

Volume-Outcome Relationship for Coronary Artery Bypass Grafting in an Era of Decreasing Volume

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Hypothesis: We hypothesized that the recent reduction in procedure volume for coronary artery bypass grafting (CABG) has led to an increase in the in-hospital mortality rate.

Design: Hospital discharge data from the Nationwide Inpatient Sample from January 1, 1988, through December 31, 2003.

Setting: A 20% random sample of patients admitted to US hospitals.

Patients: All patients who underwent CABG or percutaneous transluminal coronary interventions. Facilities performing CABG were assigned to standard volume cutoffs.

Main Outcome Measures: Rates of cardiac procedures and the proportion of hospitals meeting standard volume cutoffs, as well as the CABG mortality rate.

Results: During our 16-year study period, the rate of CABG increased from 7.2 cases per 1000 discharges in 1988 to 12.2 cases in 1997 but then decreased to 9.1 cases in 2003, while the rate of percutaneous interventions tripled. For CABG, the proportion of high-volume hospitals declined from 32.5% in 1997 to 15.5% in 2003. Despite shifts between high- and low-volume hospitals, the CABG mortality rate steadily declined from 5.4% in 1988 to 3.3% in 2003. Hospitals performing the lowest volume of CABG experienced the largest decrease in the in-hospital mortality rate.

Conclusions: Since 1997, CABG volume has declined in the setting of a decrease in in-hospital mortality. A lower mortality rate in the setting of reduced CABG volume is a counterintuitive finding, suggesting that procedure volume is an insufficient predictor of outcome on which to base regionalization strategies.

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THE RELATIONSHIP BETWEEN increased hospital coronary artery bypass grafting (CABG) volume and lower mortality has been consistently observed in the clinical literature.¹⁻¹⁵ The robustness of this association has led some investigators to suggest that postsurgical morbidity and mortality could be reduced substantially if hospitals with little working experience in cardiac techniques

aged health care purchasers to consider CABG volume when selecting providers.²¹ The Leapfrog Group,²² a health care purchasing group of more than 170 companies and organizations, established the standard of 500 CABG operations per year as a quality criterion for selecting providers.

See Invited Critique at end of article

During the past 2 decades, the introduction and refinement of percutaneous coronary revascularization techniques have considerably affected the care of patients with coronary artery disease. The resulting drop in the number of CABG operations provides an opportunity to evaluate the effect of decreasing procedure volume on patient outcomes. These changes have led us to question what happens to the volume-outcome relationship when volume decreases significantly. Our study had the following initial aims: (1) to de-

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stopped performing procedures such as CABG.¹⁶⁻¹⁸ Other researchers estimate that the mortality rate for CABG could be reduced by 1486 deaths per year if all patients undergoing CABG were referred to hospitals that perform more than 500 CABG operations per year.^{19,20} As a result, several organizations and the lay press encour-

fine national trends in the volume of coronary revascularization techniques performed surgically (CABG) or by percutaneous transluminal coronary intervention (PTCI) and (2) to define trends in valve replacement and repair (VRR) to correct for potential database sampling bias. Next, we characterize trends in hospital volume for CABG (based on established criteria for volume¹³) to characterize the proportion of patients treated at low-, mid-, and high-volume hospitals. Therefore, 2 additional aims were the following: (3) to record mortality by year and by CABG volume to evaluate the effect of declining CABG volume on the well-defined volume-outcome relationship and (4) to quantify the difference in mortality between high- and low-volume hospitals.

METHODS

DATA SOURCES

We obtained hospital discharge data from the Nationwide Inpatient Sample (NIS) for 16 years (January 1, 1988, through December 31, 2003) via the Healthcare Cost and Utilization Project of the Agency for Healthcare Research and Quality. The NIS, the largest source of all-payer hospital discharge information in the United States, is a unique and powerful tool that includes data from about 7 million hospital stays per year in 1000 hospitals located in 35 states, approximating a 20% stratified sample of US community hospitals. Other researchers have used NIS data to review trends in surgical care and outcomes,²³ volume-outcome relationships,¹³ and disparities in care.²⁴ A data use agreement is held by the Agency for Healthcare Research and Quality; in addition, our study protocol was considered exempt by the University of Minnesota Institutional Review Board.

