Coronary Artery Revascularization

Critical Need for, and Consequences of, Objective Angiographic Assessment of Lesion Severity

Michael L. Stadius, MD, and Edwin L. Alderman, MD

The treatment of coronary artery disease patients with revascularization procedures has escalated dramatically in the 1980s. In 1989, an estimated 450,000 coronary artery revascularization procedures were performed with either percutaneous transluminal coronary angioplasty (PTCA) or coronary artery bypass graft surgery (CABG); in 1980, less than 250,000 such procedures were performed. Despite the dramatic increase in the use of coronary revascularization procedures, the relative efficacy of PTCA and CABG in the treatment of coronary artery disease patients remains poorly understood. In the last 3 years, a number of comparative randomized prospective trials evaluating the relative efficacy of PTCA and CABG have been planned and initiated. In the United States, the National Heart, Lung, and Blood Institute (NHLBI) is sponsoring two such comparative trials: the Emory Angioplasty Surgery Trial (EAST) and the Bypass Angioplasty Revascularization Investigation (BARI). Three similar trials are underway in Western Europe.

Because coronary revascularization is based on the angiographic assessment of coronary lesion severity, investigators in trials comparing PTCA and CABG have had to implement objective and reproducible methodologies for assessing coronary artery lesion severity. If one is to assess the ischemia-producing potential of a particular coronary lesion, direct measurement of impairment of coronary flow and reduction in coronary flow reserve is the reference standard against which angiographic measurements must be compared. To a variable extent, the percent coronary diameter stenosis, minimum residual lumen diameter, minimum lesion cross-sectional area, and the flow resistance (computed from the full-lesion geometric profile) all correlate with measures of resting flow and coronary flow reserve. Historically, clinical assessment of coronary artery lesion severity has relied on visual determination of the percent diameter stenosis. This measurement intuitively reflects the severity of luminal obstruction, and it is simply assessed. In the 1970s, however, a number of different investigations documented the large amount of interobserver variability and the poor reproducibility of visual assessments of coronary artery lesion percent diameter stenosis. Despite this well-documented lack of objectivity, clinical practice today continues to rely on visual assessment for the description of lesion severity. Indeed, studies that use visual assessment to describe lesion severity continue to be published in leading cardiology journals despite the well-documented problems with poor reproducibility and lack of accuracy of this methodology.

A requirement for objectivity is inherent in the design of any multicenter, randomized, prospective study in which angiography is an integral part. Thus, investigators participating in trials comparing coronary revascularization strategies have had to implement methods for assessing coronary lesion severity that are more objective than the current clinically accepted standard of visual assessment. The purposes of this editorial are to review methodologies for assessment of coronary lesion severity, to explore the consequences of a shift to more objective methods of lesion assessment relative to the current clinical standard of visual assessment, and to propose definitions that will enhance the goal of achieving a more objective and reproducible assessment of coronary lesion severity.

Computer-assisted techniques provide the most reproducible and accurate methods for assessing stenosis severity. Variability in repeated measures of percent diameter stenosis or absolute coronary dimensions using several different computer algorithms is reported in the 3−7% range (Table 1). In addition to providing accurate measures of percent diameter stenosis, computer-assisted techniques also provide the most accurate measurement of coronary vessel dimensions as long as an adequate calibration object is provided. Indeed, the full geometric profile of the coronary lesion can be ascertained, and in carefully controlled experimental studies, predictions of coronary flow reserve based on the full geometric profile of lesions accurately correspond to measured coronary flow reserve. Computer-assisted techniques, however, do have limitations. These techniques re-
quire that the lesion be demonstrated without overlapping vessels and foreshortening and that the angiographic technique be of high quality. Computer-assisted methods are less easily applied to the hazy borders of some vessels after PTCA. Finally, computer-assisted techniques currently require considerable hardware and software for the analysis, expert technical assistance to select appropriate angiogram frames for analysis, and a significant amount of time to complete the selection and analysis process.

Measurements using hand-held electronic calipers provide a second method for obtaining reproducible measurements of coronary lesion severity. Like computer-assisted methods, caliper measurements can also provide absolute measurement of the coronary lesion reference and minimum diameter. However, the accuracy of these measurements is not quite as good as the accuracy obtained with computer-assisted methods; the caliper measurements cannot provide the full geometric profile of a lesion, and caliper methods do not adequately correct for the effects of pin cushion distortion (or beam divergence) as do computer-assisted methods. Despite these limitations, caliper measurements require much less time and can be applied to many angiograms that may be technically suboptimal compared with computer-assisted measurements.

