Journal of the American College of Cardiology Vol. 46, No. 4, 2005

Published by Elsevier Inc.
ISSN 0735-1097/05/$30.00
doi:10.1016/j.jacc.2005.05.048

Interventional Cardiology

Relationship Between Operator Volume and Adverse Outcome in Contemporary Percutaneous Coronary Intervention Practice

An Analysis of a Quality-Controlled Multicenter Percutaneous Coronary Intervention Clinical Database

Mauro Moscucci, MD,* David Share, MD, MPH,* Dean Smith, PhD,† Michael J. O'Donnell, MD,‡ Arthur Riba, MD,§ Richard McNamara, MD,|| Thomas Lalonde, MD,¶ Anthony C. Defranco, MD,# Kirit Patel, MD,** Eva Kline Rogers, RN, MS,* Chris D'Haem, DO,†† Milind Karve, MD,‡‡ Kim A. Eagle, MD*

Ann Arbor, Detroit, Dearborn, Grand Rapids, Flint, Pontiac, and Lansing, Michigan

OBJECTIVES The aim of our study was to evaluate the volume-outcome relationship in a large, quality-controlled, contemporary percutaneous coronary interventions (PCI) database.

BACKGROUND Whether the relationship between physician volume of PCI and outcomes still exists in the era of coronary stents is unclear.

METHODS Data on 18,504 consecutive PCIs performed by 165 operators in calendar year 2002 were prospectively collected in a regional consortium. Operators' volume was divided into quintiles (1 to 33, 34 to 89, 90 to 139, 140 to 206, and 207 to 582 procedures/year). The primary end point was a composite of major adverse cardiovascular events (MACE) including death, coronary artery bypass grafting, stroke or transient ischemic attack, myocardial infarction, and repeat PCI at the same site during the index hospital stay.

RESULTS The unadjusted MACE rate was significantly higher in quintiles one and two of operator volume when compared with quintile five (7.38% and 6.13% vs. 4.15%, $p = 0.002$ and $p = 0.0001$, respectively). A similar trend was observed for in-hospital death. After adjustment for comorbidities, patients treated by low volume operators had a 63% increased odds of MACE (adjusted odds ratio [OR] 1.63, 95% confidence interval [CI] 1.29 to 2.06, $p < 0.0001$ for quintile [Q]1; adjusted OR 1.63, 95% CI 1.34 to 1.90, $p < 0.0001$ for Q2 vs. Q5), but not of in-hospital death. Overall, high volume operators had better outcomes than low volume operators in low-risk and high-risk patients.

CONCLUSIONS Although the relationship between operator volume and in-hospital mortality is no longer significant, the relationship between volume and any adverse outcome is still present. Technological advancements have not yet completely offset the influence of procedural volume on proficiency of PCIs. (J Am Coll Cardiol 2005;46:625–32) © 2005 by the American College of Cardiology Foundation

Prior studies have shown a relationship between physician volume and outcomes of percutaneous coronary intervention (PCI), with better outcomes reported for high volume operators when compared with low volume operators. These data have lead to the wide acceptance of volume standards as a quality indicator for PCI. (1) Many of these studies, however, were performed through analysis of claims data (2,3) or of data collected in a time period preceding the widespread use of coronary stents and glycoprotein IIb/IIIa receptor blockers in clinical practice (4). Thus, whether the relationship between operator volume and outcomes still exists in the era of contemporary PCI is not as well established. The objective of our study was to evaluate the volume-outcome relationship with contemporary PCI with a large, quality-controlled regional clinical database. A secondary objective was to determine whether the American College of Cardiology (ACC) volume guidelines of a minimum of 75 procedures/year still apply to contemporary PCI practice (1).

METHODS

Clinical, procedural, and outcome data on 18,504 consecutive PCIs were prospectively collected in 14 hospitals in Michigan in the calendar year 2002. Data were collected with a standardized data collection form and standardized definitions. The University of Michigan institutional review board and local review boards in each participating center approved this study. After several meetings for identification

From the *Division of Cardiology, University of Michigan Medical Center; ‡St. Joseph Mercy Hospital, Ann Arbor, Michigan; †Blue Cross Blue Shield of Michigan; ¶St. John's Hospital and Medical Center, Detroit, Michigan; §Oakwood Hospital, Dearborn, Michigan; ||Spectrum Health, Grand Rapids, Michigan; #McLaren Regional Medical Center, Flint, Michigan; **St. Joseph Hospital, Pontiac, Michigan; ††Ingham Regional Medical Center, Lansing, Michigan; and the ‡‡Sparrow Medical Center, Lansing, Michigan. Supported by an unrestricted grant from Blue Cross Blue Shield of Michigan (Detroit, Michigan).

Manuscript received September 24, 2004; revised manuscript received May 10, 2005, accepted May 22, 2005.

Abbreviations and Acronyms

ACC	= American College of Cardiology
AHA	= American Heart Association
CABG	= coronary artery bypass grafting
CI	= confidence interval
MACE	= major adverse cardiovascular events
MI	= myocardial infarction
PCI	= percutaneous coronary intervention
Q	= quintile

of data elements to be collected and defined, a dictionary with standard definitions was prepared by the coordinating center and distributed to the participating hospitals. Each hospital agreed to allocate a dedicated staff member to the coordination and quality assurance of data collection. All data forms were processed by the coordinating center and individually evaluated for face validity and completeness. Incomplete forms were recorded by the participating hospitals and resubmitted to the coordinating center. After completion of the initial data quality assurance process, site visits were performed by the coordinating center, and a trained nurse investigator from one of the other participating hospitals performed a site visit to the coordinating center. During the site visits, cardiac catheterization logs were compared with the database logs to ensure enrollment of every patient treated during the time-period in question. The medical records of patients who died in the hospital or who underwent coronary artery bypass surgery were reviewed and compared with the form submitted to ensure accuracy of end points and key comorbidities. In addition, 2% of cases were randomly selected for comprehensive audit with review of the medical record by a trained nurse investigator. The results of the data audits for major outcomes performed during the site visits revealed 0% missing death, 0% missing stroke or transient ischemic attack, 0% missing coronary artery bypass grafting (CABG) during the same hospital stay, 0% missing post-procedure Q-wave myocardial infarctions (MIs), a 0.5% missing rate of clinically significant non–Q-wave MI, and 0.78% missing cases. All missing cases were re-coded and entered in the database.

