Percutaneous coronary intervention (PCI) is the treatment of choice for acute myocardial infarction (MI), as well as a frequently used modality in the treatment of stable, symptomatic coronary artery disease. During the past decade, improvements in primary prevention have led to declines in the prevalence of coronary artery disease and the incidence of acute MI. During this same period, clinical trial evidence, notably from the Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation (COURAGE) trial, continues to support the use of optimal medical therapy without PCI in many patients with coronary artery disease. Together, these trends have led to declines in rates of PCI in selected populations.

Despite these trends, the number of medical facilities capable of performing PCI grew by 21.2% from 2003 to 2011, likely driven by several factors including the desire to improve timely access to PCI for ST-elevation MI, financial and marketing incentives, and the relaxation of requirements for onsite cardiac surgical backup for elective PCI. The decreasing clinical requirements for coronary revascularization and the expanding availability of centers offering PCI are likely to cause average facility and operator procedural volumes to decrease dramatically in the future.

This is of particular relevance, given the adoption of minimal volume standards for competency by several major cardiovascular professional societies. Decreasing average operator volumes may result in an increasing proportion of operators who fall below these minimum standards recommended for competency. The impact that these trends may have on quality of care hinges on the relationship between operator PCI procedure volume and patient outcomes. In this systematic review and meta-analysis, we summarize the current literature examining the relationship between operator-specific PCI volume and patient outcomes and discuss the health policy.
WHAT IS KNOWN

• Percutaneous coronary intervention volumes have decreased, potentially increasing the proportion of interventional cardiologists who do not meet the individual operator volume targets recommended by professional societies.
• Institutional volume is inversely related with mortality, but the relationship between operator volume and outcomes is less clear.

WHAT THE STUDY ADDS

• In this systematic review and meta-analysis, mortality and major adverse cardiovascular events were inversely associated with annual percutaneous coronary intervention operator volume.
• Heterogeneity in the designs of these studies raises questions about study poolability, and the results should be interpreted in context.
• Overall, this study supports that higher annual individual operator percutaneous coronary intervention volumes are associated with better outcomes, but existing study designs preclude evaluation of a specific threshold value.

Implications of our findings in light of continuing declines in the average operator PCI volume.

Methods

Data Sources and Search Strategy
We searched MEDLINE and the Cochrane Library for English-language reports published between January 1977 and November 2012. We searched combinations of keywords and Medical Subject Heading terms in the title or abstract related to volume or experience (volume, number, experience), PCI (angioplasty, percutaneous coronary, balloon coronary, PCI), and patient care outcomes (outcome assessment, treatment outcome, outcome) to find relevant studies. A detailed listing of search terms may be found in Table I in the Data Supplement. Institutional review board approval was waived because of the nature of the study.

Study Selection
We identified studies that (1) examined patients undergoing PCI (with or without stent placement), (2) reported the effects of operator-specific volume on patient mortality or morbidity, and (3) evaluated annualized volumes as opposed to career volumes. Two physicians (J.B.S. and N.J.W.) independently reviewed titles and abstracts of articles identified in the initial search for inclusion eligibility. Articles were excluded on the basis of not meeting inclusion criteria, being duplicates, evaluating career volume, and not reporting original research. The reference lists of these studies were manually reviewed for additional studies potentially eligible for inclusion. Studies that addressed both operator and hospital volume were included in the analysis.

Data Extraction
Each article meeting study eligibility was reviewed independently by 2 physicians and the data abstracted using a standardized form with the following prespecified variables: study design, study period and duration of follow-up, procedure (PCI with stent placement versus angioplasty alone), country and region, data source and population, number of patients, number of PCI-related centers, and operators included in the analysis, range and median/mean of procedural volumes per operator per year, primary and secondary outcomes analyzed, as well as time point of these outcomes, adjustment for confounders (such as demographic characteristics and case mix), adjustment for clustering of outcomes within providers or hospitals, correction for time trends, statistical tests used, P values for trend, and overall study conclusion (presence or absence of a relationship between volume and outcomes among operators). For studies dividing operator volume into multiple percentiles, the number of volume percentiles was recorded. Results were compared and reconciled between the 2 reviewers by consensus.

