Comparison of Outcomes for Off-Pump Versus On-Pump Coronary Artery Bypass Grafting in Low-Volume and High-Volume Centers and by Low-Volume and High-Volume Surgeons

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In terms of in-hospital outcomes, controversy still remains whether off-pump coronary artery bypass grafting is superior to on-pump coronary artery bypass surgery. We investigated whether the volume of off-pump coronary artery bypass procedures by hospital and individual surgeon influences patient outcomes when compared with on-pump coronary artery bypass surgery. Discharge records from the Nationwide Inpatient Sample were retrospectively reviewed for in-hospital admissions from 2003 to 2011, including 999 hospitals in 44 states. A total of 2,094,094 patients undergoing on- and off-pump coronary artery bypass surgery were included. In patients requiring 2 or more grafts, off-pump coronary artery bypass compared with on-pump coronary artery bypass was associated with increased risk-adjusted mortality when performed in low-volume centers (<29 cases per year) (odds ratio [OR] 1.32, 95% confidence interval [CI] 1.06 to 1.57) or by low-volume surgeons (<19 cases per year) (OR 1.26, 95% CI 1.02 to 1.56). In high-volume off-pump coronary artery bypass centers (≥164 cases per year) and surgeons (≥48 cases per year), off-pump coronary artery bypass reduced mortality compared with on-pump coronary artery bypass in cases requiring a single graft (OR 0.66, 95% CI 0.49 to 0.89 and OR 0.33, 95% CI 0.22 to 0.47, respectively) or 2 or more grafts (OR 0.82, 95% CI 0.66 to 0.99 and OR 0.63, 95% CI 0.49 to 0.81, respectively). In conclusion, the outcome of off-pump coronary artery bypass grafting procedures is dependent on volume at both the institution and the individual surgeon level. Off-pump coronary artery bypass should not be performed at low-volume centers and by low-volume surgeons. **(Am J Cardiol 2018;121:552–557)**

In terms of in-hospital outcomes, controversy still remains whether off-pump coronary artery bypass (OPCAB) grafting is superior to on-pump coronary artery bypass (ONCAB) surgery.[1,2] Although several large clinical trials[3–5] and institutional reports have attempted to compare the safety and efficacy of both approaches,[6,7] reported outcomes remain mixed.[8] Volume-outcome relations within surgical practice results are well known.[9–11] Studies investigating volume at the individual surgeon or hospital level are attractive to physicians and administrators because they allow for an intuitive measure of "expertise" and a proxy of enhanced safety and quality. It has been suggested that programs with greater OPCAB experience may have better results than those that perform these procedures less frequently,[12,13] but sparse and conflicting results are reported.[14–16] A recent report from the Society of Thoracic Surgeons showed that in 2012 84% of US centers performed fewer than 50 OPCAB cases per year.[17] However, the clinical implications of this observation remain unknown with some authors advocating that OPCAB should be abandoned.[8] We investigated whether OPCAB hospital and surgeon volume significantly influenced operative mortality when compared with ONCAB in a large US cohort.

Methods

The Nationwide Inpatient Sample (NIS) represents a 20% stratified random sample of all hospital discharges in the United States, and collection, validation, and maintenance of the datasets are performed by the Agency for Healthcare Research and Quality.[18] The NIS datasets represent the largest publicly available inpatient care databases within the United States. Each year, the NIS captures patient discharges reported from approximately 1,000 American Hospital Association centers. The NIS data use national hospital survey strata to weigh each of the participating hospitals. Weights are provided for each discharge record, allowing nationally representative study populations to be produced. Institutional review board approval and informed consent were not

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required for this study because it uses an unidentified administrative database. The study included discharge records from 999 hospitals and 44 states in the NIS datasets from 2003 to 2011 that specifically reported unique hospital identifiers for the study time period, with selected International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) procedure and diagnostic codes. Discharge records for patients undergoing coronary artery bypass grafting (CABG) procedures were identified using the following ICD-9-CM procedure codes: 30.10, 36.11, 36.12, 36.13, 36.14, 36.15, or 36.16. The concomitant use of cardiopulmonary bypass support was identified by records that also included the following codes: 39.61 or 39.66. Discharge records for patients with concomitant cardiac valve procedures (ICD-9-CM codes 35.20, 35.21, 35.22, 35.23, 35.24, 35.25, 35.26, 35.27, 35.28, 35.11, 35.12, 35.13, 35.14) or other cardiotomy (37.11) for purposes other than cardiopulmonary bypass were excluded. Patient-level and hospital-level variables were included as baseline characteristics. The Agency for Healthcare Research and Quality's co-morbidity measures based on the Elixhauser method were used to identify co-morbid conditions.[19] Hospital-level data elements were derived from the American Heart Association Annual Survey Database.