PATIENTS

We used diagnostic codes from the *International Classification of Diseases, Ninth Revision (ICD-9)* to identify all patients who underwent CABG (codes 36.10-36.19),¹⁵ VRR (codes 35.11, 35.21, 35.22, 35.12, 35.23, and 35.24),¹⁵ or PTCI (codes 36.01, 36.02, 36.04, 36.05, 36.06, 36.07, and 36.09) from 1988 through 2003.

HOSPITAL VOLUME

The NIS contains hospital identifiers that permit calculation of hospital-level volume. Volumes of CABG were calculated separately in each year for each facility reporting CABG. Based on previously published methods,¹³ we included all hospitals performing at least 12 CABG operations per year. Prior work by Rathore et al¹³ identified significant volume-outcome effects using the following categories of annual volume: high (≥ 500 CABG operations), mid (250-499 operations), and low (12-249 operations); the high-volume cut point (500 operations) was selected as a minimum threshold for quality standards by the Leapfrog Group²² during the period of our analysis. Therefore, we adopted these volume cutoffs to divide hospitals into 3 groups.

IN-HOSPITAL MORTALITY

The NIS contains information on vital status at the time of discharge. We determined the in-hospital mortality rate for all patients undergoing CABG during our study period. We also calculated the mean mortality rate by hospital volume group (high, mid, and low) and for each quarter of our study period (1988-

1991, 1992-1995, 1996-1999, and 2000-2003). The NIS does not include 30-day mortality rates, so the in-hospital mortality rate was the single outcome that we calculated.

COMORBIDITY

To control for changes in patient comorbidity over time, we adjusted for comorbidity using the modification of the Charlson Comorbidity Index by Deyo et al.²⁵ Briefly, we ascertained the presence of 17 comorbid conditions and then weighted them according to the original study by Pompei et al.²⁶ An elevated Charlson Comorbidity Index has been shown to correlate with increased 1-year mortality.²⁶ In addition, we calculated the proportion of patients having a diagnosis of diabetes mellitus to adjust for risk during our 16-year study period. In a study²⁷ of administrative database coding accuracy, upcoding of diabetes mellitus was not noted over time.

STATISTICAL ANALYSIS

To compare categorical variables (patient characteristics, proportion of hospitals, and mortality) between high-, mid-, and low-volume hospitals, we used the χ^2 test. We used the *t* test to compare continuous variables.

We used the joinpoint regression program²⁸ from the Surveillance Epidemiology and End Results program of the National Cancer Institute to evaluate whether volume and mortality were variable over time. We estimated statistical significance (*P* value) using Monte Carlo methods and maintained the overall asymptotic significance level using Bonferroni correction.²⁹

We used logistic regression analysis to determine the effect of study period (1988-1991, 1992-1995, 1996-1999, and 2000-2003) on the probability of mortality while controlling for comorbidity, payer status, patient sex, and patient age. Study period and payer status (Medicare, Medicaid, private, or other) were modeled as categorical variables, with comorbidity and patient age as continuous variables. To determine if the relationship between volume and mortality was consistent throughout our study period, we tested for an interaction between hospital volume (using the published cutoffs) and year of surgery on mortality. To identify potential changes in the relationship between hospital volume and mortality over time, we calculated odds ratios for mortality after adjusting for identified covariates. We then compared the odds ratios for mortality between high-volume and low-volume hospitals for 1988-1991 (quarter 1) and then plotted the results.

For statistical analyses, we used commercially available software (SAS version 9.13; SAS Institute, Cary, NC). All statistical tests were 2-sided, and $P \leq .05$ was considered statistically significant.

