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Original article

The impact of accreditation on safety and cost of bariatric surgery

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Abstract

Background: The objective of this study was to examine how much of the impact of the Centers for Medicare and Medicaid Services' national coverage decision (NCD) on bariatric surgery was driven by the restriction of reimbursements to Centers of Excellence (COE). We used inpatient care data of those with employer-sponsored insurance plans across United States using the MarketScan Commercial Claims and Encounter Database (2003–2009).

Methods: We performed a retrospective cohort study evaluating the impact of the accreditation on subjects with a difference-in-difference approach (removing the temporal changes occurring in non-COEs) on rates of inpatient mortality, 90-day reoperations, complications, readmissions, and total payments.

Results: A total of 30,755 patients (43.9 ± 11.0 years; 79.9% women) had bariatric surgery. A total of 17,896 patients underwent procedures at sites that became COEs (8455 pre-NCD and 9441 post-NCD, [+10.4%]) compared with 12,859 at non-COEs (6534 pre-NCD and 6325 post-NCD, [−3.3%]). Of the total number of bariatric procedures, laparoscopic Roux-en-Y gastric bypass and laparoscopic adjustable band procedures increased from 42.9% and 3.1% pre-NCD to 64.5% and 19.7% post-NCD, respectively. In the COEs, there were reductions in inpatient mortality (.3% to .1%; $P = .02$), 90-day reoperations (.8% to .5%; $P = .006$), complications (36.4% to 27.6%; $P < .001$), and readmissions (10.8% to 8.8%; $P < .001$) while payments remained similar ($24,543 ± $40,145 to $24,510 ± $37,769; $P = .9$). After distinguishing from temporal trends and differences occurring at non-COEs, 90-day reoperation (−.8%; $P = .02$) and complication rates (−2.7%; $P = .01$) were lower at the COEs after the NCD.

Conclusions: The accreditation-based NCD in bariatric surgery was associated with lower rates of reoperations and complications. Such policies may become a powerful tool to improve surgical safety and quality. (Surg Obes Relat Dis 2013;9:617–622.)

Keywords: Centers of Excellence; National coverage decision; Centers for Medicare and Medicaid Services; Accreditation; Bariatric surgery

The burden of obesity has become a leading health concern in the United States, and the use of bariatric surgery has been rapidly growing and is now the second most common abdominal surgery performed in United States [1,2]. Insurance coverage for bariatric surgical procedures may be a limiting factor to its broader expansion with concerns about both safety [3] and a floodgate effect (insurance coverage leading to the widespread effect of patients wanting to undergo bariatric procedures) [4].

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Although modern assessments of bariatric surgery reveal a 30-day mortality rate of .3% [5] in the 1990s, a 1.5% to 2.2% 30-day mortality rate was noted [6,7]. In response to these concerns, the Centers for Medicare and Medicaid Services (CMS) developed a national coverage decision (NCD) for bariatric surgery. Issued on February 21, 2006, NCD was unique in that it addressed safety concerns by both limiting coverage to procedures performed at designated Centers of Excellence (COE) that were accredited by either the American College of Surgeons (ACS) or the American Society for Metabolic and Bariatric Surgery (ASMBS) and by expanding the coverage of bariatric surgical procedures to include a less invasive procedure: the adjustable gastric band.

Our group evaluated fee-for-service CMS beneficiaries before and after the NCD and found that outcomes improved and costs were reduced but that this impact was most significantly influenced by a shift to safer procedures and to patients with lower risk clinical characteristics rather than through an independent effect of shifts to accredited centers [8]. We found that distinguishing the effect of centers from shifts in patients and procedures and other temporal trends can be challenging. Because after the NCD, CMS beneficiaries could only receive treatment at COEs, teasing out the effect of center accreditation using Medicare data was even more challenging.

Patients with commercial insurance are not necessarily limited to undergo bariatric surgery in COEs after the NCD. We hypothesized that commercially insured patients having surgery at non-COEs (after the NCD) might be an appropriate control to evaluate the effect of accreditation status on outcome compared with outcomes among patients with commercial insurance having surgery at COEs. Using this cohort is also important given that more than 80% of bariatric surgery is performed on this group of patients [9]. The aim of this study is to assess the impact of COE accreditation on commercially insured patients distinct from other factors using a difference in difference approach between those having surgery at hospitals that did and did not become COEs before and after the NCD.

