

**ACC CLINICAL COMPETENCE STATEMENT****Recommendations for the Assessment and Maintenance of Proficiency  
in Coronary Interventional Procedures****Statement of the American College of Cardiology\*****WRITING GROUP CHAIR**

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**I. Preamble**

The mission of the American College of Cardiology (ACC) is to foster optimal cardiovascular care through professional education, promotion of research, leadership in the development of standards and guidelines and the formulation of health care policy. Coronary angioplasty and other coronary interventional procedures are frequently performed therapeutic techniques for cardiac revascularization. In keeping with its mission, the College has a responsibility to develop standards for the performance of coronary interventional procedures that will assure the public of the availability of uniformly high quality services. This document has been developed for that purpose. It compiles and reviews the current scientific knowledge base and applies it to guidelines intended to optimize the quality of coronary interventional procedures.

This document addresses the issue of assessment and maintenance of proficiency both for individual physician-operators and for the institutions in which coronary interventional procedures are performed. This issue of training requirements will be addressed in a subsequent document.

**II. Executive Summary**

*Purpose and Goals*

The mission of the ACC is to foster optimal quality cardiovascular care through professional education, promotion of research, leadership in the development of standards and guidelines and the formulation of health care policy. This

document compiles and reviews the current coronary angioplasty knowledge base and applies it to guidelines intended to optimize the quality of coronary interventional procedures. It addresses the issue of maintenance of proficiency both for individual physician-operators and for the institutions in which coronary interventional procedures are performed. The issue of training requirements will be addressed in a subsequent document.

This document was developed to review the currently available scientific data with the following purposes:

1. To characterize the expected success and complication rates for coronary interventional procedures.
2. To identify comorbidities and other risk factors that may be used for risk adjustment when assessing particular success and complication rates.
3. To study the relation between operator and institutional activity level and proficiency in coronary interventional procedures.
4. To develop recommendations for standards to assess operator proficiency and institutional programmatic quality.

*Background*

Professional organizations have addressed the issue of standards and criteria for competence in coronary angioplasty since 1986, with an increasing focus on the issue of maintenance of competence and skills. These documents have universally endorsed an annual operator case load standard, most commonly 75 procedures/year, as a threshold value for main-

tenance of competence. This figure exceeds the median annual case load of physicians practicing interventional cardiology in the United States. The ACC's current position on these issues, which also advocates the 75-procedure/year standard, was published in 1993. Until recently, few published statistical data were available to assess the validity of such recommendations. As a consequence, these positions have been controversial. Recently, multiple publications analyzing large datasets have examined this relation, making a reexamination of the issue timely and appropriate.

### *Evolution of Coronary Angioplasty Techniques*

The capability and, concomitantly, the cognitive and technical knowledge base of coronary angioplasty has also expanded. As a result, success rates for coronary angioplasty have progressively improved despite an increase in procedural difficulty. In the past 5 years multiple non-balloon devices and adjunctive antithrombotic medications that augment and extend the capability of conventional balloon angioplasty have been introduced. To use these new interventional devices and medications effectively, an operator must acquire an additional cognitive knowledge base and master the additional technical skills. These and other changing factors have placed additional cognitive and technical demands on physician-operators while improving the overall success and complication rates of coronary interventional procedures. They have led to the extension of interventional treatment to higher risk patients with more complex coronary anatomy and comorbid disease.

The institution in which interventional procedures are performed has an important impact on procedural success. The physical facility must provide optimal radiologic, monitoring and patient support equipment to enable operators to perform at the best of their ability. An extensive support system of specifically trained laboratory personnel and immediately available cardiothoracic surgical, respiratory and anesthesia services is essential to respond to emergency situations to minimize their detrimental outcomes. In addition, the institution through its systems of credentialing, governance, data gathering and quality assessment monitoring provides important quality control over the entire interventional program.

The number of non-balloon devices is increasing, and they are often more demanding to use than conventional balloon technology and are often used in patients with more complex and riskier clinical circumstances. Consequently, proficiency in the use of these devices is device specific and must be differentiated from proficiency in conventional balloon angioplasty. The goals in using these devices must be kept in mind because they are most often used as an adjunct to conventional balloon angioplasty.

There are three groups of devices:

1. Devices that are used to extend the capability of conventional balloon angioplasty. Not all interventional cardiologists need to know how to use all the devices in this group

because these devices is used electively, with advance planning. Thus, the experience with these devices should be concentrated within each laboratory.

2. Devices used to treat complications of interventional procedures. The most common devices in this group are stents for treatment of abrupt or threatened closure. Every interventional cardiologist should be trained and certified in rescue stenting.
3. Devices used to prevent restenosis. This group of devices is limited to stents and directional coronary atherectomy (DCA), with stents being used most frequently.

### *Data Relating Operator and Institutional Experience and Activity to Outcome in Coronary Interventional Procedures*

Computerized literature searches of English language publications, review of recent abstract publications and solicitation of manuscripts under review for publication from many physicians and epidemiologists expert in the field were used to compile the relevant available scientific evidence relating operator and institutional activity level to outcomes.

Evaluation of the quality of individual lower volume hospitals and individual practitioners is limited by the wide confidence intervals around an estimate of risk of complications arising simply from the relatively few procedures from which to draw conclusions. This issue is more marked for individual practitioners whose annual procedural volumes are low compared with institutional volumes and is most marked for the lowest volume practitioners about whom the most questions concerning proficiency exist. This statistical power issue presents a major problem when attempting to make valid judgments of the quality of low volume programs and operators.

### *Relation of Institutional and Operator Procedural Volume to Procedural Outcome*

The preponderance of data suggest that, on average, hospitals in which fewer procedures are performed have a greater incidence of complications, notably death and need for bypass surgery for failed intervention, than do hospitals in which more procedures are performed. Multiple data sources support the existence of a curvilinear, perhaps logarithmic, statistical relation between caseload and outcome. The existence of this relation is most persuasively supported by the concordance of results from multiple sources, including the Society for Cardiac Angiography and Interventions and the most recent Medicare and New York State experiences. Consequently, concerns have been raised regarding the results of coronary interventions performed in hospitals with an annual volume of <200 to 400 cases/year.

However, procedural volume is only one of many factors contributing to the variability of measured outcomes. For an individual institution, however, such an impression must be tempered by the statistical imprecision of the estimate of risk. Furthermore, there is no clear "cutoff" above or below which

hospitals, or groups of hospitals in aggregate, perform well or poorly. There are institutions with low volumes that appear to achieve very acceptable results.

The same large data sets support the contention that there is, on average, an inverse relation between an individual operator's annual caseload and likelihood of complications. However, because of statistical power considerations, interpretation of these data is more difficult and complex than for hospital volume and outcome. The most compelling data that support a relation between volume and outcome come from the large, recently published analyses of the 1992 national Medicare experience and the 1991 to 1994 New York State experience. Both of these studies show a statistically significant, albeit modest, inverse relation, with the risk of death and emergency coronary artery bypass graft surgery (CABG) increasing as caseload falls below 75 to 100 cases/year.

Consequently, it appears highly likely that there is a statistical relation between individual operator procedural volume and outcome, such that lower volume operators tend to achieve less satisfactory results than higher volume operators. However, this relation is not universal. There are operators with annual caseloads lower than the previously defined ACC requirement for maintenance of competency of at least 75 cases/year who appear to achieve acceptable results.

The relation between individual operator volume and outcome is confounded by the fact that there may be an interaction between physician and hospital volume, such that results of lower volume operators in high volume institutions are generally more favorable than those achieved by low volume operators in low volume institutions.

### *Conclusions and Recommendations*

**General issues related to quality assessment.** The current interventional cardiology information base permits a number of broad general conclusions. Some are based on published statistical data; others are, by necessity, based on reasoned judgments:

1. Coronary interventional procedures are complex and technically demanding to perform. Optimal performance of these procedures requires an extensive cognitive knowledge base and substantial technical skill.

2. Complications of coronary interventional procedures, which may be life threatening, sometimes occur unpredictably. Optimal patient outcome, once a complication occurs, depends on proper recognition and management.

3. The most recently compiled comprehensive statistical data set (New York State 1991-1994) found overall death and emergency CABG rates for all types of coronary interventional procedures in all circumstances to be 0.9% and 3.0%, respectively. There is ample reason to believe that complication rates have decreased since those data were collected. Consequently, these rates represent an absolute upper limit for benchmark complication rates to be expected in a clinically stable population.

4. There are consistent statistical associations between operator and institutional activity levels and short-term complication rates (emergency CABG and mortality). There is also an interaction between the institutional program and the operator activity level in determining complication rates. The greatest complication rates occur when low volume operators perform procedures at low volume institutions.

5. The differences in the absolute magnitude of complication rates between low and high volume institutions and operators are small. In the New York State dataset, operators performing <75 procedures/year had mean mortality and CABG rates of 1.0% and 3.9%, respectively, whereas higher volume operators had mean mortality and CABG rates of 0.9% and 3.1%, respectively. That these differences are statistically significant is due to the large sample size.

6. The low expected complication rate for coronary interventional procedures presents a major statistical power problem when attempting to estimate the true complication rate of the low volume operator with statistically meaningful precision.

7. There are potential pitfalls in the use of complication rates to judge operator proficiency. Such monitoring may affect an operator's case selection and judgment in a way that might have an adverse impact on overall patient care.

**Benchmark complication rates for quality standards.** The best subgroups of operators and institutions in the New York State database achieved a mortality rate of 0.9% and an emergency CABG rate of 3%. With appropriate qualifications, these rates can serve as benchmark rates against which to judge operators and programs.

It should be emphasized that these data are derived from all percutaneous transluminal coronary angioplasty (PTCA) procedures, including those performed for acute myocardial infarction (MI) and cardiogenic shock. Thus, they overstate the risk of complications in clinically stable patients undergoing elective PTCA and understate the risk in high risk patients. Furthermore, these data were gathered before stents and platelet glycoprotein IIb/IIIa inhibitors were in widespread use. It is likely that the availability of these treatments has reduced the expected frequency of death and emergency CABG.

**Guidelines for institutions that offer coronary interventional services.** Institutions offering coronary interventional services should meet the following standards:

1. *Quality assessment monitoring.* It is essential that an institution have a rigorous privilege-granting and quality assessment monitoring system in place to assess the quality and efficacy of its overall program and its individual physician-operators.

2. *Institutional activity levels.* An institution should have an activity level of at least 400 coronary procedures/year. An institution with a volume of <200 procedures/year, unless in a region that is underserved because of geography, should carefully consider whether it should continue to offer the service.