Data Synthesis and Analysis
Study outcomes were grouped into 3 categories: mortality, major adverse cardiovascular events (MACE), or angiographic success. Studies were then further classified by the degree to which they addressed bias and confounding that can be found in observational research, specifically whether or not the investigators (1) accounted for differences in risk, case mix, and patient demographics by adjustment for variables independently related to the outcome of interest; (2) used statistical techniques to account for clustering of outcomes within providers such as random effects, hierarchical models, or generalized estimating equations; (3) accounted for clustering of outcomes by hospital; and (4) used statistical methods to control for time trends and variation of outcomes between years of study. Studies were subsequently grouped by the degree to which they controlled for these potential biases into the following categories: very high-quality studies incorporated all 4 criteria into their study design, high-quality studies incorporated 3 of 4 criteria, good quality studies incorporated 2 of 4 criteria, fair quality studies only incorporated 1 of 4 criteria, and poor studies incorporated none. Study selection for inclusion, as well as classification of studies by quality criteria, was performed independently by the 2 physician reviewers with differences reconciled by consensus.

When available, risk ratios for event rates comparing dichotomized higher volume and lower volume groups were extracted from the data. If these estimates were not presented, they were estimated based on the crude data presented in the original studies. A meta-analysis was performed using a random-effects model to calculate a summary statistic for each outcome. We assessed for heterogeneity between studies by computing $I^2$ and $t^2$ statistics and assessed for publication bias by constructing an Egger funnel plot. Weight was assigned according to each study’s sample size. Meta-analyses were secondarily performed separately for studies of higher (defined as very high and high) and lower (defined as good, fair, and poor) quality. All $P$ values were 2-tailed with statistical significance set at 0.05 and confidence intervals (CIs) calculated at the 95% level. Analyses were performed using R version 2.15 (University of Auckland, New Zealand).

Results

Search Results
Our literature search identified 419 citations (Figure 1), of which 54 articles were eligible for inclusion and were retrieved for full-text review. The bibliographies of these articles were queried for other references yielding an additional 9 studies. Of these articles, 31 articles were excluded because they were duplicates ($n=2$), editorials ($n=2$), focused on a procedure other than PCI ($n=1$), evaluated the effect of career volumes on outcome ($n=1$), or did not address the specific relationship of operator volume to outcome ($n=26$). Twenty-three articles were included in the analysis on the basis of meeting all inclusion criteria with 100% agreement between reviewers.

Characteristics of Included Studies
Table II in the Data Supplement provides summary characteristics, as well as more detailed information about each included study. Studies enrolled patients undergoing PCI from 1990 until 2005. Six studies (26%) enrolled patients undergoing...
balloon angioplasty alone rather than PCI with stent placement,\textsuperscript{12–17} with each of these starting enrollment before 1996. Six studies (26%) were single-center studies,\textsuperscript{18–23} with the rest ranging from 2 to 1003 centers per study (mean, 102; median, 12). The number of operators included ranged from 3 to 6534 (mean, 691; median, 108), performing from 5 to 593 PCI procedures per year (mean, 195; median, 112). Study duration ranged from 4 months to 7 years (mean, 2.8 years; median, 3 years). Data sources included mainly hospital-based databases in 9 (39%) studies and regional databases in 10 (43%) studies, with 2 studies (9%) drawing from Medicare claims data\textsuperscript{14,28} and 2 (9%) from clinical trial data.\textsuperscript{20,29}

**Study Methods and Quality**

There was considerable variability with which the studies used methods to address potential bias and confounding (Table). No studies were classified as poor quality. Six studies (26%) were classified as fair quality because they met only 1 of 4 criteria,\textsuperscript{13,23–27} with 5 only adjusting for baseline demographics and case mix\textsuperscript{13,24–27} and 1 only adjusting for clustering of outcomes by hospital.\textsuperscript{23} Five studies (22%) were considered very high quality.\textsuperscript{15,17,26–30} Overall, 11 studies (48%) were of higher (high or very high) quality.\textsuperscript{12,14,15,17,20,21,28–33}

