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EDITORIAL COMMENT

Better for Whom? Policy Implications of Acting on the Relation Between Volume and Outcome in Coronary Artery Bypass Grafting*

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In this issue of the *Journal,* Nallamothu et al. (1) provide an important addition to the extensive literature on the relation between volume and outcome in coronary artery bypass grafting (CABG). They use clinical and administrative data from 56 U.S. hospitals with CABG patients in 1997, assessing in-hospital mortality among patients in 25 low-volume and 31 high-volume CABG hospitals. Like previous investigators, they find that mortality rates are significantly higher in low-volume facilities. More importantly, they find that these differential outcomes are most clear for patients with moderate to high predicted probabilities of in-hospital death, and that there is no noticeable benefit to minimal- and low-risk patients of being in a high-volume facility. This leads the researchers to argue for a targeted strategy of regionalization that focuses on the higher-risk patients.

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My comments deal with three aspects of the study by Nallamothu et al. (1): 1) its underlying concept, 2) the empirical application of the concept, and 3) its policy implications. In brief, the underlying concept is an important step forward; the empirical implementation may suffer from some weaknesses, but despite this, the policy implications are worthy of serious discussion. That is, their study can help inform even better empirical work and more nuanced policy recommendations.

THE UNDERLYING CONCEPT

The investigators recognize that not all patients who are to undergo CABG are the same, that various patients may benefit differentially from being operated on in different settings and that policies to alter the "natural referral patterns" for CABG should take these differences into account. They focus their attention on patients for whom the CABG was not done emergently or was combined with other procedures, and who did not have coronary angioplasty during the same admission. Thus, the patients in their analysis are those for whom there is a clear "decision-making opportunity" as to where they should have their CABG.

Few of the earlier studies of the volume-outcome relationship made this distinction, although it is clearly relevant from a clinical perspective. For example, the patient with an acute myocardial infarction (AMI) who is brought into a hospital and who then needs emergency revascularization may be in a very different category of risk (and potential benefit from regionalization) than patients with elective (or at least schedulable) admissions. Thus, the separation of CABG patients into various subgroups on an a priori basis makes both clinical and policy sense.

THE EMPIRICAL APPLICATION

Nallamothu et al. (1) estimate a logistic risk model to predict in-hospital death among all the nonemergent cases. Not surprisingly, age and all patient refined-diagnosis related group (APR-DRG) severity category are the two most significant variables. The odds ratio for the APR-DRG "extreme" category is 80.5, which is so high as to suggest that the factors leading a patient to be in this category are not preexisting comorbidities, but rather complications. This is not surprising; the APR-DRG categories were originally designed to capture costs, rather than mortality risks (2,3). Thus, the risk model may actually overcompensate for true risk differences among hospitals.

The risk model is then used to categorize patients into various groups, ranging from minimal risk ($<$0.5% chance of in-hospital death) to moderate (2% to 5%), high (5% to 20%), and severe ($\geq$20%) risk of death. Splitting hospitals in terms of those with $<$200 cases of nonemergency isolated CABG versus those with 200 or more such cases, the investigators (1) find that death rates are significantly higher in low-volume hospitals for moderate- and high-risk patients but not severe-risk patients. Although there is risk stratification in this approach, there is not full risk adjustment. That is, the researchers test for whether a difference exists in the number of deaths between low- and high-volume hospitals within a risk category, but not whether there are more or less than the *expected* number of deaths. This is problematic primarily for the top risk category, in which risk may be between 20% and 100%. This is also the category with the most potential problems arising from using APR-DRG categories rather than building a risk model based on diagnoses that are fairly certain not to be complications. Thus, the lack of significant volume-outcome effect for the highest-risk cases may be an artifact.

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Table 1. Distribution of Cases by Estimated Risk Level in Hospitals With <200 and ≥200 Elective CABG Cases Per Year

Estimated Risk of In-Hospital Mortality	<200 Cases per Year (%)	≥200 Cases per Year (%)
Minimal-risk (<0.5%)	46.6	52.5
Low-risk (0.5%–2%)	35.1	31.8
Moderate-risk (2%–5%)	9.2	9.3
High-risk (5%–20%)	4.6	3.1
Severe-risk (≥20%)	4.4	3.2

Adapted from Nallamothu et al. (1), Table 3.
CABG = coronary artery bypass grafting.

POLICY IMPLICATIONS

Nallamothu et al. (1) build upon their estimated empirical relationship to examine the implications of various regionalization policies. They examine several volume thresholds (100, 200 and 300 schedulable CABGs per year) and the transfer of moderate risk and above, low risk and above, and all patients from institutions below the threshold. The concerns raised above about the empirical results are not likely to alter significantly the potential policy implications of such analyses. The problematic aspects of the risk adjustment that have been pointed out are likely, if corrected, to result in somewhat better outcomes among the higher-volume institutions and thus increase the observed differences.

Roughly half of all the patients are in the lowest risk category where there is no mortality benefit to their being treated in high-volume hospitals. Likewise, there is essentially no benefit for the roughly one-third of patients with estimated risk of 0.5% to 2.0%. Thus, Nallamothu et al. (1) argue for a transfer policy targeted at patients with moderate or higher risk. This makes sense, but the real question is how to design such a policy.