Methods

Data sources and setting

This study was approved by the University of Washington Institutional Review Board. MarketScan Commercial Claims and Encounter Database records (January 1, 2003, through September 30, 2009) were obtained through Thomson Reuters. These data represent claims for inpatient care for about 29.1 million patients <65 years of age who have employer-sponsored insurance plans across broad geographic coverage [1,10]. The Medicare Supplemental database also contains data for about 3.1 million of those who are Medicare beneficiaries (age ≥ 65 years) with private supplemental insurance [11].

Cohort selection

We used a retrospective cohort design. Subjects were those with a diagnosis of morbid obesity (international classification of disease [ICD]-9 code 278.01) and a standard set of current procedural terminology (CPT) codes in the inpatient file (Appendix 1). The inclusion rule parallels previous bariatric studies using administrative databases [6,12]. Only those patients without Medicare Supplemental ($n = 84{,}620$) were included in the study.

Variable definitions

Patient risk factors and Centers of Excellence (COE). Patient covariates include age at time of bariatric surgery and gender. Associated health conditions were classified using the Deyo modification [13] of the Charlson co-morbidity index (categorized 0–3, with ≥ 3 indicating greatest number of co-morbidities), calculated for each patient based on ICD-9 diagnostic codes from all records within 6 months before the operation. The inpatient hospital claims were used to identify the number of unique sites performing bariatric surgeries. Using the Medicare Supplemental database, we identified those sites performing bariatric surgeries in the Medicare population after the NCD. These sites were designated as COEs. Those sites at which bariatric surgeries were performed on Medicare population before NCD but no longer after the NCD were designated as non-COE sites. A total of 56,114 patients out of 88,519 patients did not have a unique hospital ID. The missing data did not arise at the hospital level, but from certain insurance plans requiring hospital IDs to be removed at the time of data entry. We performed a sensitivity analysis looking at demographic characteristics and outcomes of patients without hospital IDs.

Primary and secondary outcomes

Primary outcome was inpatient mortality. We also evaluated 90-day reoperative rates (Appendix 2) and readmission to a hospital within 90 days of the procedure. Other outcomes included surgical complications using previously defined codes by Encinosa et al. [1,10]. Finally, we evaluated total medical payments at 90 days, which were defined as the sum of the amounts paid by an employer, beneficiary through co-insurance, and deductibles. Reported payments were converted to 2009 dollars using the Consumer Price Index (CPI).

Statistical analysis

We calculated a priori that to demonstrate that the outcome (inpatient mortality and major reoperative morbidity

rate) of bariatric procedures in patients undergoing procedures before the NCD was 2 times the rate after the NCD (the least important clinically significant difference) would require at least 44,600 subjects for mortality (i.e., outcome .3% to .15%; power .9; alpha .05) and at least 398 subjects for complications (i.e., outcome 15% to 7.5%; power .9; alpha .05). The baseline rates of .2% and 15% are an extrapolation from previous studies [1,5,12,14].

Descriptive statistics of patient and procedure variables, procedure outcomes, and cost per case was calculated for the entire cohort and compared for the 3 years before and about 3.5 years after the CMS policy change. Categorical variables were compared using Pearson chi-square statistics and continuous variables were compared using Student's *t* test and analysis of variance. We used a difference-in-difference (DD) approach [15] to evaluate the effect of accreditation on outcomes. DD approach is an effective method to study the impact of a policy by comparing the differences in the outcomes before and after a policy for the population affected by the policy to the outcomes before and after a policy for those unaffected by the policy [15–19]. Given bariatric surgery is a dynamic field with improving outcomes over time, DD helps control for unobservable characteristics that may be affecting both groups over the same time period. In addition to allowing for fixed effects (nonrandom effects) attributable to the implementation of the NCD and hospital accreditation, we controlled for patient covariates (age, gender, Charlson co-morbidity index), procedure types, and time trend in quarters. For the inpatient payments model, we use a generalized linear model with a gamma distribution and log-link. For other outcome measures, we used a logit multivariate regression. Data analysis was conducted using SAS 9.1 (SAS Institute, Cary, NC) and Stata 11.1 (Statacorp, College Station, TX).