**Outcomes of Included Studies**

**Mortality**

Mortality was included as the primary outcome for 13 studies (57%), with 11 (85%) evaluating in-hospital mortality\textsuperscript{12,13,15,16,22,23,25,28,30–32} and the rest evaluating mortality at 30 days\textsuperscript{26,29} (Figure 2). Among the group of studies rated as high or very high quality,\textsuperscript{12,15,28–30,32} most (4 of 6 [67%]) studies showed a significant or strong trend toward reduced mortality with increasing volume compared with 2 of 7 (29%) lower quality studies. Among higher quality studies, effect estimates ranged from a significant reduction in mortality of 57%\textsuperscript{15} for operators performing $\geq 11$ versus 1 to 2 percutaneous coronary transluminal angioplasties per year to a nonsignificant increase in mortality of 2%\textsuperscript{29} for operators performing $\geq 100$ versus $<100$ PCIs per year. The summary estimate showed no overall effect of operator volume on mortality, with an odds ratio of 0.96 (95% CI, 0.86–1.08), with significant heterogeneity ($I^2 = 61.4\%$; $P=0.0019$), and no evidence of publication bias ($P=0.55$). When the analysis was restricted to very high-quality and high-quality studies (figure not shown), the summary estimate demonstrated a nonsignificant reduction in

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**Table**. Quality Rating and Sample Size of Included Studies

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Quality Rating*</th>
<th>No. of Studies, n</th>
<th>Total Sample Size, n†</th>
<th>Studies Concluding Existence of Relationship, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mortality</td>
<td>Very High</td>
<td>4</td>
<td>197 867</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>2</td>
<td>170 383</td>
<td>100</td>
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<td>Good</td>
<td>3</td>
<td>129 857</td>
<td>33</td>
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<tr>
<td></td>
<td>Fair</td>
<td>4</td>
<td>55 594</td>
<td>0</td>
</tr>
<tr>
<td>MACE</td>
<td>Very High</td>
<td>1</td>
<td>452 404</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>3</td>
<td>117 011</td>
<td>100</td>
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<tr>
<td></td>
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<td>3</td>
<td>17 783</td>
<td>67</td>
</tr>
<tr>
<td></td>
<td>Fair</td>
<td>1</td>
<td>6510</td>
<td>0</td>
</tr>
</tbody>
</table>

MACE indicates major adverse cardiac events.

*Studies were categorized by the degree to which they addressed bias and confounding in observational research, specifically whether the investigators (1) accounted for differences in risk, case mix, and patient demographics; (2) used statistical techniques to account for clustering of outcomes within providers; or (3) by hospital and whether they (4) used statistical methods to control for time trends. Quality ratings are as follows: very high=accounting for all 4 aforementioned criteria; high=accounting for 3 criteria; good=accounting for 2 criteria; fair=accounting for 1 criterion. No studies accounted for zero criteria.

†Sample size refers to the number of patients. In studies not reporting number of patients, the number of percutaneous coronary interventions included in the analysis was used.
mortality with an odds ratio of 0.90 (95% CI, 0.79–1.01) for higher versus lower volume operators and significant heterogeneity among studies (F = 60.9%; P = 0.0256).

The definitions of lowest and highest volume operators were, however, variable. Studies differed in the number of volume percentiles used, from 1^19^ to 5^21^, and in the number of PCIs per operator per year in the lowest percentile, with <75 PCIs per operator per year being most common^12^, but ranging from <10^15^, 10^15^, to >155^26^ and from ≥11^16^ to >195^26^ in the highest quintile. Two studies^15^, 12 described a threshold volume below which mortality worsened, one suggesting a threshold of 10 PCIs per year and the other suggesting a threshold of 75 PCIs per year, although the latter was no longer statistically significant when adjusting for hospital volume.2^12^  

Major Adverse Cardiac Events

Eight studies (35%) reported MACE as the primary outcome^14^, 17–19, 21, 27, 33, 34 (Figure 3). MACE was variably defined from a composite outcome of death, MI, or emergency coronary artery bypass grafting surgery^14^ to a composite of death or emergency coronary artery bypass grafting^14^, 17 or major complications (MI, cardiac tamponade, coronary perforation, emergency bypass surgery, death, or blood transfusion^27^); a composite of death, MI, cardiogenic shock, ventricular tachycardia or fibrillation, or thromboembolism^19^; or a composite of death, MI, or symptom-driven revascularization. Four studies (50%) reported in-hospital outcomes,^14^ 27 with the rest reporting outcomes at 30 days^14^, 21 1 year,^17^ 2 or 3 years.^19^  