Coronary artery stenoses were classified with the modified ACC/American Heart Association (AHA) lesion classification. In addition, angiographic characteristics, including the presence of visible thrombus and of moderate or heavy calcification, were collected for each lesion.

Operator volume. A total of 165 operators performing PCI on 18,504 patients during the full calendar year 2002 were included in this analysis. All participating institutions collected operator volume data as part of their own quality assurance program. The volume data collected included procedures performed in the specific institution and in other institutions. In the registry, to ensure operator confidentiality, each operator is assigned a code number by the submitting institution. Therefore, to ensure accuracy in the assigned volume variable—particularly for operators who might have been performing procedures in more than one institution—for each operator, the annual procedure volume in the registry was confirmed against the procedure volume provided by the hospital administration of each institution.

Operators were grouped by quintile (Q) according to the number of procedures performed as follows: the first quintile included operators performing 1 to 33 PCI/year (393 or 2.2% of total procedures), the second quintile included operators performing 34 to 89 PCI/year (2,105 or 11.4% of total procedures), the third quintile included operators performing 90 to 139 PCI/year (3,117 or 16.8% of total procedures), the fourth quintile included operators performing 140 to 206 procedures/year (5,134 or 27.9% of total procedures), and the fifth quintile included operators performing 207 to 582 procedures/year (7,755 or 41.9% of total procedures). The ACC and AHA currently recommend a minimum of 75 PCI/year per operator (1). Therefore, a secondary analysis was performed with the 75 PCI/year as a cutoff to differentiate "low volume operators" from "high volume operators."

Missing data. Baseline demographics (including age and gender), comorbidities, procedure, and outcome data were recorded in every case. Among the other data elements, baseline creatinine and ejection fraction were missing in 8.7% and 19.7% of cases, respectively. Missing values for creatinine were coded as $\leq$1.5 mg/dl, whereas missing values for the ejection fraction were imputed with a linear regression model, including age, left ventricular end diastolic pressure, cardiogenic shock, history of prior CABG, history of prior MI, gender, and history of congestive heart failure (5–7).

Clinical end point. The primary end point was a composite of major adverse cardiovascular events (MACE), including in-hospital death, CABG surgery, stroke or transient ischemic attack, MI, and repeat PCI at the same site during the index hospital stay. The secondary end point was in-hospital death.

Statistical analysis. Data are expressed as mean $\pm$ standard deviation or as percentage. Analysis of variance was used for differences between means, and Pearson chi-square test was used for differences in frequencies. Trends across quintile of procedure volume were evaluated with the Cochran-Armitage trend test for significance.

Independent predictors of in-hospital mortality and MACE were determined by stepwise multivariate logistic regression analysis. Those variables with p value $<$0.2 in univariate analysis were included in stepwise regression procedures for MACE and for in-hospital mortality. The following variables were evaluated in the stepwise regression process: age, gender, hypertension, diabetes mellitus, extracardiac vascular disease (defined as any history of peripheral vascular disease or stroke), congestive heart failure, renal failure requiring dialysis, gastro-intestinal bleeding, chronic obstructive pulmonary disease, atrial fibrillation, history of cardiac arrest, prior history of percutaneous intervention, prior history of coronary artery bypass surgery, creatinine ≥1.5 mg/dl, MI within 7 days, MI within 24 h, cardiac arrest, prior thrombolysis, cardiogenic shock, ventricular tachycardia or fibrillation in the setting of acute MI, emergency angioplasty, rescue angioplasty after failed thrombolysis, unstable angina (requiring intravenous nitroglycerin and heparin treatment), number of diseased vessels (>70% stenosis), left ventricular ejection fraction <50%, ACC type C stenosis, visible thrombus on the initial coronary angiogram, prior history of MI, left main stenosis (>70%), anemia (hemoglobin <10 g/dl), and the presence of moderate or heavy calcification. Model discrimination was assessed with the *c*-statistic, and goodness of fit was assessed with the Hosmer-Lemeshow statistics. Three groups of models were fitted. In the first group, hospitals were considered as fixed effects; in the second group, a random effect was included, assuming normal hospital-effect distributions; and in the third group, generalized estimating equations were fitted to control for clustering and variation by hospital (8). Standardized event ratios (observed/predicted) and 95% confidence intervals were also calculated (9).

A prior study has suggested that low volume of procedures (coronary artery bypass surgery) might be a negative correlate of worse outcomes in high-risk patients, but not in low-risk patients (10); however, a more recent study has shown that the relationship between operator volume and outcomes might be independent of patients' risk (11). To explore this potential relationship further, predicted probabilities of MACE for individual patients were calculated. Patients were stratified in quartiles of predicted risk of MACE, and observed and predicted rates of MACE were then calculated according to the quintile of operator volume. An additional analysis was performed by dividing procedures according to the day of the week (weekend vs. weekday).