3. *Coronary interventional program director.* An institution offering coronary interventional services should have a physician-director who is responsible for the program's overall quality. The director should be an experienced operator with a career experience of >500 procedures and should perform procedures at the facility that he or she directs. The director should be certified in the commonly used adjunctive interventional devices and should be certified in interventional cardiology by the American Board of Internal Medicine (ABIM) (once the ABIM Added Qualification Examination in Interventional Cardiology is in place).

4. *Facility equipment and staff requirements.* The facility should provide an optimal physical and intellectual infrastructure to support procedures. Radiologic equipment must provide high resolution fluoroscopic imaging with digital video processing to permit ready immediate review of high quality cineradiographic images. The nursing, technical and physician support staff must be experienced and able to respond readily to emergency and other unusual situations.

**Guidelines for physician-operators who perform coronary interventional procedures.** Physicians who perform coronary interventional procedures should meet the following standards:

1. *Quality assessment monitoring.* A physician-operator's proficiency should ultimately be judged by his or her clinical results. The procedural success and complication rates for all physician-operators should be rigorously compiled and periodically reviewed. The overall performance of physicians whose complication rates exceed the benchmark standards for any period should be reviewed by the program director, with careful attention to statistical power and risk adjustment issues. Interpretation of complication rates must carefully consider case-mix. Review of an operator's performance should be based on analysis of both current and cumulative quality assessment statistics.

2. *Operator activity levels.* An operator should perform at least 75 procedures/year to maintain optimal proficiency. Operators who perform 50 to 75 procedures/year should be very cautious in case selection. Their quality assessment statistics should be carefully reviewed with respect to case selection and outcome. Ideally, operators with an annual procedural volume <75 should only work at institutions with an activity level >600 procedures/year.

3. *Renewal of privileges.* Granting and renewal of privileges is the responsibility of the governance of the local health care institution. The privileges of operators whose complication rates exceed benchmark rates (currently 4% for combined death and emergency CABG) should be reviewed carefully, with particular attention to case-mix-based risk adjustment and statistical power issues. Consideration should be given to not renewing privileges if an operator's complication rate exceeds benchmark rates over a 2-year monitoring period.

4. *Mentoring of operators.* Operators who perform <75 procedures/year should develop a defined mentoring relationship with a highly experienced operator who has an annual procedural volume >150 procedures/year. The purpose of this

relationship is to ensure that the operator's patients can benefit from the skills and knowledge of a more experienced physician and to facilitate the operator's acquisition of additional sophistication and skills.

### III. Introduction and Purpose

It is now over 20 years since Andreas Gruentzig performed the first percutaneous coronary balloon angioplasty (PTCA) (1,2). During this period, coronary angioplasty has evolved from an investigational procedure to a widely practiced technique. In addition, several new non-balloon devices for coronary intervention have received Food and Drug Administration approval and are currently in active clinical use. It is estimated that in 1994, 428,000 coronary angioplasty procedures were performed in the United States by ~6,100 physicians (3). These physicians represent 40% of board-certified cardiologists in the United States.

Coronary balloon angioplasty is a complex, demanding procedure, and the newer non-balloon interventional devices present additional technical and cognitive challenges. To perform coronary interventional procedures optimally, an operator must possess both considerable technical skill and a substantial cognitive knowledge base. In addition, the technical difficulty of a particular procedure varies considerably from one patient to another. Consequently, as there can be variation both among procedures in technical difficulty and among operators in skill and cognitive knowledge, there is substantial potential for variation in procedure safety and efficacy. In addition, serious complications of coronary interventional procedures may occur unpredictably, even in procedures that appear to be straightforward. Recognition and management of complications is a complex discipline that requires skill, knowledge, experience and judgment.

Now that the technique of coronary intervention has matured and its role in the management of coronary heart disease has become clarified, there is a need for standards of proficiency and quality.

Credentialing physicians to perform procedures is the responsibility of the governance of the local health care facility. The Joint Commission on the Accreditation of Health Care Organizations requires that medical staff privileges be granted to applicants only after assessment based on professional criteria. Physicians are charged with the responsibility to establish the criteria that constitute professional competence and to evaluate their peers on the basis of such criteria. The U.S. health care system relies, in part, on this process of granting and renewing clinical privileges to maintain quality.

The issue of determining quality standards and credentialing criteria for physician-operators to perform coronary interventional procedures has presented a major challenge to the medical profession. The task of developing standards has been difficult because, until recently, there were few data available on which to base them and because coronary angioplasty techniques, indications and capability have evolved rapidly. During the past 9 years, a number of documents have been

published that have offered guidelines and standards for training and maintenance of competence (4-12). Because of the paucity of clinical data, the earlier standards were developed principally through observation, experience and intuition. These standards relied heavily on operator activity level as a surrogate for skill and quality. They proposed minimal threshold values both for training and experience and ongoing activity levels. The activity level thresholds incorporated into these standards were derived in part from the intuitive reasoning that to maintain skills and learn new techniques, an operator must perform procedures at a requisite frequency.

The most recent document published by the ACC was based on the information available in 1993 (6). The recommendations of this and other similar documents have been criticized as arbitrary and restrictive. This issue has great significance because it is estimated that currently as many as half of all physicians who perform coronary angioplasty have activity levels below the current guideline threshold of 75 procedures/year (3).

The present document was developed to review the currently available scientific data with the following purposes:

1. To characterize the expected success and complication rates for coronary interventional procedures when performed by highly skilled operators. These expected rates may change over time as instrumentation and technique improve and the reservoir of highly skilled operators increases.
2. To identify comorbidities and other risk factors that may be used for risk adjustment when assessing particular success and complication rates.
3. To study the relation between operator activity level and proficiency in coronary interventional procedures as assessed by risk-adjusted outcome statistics.
4. To study the relation between institutional activity level and success rates in coronary interventional procedures as assessed by risk-adjusted outcome statistics.
5. To develop recommendations for standards to assess operator proficiency and institutional program quality. These include standards for data collection to permit monitoring of effectiveness and appropriateness for coronary interventional procedures both at the level of the operator and the institution.

## IV. Method of Data Collection and Analysis

### A. Writing Group Composition

The document writing group was selected to bring a broad range of experience and expertise to bear on this issue. The members of the writing group were identified on the basis of one or more of the following attributes: highly experienced coronary interventional operators; individuals who have done clinical research studying the outcome of coronary interventional procedures; individuals who direct catheterization laboratories with a broad cross section of interventional operators; and individuals with broad clinical experience who have had considerable previous involvement with the issue.

### B. Literature Review

A literature search was conducted with three goals:

1. To identify published coronary angioplasty outcomes data that could be used as benchmarks for quality assessment. In addition, the process sought to identify those risk adjustment variables that affect the likelihood of success and complications. Such variables can be used for modeling both outcome and appropriateness. The review also focused on the impact of the newer interventional devices other than conventional balloon angioplasty.
2. To identify data that examine the relations between operator experience and activity and procedural success and complication rates.
3. To assess the issues and problems associated with judging operator proficiency based on outcome statistics—in particular, the challenge of accurately assessing the low volume operator's performance.

## V. Historical Background

### A. Evolution of Competence and Training Standards

Initially, because experience was limited, the coronary angioplasty technique was disseminated informally among physicians who were highly experienced at diagnostic cardiac catheterization. During this period, physicians acquired angioplasty skills through "on the job" experience, and no standards existed either for training requirements or for demonstration of competence.

As the coronary angioplasty knowledge base grew and techniques evolved, standards were developed for training. Formal angioplasty training programs were first organized in the early 1980s. Proposals for training standards were first published in 1986 (4). The most recent recommendations were published by the ACC in 1995 (11). The specialized nature of coronary angioplasty was recognized by the ABIM in 1996 with its decision to develop an Added Qualification Examination in Interventional Cardiology.

Professional organizations have addressed the issue of standards and criteria for proficiency in coronary angioplasty since 1986, with an increasing focus on the issue of maintenance of proficiency and skills (4-12). These documents have universally endorsed an annual case load standard as a threshold value for maintenance of proficiency. The most commonly endorsed activity level has been 75 procedures/year, a figure that exceeds the median annual case load of physicians practicing interventional cardiology in the United States. Until recently, few published statistical data were available to assess the validity of such recommendations. As a consequence, these positions have been controversial.

Three issues have been raised concerning previously published guidelines:

1. Volume is not absolutely related to quality.

**Table 1.** Changes in Percutaneous Transluminal Coronary Angioplasty Practice and Outcome

| Variable             | Study (ref no.) |               |           |           |           |
|----------------------|-----------------|---------------|-----------|-----------|-----------|
|                      | NHLBI-I (20)    | NHLBI-II (21) | MAPS (22) | BARI (23) | MCD (22)  |
| Years of entry       | 1977-1981       | 1985-1986     | 1991      | 1989-1992 | 1990-1994 |
| No. of patients      | 1,155           | 1,802         | 200       | 915       | 3,787     |
| New device use       | No              | No            | Yes       | No        | Yes       |
| Baseline factors     |                 |               |           |           |           |
| Mean age (yr)        | 54              | 58            | 62        | 62        | 61        |
| Women                | 25%             | 26%           | 28%       | 27%       | 32%       |
| Unstable angina      | 37%             | 49%           | 52%       | 63%       | 63%       |
| Multivessel disease  | 25%             | 53%           | 100%      | 100%      | 51%       |
| Angiographic success | 68%             | 91%           | 92%       | 88%       | 89%       |
| Clinical success     | 61%             | 78%           | 90%       | 80%       | 87%       |
| Complications        |                 |               |           |           |           |
| Death                | 1.2%            | 1.0%          | 1.0%      | 1.1%      | 0.9%      |
| Q wave MI            | 4.9%            | 4.3%          | 1.5%      | 2.1%      | 1.0%      |
| Emer. CABG           | 5.8%            | 3.4%          | 1.0%      | 6.3%      | 1.4%      |

BARI = Bypass Angioplasty Revascularization Investigation; Emer. CABG = emergency coronary bypass graft surgery; MAPS = Multivessel Angioplasty Prognosis Study; MCD = multicenter database; MI = myocardial infarction; NHLBI = National Heart, Lung, and Blood Institute; ref = reference.

- The numbers chosen have no solid basis.
- If volume is the criterion, physicians with marginal numbers will be prompted to alter case selection criteria to increase their volume to satisfy requirements.