Figure 2. Results of studies evaluating the relationship between annual percutaneous coronary intervention (PCI) operator volume and mortality. *Studies were categorized by the degree to which they addressed bias and confounding in observational research, specifically whether the investigators (1) accounted for differences in risk, case mix, and patient demographics; (2) used statistical techniques to account for clustering of outcomes within providers; or (3) by hospital and whether they (4) used statistical methods to control for time trends. Quality ratings are as follows: very high = accounting for all 4 aforementioned criteria; high = accounting for 3 criteria; good = accounting for 2 criteria; fair = accounting for 1 criterion. No studies accounted for zero criteria. ACC indicates American College of Cardiology Registry; CI, confidence interval; OR, odds ratio; PCI/yr, number of PCIs per operator per year; and PTCA/yr, number of PTCA per operator per year.

Figure 3. Results of studies evaluating the relationship between annual percutaneous coronary intervention (PCI) operator volume and major adverse cardiac events. *Studies were categorized by the degree to which they addressed bias and confounding in observational research, specifically whether the investigators (1) accounted for differences in risk, case mix, and patient demographics; (2) used statistical techniques to account for clustering of outcomes within providers; or (3) by hospital and whether they (4) used statistical methods to control for time trends. Quality ratings are as follows: very high = accounting for all 4 aforementioned criteria; high = accounting for 3 criteria; good = accounting for 2 criteria; fair = accounting for 1 criterion. No studies accounted for zero criteria. ACC indicates American College of Cardiology Registry; CI, confidence interval; OR, odds ratio; PCI/yr, number of PCIs per operator per year; and PTCA/yr, number of PTCA per operator per year; and RR, relative risk.
Overall, 5 studies (63%) reported a significant association between lower operator volume and increased risk of MACE. Among the 4 higher quality studies,14,17,21,33 3 reported significant reductions in MACE with increasing operator volume, and the fourth showed a strong trend, with risk reductions ranging from 0.42 to 0.78 for higher volume compared with lower volume groups, with a mean reduction in MACE of 39% when comparing highest with lowest volume cohorts. The summary estimate demonstrated a significant reduction in MACE comparing high- with low-volume operators with an odds ratio of 0.62 (95% CI, 0.4–0.97), as well as significant heterogeneity (I²=96.6%; P<0.0001) and no publication bias (P=0.88). Restricting the analysis to very high-quality and high-quality studies (figure not shown) did not markedly change the size of the effect with an odds ratio of 0.67 (95% CI, 0.53–0.85), although with improved and nonsignificant heterogeneity (I²=46.9%; P=0.1297). These studies defined lower and higher volume operators variably, with low-volume cutoffs ranging from <25 to 100 PCI/ys and high-volume cutoffs ranging from >50 to >720 PCI/ys per year. Of studies initiated before the year 2000, 5 of 6 (83%) demonstrated a relationship14,21 compared with 1 of 2 (50%) after 2000.33

Discussion

In a comprehensive systematic review and meta-analysis of the association between operator procedure volume and outcomes in PCI, we found that in the majority of high-quality studies, there was an inverse relationship between yearly operator volume and clinical outcomes, particularly MACE. However, there was significant heterogeneity in the quality and designs of studies included, which preclude the ability to definitively evaluate the magnitude of this effect or the existence of a threshold above which volume differences are no longer meaningful.

Current PCI guidelines dictate a class I indication for PCI operators to perform >50 elective PCIs annually averaged over to years (and >11 primary PCIs) at an institution volume of >200 elective PCIs annually (and >36 primary PCIs).11 For individuals with an annual case volume <50 PCI/ys, current guidelines recommend that facilities establish internal review strategies to assess these individuals.11 Our findings support the recommendations for operators to achieve a higher annual PCI volume, but do not clearly endorse the value 50 as the appropriate threshold. Although the annual recommended case volume was decreased to >50 PCI/ys from the prior threshold of >75 PCI/ys to accommodate the growing number of PCI operators performing <50 PCI/ys per year, our findings support recommendations to achieve a higher annual PCI volume through means such as increasing PCI regionalization and PCI center consolidation.

