A guideline tells you how to get someplace, whereas a lighthouse keeps you off the rocks; both can shepherd you on a safe journey toward your goal. The American College of Cardiology (ACC), in concert with the American Heart Association (AHA), has been at the forefront of developing guidelines for percutaneous coronary interventions (PCI). In an era in which there are multiple data sets to draw from, guidelines help to sort out optimal from less optimal evidence-based approaches. Application of these guidelines makes intuitive sense as we counsel our individual patients about the risk/benefit ratio of PCI and as we develop treatment strategies for healthcare delivery systems to employ.

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Although the guidelines approach makes intuitive sense, there are very limited data about the impact guidelines have had on PCI. The current article by Anderson et al2 is a substantial effort to remedy that shortfall. As the authors point out, the ACC’s National Cardiovascular Data Registry (ACC-NCDR) was developed to apply rigorous methodology to the collection of data about interventional procedures using uniform data entry, written definitions, and data quality checks. It has become a robust tool and, in the present study, provides the results of 463,088 procedures performed from January 1, 2001, to March 31, 2004. Given the large size of the data set, important statistical and clinically meaningful conclusions could be expected, and in fact, some were identified.

**What Did We Learn?**

The majority of non-STEMI procedures are performed for either class I (“evidence and/or general agreement that the procedure is useful and effective”); 69%) or class IIA (“weight of evidence of opinion is in favor of usefulness and efficacy”; 21%) indications. Only 7% of the procedures were class III, defined as “evidence or general agreement that the procedure/treatment is not useful or effective and in some cases may be harmful.” Although that 7% is a single-digit percentage, in the ACC-NCDR database used in the present study, it involved 33,009 patients. Much could be learned from a careful detailed analysis of these class III patients and their outcomes. Were these patients in whom judgment was not optimal, patients in whom PCI was the only option, or patients who strongly preferred PCI even after the risk/benefit ratio had been fully discussed, or were they part of high-risk clinical research protocols? Those are all important considerations when outcomes in this patient subset are being examined.

The classifications and guidelines are based on perceived risk, and so, not surprisingly, clinical profiles of class I patients were better than those of patients in class II or III, with fewer risk factors, including advanced age, diabetes, 3-vessel disease, prior myocardial infarction, and coexistent renal disease. Having said that, however, even in class III patients, the risk profile did not appear to be prohibitively high.

Drug-eluting stents were used infrequently (in <20% of cases), but it is likely that this low number reflects the fact that patient entry for this study started before the widespread introduction of these stents.

The essential part of this study is the relationship between guideline classification and outcome. Clinical success rates decreased successively across the classes. The magnitude of the decline varied: it was small between class I and class IIA (92.8% versus 94.0%) but rather large between class I and class III (92.8% versus 85.5%). In-hospital mortality rose from 0.5% in class I to 1.7% in class III; however, mortality was not risk-adjusted, which may mask some of the true difference. The rate of CABG during the same admission was lowest in class III, probably related to the fact that many of these patients were considered too high risk for surgery.

**What Are the Problems With the Study?**

The first problem with this study is that despite the very high number of procedures in the data set, the outcome of PCI was not risk-adjusted. With the availability of excellent discriminatory risk models, it would have been better to report risk-adjusted analyses.

Class III patients’ higher-risk demographic and angiographic variables, eg, older age, congestive heart failure, renal disease, worse angiographic lesions, and lower ejection fraction, would put them at increased risk for complications during the procedure.

Second, the aforementioned high-risk features may have led interventionalists performing the procedures to choose PCI despite familiarity with the guidelines.

Third, often class III indications are due to left main interventions, chronic total occlusion in the setting of prior surgery, multivessel vein-graft interventions in patients with left ventricular dysfunction, and relatively asymptomatic patients with 1- or 2-vessel disease without diabetes mellitus and without inducible ischemia. Anderson et al2 have not separated patients in the class III category into different contraindications. A patient with single-vessel disease, no diabetes, and no inducible ischemia, for example, is likely to

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have lower risk than a patient with unprotected left main disease who is not a surgical candidate. If most interventions were performed on patients with prior cardiac surgery, the threshold of the operator to recommend another open-heart surgery would be high and may match the unwillingness of the patient.

Next, the guidelines in this observational registry were retrofitted. The circumstances surrounding the decision to perform coronary angioplasty are complex and cannot be accurately captured in the ACC-NCDR database. Such decisions involve not only the demographic and angiographic features that most current databases include but also family, social, and patient-centered issues such as cognitive skills, depression, and quality of life.

Finally, there are ample data demonstrating the volume/outcome relationship, and most of the hospitals reporting data in this registry are in the high-volume category. Therefore, the generalizability of the results across different practices is uncertain.

What Are the Take-Home Messages?
Guidelines play an important role. The process by which they are developed leads to results that support the recommendations of those guidelines. The data set, however, is not perfect. The classifications were derived from collected clinical data and are not specifically captured, discrete data points. Missing data in this large data set are significant; eg, in 11% of cases, missing data precluded classification of the patient. This group had higher mortality (1.6%), which raises important, but unanswerable, questions.

Analyses of outcome data based on classification guidelines do not allow for risk stratification, although that is part of the process used in the development of some parts of the guidelines. In addition, this data set deals only with in-hospital outcomes, although it may have distinct relevance to longer-term events.

Guideline development is a vital part of the charter of professional societies; it influences the care of specific patients and the development of strategies for groups of patients. The process is demanding and time consuming: weighing all the evidence, coming to an expert consensus on the strength of data, and then crafting, modifying, and publishing the specific guidelines. Despite the laborious process, guidelines must be living documents; they must continue to evolve to meet the needs of interventional cardiologists faced with increasingly complex patients and an ever-changing array of new widgets. Studies such as this one by Anderson et al\textsuperscript{2} have demonstrated value; by pointing out the results of guidelines-led procedures, they act like the lighthouses that can keep our patients and systems safe. Initial exploratory reports like this are a toe in the water, testing it, and the present report sets the stage for the full plunge into this extraordinary data set.

References

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