### B. Evolution of Coronary Angioplasty Capabilities

Coronary angioplasty's capability and, concomitantly, its cognitive and technical knowledge base has also expanded. The fundamental concepts of coronary angioplasty technique, namely the coaxial guide catheter and the dilation catheter with a minimally compliant cylindrical balloon were formulated by Andreas Gruentzig (13). Initially, because of crude equipment design and capability, coronary angioplasty was only applicable to readily accessible discrete proximal coronary stenoses. Subsequent instrumentation refinement has greatly enhanced the technique's capability and extended its indications. Complex anatomic situations now considered technically suitable for coronary angioplasty include distal and bifurcation stenoses; total occlusions (14); saphenous vein graft stenoses (15); and geometrically complex stenoses, such as the ACC/American Heart Association (AHA) lesion score (7) types B and C. Challenging clinical situations now considered appropriate for coronary angioplasty include unstable angina (16,17), acute MI (18,19) and high risk situations in which the only remaining patent coronary vessel is treated.

In the past 5 years, other non-balloon devices, including directional, rotational and laser atherectomy devices, and coronary stents have been introduced. These devices augment conventional balloon angioplasty and extend its capability. To use any of the new interventional devices effectively, an operator must acquire the additional cognitive knowledge base and master the additional technical skills specific to that device.

Recently, a number of adjunctive antithrombotic medica-

tions have been introduced for the purpose of reducing acute thrombus-related lesion site complications. Understanding the appropriate indications for and uses of these medications, which are powerful anticoagulants, requires a specialized cognitive knowledge of hemostatic mechanisms.

More recent clinical studies have demonstrated that despite a further increase in clinical and angiographic complexity, procedural and clinical success has remained high and complications low (Table 1) (20-24). Since the National Heart, Lung, and Blood (NHLBI) II registry data were collected, the average age has increased to >60 years, a higher percentage of women now undergo the procedure, and the majority of patients have unstable angina and multivessel coronary disease. Angiographic success (at least one lesion successfully dilated by >20%, with a residual stenosis of <50%) occurs in nearly 90% of patients with an average mortality rate of 1%, a Q wave MI rate of 1% to 2% and an emergency CABG rate of 1% to 6%. With the widespread use of coronary stents, complications have fallen further, and emergency CABG appears to be no greater than 1% to 2% currently. Thus, in contemporary practice it should be expected that the overall procedural success be at least 90%, clinical success at least 85%, death <1%, Q wave MI <1.5% and emergency CABG <2%.

## VI. Complications of Coronary Interventional Procedures

An adverse event related to a coronary angioplasty procedure may be categorized either by the mechanism of the complication or by the adverse outcome event caused by it. A given adverse event, such as death, may be caused by a variety of complications.

Complications can be divided into three mechanistic categories:

1. **Coronary vascular injury.** Although the angioplasty process produces a controlled vascular injury, on occasion, the treated site's response to the intervention fails to achieve a stable patent result. Catheter-induced coronary vascular injury can also occur at sites remote from the target site, and embolization of thrombotic or atherosclerotic material can originate either from the catheters or from the coronary vessels.

2. **Other vascular events.** Other vascular events are caused either by injury to a noncardiac vessel by catheter insertion and manipulation or by embolization of thrombotic or atherosclerotic material.

3. **Systemic nonvascular events.** Systemic nonvascular events are adverse events caused by the procedure but not due to vascular injury. They include all the systemic hazards of cardiovascular X-ray angiographic procedures, including contrast agent-induced adverse events. The two most prominent events are contrast agent-induced nephropathy and acute pulmonary vascular congestion.

Complications may be divided into six basic outcome categories:

1. **Death:** related to the procedure, regardless of mechanism
2. **MI:** related to the procedure, regardless of mechanism
3. **Emergency CABG:** either as a result of procedure failure or a procedure complication
4. **Vascular access site complications**
5. **Stroke**
6. **Contrast agent nephropathy**

Because adverse events are hard end point outcome events, they are easily recognized and captured for statistical summary purposes. The ACC, through its database program, has developed a comprehensive data dictionary of recognized adverse events with rigorous definitions (25). It may be possible to determine conclusively whether death or a complication was caused by a procedure. Nonetheless, for the purposes of monitoring performance, a rate of complications or deaths substantially above that expected, after adjustment for patient risk factors, is cause for concern about poor quality.

## VII. Patient, Lesion and Institutional Variables Influencing Success and Complication Rates

A number of changing factors have improved the overall success and complication rates of coronary interventional procedures. These include increased operator experience, improvements in conventional instrumentation (balloon catheters, guide catheters, guide wires), newer interventional devices (stents, atherectomy devices) and newer adjunctive pharmacologic therapy. Concurrently, these improvements

have also led to the extension of interventional treatment to higher risk patients with more complex coronary anatomy and comorbid disease. These factors together have influenced overall acute and long-term outcome associated with coronary interventional procedures.

### A. Measures/Definitions of Success

1. **Anatomic success.** This definition focuses exclusively on the enlargement of the lumen at the target site. Although there has been disagreement over the definition of a qualifying increase in minimal lumen diameter, the current consensus definition is the achievement of a minimal stenosis diameter reduction to <50% (assessed by angiography) (7). There frequently is a disparity between the visual assessment of lumen diameter and computer-aided quantitative measurement (26,27). This disparity potentially makes the determination of this important measure problematic, particularly when success rates are self-reported.

2. **Procedural success.** Procedural success may be defined as the achievement of anatomic success without major complication (death, MI, emergent CABG) (7,20). Although the occurrence of emergent CABG and death are easily identified end points, the definition of periprocedural MI has been more problematic. Some definitions require the development of Q waves in addition to a threshold value for creatine kinase (CK) elevation. However, more recent reports have identified non-Q wave MIs with CK elevations three to five times the upper limit of normal as having clinical significance (28).

3. **Short-term clinical success.** Short-term clinical success requires, in addition, to procedural success, the successful relief of signs or symptoms, or both, of myocardial ischemia after the patient recovers from the procedure.

4. **Long-term clinical success.** Long-term clinical success requires that the short-term clinical success remains durable and that the patient has persistent relief of signs and symptoms of myocardial ischemia for >6 months after the procedure. Restenosis is the principal cause of lack of long-term clinical success when a short-term clinical success is achieved. The frequency of clinically important restenosis may be judged by the frequency with which subsequent revascularization procedures are performed after the index procedure.

### B. Patient and Lesion Characteristics Related to Procedural Success and Complication Rates

Angioplasty procedural success and complication rates are heavily influenced by a variety of patient and target lesion characteristics. These variables must be taken into consideration through risk adjustment when assessing adverse event rates. In addition, they must also be weighed in determining procedure appropriateness.

1. **Patient clinical characteristics.** Several studies have reported specific clinical factors to be associated with an increased risk of an adverse outcome after balloon angioplasty.



**Table 2.** Multivariate Predictors of Procedural Success\* in 3,706 Patients

| Variable                              | OR (95% CI)       | P Value |
|---------------------------------------|-------------------|---------|
| Modified ACC/AHA lesion score B2 or C | 0.65 (0.52, 0.80) | 0.000   |
| Modified ACC/AHA lesion score C       | 0.67 (0.52, 0.86) | 0.002   |
| Previous restenosis                   | 1.37 (1.01, 1.87) | 0.045   |
| Age > 80 yr                           | 0.61 (0.37, 1.00) | 0.051   |

\*Data from Ellis et al. (29). ACC/AHA = American College of Cardiology/American Heart Association; CI = confidence interval; OR = odds ratio.

These include advanced age, female gender, unstable angina, congestive heart failure and multivessel coronary disease (29-32). The Bypass Angioplasty Revascularization Investigation (BARI) trial (23) found diabetes mellitus in patients with multivessel disease to be associated with increased periprocedural ischemic complications and increased mortality over 5 years compared with patients without diabetes or patients with diabetes undergoing CABG. Patients with impaired renal function, particularly diabetic patients, are at increased risk for contrast agent nephropathy (33).

**2. Target lesion anatomic factors.** Numerous studies have identified particular lesion morphologic characteristics and the absolute stenosis severity as predictors of immediate outcome during coronary angioplasty (29,30). Features such as lesion eccentricity, angulation, length and presence of thrombus have been independently associated with abrupt vessel closure and major ischemic complications. On the basis of these observations, the ACC/AHA task force (5) proposed a classification scheme based on lesion morphology to estimate the likelihood of procedural success and complications. This scheme was subsequently modified by other investigators (29) but has served as a useful guide for assessing the risk of an adverse outcome associated with a particular lesion. However, more recent experience suggests that improved devices and techniques have improved success rates in more complex lesions (34,35). As a result, lesion morphology may be a less important predictor of complications currently than it has been in the past.

### C. Strategies for Risk Stratification

Several large retrospective studies of patients undergoing coronary angioplasty have identified both clinical and angiographic characteristics that correlate with procedural success as well as in hospital morbidity and mortality. The independent predictors of procedural success and major complications during coronary angioplasty noted in these studies are shown in Tables 2 and 3. These observations have been used to develop multivariate logistic regression models that can stratify patients into risk groups before the procedure (20,29-32).

### D. Impact of the Facility on Procedural Success

**1. Physical facility requirements.** The physical facility in which interventional procedures are performed has an impor-

**Table 3.** Multivariate Predictors of Complications\* During Coronary Angioplasty

| Study (ref no.) and Variable   | OR (95% CI)        | P Value |
|--------------------------------|--------------------|---------|
| Kimmel et al. (32), 10,622 pts |                    |         |
| Age                            | 1.01 (1.00, 1.03)  | < 0.05  |
| Acute MI within 24 h           | 2.20 (1.25, 3.86)  | < 0.01  |
| Geographic region              |                    |         |
| Northeast                      | 1.00               |         |
| South                          | 1.51 (1.03, 2.21)  | < 0.05  |
| West                           | 4.64 (1.99, 10.8)  | < 0.001 |
| LMCA attempted                 | 5.91 (2.36, 14.8)  | < 0.001 |
| Multivessel disease            | 1.59 (1.03, 2.45)  | < 0.05  |
| Previous CABG                  | 0.50 (0.25, 0.98)  | < 0.05  |
| Shock                          | 4.11 (2.13, 7.92)  | < 0.001 |
| Unstable angina                | 1.54 (1.17, 2.03)  | < 0.001 |
| Type C lesion                  | 1.67 (1.13, 2.46)  | < 0.001 |
| Ellis et al. (29), 4,860 pts   |                    |         |
| LVEF < 0.40%                   | 2.63 (1.70, 4.06)  | 0.000   |
| Modified ACC/AHA type C lesion | 2.50 (1.55, 4.02)  | 0.000   |
| AMI                            | 4.31 (1.60, 11.64) | 0.005   |
| Shock                          | 7.47 (1.37, 40.74) | 0.020   |
| Previous CABG                  | 0.53 (0.28, 1.02)  | 0.059   |
| Prior restenosis               | 0.53 (0.27, 1.03)  | 0.061   |

\*Death, myocardial infarction, emergency coronary artery bypass graft surgery. LMCA = left main coronary artery; LVEF = left ventricular ejection fraction; pts = patients; other abbreviations as in Tables 1 and 2.

tant impact on procedural success. The facility must provide optimal radiologic, monitoring and patient support equipment to enable operators to perform at the best of their ability. Radiologic imaging equipment must provide optimal live video and film image quality to facilitate accurate catheter and device placement and to enable proper assessment of procedure results (8). Physiologic monitoring equipment must function to provide continuous, accurate information about the patient's condition. Requisite support equipment must be available and in good operating order to respond to whatever emergency situations may arise.

