

EDITORIAL COMMENT

# The Volume–Outcome Relationship Revisited

## Does It Matter for High-Risk PCI?\*



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*How many have you done?*

—Anna Reisman, MD (1)

Considerable published research exists examining the relationship between surgical case volume and outcomes. For example, surgeon case volume was inversely related to operative mortality for 8 procedures examined by Birkmeyer et al. (2) and was most striking for complex surgical procedures such as pancreatic resection and esophagectomy. The relationship between operator volume and clinical outcomes has also been extensively studied for percutaneous coronary intervention (PCI). The 2013 American College of Cardiology Foundation, American Heart Association, and Society for Cardiovascular Angiography and Interventions clinical competence statement for coronary artery interventional procedures provides a thorough discussion of the relationship between PCI volume and outcomes, concluding that an institutional volume threshold of <200 PCIs annually appears to be consistently associated with worse outcomes, but there is less evidence to support a threshold for individual operator volume for both elective and primary PCI (3). The 2011 clinical practice guideline for PCI, published by the same organizations, also discusses the volume–outcome relationship (4). Evidence supporting the existence of a volume–outcomes relationship for PCI can be criticized, as much of it is derived from administrative rather

than clinical sources, and a substantial number of the large studies use data from the pre-stent era. Thanks to the advances in PCI technology and stents, intracoronary imaging to improve our understanding of coronary artery disease, and adjunctive antiplatelet and antithrombotic therapies to minimize the occurrence of stent thrombosis, PCI now has a low periprocedural mortality risk. These advances allow operators to safely perform more technically challenging cases but, at the same time, make the assessment of volume–outcome relationships more difficult.

The National Cardiovascular Data Registry (NCDR) CathPCI registry collects clinical data from >90% of all PCIs performed in the United States. Excluding patients with ST-segment elevation myocardial infarctions, aggregate data from 2015 show an in-hospital mortality rate of 0.89%, while elective PCI mortality is 0.65% (5,6). The small number of deaths for a given operator, coupled with estimates of the case volume for operators in the United States (mean 59 cases annually, with 61% of operators performing <40 cases annually in 2008), results in a very wide confidence interval around the point estimate of PCI mortality for an operator (7). In addition, the interplay between facility and individual operator volumes, the operator's lifetime experience, and the operator's performance of non-PCI procedures (structural and peripheral arterial interventions) confound the assessment of a relationship between operator PCI case volume and outcomes (3). On the basis of these considerations, there are 2 possible approaches for a continuing examination of the relationship between operator volume and outcomes. One approach would require the collection of operator mortality data over many years to obtain a sample size that would allow meaningful differentiation among operators. For an individual operator, this would likely include mostly low-complexity, low-risk cases mixed with a few high-complexity, high-risk

\*Editorials published in *JACC: Cardiovascular Interventions* reflect the views of the authors and do not necessarily represent the views of *JACC: Cardiovascular Interventions* or the American College of Cardiology.

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cases. Given the low and decreasing case volume for U.S. operators, the time required to obtain an adequate number of cases is impractical. The alternative approach is to focus on high-complexity, high-risk cases, for which the number of cases needed to discriminate among operators should be lower and obtainable. This latter approach was examined by Xu et al. (8) in a report in this issue of *JACC: Cardiovascular Interventions*.

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Xu et al. (8) examined the impact of operator experience and volume on the outcomes of unprotected left main coronary artery (ULMCA) PCI. They defined an experienced, high-volume operator as one performing >15 ULMCA PCIs each year for at least 3 consecutive years. Outcomes among these operators were compared with those of less experienced operators, who performed a mean of  $4 \pm 3$  ULMCA PCIs each year. The high-volume operators' patients had more extensive coronary artery disease, more complex lesions as assessed by higher SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) scores and more often had complex lesions, including distal left main bifurcation stenoses. Despite these adverse characteristics, mortality within 30 days was 0.6% for high-volume operators compared with 2.1% for low-volume operators ( $p = 0.008$ ). Being treated by a high-volume operator was associated with a lower adjusted risk for cardiac death (adjusted hazard ratio: 0.22; 95% confidence interval: 0.09 to 0.59;  $p = 0.003$ ) and a strong trend toward a decreased risk for stent thrombosis (adjusted hazard ratio: 0.34; 95% CI: 0.11 to 1.06;  $p = 0.06$ ). After 3 years of follow-up, patients treated by high-volume operators had a lower risk for cardiac death (2.5% vs. 4.6%,  $p = 0.02$ ) but no significant differences in rates of myocardial infarction, stent thrombosis, or target vessel revascularization. One particular strength of the study is that it was performed at a single institution, so the confounding effect of volume differences among facilities should not exist.

There is a growing body of research on the results of ULMCA PCI and comparative studies against coronary artery bypass surgery, but none of these contemporary studies examine the volume–outcome relationship (9,10). Moreover, as has been shown for many observations, the research environment

may not reflect results obtained in real-world clinical practice. The CathPCI registry of the NCDR is the largest collection of clinical data available, and it is interesting to speculate whether a similar analysis of ULMCA PCI could be performed using NCDR data. For a 12-month period (April 2015 to March 2016), 8,420 ULMCA PCI procedures were performed by approximately 3,158 interventionalists in the United States (James Beachy, personal communication, August 18, 2016). This number is likely a modest underestimation of the actual total number of ULMCA PCIs performed, as NCDR patient records with inadequate or low-quality data and patient records without identifiable physician operator (National Provider Identifier number) are excluded. The mean number of ULMCA PCIs per operator was 2 per year within the NCDR data. Using the same criteria for low- and high-volume operators as Xu et al. (8), 86% of the NCDR operators performed 4 or fewer ULMCA PCIs annually, and only 1% of NCDR operators performed  $\geq 15$  ULMCA PCIs per year. The high-volume NCDR operators performed 709 of the 8,420 annual ULMCA PCI procedures in the United States (8.4%) (James Beachy, personal communication, August 18, 2016). These numbers are a stark contrast compared with the experience reported by Xu et al. (8) and perhaps should be a wake-up call to the interventional community. The concept of a “center of excellence” has been widely promoted and frankly overused to the point that it now has little meaning. If the interventional community follows the lead of Xu et al. (8), a “center of excellence” for ULMCA PCI should be one with experienced, high-volume operators that can show good outcomes. The NCDR data demonstrate some evidence of a modest pattern of selective referral to high-volume operators, but clearly the vast majority of these procedures are performed by low-volume operators. In a recent opinion piece, Dr. Anna Reisman described her experience as a patient; the piece was titled “How Many Have You Done?” (1). Perhaps that is a question we should be asking ourselves before every ULMCA PCI procedure.

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- KEY WORDS** outcome, PCI, quality, unprotected left main PCI, volume