Do You See What I See? Time for a Standardized Approach to Angiography-Based Decision Making

Eric A. Osborn, MD, PhD; Donald E. Cutlip, MD

There are 2 ways to be fooled. One is to believe what isn’t true; the other is to refuse to believe what is true.

—Søren Kierkegaard (1813–1855)

The relative merit of percutaneous coronary intervention (PCI) for the treatment of stable ischemic heart disease remains a debated issue. Clinical trials that have relied mostly on a visual estimate of angiographic stenosis severity for subject selection have failed to demonstrate a clinical benefit for PCI when compared with guideline-directed medical therapy alone. Meanwhile, studies using a measure of coronary physiology, the fractional flow reserve (FFR), have not only confirmed a benefit for PCI in treatment of lesions assessed as hemodynamically significant (FFR≤0.80) but also shown the potential for unnecessary PCI and associated harm using a visual angiography-guided strategy. Indeed, the discordance between visual estimates and FFR is 65% for lesions judged to have 50% to 70% diameter stenosis and 20% even for those lesions judged to have 70% to 90% diameter stenosis. On the basis of available data, current consensus guidelines in the United States and Europe recommend FFR-guided PCI as class IIa and I indications, respectively. Likewise, the appropriate use criteria for coronary revascularization endorsed by multiple cardiovascular societies incorporate FFR measurements for assessment of borderline lesions.

Despite guideline recommendations, registry data on FFR assessment of intermediate stenoses indicate that only 6% of PCI are FFR guided, with the use limited mainly to academic teaching hospitals. In this issue of Circulation: Cardiovascular Interventions, Toth et al address some of the factors influencing FFR use. They report on an anonymous Web-based survey that aimed to evaluate the clinical decision-making strategies for PCI when compared with guideline-directed medical therapy alone. Meanwhile, studies using a measure of coronary physiology, the fractional flow reserve (FFR), have not only confirmed a benefit for PCI in treatment of lesions assessed as hemodynamically significant (FFR≤0.80) but also shown the potential for unnecessary PCI and associated harm using a visual angiography-guided strategy. Indeed, the discordance between visual estimates and FFR is 65% for lesions judged to have 50% to 70% diameter stenosis and 20% even for those lesions judged to have 70% to 90% diameter stenosis. On the basis of available data, current consensus guidelines in the United States and Europe recommend FFR-guided PCI as class IIa and I indications, respectively. Likewise, the appropriate use criteria for coronary revascularization endorsed by multiple cardiovascular societies incorporate FFR measurements for assessment of borderline lesions.

The results from Toth et al suggest that FFR might be regarded as hemodynamically significant. For visually nonsignificant lesions, they were given a choice of FFR, quantitative coronary angiography (QCA), or invasive imaging with intravascular ultrasound or optical coherence tomography to assess lesion significance further.

Within the limitations of an anonymous survey tool, the study provides useful information on contemporary decision making for PCI. The results should be disappointing to the interventional cardiology community, given current guideline recommendations and the publicity surrounding the lack of benefit and potential harm of unnecessary PCI. More than 70% of decisions were made solely on the estimated visual interpretation. Referenced to the known lesion FFR values, the visual estimate was discordant ≥50% of the time. Nevertheless, survey participants were highly confident in their visually based decisions, including 27% that did not select FFR assessment for any of the intermediate lesions. Although increasing experience with FFR technology tended to influence FFR use positively, the most experienced group still only selected FFR in 28% of the cases, resulting in a rather small improvement in discordance between visual estimates and FFR (range, 49%–57%).

The results are especially concerning because the survey method probably yields a best-case scenario, without the necessity for the respondents to consider any of the practical constraints to performing FFR in clinical practice. Thus, the responses may reflect more serious conceptual deficiencies within the practice of interventional cardiology, including problems with estimating lesion severity, belief that the visual estimate at the operator-specific threshold reflects true functional significance, or a lack of belief that functional significance is important for determining PCI appropriateness or outcomes. Each of these possibilities can be supported by the data from Toth et al and raise concern that operators and patients may be fooled by the angiographic interpretation into unnecessary, potentially harmful procedures. The question for our specialty is what we can do to improve decision making using both the anatomic and the physiological tools available.