However, when restricting the meta-analysis to very high-quality and high-quality studies, a significant reduction in MACE was observed with high- versus low-volume operators of 33%. In addition, higher quality studies also suggested a trend for reduction in mortality for high- versus low-volume operators of borderline significance. Although our review of the literature suggests the existence of a relationship between operator volume and clinical outcomes among studies using more rigorous observational study design, most studies13,16,18,19,22–27,31,34 did not effectively deal with methodological problems that are inherent in observational research. Certain studies failed to adjust for degree of baseline risk and known confounding variables,23 others failed to address clustering of outcomes by operator13,14,16,18–27,31,33 or hospital,13,16,24-27 and still others failed to adjust for time trends.12,13,18,19,22–27,31,32,34 Future studies accounting for these factors and specifically designed to assess volume thresholds could be a useful addition to the existing literature.

Furthermore, significant variation in study design limited any conclusions that could be made about the existence of a threshold value at which risk decreases more substantially. In general, studies most often created categories of volume and used either the lowest or highest volume range as the reference range for comparison versus analyzing volume as a continuous variable. This variation in design limits conclusions about a threshold value above which outcomes change. However, among high-quality studies, there seemed to be a strong trend toward increased MACE among lower volume operators at cutoffs as high as 50 PCI/ys per year and for increased mortality at a cutoff of 11 PCI/ys per year. In future studies, analysis of volume as a continuous variable may permit determination of a threshold effect, should one exist.

Although overall our review suggests a relationship between operator volume and outcomes in PCI, particularly with regard to MACE, temporal trends in PCI performance and technological advances may influence the degree to which operator volume influences outcomes. As noted previously, 3 of 4 (75%) studies evaluating balloon angioplasty alone showed a relationship compared with 2 of 7 (29%) PCI studies, suggesting that operator volumes may have had a larger effect on outcomes in the early stages of development of modern PCI and that refinement in technology, physician training, and standardization and improvement in catheterization laboratory procedures has led to improvement in outcomes across volume ranges. Furthermore, improvements in medical therapy before, during, and after PCI may further confound this relationship.

Our study has several important limitations. Our review included only English-language studies and did not include information from nonindexed journals, conferences, or unpublished abstracts. Furthermore, variability in which studies are indexed under particular search terms may have prevented the inclusion of some eligible studies. Definitive study in this area is difficult for several reasons. First, defining the optimal research question is challenging because there are several reasonable and related questions for consideration. Examples include the following: what is the role of lifetime procedural volume beyond procedural volume in the year under study? What is the modifying relationship between hospital volume and individual clinician volume? Is there a different volume–outcome relationship for primary PCI than for procedures performed on more stable patients? What is the role of operator volume in academic medical centers where trainees are participating in the performance of procedures? Finally, although we chose to conduct a quantitative meta-analysis to synthesize the data, heterogeneity in the designs of these studies raises questions about study poolability. The results should be interpreted in this context.
The existence of a relationship between operator volume and patient outcomes has important implications for patients, as well as structuring of training programs, maintenance of PCI competency, and regionalization of PCI care. In the current economic climate, the growth of PCI centers has outpaced both population growth and rates of coronary artery disease, which in turn have declined.2,3 With new data supporting the safety of carefully selected, nonemergent PCI in centers without on-site surgical backup and continued economic incentives for growth,35 it is likely that the number of PCI centers will continue to increase. As a result, PCI operators may perform fewer procedures, and many may fall below the threshold levels for competency as set by professional societies.

Trainees at lower volume centers may have insufficient volumes to develop competency in PCI, suggesting the need for low-volume training programs to partner in order for their trainees to develop sufficient volume credentials. The existence of a relationship between operator volume and outcomes in PCI suggests that the addition of more PCI-capable cardiac catheterization laboratories may not lead to improved clinical outcomes. PCI suggests that the addition of more PCI-capable cardiac catheterization laboratories may not lead to improved clinical outcomes, which in turn have declined.2,3 With new data supporting the safety of carefully selected, nonemergent PCI in centers without on-site surgical backup and continued economic incentives for growth,35 it is likely that the number of PCI centers will continue to increase. As a result, PCI operators may perform fewer procedures, and many may fall below the threshold levels for competency as set by professional societies.

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Jordan B. Strom, Neil J. Wimmer, Jason H. Wasfy, Kevin Kennedy and Robert W. Yeh

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