**2. Overall institutional system requirements.** The interventional laboratory does not function in a vacuum. An extensive support system of specifically trained laboratory personnel and immediately available cardiothoracic surgical, respiratory and anesthesia services is essential to respond to emergency situations to minimize their detrimental outcomes. In addition, the institution through its systems of credentialing, governance, data gathering and quality assessment monitoring provides important quality control over the entire interventional program.

## VIII. Non-Balloon Devices for Coronary Interventions

There are an increasing number of devices that can be used to enhance the results of percutaneous coronary revascularization. Some of these are alternative stand-alone devices, but the majority require balloon dilation either before, during or after

**Table 4.** Non-Balloon Devices and Indications for Use

| Device or Procedure* | Planned Procedure† | Unplanned Procedure‡ |
|----------------------|--------------------|----------------------|
| Stents               | Stents             | Stents               |
| DCA                  | DCA                | DCA                  |
| Rotablator           |                    |                      |
| TEC                  |                    |                      |
| Laser                |                    |                      |

\*Used to extend percutaneous revascularization to a wider number of patients and lesions. †Prevention of restenosis. ‡Treatment of complications of interventional procedures. DCA = directional coronary atherectomy; TEC = transluminal extraction atherectomy.

their use to fully optimize the final result. The specific utility of these new devices is constantly changing as operator experience and technological improvements occur and as a result of refinements in an understanding of their indications based on results of single and multicenter registries and randomized trials.

### A. Classification of Non-Balloon Devices

One conceptual framework for categorizing these newer devices divides them into three categories (Table 4): 1) those that can be used to extend the application of percutaneous procedures to lesion or patient groups that are usually considered to be treated suboptimally by conventional dilation technology; 2) those that are used to treat complications of percutaneous revascularization; and 3) those that can be used to prevent restenosis. New devices continue to be added to each of these categories. Some devices fall into more than one group, such as stents, which are commonly used for all three indications.

**1. Devices that extend application of percutaneous revascularization.** This is the largest category of devices and includes stents, rotational atherectomy, DCA, transluminal extraction atherectomy (TEC) and laser atherectomy. The use of these devices is predicated on the concept that specific angiographic lesion characteristics are associated with suboptimal results with conventional balloon angioplasty. This concept forms the basis for the modified ACC/AHA classification (5). Some of the lesion characteristics that are associated with increased complications include old vein graft lesions, ostial lesions, diffuse disease and total chronic occlusion (30,36-39). Because the use of these non-balloon devices is often elective, not every operator needs to be trained in the performance of all devices in this category. Non-balloon devices have been demonstrated to improve the acute angiographic and clinical results in these situations (40-46); however, even with adverse lesion morphology, conventional dilation may still yield an excellent result and may continue to improve with development of new catheter technology.

**2. Devices used to treat complications of interventions.** In contrast to the devices that are used electively to extend the application of percutaneous intervention and do not need to be

learned by all interventional cardiologists, all interventionalists need to be able to react to salvage a failed angioplasty procedure. The most common complication treated is coronary dissection and subsequent acute or threatened closure (30,47,48). Stents are most commonly used to treat these complications, although DCA may also play a role. Other less frequent complications include perforation or atherothromboembolism (49). Thus, competence in stent placement is a required skill for all interventional cardiologists.

**3. Devices used to prevent restenosis.** Coronary stents have been shown to reduce restenosis in selected patients with primary stenoses in large native coronary arteries (50,51). Recent studies have documented that DCA also reduces restenosis (52). Although both devices can reduce restenosis in selected patients, it has yet to be shown that they are effective in less favorable anatomic situations. Given the improvement in outcome with stents and DCA in selected patients, it can be argued that all interventional cardiologists should have access to them. Not all interventionalists need to be able to perform DCA themselves because its use is generally elective. However, each facility should have interventionalists trained in DCA.

### B. Competence in Non-Balloon Devices

**1. Specific cognitive and technical skills required.** Each operator utilizing the newer interventional devices must be experienced with conventional balloon PTCA. Given the different technical skills and clinical application of each device, the specific cognitive and technical skills for the newer devices vary substantially. Some of the non-balloon procedures, such as DCA and rotational atherectomy, are complex and require additional skills because the procedure is significantly different than conventional PTCA. DCA utilizes large devices and requires more technical skill and experience in selective cutting and knowledge to determine when optimal tissue removal has been achieved. Rotational atherectomy requires technical skill to prevent complications, such as dissection, no reflow and hemodynamic compromise, which are usually not seen with conventional PTCA. Other devices also have their own technical considerations, such as saline flushing with laser and minimizing of distal embolization with TEC. Stents are technically easier to use but still have unique potential problems, such as inadequate expansion of the stent, side branch occlusion by the stent and device movement. Current stent technology available in other countries makes these problems considerably less formidable. Finally, the adjunctive medications required may vary among devices, including, among others, newer antiplatelet agents, which may not be routinely required for conventional PTCA.

**2. The learning curve and obtaining and maintaining competence.** The learning curve includes both cognitive and technical aspects. Appropriate patient and lesion selection is essential to optimize outcome. As previously mentioned, the initial requirement is demonstrated competence and experience with conventional balloon PTCA. Participation in educational programs devoted to the specific device is also necessary.

**Table 5.** Role and Performance of Specific Non-Balloon Devices

| Device or Procedure | Indication* | For Use By                                    | Alternative to Use                                      |
|---------------------|-------------|---|---|
| Stents              | 1, 2, 3     | Required for all interventional cardiologists | Perfusion balloon, CABG                                 |
| Rotablator          | 1           | Selected experienced interventionalists       | Patient referral, mentor/proctor, CABG, alternative Rx  |
| DCA                 | 1, 2, 3     | Selected experienced interventionalists       | Patient referral, stent placement, mentor/proctor, CABG |
| TEC                 | 1           | Selected experienced interventionalists       | Patient referral, mentor/proctor, alternative Rx        |
| Laser               | 1           | Selected experienced interventionalists       | Patient referral, mentor/proctor, CABG, alternative Rx  |

\*1 = extend application of treatment to a wider number of lesions; 2 = treatment of complications; 3 = prevention of restenosis. Rx = therapy; other abbreviations as in Tables 1 and 3.

These programs should specifically address technical details of device performance, patient selection, risks/complication management and adjunctive treatment. Finally, performing the new procedure with the assistance of an experienced operator/mentor highly skilled in the procedure is essential.

**3. Maintenance of competence.** After initial training, maintenance of competence is critically important. The number of cases required for maintenance of competence depends on the operator's overall experience as well as the complexity of the procedure. More complex procedures using non-balloon devices require a greater level of continued experience. Every attempt should be made to concentrate the experience of these more complex and less frequently performed procedures in the hands of a small number of higher volume interventionalists. Maintenance of competence should require that patient outcome be determined longitudinally for each procedure by the institution's quality assessment program, which includes performance evaluation and feedback to the operator.

### C. Role of and Indications for New Devices Compared With Other Technology

The role of non-balloon devices continues to evolve as experience grows and technology improves (Table 5). These devices are often more demanding to use than conventional balloon technology and are often used in patients with more complex and riskier clinical circumstances. The goals in using these devices must be kept in mind because they are most often used as adjuncts to conventional balloon PTCA. The ability to use stents to treat acute or threatened closure is an essential skill for all interventional cardiologists. Other procedures, such as DCA and rotational atherectomy, can be used as part of a preplanned strategy. Thus, not all interventionalists need to be trained to use these devices. In such circumstances, if a physician is not trained with one of these types of devices, the patient can be transferred, an alternative approach selected, or

a colleague with greater experience can be called on to assist. This mentoring approach is particularly valuable with non-balloon devices, where rapidly changing technology and highly selected indications make it impossible for all interventionalists to be adequately skilled to perform an optimal procedure.

## IX. Components of Operator Competence and Skill in Coronary Interventional Procedures

### A. Cognitive Knowledge Base

The cognitive knowledge needed to perform coronary intervention has been addressed previously by expert panels and independent authors (4-7,9-11,53). This core knowledge along with certain technical skills, will be evaluated in the future by the Added Qualification Examination Interventional Cardiology of the ABIM. It is the consensus of the authors of this and earlier reports that a competent operator must have a knowledge of the anatomy, physiology and pathophysiology of the heart and of the coronary and systemic circulation. A particular requirement is an in-depth understanding of the interactions of these entities with left ventricular dysfunction and acute myocardial ischemia and infarction.

The pivotal role of blood coagulation and vascular biology in coronary artery disease makes it essential that operators have a thorough understanding of those elements of coagulation, atherosclerosis and vascular repair that relate to the pathogenesis and treatment of stable and unstable ischemic syndromes. Of particular importance is an understanding of the physiology, pharmacology and potential value of antiplatelet, antithrombin and thrombolytic agents because they are used frequently in coronary interventional procedures. Specific knowledge of the treatment of bleeding complications related to these agents is necessary. Knowledge of the results of observational and randomized trials that have evaluated these agents is essential to guide their application.

Competent operators must have knowledge of the indications for percutaneous coronary intervention, medical therapy and operation in the broad spectrum of patients with coronary disease. This knowledge should be based on an in-depth understanding of published clinical trials (both randomized and observational of treatment strategies in coronary artery disease, including comparisons of coronary angioplasty with surgical and medical therapy; comparisons of conventional coronary angioplasty with DCA stents and other devices; comparisons of direct coronary angioplasty with thrombolytic therapy as the primary therapy in acute MI; and the role of coronary angioplasty as a treatment for recurrent ischemia and other clinical problems after MI. This knowledge, supported by personal clinical experience, enables the rational selection of patients to be treated with percutaneous intervention. It also guides the selection of the optimal procedure strategy based on specific anatomic and clinical features, with the aim of achieving myocardial revascularization that is safe, effective, as durable as possible and cost-effective.