RESULTS

PATIENT CHARACTERISTICS

For our 16-year study period, we found NIS discharge abstracts for 108 087 386 patients: CABG was performed in 1 082 218 patients (1.0%), VRR in 186 483 patients (0.2%), and PTCI in 1 589 942 patients (1.5%) (**Table 1**). During our study period, 2 858 643 (CABG, VRR, or PTCI) procedures were performed. The mean age of all patients was 64.6 years; patients who underwent VRR and CABG were slightly older. About half of all patients were enrolled in Medicare. The mean Charlson Comorbidity Index score was 1.02, and the highest

Table 1. Patient Characteristics by Procedure^a

Characteristic	Total (N=2 858 643)	Procedure		
		CABG (n=1 082 218)	VRR (n=186 483)	PTCI (n=1 589 942)
Age, mean (SD), y	64.6 (0.007)	65.8 (0.010)	65.7 (0.020)	63.6 (0.009)
Sex, %				
Male	67.5	70.6	59.2	66.3
Female	32.5	29.4	40.8	33.7
Missing	<0.01	<0.01	<0.01	<0.01
Payer, %				
Medicare	52.0	54.8	61.0	48.7
Medicaid	3.7	3.4	4.3	3.7
Private	38.6	36.0	29.4	41.2
Self or other	5.5	5.0	4.6	5.9
Missing	0.3	0.8	0.6	0.5
Diabetes mellitus, %	22.3	24.1	13.1	22.2
≥3 Comorbidities, %	5.6	6.8	4.6	4.9
Charlson Comorbidity Index score, mean (SD)	1.02 (0.0007)	1.08 (0.0010)	0.94 (0.0030)	0.99 (0.0010)

Abbreviations: CABG, coronary artery bypass grafting; PTCI, percutaneous transluminal coronary intervention; VRR, valve replacement or repair.
^a*P* < .001 for all comparisons across procedures.

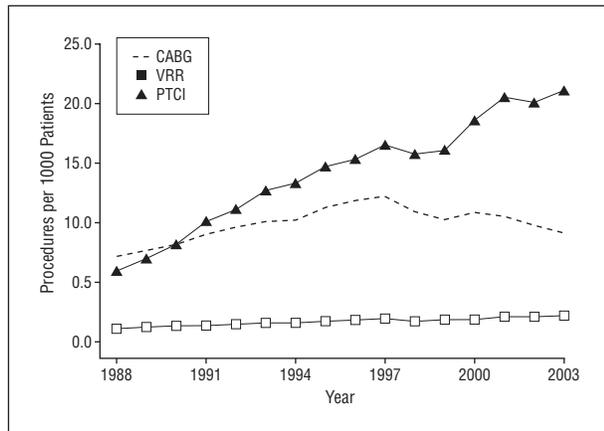


Figure 1. Coronary artery bypass grafting (CABG), valve replacement or repair (VRR), and percutaneous transluminal coronary intervention (PTCI) per 1000 patients per year.

score was for patients who underwent CABG. Diabetes mellitus was present in 24.1% of all patients undergoing CABG; its prevalence increased from 14.0% in 1988 to 31.5% in 2003.

PROCEDURE TRENDS

The number of CABG operations increased from 37 838 in 1988 to 87 160 in 1997 but decreased to 72 939 in 2003. The rate of CABG increased from 7.2 procedures per 1000 hospitalized patients in 1988 to 12.2 procedures per 1000 patients in 1997 and then declined to 9.1 procedures per 1000 patients in 2003 (*P* < .001) (**Figure 1**). Our jointpoint trend analysis revealed an increase in the rate of CABG over time until 1996 (slope, 0.60; *P* < .001). After that, our analysis revealed a reduction in the rate of CABG (slope, -0.36; *P* < .001). In contrast, the number of VRR procedures increased from 5908 in 1988 to 17 408 in 2003. The rate of VRR gradually increased from 1.1 procedures per 1000 patients in 1988 to 2.2 procedures per 1000 patients

in 2003: this increase was consistent over time (our jointpoint trend analysis revealed a slow increase, without a major change in the trend [slope, 0.07; *P* < .001]).

