Keeping the Patient in View
Defining the Appropriateness of Percutaneous Coronary Interventions
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Since the original report by Andreas Gruenzig and colleagues, the obvious esthetic and symptomatic benefit of opening narrowed coronary arteries to improve epicardial blood flow has led to remarkable growth in interventional cardiology. This growth has been fueled in part by advances in our understanding of the biology of atherosclerosis and clinical trials demonstrating that percutaneous coronary intervention (PCI) provides a viable alternative to medical therapy or coronary artery bypass surgery for appropriately selected patients. Nevertheless, the sheer volume of cases (>1.2 million PCIs were performed in the United States alone in 2000) and the known geographic variations in the use of this procedure1 raise concerns that increases in the use of PCI have outpaced efforts to ensure that this procedure is being used in the most appropriate manner.

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What are the benefits of PCI? Current evidence would suggest that outside the setting of an acute myocardial infarction, the principal, if not the only, benefit of PCI is to reduce angina and improve quality of life. Randomized trials of PCI versus medical therapy in patients with chronic stable angina suggest that routine revascularization has no effect on the risk of death or myocardial infarction and that its benefits are restricted to reducing angina and improving exercise tolerance.4,5 These findings are supported by a meta-analysis of all randomized trials of PCI versus medical therapy in which PCI was associated with a significant reduction in angina but nonsignificant increases in the risk of myocardial infarction, death, and bypass surgery.6 The counterintuitive notion that opening tight stenoses does not extend life or prevent myocardial infarction has been explained by the paradigm of plaque rupture, wherein the majority of culprit lesions arise from previously noncritical stenoses.7 At present, the Asymptomatic Coronary Ischemia Pilot study is unique in its support of the contention that routine revascularization of patients with stable coronary disease reduces the risk of myocardial infarction and death.8 It is important to keep in mind, however, that the study was small and intended to serve as a precursor to a larger, more definitive trial. Cardiologists are familiar with trials in which a surprising mortality benefit in a pilot study was not supported by a larger, appropriately sized study.9 In addition, more contemporary trials have demonstrated the potential superiority of intense medical therapy, incorporating either exercise training or aggressive lipid-lowering therapy, in improving event-free survival as compared with PCI.10,11

Thus, given the available evidence and our current understanding of the pathophysiology of acute coronary syndromes, the major benefit of PCI should be considered to be improvements in quality of life and not reductions in cardiovascular events. What is surprising, then, is the relative paucity of data examining the long-term effect of PCI on quality of life in routine clinical practice. Previous investigations have noted improvements in health status after PCI12-15; however, these studies were limited by being restricted to patients who were enrolled in clinical trials, failing to use disease-specific measures of health status, or not identifying correlates of improved quality of life.

In this issue of Circulation, Spertus and colleagues16 provide new insights into the benefits of PCI by carefully examining the effect of PCI on quality of life at 1 year. At a single center, they prospectively collected health status and quality-of-life information from 1518 consecutive patients undergoing PCI for indications other than an acute myocardial infarction. Overall, patients undergoing PCI experienced a substantial improvement in their quality of life at 1 year. Although a 5-point increase is considered clinically significant, patients participating in the study experienced on average an increase of 30 points in the quality-of-life domain of the Seattle Angina Questionnaire. This contribution is notable in that the authors sought to determine the predictors of improvement in health status so that the expected benefit could be estimated for individual patients. Too often in clinical research our approach is reductionist, as we report average results for large numbers of patients. This approach can obscure the heterogeneity of experience among individual patients and make it appear that everyone shares the same benefits and the same risks. As patients and physicians contemplate decisions about procedures, each would benefit from knowledge about the patient’s own expected risks and benefits, not the average for all those who undergo the intervention. We are just beginning to examine the heterogeneity of experience in a variety of procedures. Such contributions will help us tailor treatments more appropriately for individual patients.
Spertus and colleagues found marked variations in the change in health status after PCI. Although many patients reported an improved quality of life 1 year after their PCI, a large number reported no change, and a small but substantial number reported worse quality of life than before undergoing the procedure. In multivariable models, this variation was not predicted by demographics, clinical characteristics, or procedural variables. Instead, baseline health status proved to be the strongest correlate of improved quality of life after PCI. Not unexpectedly, patients with more frequent angina and more severe physical limitations experienced substantially greater improvements in quality of life than those with less severe or no symptoms. This study quantifies what should be obvious: If a person has few or no symptoms at the outset, then significant improvement will not be seen after PCI, even if the procedure is technically successful. What was striking, however, was that >10% of asymptomatic patients reported moderate or large decreases in quality of life after PCI. It cannot be shown that these changes were the result of the procedure, but this finding raises concerns and emphasizes the need to understand the determinants of these decrements in health status.