Statistical analysis was performed with SAS version 8.2 (SAS Institute, Cary, North Carolina).

Table 1. Clinical and Procedural Characteristics According to Quintile of Operator Volume

	Quintile 1 1–33† (n = 393) 33‡ n (%)	Quintile 2 34–89† (n = 2,105) 34‡ n (%)	Quintile 3 90–139† (n = 3,117) 32‡ n (%)	Quintile 4 140–206† (n = 5,134) 34‡ n (%)	Quintile 5 207–582† (n = 7,755) 32‡ n (%)	p Value*
Demographics						
Age mean (± SD)	63.2 (13.3)	64.1 (12.2)	63.7 (12.3)	63.5 (12.2)	63.8 (12.2)	0.32
Female gender	150 (38.2)	770 (36.6)	1,064 (34.1)	1,774 (34.6)	2,625 (33.9)	0.09
Smoking	108 (27.5)	526 (25.0)	769 (24.7)	1,346 (26.2)	2,038 (26.3)	0.32
Historical						
CHF	49 (12.5)	258 (12.3)	380 (12.2)	479 (9.3)	926 (11.9)	<0.0001
Hypertension	276 (70.2)	1,607 (76.3)	2,277 (73.1)	3,737 (72.8)	5,574 (71.9)	0.001
ECVD	70 (17.8)	420 (20.0)	565 (18.1)	985 (19.2)	1,707 (22.0)	<0.0001
Diabetes	102 (26.0)	640 (30.4)	964 (30.9)	1,608 (31.3)	2,333 (30.1)	0.17
Renal failure on dialysis	9 (2.3)	32 (1.5)	42 (1.4)	48 (0.9)	104 (1.3)	0.05
MI	132 (33.6)	701 (33.3)	1,055 (33.9)	1,692 (33.0)	2,736 (35.3)	0.07
CABG	66 (16.8)	400 (19.0)	567 (18.2)	1,053 (20.5)	1,667 (21.5)	0.0004
PCI	142 (36.1)	724 (34.4)	1,146 (36.7)	2,015 (39.3)	3,112 (40.1)	<0.0001
Clinical presentation at time of PCI						
Ejection fraction mean (± SD)	52.8 (11.6)	52.2 (11.7)	52.7 (12.1)	52.3 (11.3)	52.3 (11.9)	0.37
Creatinine ≥1.5 mg/dl	42 (10.7)	235 (11.2)	338 (10.8)	510 (9.9)	754 (9.7)	0.20
Creatinine ≥2.0 mg/dl	13 (3.3)	71 (3.4)	110 (3.5)	179 (3.5)	250 (3.2)	0.91
MI within 24 h	101 (25.7)	335 (15.9)	572 (18.4)	880 (17.1)	1,244 (16.0)	<0.0001
Rescue PCI	21 (5.3)	61 (2.9)	126 (4.0)	175 (3.4)	255 (3.3)	0.04
Cardiogenic shock	8 (2.0)	56 (2.7)	85 (2.7)	100 (2.0)	173 (2.2)	0.14
Cardiac arrest	23 (5.9)	149 (7.1)	174 (5.6)	270 (5.3)	404 (5.2)	0.02
Procedural characteristics						
Three vessel disease (>70%)	87 (22.1)	428 (20.3)	596 (19.1)	1,021 (19.9)	1,693 (21.8)	0.009
Thrombus	70 (17.8)	456 (21.7)	541 (17.4)	634 (12.4)	1,405 (18.1)	<0.0001
Type C lesion	78 (19.9)	409 (19.4)	587 (18.8)	1,107 (21.6)	1,737 (22.4)	0.0002
Severe calcification	70 (17.8)	580 (27.6)	749 (24.0)	1,156 (22.5)	1,288 (16.6)	<0.0001
MCD exceeded	50 (14.1)	186 (9.6)	300 (10.7)	350 (7.9)	528 (7.7)	<0.0001
Stent	313 (80.5)	1,694 (81.0)	2.541 (82.7)	4,102 (81.3)	6,288 (81.8)	0.44
Glycoprotein IIb/IIIa blockers	309 (78.6)	1,666 (79.1)	2.597 (83.3)	4,048 (78.9)	5,249 (67.9)	<0.0001
Total contrast/case (ml), mean (± SD)	233 (103.2)	214 (90.4)	230 (99.2)	208 (93.3)	207 (103.2)	<0.0001

*p values are from the Pearson chi-square test for categorical variables and from analysis of variance for continuous variables. †Qualifying yearly number of procedures. ‡Number of operators.

CABG = coronary artery bypass grafting; CHF = congestive heart failure; ECVD = extra-cardiac vascular disease; MCD exceeded = exceeding a weight and creatinine adjusted maximum contrast dose calculated using the formula: body weight in kg × 5 cc/serum creatinine (21); MI = myocardial infarction; PCI = percutaneous coronary intervention.

RESULTS

Baseline clinical characteristics are shown in Table 1. Compared with patients treated in the other quintiles, patients treated in the lowest volume quintiles (Q1 and Q2) had similar rates of historical risk factors. Compared with the other quintiles, the first quintile had a higher percentage of patients undergoing PCI within 24 h from an MI. Significant variation was observed in the reported frequency of visible thrombus and severe calcification on the initial angiogram, whereas the frequency of type C lesions was significantly higher in the high volume quintiles (Q4 and Q5). No significant differences were observed in the frequency of coronary stenting, although significant practice variation was observed across the five volume quintiles in the use of glycoprotein receptor blockers, with the lowest use in patients treated by high volume operators (Table 1). Baseline demographic data and procedure variables in the two groups of patients, stratified according to the <75-procedure/year criterion of operator volume, are shown in Table 2.