No matter what objective method of lesion measurement is used, there are important and relatively consistent differences between the more objective methodologies and visual interpretation of lesion severity. Figure 1 is a simplified representation of the “relation” between visual observations and objective (computer-assisted or caliper) measurements of percent diameter stenosis that illustrates several interpretive biases. In general, lesions less than 50% diameter stenosis severity tend to be underreported. Yet, these lesions provide the substrate for the development of more significant lesions. Moreover, from angiograms obtained after thrombolytic therapy in acute infarction patients, “minor” lesions have been shown to initiate coronary thrombosis. The severity of lesions greater than 50% diameter stenosis tends to be overestimated by visual reading. The underreporting of lesions less than 50% diameter stenosis and the consistent overestimation of severity of lesions greater than 50% diameter stenosis is termed “visual assessment” bias.

Figure 1 highlights a second practice of the clinical cardiology community, that is, an attachment to fixed thresholds of stenosis severity that have been shown to be important in prior studies of coronary flow reserve. Thresholds of 50%, 70%, and 95% diameter stenosis have become somewhat ingrained demarcations affecting choice or urgency of therapy. This threshold bias probably reflects causal attitudes about lesion significance. When threshold bias occurs and, particularly, when it is combined with visual assessment bias, the potential for inappropriate assessment of lesion severity becomes quite real. Threshold bias and visual assessment bias underlie the consistent tendency for estimates of lesion severity obtained by visual observation to range from 15% to 25% above those obtained by direct measurement as diagrammatically illustrated in Figure 1.

An ancillary issue to observer bias is the problem of measuring lesions that are greater than 85–90% diameter stenosis. The residual lumen of a 90% compromised 3-mm diameter vessel is 0.3 mm. Current high-quality cineangiographic imaging systems provide resolution that permits detection of contrast borders in coronary arteries 0.3 mm in diameter or more. It is simply not possible to accurately measure a lesion lumen less than 0.3 mm given current angiographic capability and radiation exposure standards. Rather than making measurements of lesion severity that are inherently unreliable, investigators in BARI have decided to use morphological definitions for severe lesions that cannot be reproducibly measured. These definitions are arbitrarily assigned numeric values of 95%, 99%, and 100%, although these designations almost certainly do not reflect actual lesion severity if such measurements were possible. A “95%” diameter stenosis lesion is defined as retention of a visible residual lumen, albeit narrow or faint, but with sufficient lack of resolution such that the lumen cannot be reproducibly measured. Coronary flow according to Thrombolysis in Myocardial Infarction trial (TIMI) criteria is commonly grade 2 or 3. A “99%” diameter stenosis lesion is defined by the presence of antegrade flow but without clear visibility of a residual lumen. Antegrade collaterals or recanalization channels are not considered as direct luminal flow. TIMI flow may be grades 1, 2, or uncommonly 3. A “100%” lesion is defined by the complete lack of direct luminal flow. Antegrade collaterals or recanalization channels,

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**Table 1. Variability of Coronary Lesion Measurement With Computer-Assisted Methodology**

<table>
<thead>
<tr>
<th>Reference</th>
<th>Coronary lesion parameter measured</th>
<th>Variability of measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown et al⁹</td>
<td>Percent diameter stenosis</td>
<td>3.0%</td>
</tr>
<tr>
<td>Alderman et al¹⁰</td>
<td>Minimum lesion diameter</td>
<td>3.5%</td>
</tr>
<tr>
<td>Cashin et al¹¹</td>
<td>Percent diameter stenosis</td>
<td>6.8%</td>
</tr>
<tr>
<td>Reiber et al¹²</td>
<td>Percent diameter stenosis</td>
<td>2.7%</td>
</tr>
</tbody>
</table>

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*This estimate is based on 4 line pair/mm resolution in static images. The resolution obtained in moving images (such as coronary arteries) is less than this, so that measurement of contrast borders 0.3–0.5 mm in diameter is often quite difficult.*
however, may be present. TIMI flow is always graded zero for such lesions. Thus, it is possible to construct a continuum of measures of lesion severity that is reproducible using a combination of objective methodology and morphological definitions. For lesions greater than 0% diameter stenosis and less than 85–90% diameter stenosis, caliper or computer-assisted methodology provides reproducible measurement of lesion severity. For lesions greater than 85–90% diameter stenosis, arbitrary morphological definitions allow reproducible categorization of lesion severity.