A knowledge of contraindications to percutaneous intervention is essential. Among those patients in whom coronary intervention is, in general, contraindicated are patients with left main coronary disease who are candidates for coronary bypass and asymptomatic patients with critical stenoses in relatively unimportant coronary arteries or with noncritical stenoses.

To perform coronary intervention competently, physicians must have a thorough knowledge of the specialized equipment used, including 1) the theoretical and practical aspects of X-ray imaging, radiation physics and safety (use of image intensifiers and other equipment to generate digital images, quality control of images, image storing, consequences of exposure of patients and personnel to ionizing radiation and methods of reducing their exposure); 2) a working knowledge of catheterization laboratory equipment (physiologic data recorders, pressure transducers, blood gas analyzers, defibrillators); and 3) a thorough knowledge of supplies and devices used in coronary intervention, including catheters, guide wires, balloon catheters, stents, atherectomy devices, ultrasound catheters, intraaortic balloon pumps, puncture site sealing devices and contrast agents.

Operators must have an in-depth knowledge of procedural complications, including their prevention, prompt recognition and treatment. In addition to coronary dissection and abrupt closure, knowledge of a number of "new" complications and insights is essential. These include coronary perforation related to ablative devices and stents, slow and no reflow due to microembolization or macroembolization or microcirculation alterations, the importance of prevention of non-Q wave MI, the hemorrhagic complications of newer and more potent antithrombotic agents, the prevention and management of peripheral vascular complications (expanding hematoma, pseudoaneurysm, arteriovenous fistula), the recognition and treatment of embolic and hemorrhagic stroke and the prevention of contrast agent-induced nephropathy.

For informed consent, a basic patient right, to be exercised and documented, it is essential that interventional operators have a clear understanding and ability to communicate the risk, potential benefits, treatment alternatives and results of percutaneous intervention to the patient, his or her family, to the medical record and to others involved in the care of the patient.

### **B. Technical Skills**

As in any surgical procedure, percutaneous coronary artery revascularization requires that the operator possess certain requisite technical skills. Many of the skills are closely related to those needed to perform diagnostic cardiac catheterization and coronary angiography. These include a degree of manual dexterity and the ability to maintain sterile surgical technique and to obtain percutaneous arterial and venous access.

Most of the other required technical skills are unique to coronary interventional procedures and can only be acquired by training in actual procedures under the direction of an

experienced interventionalist. These include the manipulation and operation of guide catheters, coronary angioplasty guide wires, coronary angioplasty balloon catheters, atherectomy devices, stents, intracoronary ultrasound catheters and other intracoronary devices. Because there is a substantial variation from procedure to procedure in the nature of device manipulation maneuvers, the interventionalist must be exposed to a comprehensive mix of simple and complex cases.

Operators must have the technical skill to perform procedures necessary to diagnose and treat complications of coronary intervention that are frequently life threatening if not treated in a precise and timely fashion. These include placement of coronary perfusion catheters, intraaortic balloon pumps, cannulation for percutaneous cardiopulmonary bypass and emergent placement of stents to stabilize an angioplasty site that exhibits abrupt or threatened closure.

Because adverse events occur rarely, operator competence requires specific training and ongoing experience in managing them so as to be prepared to react optimally when they occur. In the training phase and subsequently, it is desirable to use supplemental case studies of the technical management of infrequent but serious complications of these procedures.

## **X. Determinants of Appropriateness in Coronary Interventional Procedures**

Judgment of the overall quality of an interventional cardiology program and individual physician-operators must also consider procedure appropriateness. The ability to perform a given procedure successfully without acute complications does not necessarily mean that the procedure was appropriate.

The ultimate determinant of the appropriateness of a cardiovascular therapy is whether it has the optimal beneficial impact on long-term patient outcome. Because coronary intervention is one of several potential treatment options available, its appropriateness to a particular patient's clinical situation is determined by what it can achieve compared with alternative treatment strategies, such as surgical revascularization and medical therapy.

A number of elements contribute to determining the appropriateness of a coronary interventional procedure. These include

1. *The likelihood of the procedure's short-term success* is determined principally by anatomic characteristics of the target lesion or lesions. The determinants of likelihood of procedural success are discussed in detail in Section VIIB. The target lesion's anatomic characteristics influence the technical difficulty of executing the procedure and the likelihood that the lesion will respond appropriately to the intervention. The likelihood of success is also heavily influenced by the particular physician-operator's technical skill, cognitive knowledge and selection of the particular interventional technique.

2. *The likelihood and potential consequences of procedural failure and complications* determine the risk of the procedure.



They are determined by the patient's overall clinical condition, the anatomy of the patient's coronary artery disease and ventricular function.

3. *The likelihood that a successful procedure will achieve a durable long-term result.* The principal deficiency of coronary interventional procedures is restenosis. The lesion attributes that determine the likelihood of restenosis are well characterized. The appropriateness of interventional treatment for a lesion that has an extremely high likelihood of recurrence is questionable if alternative treatment strategies exist.

4. *The relative efficacies of alternative treatment strategies.* For a particular patient it is important first to consider the relative benefit of a revascularization treatment strategy as opposed to a purely pharmacologic approach. A revascularization treatment strategy is appropriate if it provides a clinically important long-term benefit in terms of symptoms or survival superior to that which can be achieved by pharmacologic therapy. If revascularization is the optimal treatment strategy, it is then important to consider the relative benefits of interventional versus surgical approaches. These judgments are influenced by the relative likelihoods of long-term success, complications and the associated morbidities that accompany alternative procedures.

Consequently, in a number of circumstances, short-term outcome statistics may fail to disclose the inappropriateness of coronary interventional procedures and, accordingly, do not fully assess overall operator proficiency and clinical judgment. For example,

1. An overly conservative or cautious physician might restrict case selection to patients with a straightforward anatomic situation. Such selection criteria will optimize short-term procedural outcome statistics, suggesting that the physician is a skilled, proficient operator. However, these conservative selection criteria may deny the potential benefits of interventional therapy to other patients with more complex, challenging clinical and anatomic situations who might benefit from it.

2. An aggressive physician may perform interventional procedures in patients with relatively mild coronary disease who would be expected to do well with pharmacologic therapy alone. This strategy also yields excellent short-term outcome statistics but subjects patients to marginally indicated procedures.

3. A physician may select lesions with an extremely high probability of restenosis for interventional treatment. Although short-term outcome statistics may be excellent, a frequency of high restenosis may cause long-term benefit to the patients to be minimal or absent.

4. An aggressive physician may choose to perform interventional procedures in complex, seriously ill patients with extensive coronary disease, who either are candidates for surgical revascularization or are poor candidates for any revascularization procedure. This case selection strategy jeopardizes patients both by subjecting them to a substantial procedural risk and by failing to offer surgical revascularization where appropriate.

## XI. Data Relating Operator and Institutional Experience and Activity to Outcome in Coronary Interventional Procedures

### A. Evidence Reviewed

Computerized literature searches of English language publications, review of recent abstract publications and solicitation of manuscripts under review for publication from many physicians and epidemiologists expert in the field were used to compile the relevant available scientific evidence relating operator and institutional activity level to outcomes (Table 6 and 7). In general, greater weight was given to recent, fully peer-reviewed publications of high quality. No single work was considered definitive. It was recognized that many analyses were limited to some extent by an incapacity to fully adjust expected outcomes for differences in patient characteristics, by questionable generalizability and by changes and advances in the field of interventional cardiology. From the standpoint of statistical validity, it needs to be recognized that studies attempting to correlate hospital or physician experience with a relatively uncommon complication, such as death or unplanned bypass surgery, need to study 200 to 400 hospitals or physicians to have adequate power to detect the type of modest relation that has been suggested by the largest studies of this issue. For example, to have 90% power to detect a correlation with  $r = 0.17$  at  $p = 0.05$ , ~300 evaluatable units are required (Solo Power Analysis 1.0, BMDP Statistical Software). Many published studies are vastly underpowered. In the absence of clear-cut data, a general consensus of the expert physician panel was sought.

### B. Relation of Institutional Volume to Procedural Outcome

The preponderance of data suggest that, on average, hospitals in which fewer coronary interventions are performed have a greater incidence of procedure-related complications, notably death and need for bypass surgery for failed intervention, than do hospitals performing more procedures. Multiple data sources support the existence of a curvilinear, perhaps logarithmic, statistical relation between caseload and outcome (Table 6). Ritchie et al. (54) were the first to report this relation and analyzed administrative datasets from 24,883 interventions performed at 110 nonfederal California hospitals during calendar year 1989. The patients were classified according to whether they presented with the principal diagnosis of acute MI. In both groups, a strong statistical relation ( $p < 0.001$ ) was found when the rates of bypass surgery or death, or bypass surgery alone, between hospitals classified as low ( $\leq 200$  cases/year), intermediate (201 to 400 cases/year) or high volume ( $> 400$  cases/year) were compared. For example, the incidence of the combined end point of bypass surgery or death for patients with an acute MI in the low, intermediate and high volume hospitals was 12.4%, 10.0% and 8.3%, respectively. For patients not presenting with an acute MI, these rates were 6.3%, 4.7% and 4.4%, respectively. However, there were no statisti-