Clinical outcomes. The unadjusted MACE rate was significantly higher in the group of patients treated by low volume operators (Q1 and Q2) when compared with the group of patients treated by high volume operators (Q5) (7.38% and 6.13% vs. 4.15%, $p = 0.002$ and $p = 0.0001$, respectively) (Table 3). The higher MACE rate in the lowest quintiles was associated with a trend toward higher rates of each individual component of the combined end point, including death in the hospital, MI, stroke, need of coronary artery bypass surgery, and repeat PCI of the same site, and with higher rates of contrast nephropathy and blood transfusion. The higher rate of contrast nephropathy was associated with a higher amount of contrast media/case (Table 1) and with a higher frequency of exceeding a weight and creatinine-adjusted maximum contrast dose (12). After adjustment for comorbidities, patients treated by low volume operators had 63% increased odds of MACE (adjusted OR 1.63, 95% CI 1.29 to 2.06, $p < 0.0001$ for Q1 vs. Q5; adjusted OR 1.63, 95% CI 1.34 to 1.90, $p < 0.0001$ for Q2 vs. Q5) (generalized estimating equation modeling) (Fig. 1). The same results were observed when modeling was performed with fixed effect or random effect modeling. After adjustment for comorbidities and clinical presentation, however, there was no significant relationship between low

Table 2. Clinical and Procedural Characteristics in Patients Treated by Operator Performing ≥75 Procedures/Year and in Patients Treated by Operator Performing <75 Procedures/Year

	<75 Volume (n = 1,440) 54* n (%)	≥75 Volume (n = 17,064) 111* n (%)	p Value
Demographics			
Age mean (± SD)	63.9 (12.5)	63.7 (12.2)	0.73
Female gender	549 (38.1)	5,834 (34.2)	0.003
Smoking	377 (26.2)	4,410 (25.8)	0.78
Historical			
CHF	173 (12.0)	1,919 (11.3)	0.38
Hypertension	1,070 (74.3)	12,401 (72.7)	0.18
ECVD	272 (18.9)	3,475 (20.4)	0.18
Diabetes	416 (28.9)	5,231 (30.7)	0.16
Renal failure on dialysis	22 (1.5)	213 (1.3)	0.36
MI	492 (34.2)	5,824 (34.1)	0.98
CABG	291 (20.2)	3,462 (20.3)	0.94
PCI	507 (35.2)	6,631 (38.9)	0.006
Clinical presentation at time of PCI			
Ejection fraction mean (± SD)	52.2 (11.3)	52.4 (11.8)	0.65
Creatine ≥1.5 mg/dl	145 (10.1)	1,734 (10.2)	0.91
Creatine ≥2.0 mg/dl	49 (3.4)	574 (3.4)	0.94
MI within 24 h	267 (18.5)	2,865 (16.8)	0.09
Rescue PCI	39 (2.7)	599 (3.5)	0.11
Cardiogenic shock	36 (2.5)	386 (2.3)	0.56
Cardiac arrest	112 (7.8)	908 (5.3)	<0.0001
Procedural characteristics			
Three vessel disease	294 (20.4)	3,531 (20.7)	0.80
Thrombus	278 (19.3)	2,828 (16.6)	0.008
Type C lesion	251 (17.4)	3,667 (21.5)	0.0003
Severe calcification	336 (23.3)	3,507 (20.6)	0.01
MCD exceeded	130 (9.8)	1,284 (8.5)	0.10
Stent	1,147 (80.1)	13,791 (81.8)	0.10
Glycoprotein IIb/IIIa blockers	1,073 (74.5)	12,796 (75.0)	0.69
Total contrast/case (ml), mean (± SD)	215 (95.6)	212 (99.1)	0.27

*Number of operators.
All abbreviations as in Table 1

Table 3. Unadjusted Outcomes by Quintile of Operator Volume

Peri-Procedural Outcome	Quintile 1 1–33† (n = 393) n (%)	Quintile 2 34–89† (n = 2,105) n (%)	Quintile 3 90–139† (n = 3,117) n (%)	Quintile 4 140–206† (n = 5,134) n (%)	Quintile 5 207–582† (n = 7,755) n (%)	p Value*
Contrast nephropathy‡	17 (4.33)	94 (4.47)	116 (3.72)	149 (2.90)	256 (3.30)	0.01
Vascular complications	15 (3.82)	57 (2.71)	68 (2.18)	142 (2.77)	190 (2.45)	0.22
Transfusion	34 (8.65)	150 (7.13)	178 (5.71)	272 (5.30)	387 (4.99)	0.0001
Death	8 (2.04)	35 (1.66)	47 (1.51)	57 (1.11)	110 (1.42)	0.23
MI	6 (1.53)	32 (1.52)	45 (1.44)	70 (1.36)	100 (1.29)	0.92
Stroke or TIA	0 (0)	11 (0.52)	14 (0.45)	18 (0.35)	24 (0.31)	0.38
Emergency CABG	3 (0.76)	25 (1.19)	19 (0.61)	15 (0.29)	20 (0.26)	<0.0001
All CABG	10 (2.54)	56 (2.66)	46 (1.48)	60 (1.17)	67 (0.86)	<0.0001
Repeat PCI (same site)	6 (1.53)	13 (0.62)	25 (0.80)	35 (0.68)	59 (0.76)	0.39
MACE§	29 (7.38)	129 (6.13)	155 (4.97)	213 (4.15)	322 (4.15)	<0.0001

*p values are from the Pearson chi-square test. †Qualifying yearly number of procedures. ‡Contrast nephropathy is defined as increase in post-procedure serum creatinine ≥0.5 mg/dl over baseline. §Major adverse cardiovascular events: death, MI, stroke or transient ischemic attack (TIA), CABG, and repeat PCI (same site).
Abbreviations as in Table 1.

operator volume and risk of death in the hospital (adjusted OR for Q1 0.97, 95% CI 0.53 to 1.77, p = 0.92; adjusted OR for Q2 1.09, 95% CI 0.69 to 1.73, p = 0.70).

