An inverse relationship between the annual number of patients treated by a hospital or physician and rates of mortality and complications has been repeatedly documented. These volume-outcome relationships have been explored in particular detail in cardiovascular medicine, including for procedures such as coronary artery bypass graft surgery and coronary angioplasty and conditions such as acute myocardial infarction. There is considerable controversy regarding how these data should be interpreted and, in particular, whether policies should be based on hospital or physician volume. In the present issue of Circulation, Vakili and associates present data on the effect of operator volume on the outcome of primary angioplasty for acute myocardial infarction. To place this study in context, we will first review the data on volume-outcome relationships, then assess why these relationships exist, and finally discuss what policies might be based on these findings.

The Evidence for Volume-Outcome Relationships in Coronary Angioplasty

The relationship of coronary angioplasty volumes to outcome has been examined in many studies. Jollis and coworkers analyzed claims data from 1987 through 1990 for 217 836 Medicare beneficiaries and found an inverse relationship between mortality and the annual number of angioplasty procedures performed in a hospital. They found the volume-outcome relationship was J-shaped, ie, had a stronger inverse relationship at low angioplasty volumes than at high volumes. This study highlights several methodological issues common to all studies of volume and outcome. First, very large sample sizes are needed to provide sufficient statistical power to document a relationship between mortality and procedure volume. Second, unless a wide range of procedure volumes is examined, a real relationship between volume and outcome may be missed.

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The inverse relationship between hospital volume of coronary angioplasty and short-term adverse outcomes (mortality, need for emergency coronary bypass surgery) reported by Jollis and coworkers has been repeatedly confirmed. Kimmel and associates documented an inverse relationship between volume and outcome among 19 594 patients from the Society for Cardiac Angiography and Interventions database who were treated in 1992 and 1993. Hannan et al found a similar relationship for the 62 670 patients undergoing angioplasty in New York State between 1991 and 1994. The inverse relationship between procedural volume and outcomes has persisted, even after the introduction of coronary stents. McGrath and colleagues studied the outcomes of coronary angioplasty among 167 208 Medicare beneficiaries in 1997, and they showed that hospitals with higher procedural volumes had lower mortality rates.

An inverse relationship between volume and outcome has also been found for individual angioplasty operators. The New York State database showed a significant inverse relationship between volume and outcome for both hospitals and operators. Ellis and associates studied 5 high-volume hospitals and found that operator volume had an inverse effect on outcomes in 12 985 patients treated from 1993 to 1994. Jollis and associates found a similar relationship among 94 478 Medicare patients in 1992. The availability of coronary stents may have affected the relationship of operator volume and procedural outcome, as shown in the experience of the Northern New England group. An inverse relationship between operator volume and procedural outcome was found among 12 988 procedures in 5 high-volume hospitals in 1990 to 1993, but this relationship was not evident in 15 080 procedures in these same hospitals in 1994 to 1996.

Most of the studies just discussed analyzed elective angioplasty procedures. Because recent randomized trials have confirmed the value of primary angioplasty for acute myocardial infarction, it is reasonable to ask whether procedure volume also affects outcome in this setting. Canto and associates examined the primary angioplasty experience of 36 535 patients treated in 450 hospitals participating in the Second National Registry of Myocardial Infarction. They found hospitals with the highest volumes of primary angioplasty recorded significantly lower mortality rates than did the hospitals performing fewer procedures. Interestingly, the relationship between volume of patients treated and clinical outcome was not observed for thrombolysis. Indeed, only at higher volume hospitals did patients undergoing primary angioplasty have lower mortality rates than patients undergoing thrombolyis for acute myocardial infarction.
Vakili and associates\textsuperscript{1} examine the effect of operator volume on the outcome of primary angioplasty. They found among 1342 primary angioplasty procedures in New York State that higher primary angioplasty volumes led to lower mortality for both hospitals and operators.

\textbf{Why Is Volume Related to Outcome?}

We think the evidence for an inverse relationship between the annual volume of angioplasty procedures performed and subsequent clinical outcomes is substantial and compelling. The question is not whether this relationship exists, but why. Three possible explanations include the following: (1) better angioplasty outcomes lead to higher volume, (2) higher volume leads to better outcomes, and (3) there is no causal relationship between volume and outcome, and their correlation is due to other associated factors.