The data presented in Table 3 of the Nallamothu et al. (1) study incorporate an interesting but not highlighted finding. As can be seen in Table 1 derived from their figures, 9.0% of the "elective" patients in low-volume facilities were high- or severe-risk cases, in contrast to only 6.3% of the cases in high-volume facilities. This is despite the fact that these are the cases for whom the high-volume settings have the greatest advantage. As in the study by Showstack et al. (4), it appears that the low-volume hospitals "specialize" in the most difficult cases in which their patients fare the worst. Whereas that study contrasted emergent and nonemergent cases, Nallamothu et al. (1) focus only on the nonemergent cases.

A plausible explanation for this troublesome finding is that the referral/transfer system works only partially. That is, the apparent specialization in emergency cases by low-volume hospitals may be a reflection that most nonemergent cases are routinely sent to higher-volume and better-outcome settings, even if this confers little advantage for the low-risk cases. This leaves the low-volume facilities with a disproportionate share of the emergency cases. What might explain a similar phenomenon among the nonemergent cases? One possible explanation is that, while physicians who usually practice in the low-volume facilities in major urban areas refer their high-risk elective cases to higher-volume hospitals in those areas, physicians in rural settings and urban areas with only a single CABG-capable facility do not make such referrals. This may well be rational, and may even be good patient care. Nallamothu et al.'s (1) Table 3 indicates that the number needed to treat to avoid a death is 53 or more, with the exception of a referral strategy targeting patients of moderate risk and above and hospitals with 200 or fewer CABG patients. One would need to know whether referral away from one's usual set of health care providers—and possibly one's family—has a substantial impact on mortality. Furthermore, it is not just the mortality effect on the patients who are referred, but the possibility that some patients will not undergo the elective CABG if it requires a referral outside of the usual provider network. This may or may not frequently, or ever, be the case, but it needs to be explored in developing policy recommendations.

More importantly, it is not appropriate to focus a policy analysis on outcomes only among nonemergent cases. Nallamothu et al. (1) base their volume estimates on just the nonemergent cases, but it is likely that the experience gained with emergency CABG patients will be important in treating the nonemergent ones. Experience with the scheduled cases may also affect the outcomes of the emergency cases that may not be so readily transferred. It is possible that the mortality savings attributable to the referral or transfer of high-risk elective cases away from low-volume settings may be more than offset by the increased mortality among the nonelective cases treated in those hospitals.

The proposed transfer of high-risk elective cases, however, is not the only policy option that should be examined. Another is the closure of (or refusal to open) low-volume facilities in urban areas served by facilities having better outcomes. Open-heart surgery facilities are used for various types of patients including the elective or scheduled CABG patient, the patient requiring scheduled but complicated procedures, the patient undergoing a scheduled angioplasty who then needs emergency CABG, and the patient brought to the hospital for an AMI who may then need emergency or urgent revascularization. Nallamothu et al. (1) focus on the first type and provide evidence for a policy of selective regionalization. In rural areas, however, it may well be better, especially for the emergency cases, to have a low-volume facility than none at all. But substantial research is needed to examine whether urban patients in general are better or worse off: 1) in geographic areas with only high-volume or good-quality facilities; 2) in areas with a range of facilities and in which there is a policy of selective referral for high-risk elective cases (the suggestion of Nallamothu et al. [1]); or 3) in areas with a range of facilities and in which there is no policy of selective referral. Focusing attention on only one segment of the patient population

that may use facilities for open-heart surgery runs the risk of harming those who are not being included in the study.

It is also important to move beyond a simple focus on patient volume. There may be some low-volume facilities that provide excellent care for all their patients. This may be the case if the staff is well organized and practices in multiple facilities—after all, it is not the bricks and mortar that achieve the better outcomes. Nevertheless, one cannot use the observation of a low mortality rate in a low-volume facility to claim that quality is high, because the number of cases is usually too small to determine whether even an absence of deaths is less better than what might be expected given the case mix (5). Contrariwise, high volume does not guarantee good quality. Volume does, however, make it easier to measure statistically the risk-adjusted outcomes for patients at high-volume facilities.

Given that volume per se does little more than assure reasonable confidence intervals around statistical estimates, volume-based policies for excluding or closing facilities are inferior to policies based on the routine reporting of risk-adjusted outcomes and policies to encourage the referral of patients toward facilities with better than expected outcomes and away from those with worse than expected outcomes. However, selective referrals—especially among only the nonemergent cases—may not be enough, and consistently poor outcomes may warrant the closing of a facility. To the extent that such policies will differentially target for referral patients with different risk levels, the benefits of selective referral for one "class" of patients have to be weighed against the impact of such policies on the other "classes" of patients. This is not an easy decision to make because it requires the development of policies that may yield less expected benefit for some patients in order to achieve even greater benefit for others. Such, however, is the problem when we move from a focus on clinical policies aimed at the individual patient to health policies aimed at the population of patients. The study by Nallamothu et al. (1) appropriately forces us to make this transition, but we need an even broader empirical analysis before being able to make such policy decisions.

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