The results of the analysis of operator volume according to the standards recommended by the ACC/AHA Guidelines (≥75 PCI/year per operator) are shown in Table 4. After adjustment for comorbidities, no significant differences in MACE and mortality were observed in the group of patients treated by operators performing <75 PCI/year when compared with the group of patients treated by operators performing ≥75 PCI/year (adjusted OR for death 0.81, 95% CI 0.47 to 1.41, p = 0.46; adjusted OR for MACE 1.05, 95% CI 0.83 to 1.32, p = 0.67). This lack of difference was due to the inclusion in the high volume group (≥75 procedures/year) of operators classified as "low volume" in the quintile analysis, and to pooling all operators in only two groups; however, when data were analyzed according to the day of the week (weekends vs. weekdays), significant differences emerged. The unadjusted "weekend" MACE rate for operators performing <75 procedures/year was 15.79%, compared with a MACE rate of 8.45% for operators performing ≥75 procedures/year (p = 0.01); weekday mace rates were 3.85% and 4.32%, respectively (p = 0.41).

Relationship between operator volume and patients' risk. Figure 2 shows predicted and observed MACE rates in patients stratified by quartile of risk, with further stratification by quintile of operator volume. Overall, high volume operators had better outcomes than low volume operators in both low-risk and high-risk patients, with the highest difference observed in high-risk patients. In addition, when the analysis was limited to patients undergoing either balloon angioplasty or stenting in native coronary arteries only—thus, with the exclusion of other devices and of PCI in vein grafts—higher MACE rates were still observed in

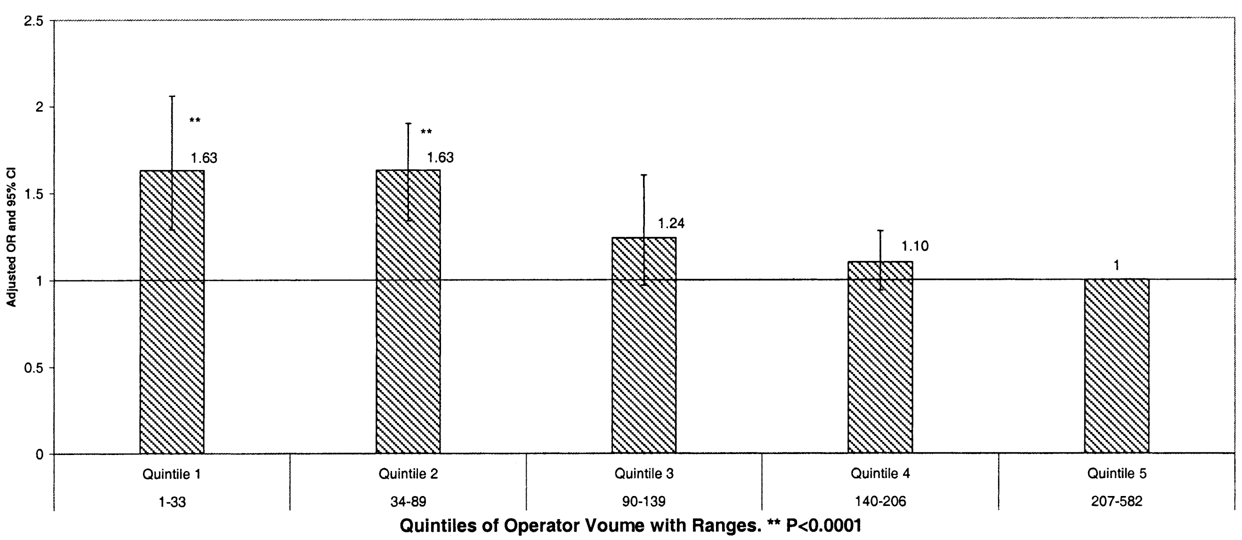

Figure 1. Adjusted odds ratios (OR) for major adverse cardiovascular events with generalized estimating equations clustering modeling. Variables included in the final model were: quintiles one to four, age, gender, history of congestive heart failure, history of prior coronary artery bypass grafting, history of extra-cardiac vascular disease, history of chronic obstructive pulmonary disease, emergency procedure, creatinine ≥1.5 mg/dl, left ventricular ejection fraction <50%, American College of Cardiology type C lesion, left main stenosis (>70%), three-vessel disease (>70%), visible thrombus on the initial coronary angiogram, cardiac arrest, acute myocardial infarction (MI), MI within 7 days, cardiogenic shock, ventricular tachycardia or ventricular fibrillation in the setting of acute MI, and unstable angina. C statistic = 0.82. Hosmer-Lemeshow chi-square = 2.9, p = 0.94. CI = confidence interval.

