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_Circulation_. 2006;114:1229-1231
doi: 10.1161/CIRCULATIONAHA.106.652818

_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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Percutaneous Coronary Intervention “Dominates” Coronary Artery Bypass Graft Surgery for High-Risk Patients

Good News for Patients, a Challenge for Healthcare Planners

Martha J. Radford, MD

In this issue of Circulation, Stroupe and colleagues present a cost-effectiveness analysis of the Angina With Extremely Serious Operative Mortality Evaluation (AWESOME) trial1 that challenges physicians, hospitals, and healthcare planners to address how to best evaluate emerging, evolving, and mature technologies for their safety, efficacy, and impact on the health of our society.

The AWESOME trial2 randomized patients with ischemic symptoms refractory to medical therapy who were at high risk for adverse events after either percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) to receive one of these as the initial revascularization strategy. These patients, encountered with increasing frequency in clinical practice, need revascularization to treat significant ischemia, but the revascularization procedure itself carries significant risk for them. “First, do no harm” is particularly difficult to apply to these patients because both the disease and the therapy may cause harm. The risk and benefit of the 2 available revascularization modalities for these patients, PCI and CABG, are particularly difficult to balance, to explain to patients, and to select with assurance that the best choice is made for each patient.

The randomized trial showed that mortality at 1 to 3 years was no different in the 2 study arms;2 but patients in the PCI strategy arm experienced unstable angina and repeat revascularization more frequently. Despite this difference in what might be a quality-of-life concern, health-related quality of life was no different in the 2 arms.3 Similarly, the Trial of Invasive Versus Medical Therapy in the Elderly (TIME), which showed in a high-risk group of patients with ischemia that mortality was not different for medical versus invasive strategy, the medical therapy group had higher symptom burden and more frequent revascularization rate.4,5 From the point of view of decision making for an individual patient, the outcomes are what matter, and mortality and quality of life are similar for PCI and CABG, and perhaps even medical therapy. These results can be presented to patients so that their preferences can be accommodated.

Stroupe and colleagues have demonstrated in their elegant cost-effectiveness analysis from the point of view of the payer—which is reasonably close to a societal perspective—that PCI is the “dominant” strategy, that the costs of the surgical strategy are higher than the costs of the percutaneous strategy, and that the outcomes are no different. Using the uniquely rich access to follow-up information on their patients through both Department of Veterans Affairs (VA) and Medicare health information, the investigators were able to take into account both inpatient and outpatient costs. Their cost assumptions, adapted from Medicare whenever possible, are reasonable and may be on the low side because in general the VA is considered a relatively low-cost delivery system. A particular strength of their analysis is the test of sensitivity of their model to changing cost assumptions and to changes in patient “mix” through reselection of patients in their cohort by randomly omitting some patients and replicating others (“bootstrapping”). Their finding that PCI is the dominant strategy in this high-risk patient cohort, in which CABG traditionally has been considered preferable,4 raises the question of which patients with coronary artery disease benefit from CABG more than any other therapy. It is conceivable that this group is now small indeed.

During the early years of any technology, assessment progresses through lower-risk populations in which harm is not expected, eventually encompassing patient groups in which harm may occur and the benefit is unknown. The elderly and patients with heart failure were excluded from early β-blocker trials7 because of concern about safety. We now know that these patients benefit from β-blocker therapy because subsequent trials and secondary analyses have shown us the benefit in higher-risk groups.8 The early randomized trials of PCI versus medical therapy examined patients with single-vessel coronary artery disease without left ventricular systolic dysfunction.9 We now know from AWESOME and TIME that higher-risk patients can be treated safely with medical or invasive strategy, perhaps because our medications, techniques, and instrumentation have improved. Perhaps the fact that the AWESOME trial could be conducted at all, that physicians are comfortable enrolling their highest-risk patients into this trial, is an indication that PCI has “come of age.” The AWESOME investigators are to be congratulated for their significant contribution to our knowledge base that supports thoughtful decision making for these high-risk patients.
How do the AWESOME study results inform healthcare planning? We know that PCI volume is growing each year, whereas isolated CABG volume ranges from stable to declining. In New York State, where all cardiovascular procedures are reported to the Department of Health, the number of patients undergoing PCI nearly tripled in the last decade, whereas isolated CABG volume has decreased by one-third (Figure) (information for 2004 provided by Edward L. Hannan, PhD, University at Albany, Albany, NY). Does this represent application of the PCI technology to more and more patients who benefit?

The patients examined in the AWESOME study and by Stroupe and colleagues are a small subset of patients who undergo CABG and PCI. Of the 22 662 patients screened, 90% were excluded because they were not high risk according to study criteria; 7% were not deemed angiographically appropriate for randomization to PCI or CABG; and 1% did not consent. Thus, 2% of those screened were randomized.2

From the AWESOME registry,11 we know that the outcomes in the high-risk patients who were angiographically appropriate for randomization were slightly worse than in those randomized but were similar for PCI and CABG, and the outcomes in those who did not consent were better than in those randomized, with outcomes favoring PCI. It is unlikely, then, that there is any high-risk patient group in which PCI does not economically “dominate” CABG.

What about lower-risk groups? To truly understand the health impact and cost-effectiveness of the explosion in PCI procedures, we need analyses similar to that of Stroupe and colleagues for a variety of patient cohorts, preferably including medical therapy as an initial strategy, preferably including quality-of-life outcomes, and preferably considering a long time horizon.12 The planned economic analysis13 of the Clinical Outcomes Utilizing Percutaneous Coronary Revascularization and Aggressive Guideline-Driven Drug Evaluation (COURAGE) trial promises to give us this information for an important lower-risk group: patients with demonstrable ischemia randomized to PCI versus medical therapy as initial strategy.14 For groups of patients who benefit from invasive revascularization, a cost-effectiveness analysis will help us understand the resources it will take to offer that benefit. For groups of patients who do not benefit, we need to recognize that our quality of care may not be optimal and that we may be overusing the technologies we have developed.15

The AWESOME study was performed at large, urban VA hospitals affiliated with medical schools. Hospitals performing a large number of procedures, both CABG16 and PCI,17 have been associated with better procedural outcomes, although this “volume-outcome” relationship has been called into question.18 To fully understand the quality of care for patients with coronary artery disease at a societal level, we need to be assured that all our procedures are performed in circumstances optimal for both quality and safety. With the number of isolated CABG procedures dropping, and the number of PCI procedures expanding, we need to monitor our performance in a variety of patient groups to be sure that we are offering our patients care that fulfills all criteria for high-quality care:19 efficacious, safe, timely, respectful of their preferences, respectful of limited resources, and available to all who need it.

Disclosures

None.

References


Key Words: Editorials  ■ coronary disease  ■ cost-benefit analysis