Improving Operator Knowledge of FFR Principles

The data from Toth et al suggest that FFR might be regarded as a correction for deficiencies in visual quantification by some operators, for which the study participants were clearly confident as reflected by infrequent consideration of the need for such correction. From a physics perspective, however, FFR measurements provide data on the effect of the stenosis on actual distal blood flow, being derived from the assumption that coronary blood flow is linearly related to the pressure beyond the stenosis at steady state under conditions of maximal blood...
flow when vessel resistance is minimal. By comparing the ratio of the pressure distal to the stenosis (Pd) to the normal aortic reference pressure (Pa), FFR thus represents the reduction of blood flow in a stenotic artery compared with a normal vessel. A distal pressure decrement is influenced by multiple factors beyond lumen diameter, so FFR also accounts for the effects of longer length lesions, collateral flow, and larger size myocardial beds. Because most patients with PCI have geometrically complex, multifocal lesions, FFR supplies critical functional information on multiple lesion-specific factors simultaneously that cannot be understood or captured by the most accurate assessment of stenosis severity alone. Developing focused instructional tools to train operators in the fundamental principles behind FFR measurements may enhance physician understanding of the significance of FFR and translate into greater FFR use.

Improving FFR Use for Angiographic Intermediate Stenoses

Given that angiography in isolation is unable to predict ischemia accurately and that a FFR-guided strategy decreases unnecessary PCI and improves outcomes, should FFR assessment be mandatory before PCI? And if so, what angiographic threshold should be used? A recent single-center experience that switched to routine FFR from usual practice sheds light on this matter, reporting that FFR use improved from 2% to 51%, resulting in more judicious stent implantation and a concomitant overall improvement in outcomes at 1 year. Although available data suggest benefit of FFR measurements even in stenoses estimated to be severe, the largest value is in intermediate stenoses ranging from 40% to 70%. Given the marked discordance between FFR and angiography for these intermediate lesions, mandatory use of FFR to determine PCI appropriateness seems reasonable as suggested by the appropriate use criteria.

Improving Individual Visual Angiographic Performance

Despite the well-described limitations of the visual estimate of angiographic severity, it is highly likely that an initial visual estimate will remain the gateway for the treatment decisions. It is also likely that some threshold of stenosis in an appropriate vessel territory and clinical scenario will be acceptable for PCI to most observers. The appropriate use criteria suggests a visual estimate of 70% for this threshold. This is not perfect, of course, but if standardization of the visual estimates could be improved such that stenoses that are clearly <70% are not treated without FFR data, it would represent a giant step forward.

How should angiographic standardization be achieved? One consideration would be through physician-level training and feedback mechanisms. Implementing routine angiographic audits to identify habitual overestimation of stenosis severity by operators or institutions would allow retraining of the eye of the beholder to reduce variation in visual assessment. Although if an audit strategy were pursued, an open question would be whether to base performance on unbiased visual assessments or a QCA gold-standard, given the high reproducibility and objectivity of QCA measurements? However, it must be recognized that there are systematic differences in angiographic stenosis severity determined by QCA and visual estimates, with QCA almost always measuring lesser severity. In a recent study, the average absolute difference between QCA and visual estimates was 8%, with larger differences noted in the important intermediate lesion group. Although we favor visual-based audits, either method is probably acceptable as long as appropriate thresholds are used, with the key objectives being reducing operator variability and increasing reliance on the reported stenosis at least within the broad diameter stenosis categories of nonobstructive (<40%), intermediate (40%–70%), and severe (>70%).

Conclusions

The study from Toth et al adds valuable contemporary insight into the longstanding controversy surrounding angiography-guided PCI. It is unfortunate that heavy reliance on angiography persists, despite the availability of FFR, a tool that is based on coronary physiology, easy to use in most cases, and clearly associated with improved outcomes. Whether the deficiency is because of purposeful or inadvertent angiographic overestimation of stenosis severity or a failure to recognize the importance of coronary physiology obtained by FFR measurements, an approach to modify behavior is needed now. Incorporating angiographic audits and FFR standardization strategies mandating FFR use for lesions ≤70% diameter stenosis would enact proactive, quality improvements in cardiac catheterization that align current practice with consensus guidelines and likely have wide-ranging benefits to both our patients and our specialty.

Disclosures

None.

References


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