The primary outcome was operative mortality for the overall cohort of isolated CABG. Secondary outcome measures were length of stay and total costs. Patients were stratified into OPCAB and ONCAB cohorts for descriptive purposes. OPCAB hospital volume was determined by calculating the total number of isolated operations performed for each center during the study period (2003 to 2011). OPCAB hospital volume was categorized into quartiles: low (<25th percentile), medium (25th to 49th percentile), high (50th to 74th percentile), and very high (≥75th percentile). OPCAB and ONCAB were compared in the whole population and across OPCAB hospital volume and surgeon quartile groups. Weighted values of patient-level observations were generated to produce a nationally representative estimate of the entire US population of hospitalized patients. Differences between categorical variables were tested using the Pearson chi-square test (Rao and Scott adjustment), and differences between continuous variables were tested using the Student *t* test. p Value < 0.05 was considered significant. Two separate hierarchical regression models with the unique hospital identification number incorporated as random effects within the model were used[20]: model 1: clustering for centers + patient level variables including age, gender, race, elective admission, and risk related to coexisting medical conditions + hospital-level variables such as hospital region, location teaching status, and bed size; model 2: model 1 + ONCAB hospital volume and year of surgery. The last 2 variables were forced into the model to correct final estimates for the influence of operative volume during ONCAB[9] and to account for potential variation in the quality of care during the study period.[21] Hierarchical mixed effects logistic regression models were used for categorical dependent variables such as primary and secondary outcomes, and hierarchical mixed effects linear regression models were used for continuous dependent variables such as cost of care and length of stay. Subgroup analysis on hospital mortality according to the number of grafts performed (1 vs ≥2 grafts) across hospital and surgeon volume quartiles was performed. The analysis was repeated according to individual surgeon OPCAB volume including cases that specifically reported unique physician identifiers for the study time period. Categorical variables are expressed as a percentage of the group of origins. Continuous variables are reported as mean ± standard error. Odds ratios with a 95% confidence interval are used to report the results of logistic regression models. Reported probability values are 2-tailed and were considered statistically significant if <0.05. Data analyses were performed using R version 3.1.2 and survey package (T. Lumley 2014 "survey: analysis of complex survey samples," R package version 3.30).

Results

The study population consisted of 2,094,094 patients who underwent isolated CABG during the period 2003 to 2011 in 999 US centers. OPCAB and ONCAB procedures were performed in 546,243 (26%) and 1,547,851 (74%) cases, respectively (Figure 1). OPCAB hospital relative volume and hospital rates were extremely heterogeneous across the centers. Median OPCAB and ONCAB hospital volume per year was 82 (interquartile range [IQR]: 29 to 164) and 308 (IQR 145 to 569) procedures, respectively. Patient-level and hospital-level variables distributed between the OPCAB and the ONCAB groups are reported in Table 1. Overall, differences between the 2 groups were not clinically relevant and operated in both directions. The number of procedures involving a single graft only was higher in the OPCAB group. An overview on unadjusted outcomes is summarized in Supplementary Table 1. Table 2 shows risk-adjusted effect of OPCAB versus ONCAB on outcomes investigated across OPCAB hospital volume quartile. In centers performing <29 cases per year, OPCAB was associated with a significantly higher risk-adjusted mortality. On the other hand, in centers performing ≥164 cases per year, OPCAB was associated with a significant 20% relative risk reduction in mortality compared with ONCAB. Similarly, OPCAB was associated with significantly higher length of hospital stay and total costs, when performed in non–high-volume centers (Table 2).