The study also reveals the high frequency with which minimally symptomatic patients undergo PCI. Of the 1518 patients included in the analysis, 46% experienced little or no physical limitations from their coronary artery disease, 23% had no angina, and 46% experienced angina less than once a week. Thus, the majority of patients were asymptomatic or had minimal symptoms and, according to the experience at this center, experienced little improvement in health status after the procedure. It seems likely that this patient series is representative of patients referred for cardiac catheterization in the United States.

Why are so many asymptomatic or minimally symptomatic patients undergoing PCI, an invasive procedure that carries small but real risks of life-threatening complications? One piece of missing information is the denominator: We do not know how many patients with significant coronary stenoses did not undergo PCI, and we do not know how such patients would have differed from those included in the analysis. In addition, the authors do not provide detailed information about the indications for angiography, although it is likely that most patients were referred in response to symptoms or an abnormal stress test and underwent PCI on the basis of angiographic findings. Nevertheless, the question remains: What benefits do clinicians and patients anticipate when the decision is made to proceed with PCI in the absence of clinically significant symptoms? Research into clinician expectations has not been performed, but we do have some insight into patients’ knowledge and expectations. Investigators have demonstrated that almost 75% of patients with stable coronary disease undergoing PCI believe that the procedure would prevent a future myocardial infarction or improve their longevity, whereas <50% could name a single potential procedural complication. Clearly, a discrepancy exists between patient expectations and the available evidence, which can only be addressed through initiatives that are designed to improve communication and ensure that patients are truly aware of both the risks and benefits of PCI.

In the absence of known benefit, is it appropriate to perform PCI on asymptomatic and minimally symptomatic patients? Current guidelines would endorse this approach, but the evidence is far from definitive. Furthermore, recent research suggests the possibility that increased use of medical resources may paradoxically be associated with worse outcomes. This should give interventional cardiologists pause before proceeding with elective PCI in asymptomatic patients. The ongoing Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation trial, which compares intensive medical therapy with the combination of PCI and intensive medical therapy, should help define the role of coronary revascularization in patients with stable coronary disease.

In the meantime, however, the decision to proceed with elective PCI should be driven by the potential symptomatic benefit, and this benefit should be clearly articulated to patients before their procedures. A standardized measure of health status such as the Seattle Angina Questionnaire may be helpful in monitoring patterns of care and standardizing the assessment of the appropriateness of PCI across sites.

There is a pressing need to reinvigorate efforts to define the appropriateness of PCI, particularly when it is clear that for many patients who undergo the procedure there is little or no expectation of improvement in quality of life, as well as little hope for prognostic improvement. In an era of growing concerns about the ability of the healthcare system to pay for increasingly expensive medical innovations, the marginal benefits of PCI in this population may not represent the best use of healthcare resources in all of the patients for whom it is being applied. Furthermore, if patients are to play a role in the decision-making process and provide truly informed consent, they need to understand that the effects of PCI on risk of myocardial infarction and death are far from certain. The contribution by Spertus and colleagues represents an important step toward improving our understanding of how baseline health status influences the impact of PCI on quality of life. The challenge remains to leverage these findings into action that will result in improved patient care and more efficient use of medical resources.

References

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