**Table 6.** Published Data Relating Hospital Coronary Angioplasty Volume to Complication Rates

| Study (ref no.)                             | Data Source                           | No. of Pts/<br>Hospitals Studied | Conclusion   | Comment  |
|---|---------------------------------------|----------------------------------|--|--|
| Hartz et al. (64)                           | 1989-1991 Wisconsin Medicare          | 2,091/16                         | No relation between volume and outcome   | Very low number of cases and hospitals examined              |
| Ritchie et al. (54)                         | 1989 California State (Adm)           | 24,883/110                       | Increased CABG (not death) < 200 cases/yr; finding is valid for both acute MI and non-acute MI pts   |  |
| Jollis et al. (55)                          | 1987-1990 MEDPAR (Adm)                | 217,836/1,194                    | Death and CABG inversely related to low volume (risk increases with Medicare pt volume* (< 100-200 total/yr for death, < 200-300/yr for CABG)) |  |
| Kimmel et al. (59)                          | 1992-1993 SCA&I                       | 19,594/48                        | Fewer major complications for labs with > 400 cases/yr   | Able to risk adjust more completely than most other analyses |
| GUSTO (IIb) Angioplasty Substudy Group (19) | GUSTO IIb trial                       | 565/59                           | No difference, 200-625 vs. > 625 cases/yr. for acute MI pts  | All operators > 50 cases/yr                                  |
| Kato and Carter (57)                        | 1991 HCFA (RAND Corp.)                | 113,576/862                      | Except for Medicare volume* < 50, higher volume hospitals had higher mortality rates   |  |
| O'Neill et al. (65)                         | PAMI II trial                         | 1,100/34                         | No difference, < 500, 501-1,000, > 1,000 cases/yr for acute MI pts   |  |
| Jollis et al. (3)                           | 1992 Medicare (Adm)                   | 97,498/984                       | Incremental decrease in death+bypass surgery as hospital Medicare volume* < 100, 100-200, ≥ 200/yr   |  |
| Tiefenbrunn et al. (66)                     | Second National Registry of MI (U.S.) | 4,939/?                          | Increased acute MI mortality for hospital < 25 acute MI cases/yr   |  |
| Hannan et al. (56)                          | 1991-1994 NY State                    | 62,670/31                        | Death alone and same-stay CABG increased with annual caseloads < 600   | Risk adjusted  |
| Zahn et al. (67)                            | 1992-1995 German Hospital Consortium  | 4,625/?                          | For pts with acute MI; increased mortality in hospitals with < 40 acute MI PTCA/yr   | No risk adjustment   |

\*Medicare patients usually comprise 35% to 50% of total interventional caseload. Adm = administrative dataset; GUSTO = Global Use of Strategies to Open Occluded Coronary Arteries in Acute Coronary Syndromes; HCFA = Health Care Financing Administration; labs = laboratories; MEDPAR = Medicare provider analysis and review; PAMI = Primary Angioplasty in Myocardial Infarction; PTCA = percutaneous transluminal coronary angioplasty; SCA&I = Society for Cardiac Angiography and Interventions; other abbreviations as in Tables 1 and 3.

cally significant differences in the end point of in-hospital mortality, although there was a weak trend for a similar relation for patients presenting with an acute MI for the low, intermediate and high volume hospitals (4.5%, 4.3%, and 3.6%, respectively).

In 1994, Jollis et al. (55) reported the results of their analysis of national Medicare provider analysis and review (MEDPAR) administrative data for all procedures in Medicare beneficiaries performed during calendar years 1987 to 1990 (217,836 patients treated at 1,194 hospitals). Using logistic regression analyses to adjust for potential imbalances in patient baseline characteristics, they found the number of PTCA procedures performed at a hospital to be a highly significant predictor of in-hospital mortality ( $p \leq 0.001$ ). This relation did not appear to be linear, with the data suggesting an inflection point <200 Medicare procedures/year (~600 total procedures). The likelihood of bypass surgery after angioplasty was similarly related to hospital volume, although the inflection point appeared to be perhaps at a somewhat higher hospital volume. However, the absolute magnitude of the differences between hospitals with varied caseloads was relatively modest. For example, the in-

hospital mortality rate for hospitals with >200 procedures/year performed in Medicare patients was ~2.5%, rising to ~3.3% for those hospitals with ~100 cases/year.

In a similar analysis using more recent data, Jollis et al. (55) analyzed data from all Medicare billing claims during calendar year 1992, obtaining data on treatment of 97,478 patients at 984 hospitals. After adjustment for age, gender, presentation with acute MI and comorbidities, they found the likelihood of bypass surgery or death to have a strong statistical association ( $p < 0.001$ ) with hospital caseload, as depicted in Figure 1A. Their analysis suggested a nonlinear relation between these complications and hospital volume, with an inflection point between 200 and 300 Medicare cases (600 and 900 total cases).

Recently, data have been available from the New York State experience (56) between 1991 and 1994 (62,670 patients treated at 31 hospitals) (Fig. 1, B and C). The strength of this analysis lies in the fact that the investigators were able to use a more comprehensive database than the administrative datasets used in previous analyses and that the data were subject to external audit. Risk-adjusted mortality rates were increased for hospitals with <400 cases/year. The risk-adjusted incidence of

**Table 7.** Published Data Relating Physician Coronary Angioplasty Volume to Complication Rates

| Study (ref no.)       | Data Source                             | No. of Pts/<br>Operators Studied | Conclusion   | Comment  |
|-----------------------|---|----------------------------------|--|--|
| Hamad et al. (68)     | 1986-1987 single center                 | 787/17                           | Lower success with complex lesions (B-C) for operators with < 100 cases/yr (no difference for simple lesions)  |  |
| Shook et al. (69)     | 1991-1994 single center                 | 2,350/38                         | Higher risk of emer. CABG with operators of < 50 cases/yr (but no difference for mortality)  |  |
| Ellis et al. (60)     | 1993-1995 high volume centers           | 12,941/38                        | Risk of death and death, MI or emer. CABG inversely related to case load but not years of experience; no volume "cutoff," but risk "accelerates" at cases < 100/yr | Able to risk adjust more completely than most other analyses |
| Krone et al. (70)     | 1992 SCA&I database                     | 7,747/122                        | No differences, < 50, 50-99, > 100 cases/yr (> 100 more complex lesions)   | Able to risk adjust more completely than most other analyses |
| Bon Tempo et al. (71) | 1992-1994 single center                 | 3,127/45                         | Weak trend toward increased risk of abrupt closure and late PTCA with higher volume operators  | No risk adjustment   |
| O'Neill et al. (65)   | PAMI II trial                           | 1,100/?                          | No difference for < 75, > 75 cases/yr  | Selected interventionalists only                             |
| Jollis et al. (55)    | 1992 Medicare (Adm)                     | 97,478/6,115                     | More death+CABG for annual Medicare volume* < 50   |  |
| McGrath et al. (61)   | 1990-1993 Northern New England Registry | 12,033/31                        | Success and emer CABG, but not death, related to volume tercile (23-85, 89-143, 153-450)   |  |
| Hannan et al. (56)    | 1991-1994 NY State                      | 62,670/?                         | Death alone and same-stay CABG increase with annual caseload < 75; an operator-hospital caseload interaction affecting outcome also observed                       | Risk adjusted  |
| Klein et al. (72)     | 1992-1995 single center                 | 1,389/9                          | Despite performing only an average of 51 PTCA/yr, results (death = 0.1%, CABG = 0.9%) were acceptable when compared with contemporary registry data                |  |

\*Medicare patients usually comprise 35% to 50% of total interventional caseload. Abbreviations as in Tables 1, 3 and 6.

bypass surgery appeared to increase in hospitals with <600 cases/year.

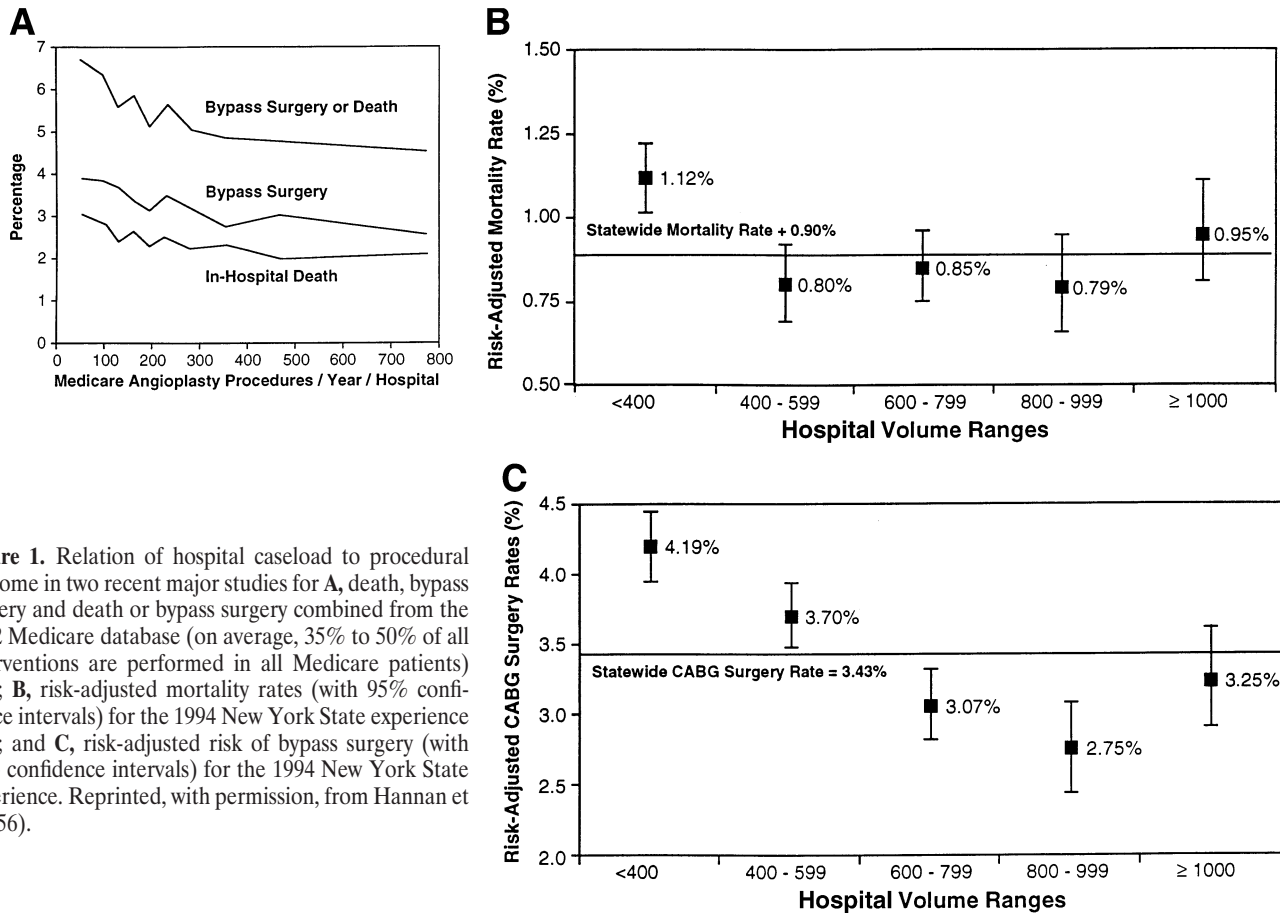
The only large-scale study not suggesting an inverse relation between caseload and complications was that of Kato and Carter (57) who analyzed 113,576 patients treated at 862 hospitals using the Health Care Financing Administration (HCFA) data from 1991. Because a full report of this analysis has not been published, it is difficult to critique. There is no description of any risk adjustment attempt.