Results

There were 30,755 patients with hospital ID information who underwent bariatric procedures within the defined time period (14,989 in the 37 months pre-NCD versus 15,766 in the 43 months post-NCD). The mean age was similar in the pre- and post-NCD era, but there were a lower proportion of men in the pre-NCD era compared with post-NCD era (Table 1). There was a significant shift from open Roux-en-Y gastric bypass (ORYGB) to laparoscopic Roux-en-Y gastric bypass (LRYGB) and a significant increase in laparoscopic adjustable gastric band (LAGB) placement from pre-NCD to post-NCD era (Table 1). A total of 7896 patients underwent procedures at sites that became COEs after the NCD. Patients undergoing procedures in COEs in the post-NCD era were more likely to be males but were similar in terms of age and extent of co-morbid conditions compared with pre-NCD era (Table 1). In the COEs, there were significant shifts to more LRYGB and LAGB and less ORYGB. A total of 12,859 patients had surgery in non-COEs before and after the NCD. Patients at non-COE hospitals in the post-NCD era were similar in age but were more likely to be males and had a higher proportion of patients, with at least 1 co-morbidity compared with the pre-NCD era (Table 1). Significant shifts in procedures to more LRYGB and LAGB and away from ORYGB were also seen in the non-COEs.

The inpatient mortality rate pre-NCD was .3% and post-NCD was .2% ($P = .1$). There was a significant reduction in the unadjusted in-hospital mortality rate from pre- to post-NCD period in the COEs (.3% to .1%; $P = .01$) but no

Table 1
Pre- and post-NCD Patient Characteristics for Non-Medicare Patients at Centers of Excellence versus Non–Centers of Excellence

Characteristics	Centers of Excellence (n = 17,896)		Non–Centers of Excellence (n = 12,859)		Overall (n = 30,755)	
	Pre-NCD (n = 8455)	Post-NCD (n = 9441)	Pre-NCD (n = 6534)	Post-NCD (n = 6325)	Pre-NCD (n = 14,989)	Post-NCD (n = 15,766)
Age	44.3 ± 10.7	44.1 ± 10.8	43.3 ± 11.0	43.5 ± 11.6	43.9 ± 10.8	43.9 ± 11.2
Female	6896 (81.6%)	7459 (79.0%)*	5296 (81.1%)	4922 (77.8%)*	12,192 (81.3%)	12,381 (78.5%)*
Charlson's co-morbidity						
0	4,404 (52.1%)	4,862 (51.5%)	3,470 (53.1%)	3,170 (50.1%)*	7,874 (52.5%)	8,032 (51.0%)*
1	2,765 (32.7%)	3,208 (34.0%)	2,101 (32.2%)	2,201 (34.8%)*	4,866 (32.5%)	5,409 (34.3%)*
2	936 (11.1%)	979 (10.4%)	696 (10.7%)	701 (11.1%)*	1,632 (10.9%)	1,680 (10.7%)*
3+	350 (4.1%)	392 (4.2%)	267 (4.1%)	253 (4.0%)*	617 (4.1%)	645 (4.1%)*
Type of operation						
ORYGB	4054 (48.0%)	1111 (11.8%)*	3526 (54.0%)	944 (14.9%)*	7580 (50.6%)	2055 (13.0%)*
LRYGB	3888 (46.0%)	6260 (66.3%)*	2547 (39.0%)	3904 (61.7%)*	6435 (42.9%)	10,164 (64.5%)*
LAGB	256 (3.0%)	1819 (19.3%)*	205 (3.1%)	1290 (20.4%)*	461 (3.1%)	3109 (19.7%)*
Other	257 (3.0%)	251 (2.7%)*	256 (3.9%)	187 (3.0%)*	513 (3.4%)	438 (2.8%)*

NCD = national coverage decision; ORYGB = open Roux-en-Y gastric bypass; LRYGB = laparoscopic Roux-en-Y gastric bypass, LAGB = laparoscopic adjustable gastric band.

*Signifies characteristics that are statistically significantly different ($P < .05$) in the post-NCD era compared with the pre-NCD era.