The number of PTCI procedures increased considerably during our study period, from 31 713 in 1988 to 168 831 in 2003. The rate of PTCI increased from 6.0 procedures per 1000 patients in 1988 to 21.2 procedures per 1000 patients in 2003 (Figure 1). Our jointpoint trend analysis revealed a rapid increase in the rate of PTCI until 1993 (slope, 1.36; *P* < .001), with a more gradual increase in the ensuing years (slope, 0.84; *P* < .001). As a result of the combined decrease in CABG and increase in PTCI, the overall ratio of CABG to PTCI procedures decreased from 1.2:1 in 1988 to 0.4:1 in 2003.

HOSPITAL CABG VOLUME

The number of hospitals routinely performing CABG ranged from 119 to 233 during our study period. Overall, 52.0% of patients received care at high-volume (≥500 CABG operations per year) hospitals. Patients treated at high-volume hospitals were slightly older (mean age, 65.9 years) but were less likely to be male (70.3%) compared with patients treated at other hospitals (**Table 2**). High-volume hospitals treated a larger proportion of Medicare patients, but low-volume hospitals treated more patients with Medicaid insurance. In addition, high-volume hospitals treated a higher proportion of patients with diabetes mellitus, as well as a higher proportion of patients with 3 or more comorbidities and with higher mean Charlson Comorbidity Index scores.

The proportion of high-volume hospitals increased from 17.7% in 1988 to a peak of 32.5% in 1997 (the year of the peak volume of CABG) but then decreased to 15.5% in 2003. Conversely, the proportion of low-volume (12-249 CABG operations per year) hospitals decreased from 49.6% in 1988 to a nadir of 35.5% in 1997 but increased to 52.4% in 2003 (**Figure 2**). The number of patients

Table 2. Patient Characteristics by Hospital Volume^a

Characteristic	Hospital Volume		
	High (n=562 519)	Mid (n=339 796)	Low (n=179 645)
Age, mean, y	65.9	65.8	65.3
Sex, %			
Male	70.3	71.2	70.4
Female	29.7	28.8	29.6
Missing	<0.005	<0.005	<0.005
Payer, %			
Medicare	56.1	54.6	52.4
Medicaid	3.0	3.3	4.8
Private	36.0	36.0	35.0
Self or other	3.9	5.5	7.4
Missing	1.0	<0.6	0.4
Diabetes mellitus, %	24.7	22.9	24.2
≥3 Comorbidities, %	7.2	6.2	6.8
Charlson Comorbidity Index score, mean	1.12	1.03	1.07

^aTwo hundred fifty-eight patients were excluded from the hospital volume calculations. *P* < .001 for all comparisons across hospital volumes.

undergoing CABG treated at high-volume hospitals increased from 16 878 (44.6%) in 1988 to 54 983 (63.1%) in 1997 but then decreased to 29 886 (41.0%) in 2003. Conversely, the number of patients treated at low-volume hospitals decreased from 7500 (19.8%) in 1988 to 9757 (11.2%) in 1997 but then increased to 17 945 (24.6%) in 2003.

CABG IN-HOSPITAL MORTALITY

In-hospital CABG mortality decreased from 5.4% in 1988 to 3.3% in 2003 (**Figure 3**). Our joinpoint trend analysis revealed a drop in mortality for CABG throughout our study period, with a more rapid decrease before 1993 (slope, -0.26; *P* < .001) compared with 1994 onward (slope, -0.09; *P* < .001). Our logistic regression analysis revealed a statistically significant reduction in mortality from 1988 to 2003 (odds ratio, 0.41; 95% confidence interval, 0.38-0.41; *P* < .001) that was not explained by changes in patient age, patient sex, payer status, or comorbidity. The overall Charlson Comorbidity Index score increased during our study period (from 0.6 in 1988 to 1.3 in 2003, *P* < .001), and the percentage of patients with 3 or more comorbidities rose from 1.2% in 1988 to 9.4% in 2003 (*P* < .01). The percentage of patients with diabetes mellitus rose from 14.0% in 1988 to 31.5% in 2003 (*P* < .001). When we excluded comorbidity from our model, we still noted a statistically significant reduction in mortality over time (odds ratio, 0.53; 95% confidence interval, 0.50-0.57; *P* < .001).