However, procedural volume is only one of many factors contributing to the variability of measured outcomes (56,58,59). Furthermore, there is no clear "cutoff" above or below which hospitals, or groups of hospitals in aggregate, perform well or poorly. There are institutions with low volumes that appear to achieve very acceptable results. For an individual institution, however, such an impression must be tempered by the statistical imprecision of the estimate of risk.

### C. Relation of Individual Operator Volume to Procedural Outcome

Interpretation of data supporting the contention that there is, on average, an inverse relation between an individual operator's annual caseload and likelihood of complications is more difficult than for hospital volume and outcome.

The four largest studies to assess a potential relation between individual operator caseload and procedural complications all find that such an inverse relation exists. In the largest study, the analysis of 1992 Medicare patient outcomes (97,478 Medicare patients) by Jollis et al. (55), the incidence of unplanned bypass surgery after angioplasty rose significantly with decreasing caseload and with no obvious inflection point (Fig. 2A). For example, the likelihood of bypass surgery was ~2.5% in Medicare patients treated by a physician performing 100 procedures/year, 3.0% for a physician performing 50 procedures/year and as high as 3.7% for physicians performing 30 procedures/year. No consistent relation was found between operator caseload and in-hospital death. The 1991 to 1994 New York State experience (56) was somewhat similar, with a significant increase in the risk of bypass surgery with lower volume operators and only a trend in a similar direction for in-hospital mortality (Fig. 2, B and C). For example, the risk-adjusted rate of bypass surgery for patients treated by physicians with caseloads in excess of 175 cases/year was 3.0% and increased to 3.9% for patients treated by physicians with >75 cases/year. A similar trend, but of lesser magnitude, was noted for in-hospital mortality. For example, the risk-adjusted likelihood of in-hospital death for patients treated by operators with  $\geq 175$  cases/year was 0.8% and increased to 1.03% for patients treated by operators with <75 cases/year.



**Figure 1.** Relation of hospital caseload to procedural outcome in two recent major studies for **A**, death, bypass surgery and death or bypass surgery combined from the 1992 Medicare database (on average, 35% to 50% of all interventions are performed in all Medicare patients) (55); **B**, risk-adjusted mortality rates (with 95% confidence intervals) for the 1994 New York State experience (56); and **C**, risk-adjusted risk of bypass surgery (with 95% confidence intervals) for the 1994 New York State experience. Reprinted, with permission, from Hannan et al. (56).

In the two other relatively large studies, Ellis et al. (60), using data from five high volume institutions and 12,985 patients treated, and McGrath et al. (61), from the Northern New England Cardiovascular Disease Study Group, evaluating 12,899 patients from five centers, found an inverse relation between caseload and death and the combined end point (death, infarction or bypass surgery) and bypass surgery but not MI or death, respectively. Single-center experiences or those derived from randomized trials with selected operator participation have yielded more disparate results. Consequently, it appears highly likely that there is a statistical relation between individual operator procedural volume and outcome, such that lower volume operators tend to achieve less satisfactory results than higher volume operators. It is uncertain whether this relation is a result of the “practice makes perfect” principle or the fact that patients are more frequently referred to high quality operators. However, this relation is not universal. There are operators with an annual caseload that is less than the previously defined ACC requirement of at least 75 cases/year for maintenance of competency who appear to achieve acceptable results.

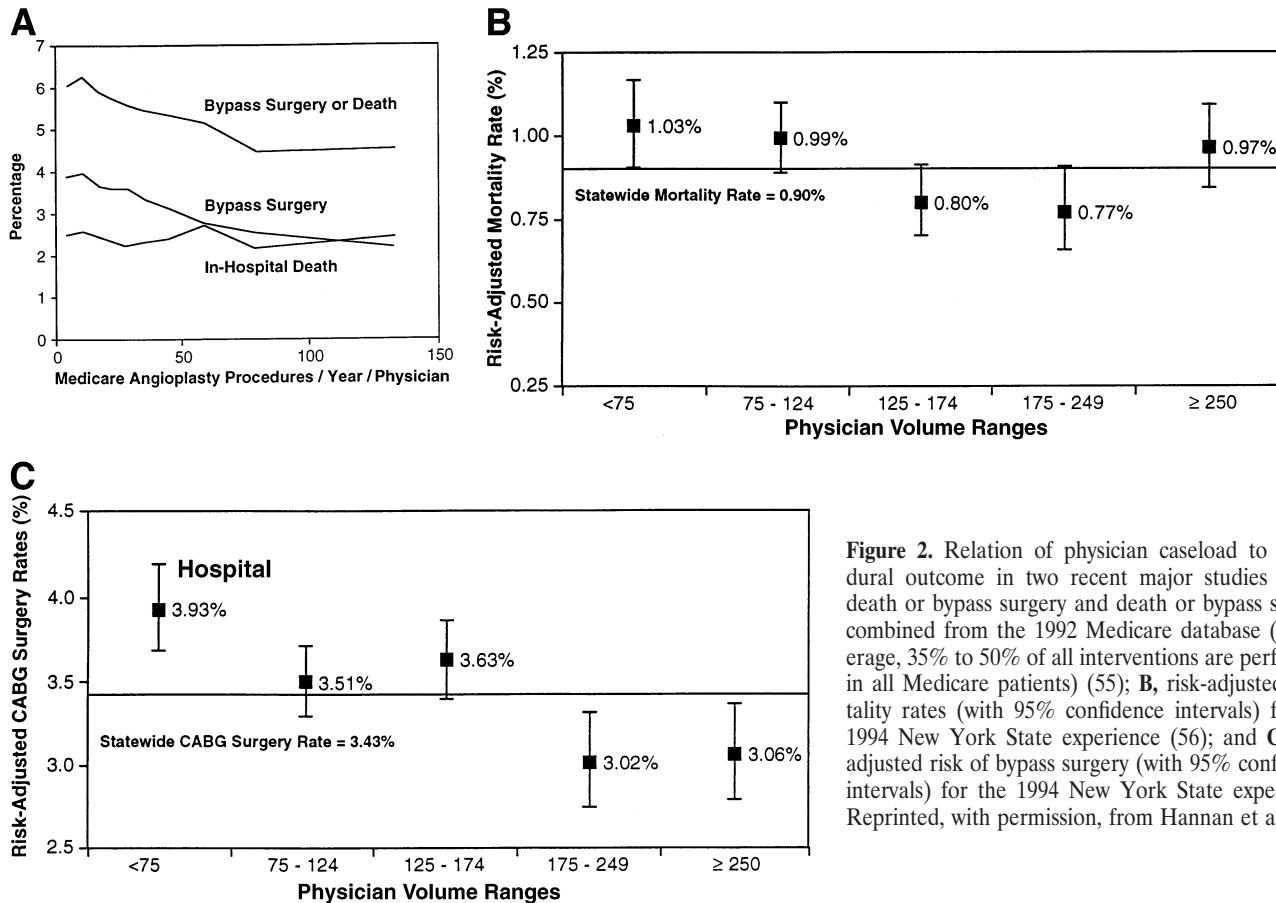
The relation between individual operator volume and outcome is confounded by a possible interaction between physician and hospital volume, such that results of lower

volume operators in high volume institutions are generally more favorable than those achieved by low volume operators in low volume institutions. For example, New York State data suggest that low volume operators (<75 cases/year) who perform procedures in laboratories with >600 to 1000 cases/year have superior outcomes to low volume operators who perform procedures in lower volume laboratories. This relation also appears to exist for higher volume individual operators (56).

As with hospital volume and outcome, data relating physician volume to measures of quality in the current era are still extremely limited. Thus, the impact of recently introduced technologies (i.e., stents and platelet glycoprotein IIb/IIIa inhibitors) on overall outcome, benchmark adverse event rates and the previously demonstrated relation between activity level and outcome has not yet been rigorously assessed (62).

Furthermore, at present, little or no data exist linking operator volume to case selection, periprocedural MI, long-term clinical outcome or measures of cost-effectiveness, each of which measures a component of outcome quality. Consequently, there are important limitations to the simplistic interpretation of raw complication rate statistics as a measure of competence and quality.





**Figure 2.** Relation of physician caseload to procedural outcome in two recent major studies for **A**, death or bypass surgery and death or bypass surgery combined from the 1992 Medicare database (on average, 35% to 50% of all interventions are performed in all Medicare patients) (55); **B**, risk-adjusted mortality rates (with 95% confidence intervals) for the 1994 New York State experience (56); and **C**, risk-adjusted risk of bypass surgery (with 95% confidence intervals) for the 1994 New York State experience. Reprinted, with permission, from Hannan et al. (56).

## XII. Conclusions and Recommendations

### A. General Issues Related to Quality Assessment

In formulating conclusions and recommendations it is important to emphasize that the ultimate goal of such standard setting is to facilitate the attainment of optimal patient outcome. Institutional and programmatic quality is ultimately determined by its success at achieving that goal.

Optimal outcome occurs when an operator selects clinically appropriate patients for interventional procedures and performs these procedures at a requisite level of proficiency. The valid comprehensive assessment of patient outcome requires more than merely compiling acute procedural success and complication rates. True outcome must be assessed using long-term measures of a patient's cardiovascular health.

The information presented in the present document demonstrates the difficulty in assessing operator proficiency and institutional programmatic quality and the complexity of developing standards for maintenance of operator proficiency. At the present time, measurement instruments for assessing overall cardiovascular health and the impact of an interventional procedure on it are not well developed. Consequently, most attempts to assess quality have been based on short-term procedural success and complication rates. As discussed, this approach, although an oversimplification, is the best approach currently available.

### B. General Observations

The current interventional cardiology information base permits a number of broad general conclusions. Some are based on statistical data published in peer-reviewed literature. Others are, by necessity, based on reasoned judgments drawing on what is known about the task of performing coronary interventional procedures.

1. *Coronary interventional procedures are complex and technically demanding to perform.* Optimal performance of these procedures requires an extensive cognitive knowledge base and substantial technical skill. A particular procedure's technical difficulty and the optimal technique required to perform it vary considerably from one case to another. The field is evolving rapidly, with frequent introductions of new techniques and instruments. Consequently, to be proficient, a practitioner must perform procedures often enough to maintain existing skills and to acquire new ones as the field changes.

2. *Complications of coronary interventional procedures, which may be life threatening, sometimes occur unpredictably.* A serious complication can occur in a procedure that appeared initially to be straightforward. Optimal patient outcome, once a complication occurs, depends on proper recognition and management. Optimal treatment of complications is a complex task

that requires that the operator possess substantial experience, knowledge and technical skill.