Table 2
Pre- and Post-NCD Changes in Outcomes According to Accreditation Status (Centers of Excellence versus Non–Centers of Excellence) among Non-Medicare Patients

	Centers of Excellence (n = 17,896)		Non–Centers of Excellence (n = 12,859)		Overall (n = 30,755)	
	Pre-NCD (n = 8455)	Post-NCD (n = 9441)	Pre-NCD (n = 6534)	Post-NCD (n = 6325)	Pre-NCD (n = 14,989)	Post-NCD (n = 15,766)
Inpatient mortality	26 (.3%)	13 (.1%)*	13 (.2%)	15 (.2%)	39 (.3%)	28 (.2%)
90-day reoperations	70 (.8%)	47 (.5%)*	41 (.7%)	35 (.5%)	105 (.7%)	88 (.6%)
90-day complications	3073 (36.4%)	2608 (27.6%)*	2372 (36.3%)	1876 (29.7%)*	5,445 (36.3%)	4484 (28.4%)*
90-day readmissions	915 (10.8%)	826 (8.8%)*	760 (11.6%)	603 (9.5%)*	1675 (11.2%)	1429 (9.1%)*
90-day total payments	$24,543 ± $40,145	$24,510 ± $37,769	$26,477 ± $29,114	$26,403 ± $37,903	$25,386 ± $37,769	$26,270 ± $37,239

NCD = national coverage decision.
*Statistically significantly different ($P < .05$) in the post-NCD era compared with the pre-NCD era.

reduction in the non-COEs (.2% to .2%; $P = .6$). Overall, there was no significant reduction in 90-day reoperations and payments, although we observed a significant reduction in the 90-day complication and readmission rates before and after the NCD (Table 2). In the COEs, there were significant reductions in all adverse outcomes but not in 90-day payments (Table 2). In the non-COEs, there were significant reductions in only the 90-day complication (36.3% to 29.7%; $P < .001$) and readmission rates (11.6% to 9.5%; $P < .001$).

Distinguishing from temporal trends and patient risk and procedural shifts we evaluated the impact of accreditation using a DD model. After controlling for covariates (age, gender, and co-morbidity index), time trends (by adjusting for changes in outcomes pre- and post-NCD occurring in non-COEs), and procedure types, there was a .04% decrease in the inpatient mortality rate ($P = .1$) at the COEs due to the NCD (Table 3). After adjusting for the same factors, there was a significant decrease in 90-day reoperation rates (–.8%; $P = .02$) and 90-day complication rates (–2.7%; $P = .01$) at the COEs attributable to the NCD. The NCD had no significant effect on 90-day readmissions or payments.

Discussion

We hypothesized that the 2006 Medicare NCD for obesity surgery would create changes in the way bariatric procedures were used. Our analyses suggest that the NCD produced a predominant shift of bariatric operations to COEs and a shift to safer procedures (LRYGB and LAGB)

Table 3
Risk-Adjusted Outcomes Using Difference-in-Difference (DD) Model Comparing the Changes Occurring in Centers of Excellence with the Changes Occurring at Non–Centers of Excellence Since the NCD among Non-Medicare Patients

Variables	In-Hospital Deaths	90-Day Reoperations	90-Day Complications	90-Day Readmissions	90-Day Payments
Age	.003%*	.02%‡	.1%*	.03%†	$51.8*
Sex	–.03%‡	–.3%†	–2.5%*	–2.3%*	–$3121.2*
Time (in quarters)	–.0001%	–.003%	–.3%*	–.07%	$227.8*
Charlson's co-morbidity index					
1	.03%‡	–.02%	2.4%*	.8%	$1021.8†
2	.05%*	.03%	5.2%*	2.2%*	$3219.4*
3+	.09%*	–.1%	13.2%*	3.9%*	$7490.8*
ORYGB	–.01%	–1.1%*	.2%	.09%	–$2677.6†
LRYGB	–.01%*	–.8%‡	–7.5%*	–2.2%*	–$7954.8*
LAGB	–.02%*	–.4%	–23.1%*	–9.6%*	–$14,790.1*
NCD	.03%	.08%	2.9%‡	.9%	–$667.1
Centers of Excellence	.02%	.4%‡	.6%	–.5%	–$2201.3*
Effect of NCD at Centers of Excellence (DD estimator)	–.04%	–.8%‡	–2.7%‡	–.2%	$590.8

NCD = national coverage decision; ORYGB = open Roux-en-Y gastric bypass, LRYGB = laparoscopic Roux-en-Y gastric bypass; LAGB = laparoscopic adjustable gastric band.
*Statistically significantly different at the 99% level.
†Statistically significantly different at the 90% level.
‡Statistically significantly different at the 95% level.

in the post-NCD period. Our DD regression model found that accreditation itself had a significant impact on 90-day complication and reoperation rates and not on inpatient mortality, readmissions, or payments.