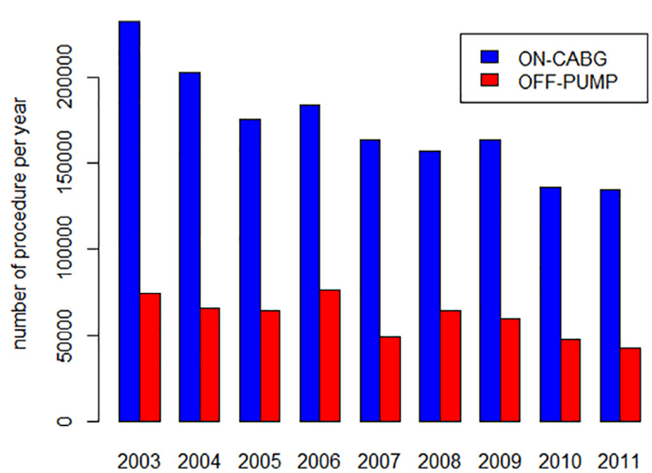

Figure 1. Total number of off-pump coronary artery bypass (OPCAB, red) and on-pump coronary artery bypass (ONCAB, blue) procedures performed during the study period. (Color version available online.)

Table 1
Descriptive statistics for patients undergoing off-pump coronary artery bypass grafting (OPCAB) and on-pump coronary artery bypass grafting (ONCAB)

	OPCAB (n = 546,243)	ONCAB (n = 1,547,851)	p-value
Age (years)	65.4 ± 0.1	65.0 ± 0.1	0.0009
Women	29.5%	26.7%	<0.0001
White	59.2%	61.6%	0.12
Other	40.8%	38.4%	
Elective admission	45.2%	46.5%	0.11
Single graft performed	20.6%	12.9%	<0.0001
Acquired immune deficiency syndrome (AIDS)	0.1%	0.1%	0.0004
Alcohol abuse	2.6%	2.4%	0.18
Chronic blood loss anaemia	1.3%	1.4%	0.26
Chronic lung disease	22.4%	21.6%	0.06
Coagulopathy	8.3%	9.9%	<0.0001
Congestive Heart Failure	1.3%	0.8%	<0.0001
Deficiency anemia	15.8%	15.0%	0.31
Depression	4.8%	4.7%	0.62
Diabetes with chronic complication	5.6%	6.1%	0.03
Drug abuse	1.0%	0.9%	0.04
Fluid and electrolyte disorders	19.8%	18.8%	0.37
Hypertension	69.9%	72.2%	<0.0001
Hypothyroidism	7.3%	7.3%	0.69
Liver disease	1.0%	0.8%	0.0002
Lymphoma	0.3%	0.3%	0.96
Metastatic cancer	0.2%	0.1%	<0.0001
Obesity	13.5%	15.0%	0.01
Other neurological disorders	2.7%	2.6%	0.22
Paralysis	1.1%	1.1%	0.64
Peptic ulcer disease excluding bleeding	0.3%	0.3%	0.92
Peripheral vascular disease	13.7%	12.7%	0.02
Psychosis	1.3%	1.3%	0.45
Pulmonary circulation disorders	0.1%	0.1%	0.21
Renal failure	10.0%	9.1%	0.001
Rheumatoid arthritis/collagen vascular diseases	1.5%	1.5%	0.56
Solid tumour without metastasis	1.1%	1.0%	0.01
Uncomplicated Diabetes	29.3%	32.1%	<0.0001
Valvular disease	0.4%	0.3%	<0.0001
Weight loss	2.1%	1.7%	0.001
Hospital location			
Urban	95.7%	95.7%	0.93
Rural	4.3%	4.3%	
Teaching Hospital	58.3%	57.5%	0.73
Hospital bed size			
Small	8.3%	6.5%	0.007
Medium	23.4%	17.3%	
Large	68.3%	76.2%	
Operative Data			
Single graft	20.6%	12.9%	<0.0001
Previous CABG	1.3%	1.3%	0.85

CABG = coronary artery bypass grafting; ONCAB = on-pump coronary artery bypass grafting; OPCAB = off-pump coronary artery bypass grafting.

The unique physician identifiers were available only from 2003 to 2009 including a total of 1,024,872 cases performed by 6,724 surgeons. OPCAB and ONCAB were performed in 295,045 (29%) and 729,827 (71%) cases, respectively. Median OPCAB and ONCAB surgeon procedural volume per year was 19 (IQR 6 to 48) and 79 (IQR 30 to 153), respectively. Risk-adjusted estimates showed that surgeons performing <48 OPCAB cases per year had a higher risk-adjusted hospital mortality compared with ONCAB. On the other hand, for surgeon performing ≥48 OPCAB cases per year, OPCAB was associated with a significant 42% relative risk reduction in mortality when compared with ONCAB. Similarly, OPCAB was associated with significantly higher length of hospital stay and total costs when performed by non–high-volume surgeons (Table 3). In cases requiring a single graft only, OPCAB compared with ONCAB did not increase mortality in low-volume hospitals and when performed by low-volume surgeons. In high-volume OPCAB hospitals and high-volume surgeons, single graft OPCAB was associated with a lower adjusted-risk mortality when compared with ONCAB (Table 4).