For elective procedures, it is possible that higher volume could be associated with better outcomes because physicians refer more patients to the best angioplasty operators, who in turn have the best outcomes. This explanation of the volume-outcome relationship is implausible in the case of primary angioplasty, however, because it is an emergency procedure with little opportunity for selective referral.

Another possibility is that higher volumes cause better outcomes (“practice makes perfect”). It is plausible that in a complex procedure such as primary angioplasty that regular experience is necessary to keep up skills and that those with low volumes of cases have poorer outcomes because they have lost a necessary edge. If this hypothesis is correct, however, it should apply to the entire team of professionals necessary to provide primary angioplasty, not just the angioplasty operator. Indeed, it seems that hospital volume is a stronger predictor of outcome than operator volume in most studies. The relative importance of various measures of volume (institutional or individual, elective or emergency cases) have not been established.

An alternative explanation is that higher volume is only a marker for the “real” cause of better outcomes in angioplasty. Higher volume hospitals and operators may simply have better processes of care, such as well-designed care plans, streamlined procedures to provide care expeditiously, and higher use of evidence-based treatments that improve outcomes. There is evidence to support this hypothesis. Hospitals that treat higher volumes of patients with acute myocardial infarction were more likely to use proven therapies such as aspirin and \(\beta\)-blockers.\textsuperscript{11} Hospitals that perform a higher volume of primary angioplasty procedures were more likely to use aspirin, \(\beta\)-blockers, and heparin in the first 24 hours.\textsuperscript{9} These hospitals were also more efficient, performing the first ECG faster and the angioplasty procedure sooner after patient arrival.\textsuperscript{5} Because time to treatment is so important in acute myocardial infarction, these efficiencies could lead directly to better outcomes of care.

\textbf{Implications}

Currently available studies have not established the mechanism that underlies the inverse relationship between angioplasty volume and outcome. If higher volume actually causes better outcomes, it would suggest very different policies than if volume was just a marker for other causal factors. This issue is further complicated by the importance of minimizing treatment delays in patients with acute myocardial infarction. There is clearly a tradeoff if time to treatment is increased by referring patients to high-volume centers or operators. The critical issue is whether a patient would have better outcomes with immediate thrombolysis, immediate primary angioplasty by a low-volume operator, or delayed primary angioplasty by a high-volume operator. The uncertainty about clinical outcomes in these alternative scenarios makes it more difficult to recommend policies based on procedure volume.

No further research is needed to recommend that centers providing primary angioplasty for acute myocardial infarction should adhere to proven best practices. Furthermore, the centers should assure high quality care by measuring, reviewing, and acting on data about their processes and outcomes.\textsuperscript{12} Recent guidelines\textsuperscript{13} suggest that centers that perform primary angioplasty should monitor key process measures, including time from presentation to balloon inflation, final TIMI flow achieved, the rate of emergency bypass surgery, the rate of primary angioplasty in patients for whom it is initiated, and the ultimate outcome measure, hospital mortality. Hospitals and operators that provide primary angioplasty should measure their performance and regularly compare it against established benchmarks by participating in national registries.\textsuperscript{9,14} In addition, participation in regional quality improvement efforts, such as those established in Northern New England\textsuperscript{15} and Michigan (M. Moscucci, MD, personal communication, 2001), could further improve outcomes. To allow fair comparisons and provide data to judge the effectiveness of primary angioplasty as one component of management, the data should include all patients presenting with acute myocardial infarction, not just those receiving angioplasty.

Whether volume standards should be applied to hospitals or operators performing primary angioplasty is a difficult and controversial issue. We do believe that experience matters in the case of these critically ill patients, and the recent suggestions of expert panels are sensible guidelines.\textsuperscript{16} Primary angioplasty is, however, only one component of the immediate management of acute myocardial infarction, and the goal should be to optimize overall care and outcomes for this condition. Reperfusion therapy should be provided rapidly, and primary angioplasty should be used only when it can be provided without delay. Volume of procedures should be measured and reviewed, but this is only one component of a complete set of performance measures for acute myocardial infarction.

\textbf{References}


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