Table 4. Unadjusted Outcomes by Operator Volume According to the 75 Procedures/Year Definition

	<75 Volume (n = 1,440) n (%)	≥75 Volume (n = 17,064) n (%)	p Value
Contrast nephropathy*	56 (3.89)	576 (3.38)	0.30
Vascular complications	41 (2.85)	431 (2.53)	0.46
Transfusion	94 (6.53)	927 (5.43)	0.08
Death	19 (1.32)	238 (1.39)	0.81
MI	16 (1.11)	237 (1.39)	0.38
Stroke	2 (0.14)	65 (0.38)	0.14
Emergency CABG	12 (0.83)	70 (0.41)	0.02
All CABG	27 (1.88)	212 (1.24)	0.04
Repeat PCI (same site)	10 (0.69)	128 (0.75)	0.81
MACE†	69 (4.79)	779 (4.57)	0.69

*Contrast nephropathy is defined as increase in post-procedure serum creatinine ≥0.5 mg/dl over baseline. †Major adverse cardiovascular events: death, MI, stroke emergency CABG, and repeat PCI (same site).
Abbreviations as in Table 1.

patients treated by low volume operators (6.4% and 6.0% for Q1 and Q2, respectively, vs. 3.9% for Q5, $p < 0.0001$).

Variability among operators. To further determine potential differences in the rates of adverse outcomes, standardized MACE ratios (observed/predicted) for each individual operator were plotted against the individual operator annual volume. As shown in Figure 3, there was a continuous relationship between operator volume and outcomes, with lower standardized ratios observed with high volume operators; however, there was also significant variation, as shown by the presence of some low volume operators with better-than-expected outcomes (standardized ratio <1), and of a small number of high volume operators with worse-than-expected outcomes (standardized ratio >1).

DISCUSSION

In this study, we analyzed the volume-outcome relationship in a large contemporary quality controlled multicenter registry of PCI. We found that, after adjustment for comorbidities and other confounders, low procedure volume continues to be a predictor of worse outcomes (MACE), and this relationship appears to be relatively independent of the patients' risk. In addition, we found that the volume threshold might be higher than the threshold of 75 procedures/year suggested by the ACC/AHA guidelines. We were not able to show a relationship between low operator volume and risk of death.

The relationship between low procedure volume and adverse outcomes has been previously shown for PCI, for coronary artery bypass surgery and more recently, for other surgical cardiovascular and cancer resection procedures (13,14). Although the continued importance of this relationship for coronary artery bypass surgery was recently confirmed with contemporary clinical data (15), for PCI, the majority of the studies available either predate the widespread introduction in interventional practice of coronary stenting and of glycoprotein receptor blockers or was obtained through analysis of Medicare claims data. Recognized limitations related to analysis of Medicare data include the need to extrapolate total number of procedures from the number of Medicare procedures, the often incomplete reporting in Medicare claims of comorbidities that

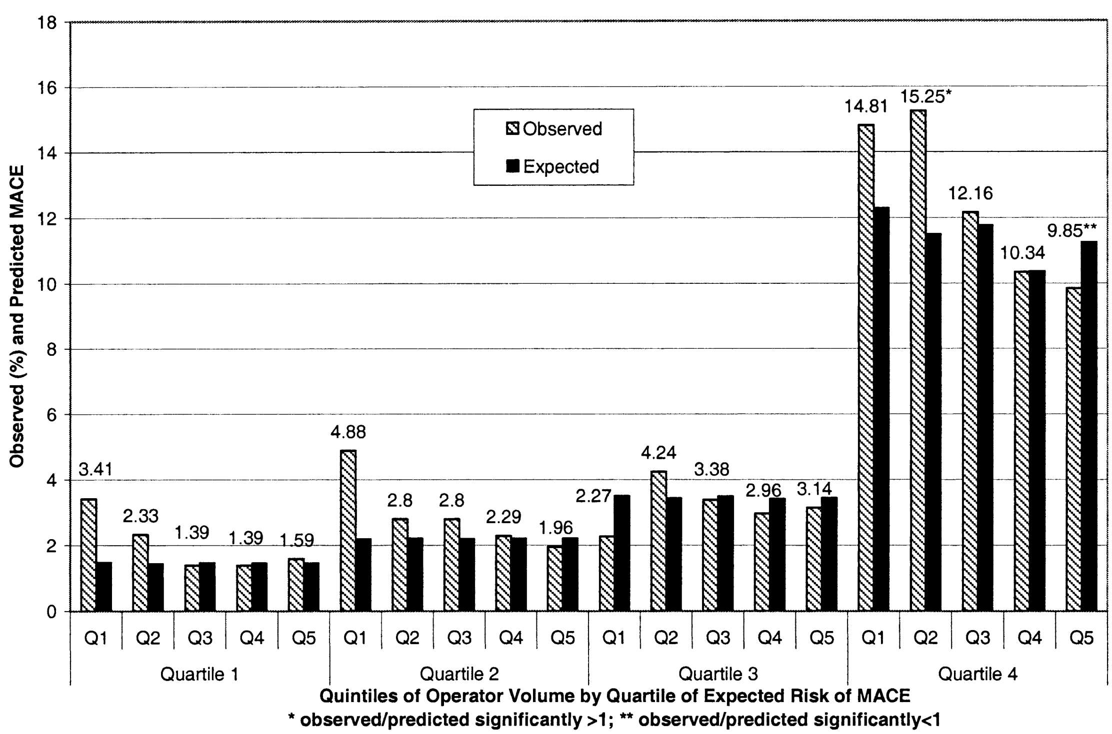

Figure 2. Relationship between operator volume and patients' risk. Predicted and observed major adverse cardiovascular events (MACE) rates are stratified by quartile of risk, with further stratification by quintile of operator volume. Q = quintile (i.e., Q1, Q2, Q3, Q4, and Q5).