Table 2
Risk-adjusted estimates for on-pump coronary artery bypass grafting (ONCAB) versus off-pump coronary artery bypass grafting (OPCAB) on outcomes according to OPCAB hospital volume (p < 0.05 in bold)

		Overall	OPCAB Hospital Volume 1st quartile (<29/yr)	OPCAB Hospital Volume 2nd quartile (29–81/yr)	OPCAB Hospital Volume 3rd quartile (82–163/yr)	OPCAB Hospital Volume 4th quartile (≥164/yr)
OPCAB(n)		546,243	48,120	107,202	145,026	245,895
ONCAB(n)		1,547,851	488,261	410,176	380,913	268,502
Mortality (%)						
	model 1	1.04 [0.94–1.14]	**1.30 [1.11–1.51]**	1.16 [0.99–1.37]	1.07 [0.93–1.24]	**0.81 [0.65–0.99]**
	model 2	1.02 [0.93–1.12]	**1.29 [1.10–1.50]**	1.11 [0.95–1.30]	1.02 [0.88–1.18]	**0.80 [0.65–0.98]**
Hospital stay (days)						
	model 1	0.19 ± 0.12	**1.09 ± 0.16**	**0.57 ± 0.15**	0.05 ± 0.13	0.05 ± 0.23
	model 2	0.19 ± 0.12	**1.03 ± 0.16**	**0.76 ± 0.15**	0.19 ± 0.12	0.20 ± 0.23
Total costs ($)						
	model 1	2063 ± 3730	**15,905 ± 3824**	**12,848 ± 4651**	**13,390 ± 3313**	2387 ± 6258
	model 2	–944 ± 3659	**11,823 ± 3159**	5630 ± 3501	4025 ± 2556	–4351 ± 4598

ONCAB = on-pump coronary artery bypass grafting; OPCAB = off-pump coronary artery bypass grafting.
Model 1: clustered for ID Hospital + patient level variables including age, gender, race, elective admission, and risk related to coexisting medical conditions + hospital-level variables such as hospital region, location teaching status, and bed size; Model 2: model 1 + ONCAB hospital volume + year of surgery.

Table 3
Risk-adjusted estimates for off-pump coronary artery bypass grafting (OPCAB) versus on-pump coronary artery bypass grafting (ONCAB) on outcomes according to OPCAB surgeon volume (p < 0.05 in bold)

		Overall	OPCAB Surgeon Volume 1st quartile (<6/yr)	OPCAB Surgeon Volume 2nd quartile (6–18/yr)	OPCAB Surgeon Volume 3rd quartile (19–47/yr)	OPCAB Surgeon Volume 4th quartile (≥48 yr)
OPCAB		295,045	31,065	39,037	65,624	159,319
ONCAB		729,827	241,540	206,588	187,573	94,126
Mortality (%)						
	model 1	1.03 [0.90–1.17]	**1.28 [1.08–1.53]**	**1.30 [1.08–1.56]**	**1.28 [1.08–1.51]**	**0.64 [0.51–0.80]**
	model 2	0.99 [0.87–1.12]	**1.23 [1.02–1.48]**	**1.30 [1.08–1.58]**	**1.26 [1.05–1.50]**	**0.58 [0.45–0.71]**
Hospital stay (days)						
	model 1	**0.36 ± 0.18**	**2.12 ± 0.22**	**1.30 ± 0.20**	**0.60 ± 0.22**	–0.16 ± 0.22
	model 2	0.31 ± 0.17	**1.76 ± 0.21**	**1.37 ± 0.20**	**0.73 ± 0.22**	–0.15 ± 0.17
Total costs ($)						
	model 1	5,534 ± 4,597	**28,480 ± 4653**	**18,258 ± 3803**	**13,028 ± 3623**	–9109 ± 5229
	model 2	1438 ± 4463	**20,773 ± 4264**	**13,096 ± 2902**	5,886 ± 3139	**–10,778 ± 4172**

ONCAB = on-pump coronary artery bypass grafting; OPCAB = off-pump coronary artery bypass grafting.
Model 1: clustered for ID Hospital + patient level variables including age, gender, race, elective admission, and risk related to coexisting medical conditions + hospital-level variables such as hospital region, location teaching status, and bed size; Model 2: model 1 + ON-CABG hospital volume + year of surgery.