In 1988, CABG mortality in high-volume hospitals was 4.9%; in 2003, it was 3.1%. We noted a statistically significant trend toward reduced mortality in high-volume hospitals from 1990 onward (*P* < .001). Similarly, in mid-volume hospitals, mortality decreased from 5.6% in 1988 to 3.4% in 2003. A statistically significant trend toward reduced mortality in mid-volume hospitals was observed throughout our study period (*P* < .002). In low-volume hospitals, mor-

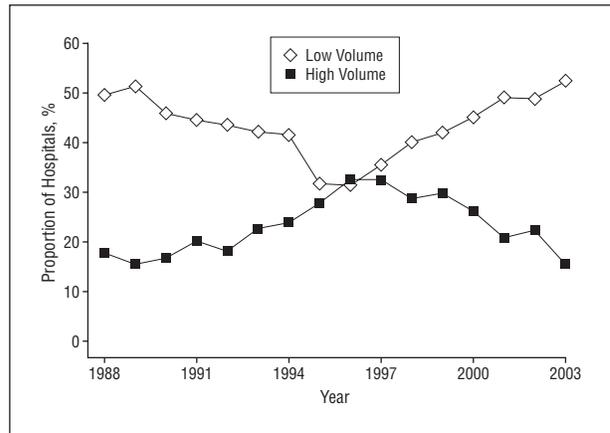


Figure 2. Proportions of coronary artery bypass grafting low-volume or high-volume hospitals by year of procedure.

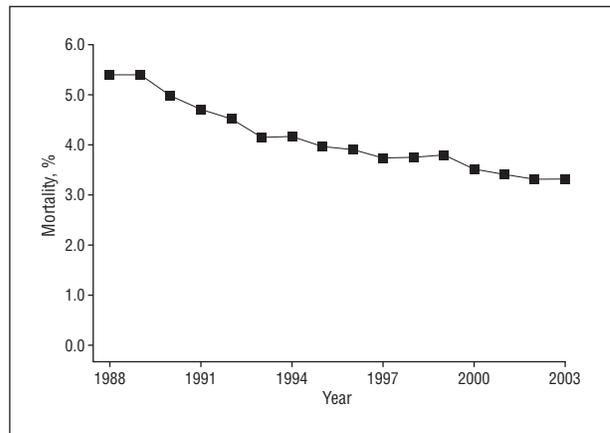


Figure 3. Overall mortality rates by year for patients undergoing coronary artery bypass grafting.

tality decreased from 5.9% in 1998 to 3.5% in 2003. Therefore, we also noted a statistically significant trend toward reduced mortality in low-volume hospitals throughout our study period (*P* < .001).

When we analyzed mortality by quarter of our study period (1988-1991, 1992-1995, 1996-1999, and 2000-2003), we observed a statistically significant difference in mortality between high-volume and low-volume hospitals, a difference that was not explained by patient characteristics or by comorbidities (*P* < .001) (**Table 3**). In addition, we identified a statistically significant interaction between quarter and hospital volume in our logistic regression model predicting mortality, indicating that the relationship between hospital volume and mortality changed over time (*P* < .05). Therefore, the difference in mortality across volume thresholds changed during the study period. The odds ratio for mortality revealed that mortality significantly decreased for all cutoffs of hospital volume over time compared with low-volume hospitals in 1988-1991. In addition, a plot of our odds ratios illustrated that the difference in mortality between high-volume and low-volume hospitals narrowed during the most recent quarter (2000-2003) (**Figure 4**).