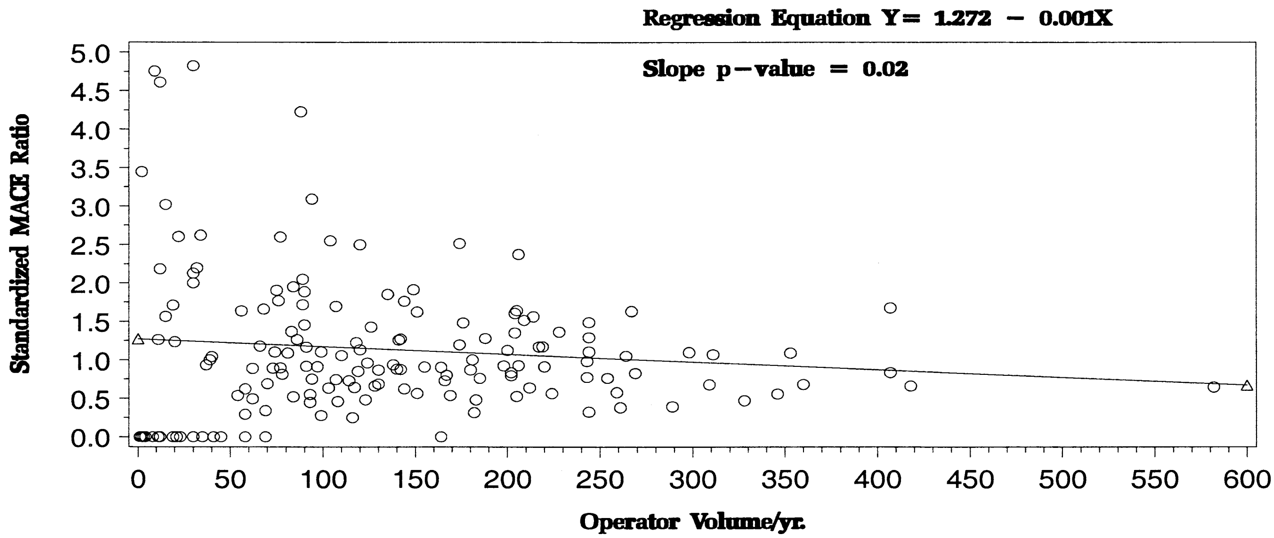

Figure 3. Linear plot of standardized major adverse cardiovascular events (MACE) ratios (observed/predicted rates) versus annual operator volume.

have been shown to be important risk factors for adverse outcomes (14,16), and the potential for miscoding of complications as comorbidities (17).

Ellis et al. (18) analyzed clinical data from a quality-controlled, clinical, multi-institutional database of PCIs. The patient population included patients treated during calendar year 1993 and 1994, a time-period predating the widespread use of coronary stents and of glycoprotein IIb/IIIa receptor blockers. They found that operators performing <70 procedures per year had significantly worse outcomes than the remainder of the group. In addition, the best outcomes were observed in a high volume group of operators performing >270 procedures per year. Similar results were reported by Hannan et al. (19) in an analysis of data from the New York State Department of Health Coronary Angioplasty Reporting System obtained between January 1, 1991, and December 31, 1994 and by Jollis et al. (2,3) in two separate analyses of claim data from the Medicare database. Both analyses also predated the widespread introduction of coronary stents and of glycoprotein IIb/IIIa receptor blockers in interventional practice, and both reports showed better outcomes with high volume operators, including lower mortality rates. More, recently, McGrath et al. (20) analyzed relatively contemporary data (calendar year 1997) from the Medicare database. Given that Medicare patients represent 35% to 45% of total PCI procedure volume, they estimated that 30 PCI per operator per year on Medicare patients could be extrapolated to a total procedure volume of 70 PCI per operator per year. Stent use was 50.6% for operators performing <30 Medicare PCI/year and 61.1% for operator performing >60 Medicare PCI/year. A significant relationship between operator volume and outcomes was also reported in their study, with better outcomes observed in patients treated by high volume operators when compared with patients treated by low volume operators.

Our results are at odds, however, with a report from the Northern New England Cardiovascular study group with data from 1994 through 1996 and using a similar sample size and methodology. In that study, no significant relationship was found between annual operator procedure volume and outcomes (21). Whether this discrepancy indicates that the results of this type of analysis cannot be generalized remains to be determined.

The ACC and AHA currently recommend a minimum of 75 PCI/year per operator. In our analysis, we were not able to confirm a relationship between operator volume and outcomes when this cutoff was used. The analysis of volume, by quintile and by individual operator, suggested that this finding was due to the inclusion in the high volume group (≥75 procedures/year) of operators classified as "low volume" in the quintile analysis and to pooling all operators in only two groups. In addition, significant variability in clinical outcomes was observed in the low volume group.

Our analysis of contemporary practice supports the hypothesis that technological advancements have not yet completely offset the influence of procedural volume in determining proficiency of contemporary PCIs. Whereas the relationship between operator volume and in-hospital mortality is no longer significant, the relationship between volume and any major adverse outcome is still present. In addition, this relationship appears to be relatively independent of patient-specific risk, thus suggesting that it remains to be determined whether it can be further offset by meticulous risk stratification and case selection. Although procedure volume is only a poor surrogate of quality and outcomes, and it should not be used as a replacement for appropriately risk-adjusted outcomes, annual procedure volume is clear and easily understandable information for patients undergoing PCI. Thus, it seems appropriate to continue to include operator procedure volume among the several quality indicators of contemporary PCI practice, with the understanding that, as of today, its value is not as

JACC Vol. 46, No. 4, 2005
August 16, 2005:625–32

important as it was in the pre-stent/pre-glycoprotein receptor blockers era.