Discussion

Despite the initial enthusiasm regarding the potential benefit from OPCAB over ONCAB in improving hospital mortality,[6,7] several randomized trials have failed to demonstrate its superiority.[3–5] These trials have been criticized by those who believe that OPCAB increases technical complexity and that hospital volume and surgeon experience plays a major role in determining outcomes.[12,13] In the ROOBY trial,[3] participating surgeons were required to have previously performed 20 OPCAB procedures; a lack of experience could explain the worse composite outcomes at 1 year. In the German off-pump CABG trial in elderly patients study,[4] where surgeons were required to be established experts with an average of 514 OPCAB procedures (median, 322) performed, no significant differences between OPCAB and ONCAB were found. In the more recent CABG off- or on-pump revascularization study trial,[5] surgeons were required to have had performed more than 100 OPCAB and ONCAB operations. Patients undergoing OPCAB required less transfusion, reoperation for bleeding, respiratory complications, and acute kidney injury. None of these trials had sufficient power to accurately assess differences in mortality. In fact, to provide a power of 80% to detect a 30% relative risk reduction in the rate of in-hospital mortality or stroke (~2%), the required total sample size would be 19,506. The CABG off- or on-pump revascularization study, German off-pump CABG trial in elderly patients, and randomized on/off bypass trials randomly assigned 4,752, 2,539, and 2,203 patients, respectively, and therefore, they were largely underpowered to detect differences in mortality or stroke. Expertise in OPCAB by individual surgeon and hospital volume seems to be an important determinant of outcomes.[17,22] However, little has been published on this topic and results have shown conflicting

Table 4
Subgroup analyisis (hospital and surgeon volume) on primary outcome (operative mortality) according to number of grafts performed (1 vs ≥2 grafts) ($p < 0.05$ in bold)

Analysis according to Hospital Volume	Overall	OPCAB Hospital Volume 1st quartile (<29/yr)	OPCAB Hospital Volume 2nd quartile (29–81/yr)	OPCAB Hospital Volume 3rd quartile (82–163/yr)	OPCAB Hospital Volume 4th quartile (≥164/yr)
1 grafts					
OPCAB(n)	112,587	10,861	22,852	31,032	47,843
ONCAB(n)	200,064	61,486	53,882	51,287	33,410
Model 2	**0.82 [0.71–0.96]**	1.06 [0.75–1.49]	0.98 [0.71–1.36]	**0.70 [0.52–0.96]**	**0.66 [0.49–0.89]**
≥2 grafts					
OPCAB(n)	433,655	37,259	84,350	113,994	198,052
ONCAB(n)	1,347,787	426,775	356,294	329,626	235,092
Model 2	1.06 [0.96–1.17]	**1.32 [1.06–1.57]**	1.13 [0.97–1.31]	1.09 [0.93–1.26]	**0.82 [0.66–0.99]**
Analysis according to Surgeon Volume	**Overall**	**OPCAB Surgeon Volume 1st quartile (<6/yr)**	**OPCAB Surgeon Volume 2nd quartile (6–18/yr)**	**OPCAB Surgeon Volume 3rd quartile (19–47/yr)**	**OPCAB Surgeon Volume 4th quartile (≥48 yr)**
1 graft					
OPCAB (n)	60,702	6,566	9,338	14,315	30,483
ONCAB (n)	94,397	33,170	27,183	23,148	10,897
Model 2	0.85 [0.69–1.05]	1.06 [0.69–1.62]	1.31 [0.86–1.99]	**1.64 [1.06–2.53]**	**0.33 [0.22–0.47]**
≥2 grafts					
OPCAB (n)	234,344	24,500	29,700	51,309	128,836
ONCAB (n)	635,429	208,370	179,405	164,425	83,229
Model 2	1.007 [0.88–1.15]	**1.26 [1.03–1.53]**	**1.26 [1.02–1.56]**	1.21 [0.99–1.47]	**0.63 [0.49–0.81]**

ONCAB = on-pump coronary artery bypass grafting; OPCAB = off-pump coronary artery bypass grafting.