When one initiates objective measurements of coronary lesion severity, whether by ruler, caliper, or computer quantification, there is often substantial lessening of lesion severity compared with prior visual estimates. It is, however, important that individual angiographers, angioplasters, and surgeons accommodate a resetting of their lesion severity thresholds if angiographic interpretation is to be recognized as an accurate and credible laboratory procedure. Objective measurements avoid the impression of biased interpretation of diagnostic test results; this is especially important when the same individuals perform diagnostic studies, interpret them and then act on the results of the interpretation by performing PTCA. In addition, continued use of visual estimates of lesion severity before and after angioplasty may be fostering unrealistic impressions about the extent of lesion reduction that is accomplished. Moreover, the lack of reproducibility of visual estimates makes it difficult to interpret clinical investigative studies. If one is to compare results of clinical research studies that evaluate such topics as angioplasty outcomes, prognosis of coronary disease subsets, or atheroma progression and regression, standardization and objective assessment of coronary lesion severity is necessary. Investigators in the NHLBI sponsored trials of coronary revascularization (EAST and BARI) have adopted objective methodologies for describing lesion severity. It is quite probable that these methodologies will lead to assessments of lesion severity in these trials that are "less severe" than many clinical cardiologists would accept as being clinically severe.18 Indeed, it is quite probable that the average lesion severity reported from these trials of revascularization treatment strategies will be in the 70% diameter stenosis range and not in the 90% diameter stenosis range as is often the case when visual assessment methods are used. As this editorial has attempted to show, this type of disparity will not reflect an "easier" patient population being enrolled in BARI and EAST compared with current clinical practice; it simply will reflect the use of objective methodologies rather than biased visual assessments. Finally, the clinical cardiovascular community must realize that appropriate integration of angiographic observations from trials such as BARI and EAST in routine clinical practice will require adoption of objective assessment methodologies for description of coronary lesion severity in everyday practice.

There are limitations of objective techniques for assessing lesion severity. For instance, the relation of objectively determined percent diameter stenosis or percent area stenosis values to the actual hemody-

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**Figure 1.** Diagram of comparison of subjective and objective reporting of percent luminal diameter stenosis.
namic significance of lesions in diffusely diseased coronary arteries is relatively poor. In this situation, absolute measurements such as minimum lesion diameter or minimum lumen cross-sectional area more accurately correspond to the hemodynamic significance of lesions than do objectively determined percent diameter stenosis measurements of lesion severity. The contrast borders defining the coronary lumen can be quite hazy and indistinct as in intraluminal filling defects that suggest thrombus or in lesions after balloon angioplasty. When indistinct contrast borders are present, the reproducibility of objectively derived indexes of lesion severity is diminished. Finally, coronary vasomotor tone can vary substantially over time and from patient to patient. Changes in coronary vasomotor tone affect both relative and absolute indexes of lesion severity. Pre-treatment of patients with coronary vasodilators such as nitroglycerin before angiography lessens the impact of changes in coronary vasomotor tone on the assessment of lesion severity. With proper awareness of these limitations, however, objective measurement techniques can be used even more effectively, and their advantages in terms of better reproducibility compared with visual assessments of lesion severity is maximized.

It must be recognized that current visual estimates of lesion percent diameter stenosis severity are often biased in the direction of heightening the degree of luminal narrowing. This bias often occurs with the honest goal of identifying patients who would benefit from revascularization; however, it is critical for the credibility and integrity of clinical decision making that biases underlying the current practice of visual estimation of lesion severity be acknowledged and corrected. We believe that the community of cardiovascular specialists can accommodate an adjustment in their perceptions and attitudes toward thresholds of lesion severity in recognition of the importance of obtaining objective and reproducible reporting of coronary lesion severity. Implementation of objective measurement techniques for assessing angiographically defined lesion severity by the clinical cardiology community is an important—and overdue—practice that will improve the reliability of angiographic findings and that will lead to improved credibility in the selection of patients for coronary revascularization.

References
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