Table 3. Patient Mortality by Hospital Volume and Quarter of the Study Period^a

Quarter	Hospital Volume, %			P Value
	High	Mid	Low	
1988-1991	4.9	5.1	5.5	<.002
1992-1995	3.9	4.3	4.8	<.001
1996-1999	3.7	3.9	4.2	<.001
2000-2003	3.2	3.5	3.7	<.001

^a P value indicates significance for comparisons across all hospital volumes.

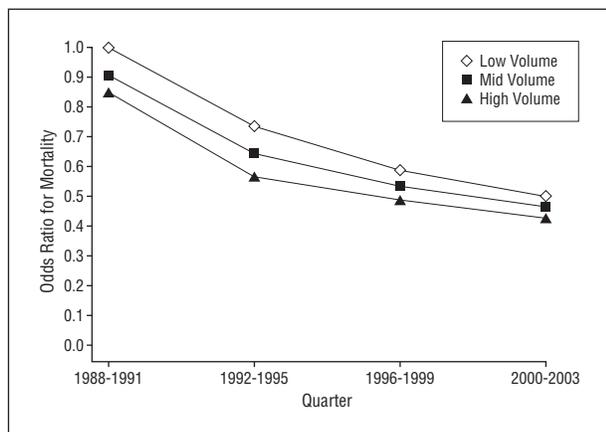


Figure 4. Odds ratios for coronary artery bypass grafting mortality compared with low-volume hospitals at the beginning of the study period. Rates are per quarter of the study period.

COMMENT

Our data confirm marked changes in CABG volume over time in the United States. Although the volumes of PTCI and VRR rose during our study period, the volume of CABG has been decreasing since its peak in 1997. Similarly, a population-based study³⁰ in Washington State found that CABG operations decreased 19% from 1997 to 2001. Explanations for the reduced rate of CABG surgery include improvements in minimally invasive approaches to coronary revascularization,³¹ enhancements in PTCI techniques, the development of drug-impregnated stents,³² and the advent of new anticoagulant agents.^{33,34} In addition, behavioral, societal, and medical efforts at prevention may have reduced the overall proportion of patients with cardiovascular risk factors and, consequently, with coronary artery disease.³⁵

The effect of decreased CABG volume has not been evaluated in the literature, to our knowledge, until our study. It stands to reason that the decreasing CABG volume has an effect on patient outcome. However, in addition to the overall reduction in CABG operations, our data demonstrate marked reductions in the proportion of institutions classified as high-volume hospitals and in the proportion of patients treated at the Leapfrog Group's high-volume hospitals. If a causal relationship exists between a high procedure volume and a good

outcome, then findings of (1) an overall reduction in CABG volume and (2) a reduction in the proportion of patients treated at high-volume hospitals should affect mortality. Specifically, with a decline in CABG volume, one would predict a rise in mortality since 1997. Instead, our study reveals a significant reduction in mortality in the face of reduced aggregate procedure volume.

As overall CABG volume declined from 1997 onward, overall CABG mortality also significantly declined from 3.7% in 1997 to 3.3% in 2003. This counterintuitive finding may be explained by (1) a dissemination of improved quality care practices to the community or (2) a shift of once high-volume hospitals, with presumed lower mortality rates because of structural variables that remained constant, into the low-volume group. A definitive explanation cannot be obtained from our data. We also found significant improvement across all volume groups over time, as well as overall improvements in the mortality rate since 1997, despite the fact that fewer patients were treated at high-volume hospitals. Therefore, care of patients undergoing CABG has improved independent of volume. Previous research confirmed a dissemination of improved quality care practices at multiple institutions in the area of CABG surgery.³⁶ Given the reduction in CABG volume and the dramatic increase in patients treated at low-volume hospitals, regionalization strategies were not responsible for the improvements in the mortality rate that we identified.

Our data indicate that in-hospital mortality rates and, possibly, quality care practices are improving everywhere independent of CABG volume. In fact, the low-volume hospitals had the most substantial reduction in CABG mortality. In 2003, the absolute difference in mortality between high-volume and low-volume centers was small. This finding should challenge the setting of any arbitrary volume cut point: positive effects on patient outcome are multifactorial and are inadequately described by procedure volume. In addition, the in-hospital mortality rate after CABG may have diminished to such low levels that it is no longer a useful marker of quality. It may still be valuable in identifying outliers, but in terms of evaluating quality of care in further CABG outcome studies, other end points may be more valuable.

