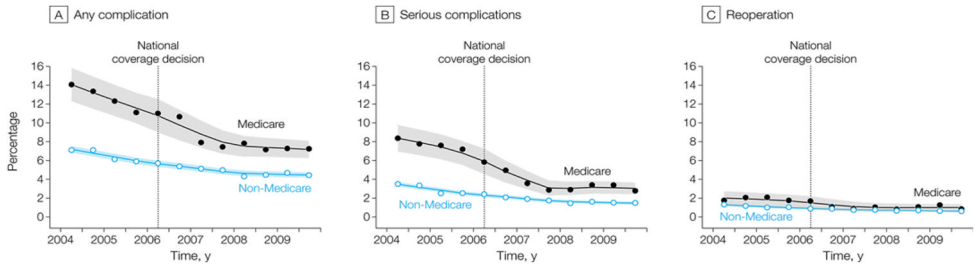

Figure.

Trends in adverse outcomes before and after the implementation of the CMS bariatric surgery national coverage decision. A. Any complication; B. Serious complications; C. Reoperations. Each half year is represented by a point on the graph. Time trend curves were fit to these points using Lowess smoothing. 95% Confidence Intervals are shown as dashed lines.

Table 1

Characteristics of Medicare and non-Medicare patients before and after the Medicare national coverage decision for bariatric surgery. NCD = National Coverage Decision.

Patient characteristics	Medicare patients undergoing bariatric surgery		Non-Medicare patients undergoing bariatric surgery	
	Before the CMS policy January 2004 to March 2006	After the CMS policy April 2006 to December 2009	Before the CMS policy January 2004 to March 2006	After the CMS policy April 2006 to December 2009
Number of patients, N	6,723	15,854	95,558	155,117
Age (Mean ± SD)	51.6 ± 11.4	55.0 ± 11.7	42.1 ± 10.5	43.0 ± 11.0
Gender (% Female)	76.7	73.5	82.0	79.4
Race (% White)	72.9	74.8	74.3	71.7
Procedure type, %				
Open gastric bypass, %	45.0	9.6	39.7	8.5
Laparoscopic gastric bypass, %	44.0	51.9	50.1	63.6
Laparoscopic gastric banding, %	6.3	34.5	6.4	24.1
Other bariatric procedure, %	4.7	4.0	3.8	3.9
Hypertension, %	64.9	68.8	47.9	50.9
Diabetes without chronic complications, %	40.1	43.6	23.9	26.7
Diabetes with chronic complications, %	3.9	3.9	0.9	1.1
Chronic pulmonary disease, %	26.2	23.8	16.9	17.0
Depression, %	20.8	20.4	16.2	17.5
Liver disease, %	10.1	9.1	8.9	9.9
Hypothyroidism, %	12.9	12.9	8.8	9.2
Psychoses, %	4.9	5.5	1.0	1.3
Fluid & electrolyte disorders, %	4.6	3.2	2.3	1.9
Congestive heart failure, %	4.3	3.7	0.8	0.7
Anemia, %	2.9	3.2	2.5	3.0
Other neurological disorders, %	2.3	3.0	0.6	1.1
Renal failure, %	1.3	3.1	0.2	0.5
Pulmonary circulation disease, %	1.2	1.1	0.3	0.3
Coagulopathy, %	0.4	0.5	0.3	0.3
Paralysis, %	0.5	0.3	0.1	0.1
Peripheral vascular disease, %	1.0	1.0	0.4	0.3

Table 2

Rates of adverse outcomes before and after the implementation of the Center for Medicare and Medicaid Services (CMS) policy restricting bariatric surgery to Centers of Excellence (COEs).

Adverse outcomes	Patients with adverse outcome (%)		Relative Risk of Adverse Outcome, After vs. Before the CMS Policy Restricting Coverage to COEs (95% CI)		
	Before the CMS policy January 2004 to March 2006	After the CMS policy April 2006 to December 2009	Simple pre-post analysis Adjusted for patient factors only	Simple pre-post analysis Adjusted for patient factors and procedure type	Independent effect of the CMS policy Difference-in-difference estimate*
ALL BARIATRIC SURGERY (N=102,281 patients before and N=170,961 patients after)					
Any complications					
Medicare	12.3	7.9	0.67 (0.60,0.74)	0.89 (0.77, 1.00)	1.14 (0.95, 1.33)
Non-Medicare	6.5	4.8	0.79 (0.75,0.84)	0.92 (0.84, 0.99)	[Reference]
Serious complications					
Medicare	7.5	3.4	0.48 (0.42,0.55)	0.64 (0.44, 0.83)	0.92 (0.62, 1.22)
Non-Medicare	2.9	1.7	0.66 (0.61, 0.70)	0.81 (0.70, 0.92)	[Reference]
Reoperations					
Medicare	1.9	1.0	0.58 (0.46,0.73)	0.85 (0.58, 1.12)	0.90 (0.64, 1.17)
Non-Medicare	1.1	0.7	0.66 (0.59,0.75)	0.87 (0.71, 1.03)	[Reference]
GASTRIC BYPASS SURGERY (N=91,801 patients before and N=121,454 patients after)					
Any complications					
Medicare	12.9	10.3	0.79 (0.72, 0.88)	0.88 (0.75, 1.00)	1.19 (1.01, 1.38)
Non-Medicare	6.9	5.8	0.89 (0.85, 0.93)	0.91 (0.83, 0.99)	[Reference]
Serious complications					
Medicare	7.6	4.6	0.59 (0.51, 0.68)	0.66 (0.46, 0.87)	0.98 (0.69, 1.28)
Non-Medicare	3.1	2.1	0.76 (0.72, 0.80)	0.81 (0.70, 0.92)	[Reference]
Reoperations					
Medicare	1.9	1.3	0.69 (0.54, 0.88)	0.89 (0.61, 1.17)	0.90 (0.62, 1.18)
Non-Medicare	1.2	0.9	0.74 (0.66, 0.84)	0.91 (0.75, 1.06)	[Reference]

*The independent effect of the CMS coverage decision is derived from a difference-in-difference model that represents improvement in outcomes before and after the policy change in Medicare patients compared to non-Medicare patients, the control group not exposed to the CMS policy. These logistic regression models also controls for patients characteristics, changes in procedure type, and any differences in pre-implementation trends in outcomes between Medicare and non-Medicare patients.