Restricting access to COEs was a unique use of the NCD policy to address safety concerns. The impact and value of this policy decision has been questioned, and the main mechanism of its effect (procedure shift, patient risk shift, or center accreditation status-effect) has not been well explored. Although studies at single centers [20] and across multiple centers [21–23] have shown a positive impact of COEs on outcomes, others have found no improvements [24,25] but decreased access to care [26,27]. One significant problem in assessing the effect of the NCD is the difficulty of separating out the effect of temporal trends, improvements in surgical techniques, shifts to safer procedures, and changes in patient population from the effect of the center's accreditation status. Our previous analysis [8] and previous studies have lacked a comparator group that would allow an analytic focus on the changes taking place in the COEs. In this analysis, we applied a DD analytical approach using a control group (patients having surgery at non-COEs) to isolate out the impact of the NCD. Compared with other analytical approaches, DD provides an advantage in prepolicy and postpolicy study by controlling for unobservable changes that may be affecting both groups over time and would otherwise lead to biased results. Using the DD approach, we saw a significant drop occurring in the 90-day complication and reoperation rates occurring in the COEs associated with the NCD. The inpatient mortality also decreased but this change but was not statistically significant (–.04%; $P = .1$). Given the low rate of inpatient mortality, there may have been a significant decrease that would have been observed with a larger sample size.

A main criticism of the NCD has been that COE accreditation is based in part on bariatric surgical volume for both the centers and the surgeons. A "volume-outcome" relationship in bariatric surgery has been controversial, with studies reporting benefit [20,28–31], especially in the early case volume of a surgeon [6], while others have questioned this relationship and called for using risk-adjusted outcomes, independent of volume for accrediting COEs [32–34]. There may be other mechanisms by which the NCD may have exerted a center effect other than through shifts to higher volume hospitals. COE status through either accrediting body calls for multidisciplinary care teams, educational activities for patients, care pathways, mandatory reporting of outcomes and best practice infrastructure and personnel requirements. When evaluating COE effects on outcome, any of these factors may play a role, and distinguishing them is difficult if not impossible.

This study was limited because this data set did not include hospital information such as their actual accreditation status at the time of the operation. Rather, we relied on a labeling strategy for COE looking for those centers performing bariatric surgery on Medicare patients. Those centers that continued to perform surgery on CMS beneficiaries after the NCD were labeled COEs given that the risk of not being reimbursed likely compelled centers to perform surgery on CMS beneficiaries only if they were accredited. Patients may have been essentially misclassified into the group undergoing operations at non-COEs when having their operations in the months before a center became a COE and some patients would have been misclassified as having their operation at a non-COE hospital if the hospital was a COE but performed no operations on CMS beneficiaries after the NCD. If this led to nondifferential misclassification then we might be expected to bias our findings to the null but we cannot be certain of that. Although our study used unique hospital IDs, many patients did not have this information available in this data set. This was not due to bias in reporting by certain hospitals but secondary to certain insurance providers prohibiting hospital ID reporting. We looked at the patient and procedural characteristics along with outcomes (including pre- and post-NCD outcomes) in the missing group, and they did not differ significantly from the cohort with hospital ID information. Analytically, although DD has been used to distinguish the effect of policy decision from other changing factors distinct from the NCD, an untestable assumption was made that a change in outcome in the COEs during our study period would have been the same as the change in the non-COEs had the NCD not occurred. Other insurers developed or adopted accreditation programs akin to the NCD criteria and may have affected non-COEs during this time period. Last, our study is limited given the nature of administrative database. We did not have other important predictors of adverse outcomes to include in our risk adjustment regression analyses such as functional status, body mass index, and certain clinical conditions (e.g., obstructive sleep apnea). Future studies using clinical databases such as National Surgical Quality Improvement Program, Bariatric Outcomes Longitudinal Database, and Longitudinal Assessment of Bariatric Surgery Study would be important to address the limitations of administrative database.

Conclusions

We conclude that the component of CMS's NCD on bariatric surgery that related to shifting procedures to accredited centers did exert a positive effect on patient outcomes distinct from other factors. However, studies assessing the NCD's impact on long-term effects, nonsafety outcomes such as weight loss and co-morbid condition improvements, costs, and quality of care are needed.

Disclosures

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

Appendix A

Supplementary data

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1016/j.soard.2012.11.002.

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