Our study has several limitations. All the hospitals participating in the consortium were relatively high volume institutions performing ≥644 procedures/year, and therefore, we could not evaluate the interaction between low volume institutions (<400 procedures/year) and low volume operators. Biomarkers of myocardial necrosis after the procedure were not obtained on a routine basis in all patients, but were rather obtained when it was felt indicated by the physicians in charge of post-procedure care. Further analysis (data not shown) revealed no changes in the results, however, when post-procedure MI was excluded from the combined outcome (MACE) variable. Low volume operators appeared to have a higher case-mix of difficult cases—lesions with higher frequency of visible thrombus or calcification—but a lower frequency of type C lesions. We could not determine whether these differences were due to a different case-mix or to a different interpretation of the coronary angiograms. Although the risk adjustment model accounted for these differences, we cannot exclude that we were unable to adjust fully for these differences.

We were also unable to determine the potential effect of board certification or of number of years in practice, operator-specific characteristics that might offset the influence of volume. In addition, since we only analyzed data from a regional consortium, our results should not necessarily be generalized to other regions of the nation or of the world.

Reprint requests and correspondence: Dr. Mauro Moscucci, University of Michigan Hospital, Division of Cardiology, Taubman Center B1-226, 1500 East Medical Center Drive, Ann Arbor, Michigan 48109-0311. E-mail: moscucci@med.umich.edu.

REFERENCES

1. Smith SC Jr., Dove JT, Jacobs AK, et al. ACC/AHA guidelines of percutaneous coronary interventions (revision of the 1993 PTCA guidelines)—executive summary. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). J Am Coll Cardiol 2001;37:2215–39.
2. Jollis JG, Peterson ED, DeLong ER, et al. The relation between the volume of coronary angioplasty procedures at hospitals treating Medicare beneficiaries and short-term mortality. N Engl J Med 1994;331:1625–9.
3. Jollis JG, Peterson ED, Nelson CL, et al. Relationship between physician and hospital coronary angioplasty volume and outcome in elderly patients. Circulation 1997;95:2485–91.
4. Hannan EL, Arani DT, Johnson LW, Kemp HG Jr., Lukacik G. Percutaneous transluminal coronary angioplasty in New York State. Risk factors and outcomes. JAMA 1992;268:3092–7.
5. Moscucci M, Kline-Rogers E, Share D, et al. Simple bedside additive tool for prediction of in-hospital mortality after percutaneous coronary interventions. Circulation 2001;104:263–8.
6. Little RJA, Rubin DB. Statistical Analysis With Missing Data. New York, NY: John Wiley & Sons, 1987.
7. Rubin DB, Schenker N. Multiple imputation in health-care databases: an overview and some applications. Stat Med 1991;10:585–98.
8. Panageas KS, Schrag D, Riedel E, Bach PB, Begg CB. The effect of clustering of outcomes on the association of procedure volume and surgical outcomes. Ann Intern Med 2003;139:658–65.
9. DeLong ER, Peterson ED, DeLong DM, Muhlbaier LH, Hackett S, Mark DB. Comparing risk-adjustment methods for provider profiling. Stat Med 1997;16:2645–64.
10. Nallamothu BK, Saint S, Ramsey SD, Hofer TP, Vijan S, Eagle KA. The role of hospital volume in coronary artery bypass grafting: is more always better? J Am Coll Cardiol 2001;38:1923–30.
11. Wu C, Hannan EL, Ryan TJ, et al. Is the impact of hospital and surgeon volumes on the in-hospital mortality rate for coronary artery bypass graft surgery limited to patients at high risk? Circulation 2004;110:784–9.
12. Freeman RV, O'Donnell M, Share D, et al. Nephropathy requiring dialysis after percutaneous coronary intervention and the critical role of an adjusted contrast dose. Am J Cardiol 2002;90:1068–73.
13. Birkmeyer JD, Stukel TA, Siewers AE, Goodney PP, Wennberg DE, Lucas FL. Surgeon volume and operative mortality in the United States. N Engl J Med 2003;349:2117–27.
14. Birkmeyer JD, Siewers AE, Finlayson EV, et al. Hospital volume and surgical mortality in the United States. N Engl J Med 2002;346:1128–37.
15. Hannan EL, Wu C, Ryan TJ, et al. Do hospitals and surgeons with higher coronary artery bypass graft surgery volumes still have lower risk-adjusted mortality rates? Circulation 2003;108:795–801.
16. Hannan EL, Kilburn H, Jr., Lindsey ML, Lewis R. Clinical versus administrative data bases for CABG surgery. Does it matter? Med Care 1992;30:892–907.
17. Hannan EL, Racz MJ, Jollis JG, Peterson ED. Using Medicare claims data to assess provider quality for CABG surgery: does it work well enough? Health Serv Res 1997;31:659–78.
18. Ellis SG, Weintraub W, Holmes D, Shaw R, Block PC, King SB III. Relation of operator volume and experience to procedural outcome of percutaneous coronary revascularization at hospitals with high interventional volumes. Circulation 1997;95:2479–84.
19. Hannan EL, Racz M, Ryan TJ, et al. Coronary angioplasty volume-outcome relationships for hospitals and cardiologists. JAMA 1997;277:892–8.
20. McGrath PD, Wennberg DE, Dickens JD Jr., et al. Relation between operator and hospital volume and outcomes following percutaneous coronary interventions in the era of the coronary stent. JAMA 2000;284:3139–44.
21. Malenka DJ, McGrath PD, Wennberg DE, et al. The relationship between operator volume and outcomes after percutaneous coronary interventions in high volume hospitals in 1994–1996: the Northern New England Experience. Northern New England Cardiovascular Disease Study Group. J Am Coll Cardiol 1999;34:1471–80.