Clustered for hospital ID and adjusted for patient level variables including age, gender, race, elective admission, and risk related to coexisting medical conditions and hospital-level variables such as hospital region, location teaching status, and bed size.

outcomes.[12–17] Large registries have the potential to overcome the limitation of underpowered randomized controlled trials by detecting differences in hard clinical end points such as mortality. The present analysis on the US NIS with a very large number of procedures provides important insights into the relative impact of OPCAB hospital and surgeon volume on outcomes. We used quartiles to stratify hospital and volume experience with the 2 procedures. We found that OPCAB, when performed in low-volume centers and by low-volume surgeons, was associated with significantly increased risk-adjusted mortality, length of stay, and overall costs compared with ONCAB. On the contrary, OPCAB was associated with a lower risk adjusted mortality when performed in high-volume hospitals (≥164 cases/year) and by high-volume surgeons (≥48 cases/year). Subgroup analysis suggested that single-graft OPCAB is as safe as ONCAB even in low-volume hospitals and by low-volume surgeons. On the other hand, single graft OPCAB by high-volume hospitals and surgeons was associated with a lower risk-adjusted mortality when compared with single ONCAB graft. It could be argued that patient selection bias, not accounted for by the present risk-adjusted model, might partially explain the increased mortality after OPCAB in case of low-volume performance (only high-risk patients received OPCAB). However, the fact that in low-volume centers, single-graft OPCAB was as safe as ONCAB supports the hypothesis that the increased technical complexity, particularly in case of multiple OPCAB grafts, has the potential to increase mortality and morbidity in a low-volume setting.[3] Nevertheless, this result suggests that "sporadic" OPCAB practice is unlikely to neutralize the excess of mortality compared with ONCAB in selected cases and, therefore, this strategy seems questionable. The reduced risk-adjusted mortality in patients undergoing OPCAB in a high-volume hospital (≥164 cases/year) provides evidence of its potential superiority over ONCAB. Moreover, the comparable sample size of the 2 groups (Table 3) in OPCAB high-volume hospital setting underlies a neutral patient selection process, which strengths our conclusions. The association between surgical case volume and outcome after coronary artery bypass graft surgery has been extensively studied and has led to the development of guidelines by the American Heart Association/American College of Cardiology,[23] specifying the minimum number of procedures performed annually by cardiac surgeons. Based on our findings, future guidelines should include OPCAB high-volume programs as well. Low-volume OPCAB hospitals and surgeons should be discouraged from undertaking multiple graft OPCAB surgery.

This study has some limitations. First and most importantly, the baseline characteristics of the 2 patient groups were very different. We used complex statistical modeling to minimize confounders, but we recognize the limits of matching algorithm in neutralizing unmeasured biases. As previously discussed, the inherent selection bias represented at the surgeon level must be considered, in particular, in low-volume settings. Furthermore, conversion rate from OPCAB to ONCAB is a well-known risk factor for hospital mortality[24] but it is not captured by NIS. However, surgeons with very low case volumes are more likely to convert OPCAB procedures to ONCAB compared with surgeons with high case volumes.[24] Therefore, such an inherent bias is likely to underestimate the detrimental effect of OPCAB over ONCAB in case of low OPCAB volume. We used operative mortality rate as the primary outcome measure. Because of the absence of granularity of the NIS, preoperative variables could not be better defined. Also, we were unable to obtain data on out of hospital deaths (e.g., 30 days), which would have been preferred. It would also have been desirable to include other risk-adjusted adverse outcome measures such as surgical complications. Although conditions like stroke and acute renal failure are reported in the NIS, it is not possible to discriminate if there were present on the admission or if they occurred after surgery and therefore, we decided not to include them in the analysis. Length of stay and total costs are unbiased secondary outcomes anticipated to be associated with rate of postoperative complications. Finally, the potential for unrecognized miscoding of diagnostic and procedure codes must be recognized. Nevertheless, the use of NIS provides great strength in its ability to capture a large patient population and surgeons with a great range of experience.

In conclusion, for multivessel OPCAB procedures, outcomes are clearly dependent on the surgical volume of both the institution and the individual surgeon. Our data suggest that multivessel OPCAB should not be performed by low-volume centers and surgeons.

Disclosures

The authors have no conflicts of interest to disclose.

Supplementary Data

Supplementary data associated with this article can be found, in the online version, https://doi.org/10.1016/j.amjcard.2017.11.035.

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