Our use of an administrative database for analysis of medical services has limitations and strengths. First, ICD-9 procedure coding was consistently recorded throughout our 16-year study period and is known to be highly accurate. Yet, despite the noted accuracy of ICD-9 coding, a significant limitation of our study is the lack of all potential medical items in the hospital record. In addition, we were unable to directly compare in-hospital mortality rates with 30-day mortality rates; however, these 2 rates have been shown to be highly correlated.³⁷ Second, we noted a secular trend toward higher comorbidity coding; however, the results of our logistic regression model were similar with and without adjustment for comorbidities. Our data represent a large sample of CABG operations in the United States, not restricted to subjects enrolled in Medicare. Therefore, we believe that our

results provide generalizable population-based estimates of the CABG volume-outcome relationship.

In conclusion, our study revealed a significant decrease in CABG volume since 1997 in the setting of a significant rise in PTCI. Also since 1997, the number of patients undergoing CABG treated at high-volume hospitals and the proportion of high-volume hospitals have decreased significantly. Despite this reduction in patients undergoing CABG at high-volume hospitals, the overall pooled CABG mortality decreased significantly during the study period. Reduced CABG volume in the setting of decreased mortality is a counterintuitive finding given the robust converse relationship between volume and outcome. Therefore, our findings have important implications for our understanding of the volume-outcome relationship and should dampen enthusiasm for regionalization of CABG care based solely on volume.

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Author Contributions: Dr Ricciardi had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Ricciardi, Virnig, and Baxter. *Analysis and interpretation of data:* Ricciardi, Virnig, Ogilvie, Dahlberg, Selker, and Baxter. *Drafting of the manuscript:* Ricciardi, Virnig, Selker, and Baxter. *Critical revision of the manuscript for important intellectual content:* Ricciardi, Virnig, Ogilvie, Dahlberg, Selker, and Baxter. *Statistical analysis:* Ricciardi and Virnig.

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INVITED CRITIQUE

It has been assumed by many, based on previous studies,^{1,2} that there is a linkage between hospital cardiac surgical case volumes and outcomes, whereby improved outcomes are associated with high-volume centers. Regionalization strategies and recommendations, adopted by state certificate of need regulations and health care industry consortia (eg, the Leapfrog Group), are largely predicated on these assumptions in that they espouse concentrating bypass surgery procedural volumes in the interest of improving quality and outcomes. Findings from this article suggest that such traditional volume-outcome tenets may be overly simplistic and inaccurate in assessing current CABG practices. In an analysis of the Society of Thoracic Surgeons' National Cardiac Surgery Database, DiSesa et al³ recently reported that, although certificate of need regulations have been successful in increasing hospital CABG volumes, their effect on procedural mortality or morbidity seems to be negligible. There is growing experiential evidence that hospital-based quality control, monitoring, and best-practice programs may have a more significant effect on outcomes.

It is intriguing that Dr Ricciardi and colleagues found that lower-volume CABG centers have recently experienced reduced mortality rates, fueling the notion that lower-volume community centers with rigorous quality control mechanisms may be better able to provide superior perioperative care than traditional high-volume academic centers. Although difficult to evaluate objectively, high-volume academic centers should not underestimate the negative effect of recently enforced re-

stricted residency hours on the quality of perioperative care readily available to high-acuity postoperative patients.

Coronary artery bypass grafting has been selected as an index operation for this and other outcome analyses presumably because of its high volume, high acuity, and expense. One must be cautious, however, in applying the conclusions of such analyses based on generally routine operations to other less frequently performed, more technically complex, and specialized cardiac operations (eg, complex mitral valve repair, aortic root or arch reconstructions, and Norwood procedures). It would seem that operative outcomes among such operations might better adhere to traditional volume-outcome assumptions.

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