VIEWPOINT

Proposed Framework for the Optimal Measurement of Quality Assessment in Percutaneous Coronary Intervention

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Despite substantial efforts to define and develop methods to evaluate the quality of individual operators and programs performing percutaneous coronary interventions (PCI), existing approaches have acknowledged limitations.[1-3] The difficulties arise from the complex nature of decision-making; both the proper selection of patients and the objective appraisal of technical performance of the procedure are relevant to assess, but neither is simple to measure.

This is not a problem that can be resolved simply by improved data collection or more sophisticated statistical algorithms. We propose a novel heuristic approach: collecting a group of process and outcomes measures encompassing all aspects of quality practice. By selecting a comprehensive portfolio of carefully selected metrics balanced for their complementary strengths and weaknesses (**Box**), the elusive resolution may be achievable.

Why Do Current Metrics Fail?

Unlike most surgical procedures, PCI quality cannot be accurately assessed by complication rates alone. The main reason is that the occurrence of PCI complications is more dependent on patient-specific factors than procedural errors. Moreover, the overall rate of complications during PCI with contemporary pharmacotherapy and equipment is very low, regardless of operators' technical and cognitive abilities.

There is minimal evidence that existing PCI quality measures, including those being publicly reported, lead to improved health outcomes. Moreover, selection of patients for PCI who are at very low risk for complications makes some performance measures, particularly survival, highly subject to gaming. The 30-day risk-adjusted survival (risk-adjusted mortality rate [RAMR]) has become a widely accepted surrogate metric of quality, in large part because it is easy to measure rather than an actionable indicator. The reporting of PCI-associated RAMR focuses exclusively on periprocedural mortality; a death is counted only when a procedure is performed, regardless of cause, and the measure ignores comparative outcomes if the procedure is not performed,[4-6] making it impossible to weigh risks and benefits. Additionally, since case selection is the most important factor associated with survival, the metric unintentionally promotes risk aversion.

A New Approach

Current approaches to quality assessment typically begin with evaluating which variables are feasible to measure.[7] In contradistinction, the framework proposed here begins by asking, "What elements are the

Box. Proposed Quality Assessment Parameters[a]

1. Case selection
   a. Rate of appropriate use criteria classified as "rarely appropriate" and "unclassifiable" (because of missing data)
   b. Random on-site case reviews (approximately 10% of cases is optimal)[b]
   c. An operator percutaneous coronary intervention annual volume greater than 100 cases
   d. Rate of instantaneous wave-free ratio or fractional flow reserve use
2. Technical expertise
   a. Rate of radial access
   b. Rate of saphenous vein graft protection device use and thrombectomy, when indicated
   c. Rate of atherectomy device and other advanced device use
   d. Rate of bifurcation cases (with or without side-branch protection)
3. Case complexity
   a. Expected mortality calculated after risk adjustment
   b. Rate of multivessel percutaneous coronary intervention cases
   c. Annual ST-elevation myocardial infarction volume greater than 20 cases
   d. Rate of use of hemodynamic support devices (eg, left ventricular assist device, intra-aortic balloon pump)
4. Outcomes
   a. Thirty-day risk-adjusted mortality rate or ratio of observed mortality to expected mortality, compared with that of all patients with coronary artery disease, including those in whom a percutaneous coronary intervention is not performed (ie, reporting disease-based outcomes)
   b. Improvement in quality of life measures (angina class, stress test findings) compared with baseline
   c. Incidence of vascular bleeding requiring procedural intervention, benchmarked by predictive algorithm
   d. Proportion of preexisting stage II or greater renal insufficiency treated with a prehydration algorithm

[a] Suggested use of these metrics: evaluate each program or operator for each metric, and identify those whose results are 2 SDs greater than or less than the mean in each. Those with findings below this cutoff should consider this an opportunity for improvement and make efforts to improve the relevant area(s) of practice.

[b] For random on-site case reviews, each case should be appraised to include case indication, appropriate use criteria classification, and angiographic and clinical results.

foundations of quality practice?" Public reporting and third-party rankings remain focused entirely on RAMRs. We propose an alternative framework that more accurately appraises PCI quality. Crucial to its potential value are the innovative proposals that (1) disease-based rather than procedure-based outcomes data be collected and (2) random case reviews become a routine aspect of quality assessments.

Four general aspects of practice form the basis of quality: case selection, technical expertise, case complexity, and clinical results. To accurately evaluate program quality, there should be measurable and potentially modifiable metrics in all of these quality categories. Parameters for each of these components exist, but each poses problems of accuracy and strength of correlation. Combining them allows metrics with complementary strengths to be advantageously considered while limiting the weaknesses of individual parameters. Choosing metrics that can be modified, leading to changes in practice that improve patient care, is crucial to the success of this structure.

Another consideration is assuring the incorporation of the Donabedian[8] triad of structure, process, and outcomes. Existing models primarily are concerned with procedural outcomes and only minimally with process. Although structure (eg, physical facility, equipment, organizational character) can be observed directly, it is not easily quantitated. Therefore, several factors must be included that are dependent on a strong organizational structure and commitment to excellence.

Constituents of Optimal Quality Assessment

We are advocating a new structure of quality assessment in which a comprehensive portfolio of carefully selected metrics, balanced for their complementary strengths and weaknesses, is integrated. Instead of relying on quality assessment based on procedural mortality, assessment of disease-based outcomes is advocated. The indicators would include nonfatal complications and clinically relevant results. The Box summarizes the necessary components.

The breadth of proficiencies involved in interventional cardiology[9] is extensive. Deciding which ones to gauge as components of quality depends on the recognition that, once selected, increased use should be anticipated, so the metrics chosen must be those that are widely established as requiring valuable skills. It is necessary to choose metrics that are associated with excellence and that, even if gamed, would lead to improved quality. Moreover, definition drift must be assumed. Cases will be reported to fit these criteria, even if the accuracy of classification is borderline. These metrics run the spectrum from entirely new measures of quality to those that are well known; several require substantial changes in data collection methods.

Critical to the success of this approach is the necessity of appraising reported results accurately and impartially. Random case reviews incorporating evaluation of all relevant features, including case selection and technical performance, should become the foundation of quality assessment. We recommend periodic internal random reviews to identify systemic and individual opportunities for improvement and correct classification, as previously recommended.[2] Outside focused review may be considered when necessary. Optimally, a national society would develop a program for this purpose to assure objectivity and uniformity.

The value of RAMR should be retained, but recognizing its limitations, it should be balanced with measures of case complexity as well as the mortality of those treated medically. The set of measures should also assess case acuity, appropriateness, and nonfatal complications, such as bleeding and acute kidney injury. Additional measures of technical and cognitive components of practice should also be included.

Comparing procedurally treated outcomes with disease-based outcomes without intervention would reduce risk aversion, an important limitation of current methods. This innovation would be especially valuable in high-risk cases and would improve appropriateness of case selection.

In summary, we propose ending quality assessment based mainly on procedural mortality. Instead, numerous, carefully selected factors associated with high-quality, disease-based outcomes would take its place. By supplementing operator reporting with random case reviews and using disease-based outcomes as benchmarks, a more accurate and actionable assessment of PCI quality can be expected.

ARTICLE INFORMATION

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