3. *The most recently compiled comprehensive statistical data set (New York State 1991 to 1994 [56]) found overall death and emergency CABG rates for all types of coronary interventional procedures in all circumstances to be 0.9% and 3.0%, respectively.* Risk-adjustment algorithms permit identification of high and low risk subsets. There is ample reason to believe that complication rates have decreased since those data were collected (62). Consequently, these rates represent an absolute upper limit for benchmark complication rates to be expected in a clinically stable population.

4. *There are consistent statistical associations between activity levels and short-term complication rates (emergency CABG and mortality) (3,55,56,58-60).* These associations exist both for institutions and for individual operators. The relations between activity levels and complication rates are curvilinear, with rates decreasing as institutional activity increases to 600 procedures/year and operator activity increases to 175 procedures/year (3,56). As a group, operators with activity levels <75 procedures/year have both death and emergency CABG rates that are statistically significantly greater than the rates for operators with annual procedure volumes >75. Institutional activity rates >600 procedures/year and operator activity rates >175 procedures/year are not associated with a further decrease in complication rates. Although these relations do not identify a clear-cut "competence threshold," it is clear that on average, operators and institutions with activity levels below the above-cited values achieve poorer outcomes. Furthermore, because most geographic areas have both a large number of operators performing PTCA and a large number of PTCA programs, there is little justification in terms of community need for low volume operators and programs.

5. *It is likely that there is an interaction between the institutional program and the operator activity level in determining complication rates.* The highest complication rates occur for low volume operators who perform procedures at low volume institutions, whereas lower complication rates occur for low volume operators who work at high volume institutions (3,56). Thus, the institution, as the programmatic platform from which individual operators perform procedures, has an important impact on overall procedural effectiveness and safety.

6. The differences in the absolute magnitude of risk-adjusted complication rates between low and high volume institutions and operators are small. In the New York State dataset (56), operators performing <75 procedures/year had mean mortality and CABG rates of 1.0% and 3.9%, respectively, whereas higher volume operators had mean mortality and CABG rates of 0.9% and 3.1%, respectively. The statistical significance of these relations could be detected only with large sample sizes, which indicates that not all low volume operators and institutions are low volume nor are all high volume institutions and operators necessarily of the highest quality. The activity level effect appears to be stronger for emergency CABG than for mortality, most likely because the three-

fold greater frequency of CABG permits more precise rate estimates.

7. *The low expected complication rate for coronary interventional procedures presents a major statistical power problem when attempting to estimate the true complication rate of the low volume operator with statistically meaningful precision.* For example, an operator must perform 100 complication-free procedures to reasonably show that his or her true complication rate is <3.6% (the upper limit of the 95% confidence interval). The statistical power problem is further compounded in that complication rates must be risk-adjusted to be interpretable. As a result, the confidence intervals for estimates of low volume operator complication rates will, in general, be too large to permit accurate determination of an individual operator's true performance relative to benchmark standards.

8. *Unadjusted complication rates, although of some value for assessing outcome, are incomplete assessments of overall operator proficiency because they do not take into account patient characteristics that influence risk.* Furthermore, they do not assess the appropriateness with which an operator selects cases. Nonetheless, they do constitute a measurable parameter that is linked to overall quality assessment.

9. *Programmatic quality and individual operator proficiency must be judged by rigorous quality assessment monitoring according to standardized protocols using data that are not self-reported.* Because of statistical power issues, and to track trends over time, outcome reporting from such a monitoring process must be cumulative as well as limited to defined time periods.

10. *Because there is a clear linkage between operator activity level and outcome, there is a natural and appropriate focus on operator activity levels that requires a rigorous standard for measuring operator activity.* One important ambiguity in assessing operator activity occurs when more than one physician participates in a procedure. Whether all physicians who participate in a procedure may claim credit for having performed the procedure has not been defined. The term "primary operator" has been used frequently but has not been defined precisely (see Appendix 1 for a definition of primary operator developed by the Writing Group).

11. *There are potential pitfalls in the use of complication rates to judge operator proficiency.* Such monitoring may affect an operator's case selection and judgment in a way that might have an adverse impact on overall patient care. For example, the pressure of complication rate monitoring might lead an operator to withhold PTCA inappropriately from a challenging patient who might benefit from the procedure. Similarly, concern over his or her emergency CABG rate might cause an operator to "ride out" an ischemic complication of a PTCA procedure rather than refer a patient for emergency CABG.

### *C. Benchmark Complication Rates for Quality Standards*

The best subgroups of operators and institutions in the New York State database (56) achieved a mortality rate of 0.9% and an emergency CABG rate of 3%. With appropriate qualifica-

tions, these rates can serve as benchmark rates against which to judge operators and programs.

It should be emphasized that these data are derived from all PTCA procedures, including those performed for acute MI and cardiogenic shock. Thus, they overstate the risk of complications in clinically stable patients undergoing elective PTCA and understate the risk for high risk patients.

In principle, risk adjustment should be considered when applying these rates as benchmarks. Application of risk adjustment techniques to new data sets has had limited validation to date. Consequently although risk adjustment is clearly important, it should be applied carefully when making judgments about individual operators and programmatic performance.

Furthermore the New York State data were gathered before stents and platelet glycoprotein IIb/IIIa inhibitors were in widespread use. It is likely that the availability of these treatments has reduced the expected frequency of death and emergency CABG. Consequently, these data may not accurately reflect current practice, and the true current benchmark complication rates may be lower. This emphasizes the need for ongoing data gathering to determine the current benchmark complication rates. The standard for benchmark complication rates should be subject to future revision in response to the emergence of newer data.

#### *D. Guidelines for Institutions That Offer Coronary Intervention Services*

The institution, as the platform from which coronary interventional procedures are performed by individual physicians, provides an important infrastructure that is essential to procedural success. This infrastructure consists of both physical (equipment) and intellectual (human) resources. Failure to provide a high quality infrastructure will degrade the quality of the services performed. In addition, the institution, as the basis of governance of the health care system, is fundamentally responsible for its program quality.

Institutions offering coronary interventional procedure services should meet the following standards:

1. **Quality assessment monitoring.** It is essential that an institution that offers a complex and potentially hazardous procedure have a rigorous privilege-granting and quality assessment monitoring system in place to determine the quality and efficacy of its overall program and its individual physician operators. Features of this program should include 1) established criteria for privilege granting and privilege renewal; 2) prospective recording of patient characteristic data to permit appropriate risk stratification (the data elements of the ACC PTCA database are ideally suited to serve as a template for this function); 3) gathering and tabulating complete objective outcome data by a disinterested party (i.e., physicians should not self-report their results)—ideally, as outcome assessment standards mature, such data gathering would also include long-term functional data; 4) oversight and privilege granting by a physician program director (described below), including

consultation with operators over case selection and procedure conduct, periodic review of operators' results and responsibility for renewal of individual privileges; 5) periodic conferences at which the laboratory physician staff reviews and analyzes adverse events; 6) periodic review of the program and physician quality assessment statistics and comparison of institutional statistics with benchmark rates by the institutional medical staff leadership.

2. **Institutional activity levels.** An institution should have an activity level of at least 400 coronary interventional procedures/year. An institution with <200 procedures/year, unless in a geographically underserved region, should carefully consider whether it should continue to offer the service.

3. **Coronary interventional program director.** An institution offering coronary interventional procedures should have a physician-director who is responsible for the program's overall quality. The director should be an experienced operator with a career experience of >500 procedures. The director should perform procedures at the facility that he or she directs. The director should be certified in the commonly used adjunctive interventional devices and should be certified in interventional cardiology by the ABIM (once the ABIM Added Qualification Examination is in place). The program director should assume responsibility for 1) quality assessment monitoring; 2) maintaining a mentoring system for less experienced physicians with a volume of <75 procedures/year; and 3) maintaining an optimal working environment in terms of equipment operation and ancillary support.

4. **Facility equipment and staff requirements.** The facilities and staffing requirements for performing coronary interventional procedures have been addressed in detail elsewhere (63). It is important to emphasize that optimal radiologic imaging and sophisticated clinical staff support are essential. Radiologic equipment must provide high resolution fluoroscopic imaging with digital video processing to permit readily immediate review of high quality cinefluorographic images. The nursing, technical and physician support staff must be experienced and able to respond readily to emergency and other unusual situations.

#### *E. Guidelines for Physician-Operators Who Perform Coronary Interventional Procedures*

As outlined in the beginning of this section, the development of fair and appropriate standards for judging physician-operator proficiency presents a complex and difficult challenge. Intuition and statistical data both support the premise that a physician who performs coronary interventional procedures infrequently is unlikely to be as proficient as one who performs them more often. The low volume operator not only has fewer opportunities to maintain skills, but is less able to acquire the additional skill sets needed to become proficient in the use of new techniques and devices. Furthermore, the low volume operator is likely to be less experienced at recognizing and managing procedural complications. Statistical data demonstrate that operators who perform <75 procedures/year have

the highest complication rates. This trend is most pronounced in institutions with an annual procedural volume <600 (56).

In view of the above issues, physicians who perform coronary interventional procedures should meet the following standards:

**1. Quality assessment monitoring.** A physician-operator's proficiency should ultimately be judged by his or her clinical results. The procedural success and complication rates for all physician-operators should be rigorously compiled and periodically reviewed. The overall performance of physicians whose complication rates exceed the benchmark standards for any period should be reviewed by the program director, with careful attention to statistical power and risk adjustment issues. Interpretation of complication rates must carefully consider case-mix. For example, overall benchmark rates may not apply if an operator's case-mix includes a disproportionate fraction of patients with acute MI and cardiogenic shock. Review of an operator's performance should be based on analysis of both current and cumulative quality assessment statistics. Monitoring of physicians with an annual procedural volume <75 should be particularly detailed and careful because of the difficulty of estimating their true complication rate and the statistical evidence that these operators, as a group, have the highest rate of complications.

**2. Operator activity levels.** An operator should perform  $\geq 75$  procedures/year to maintain proficiency. Physicians who perform <75 procedures/year are at a disadvantage when attempting to maintain familiarity and competence with the panoply of currently available interventional techniques or when required to deal with a complication. Therefore, those operators who perform 50 to 75 procedures/year should be very cautious in case selection. Their quality assessment statistics should be carefully reviewed with respect to case selection and outcome. Ideally, operators with an annual procedural volume <75 should work at institutions with an annual procedural volume >600 to have optimal access to mentoring and backup support.

**3. Renewal of privileges.** The granting and renewal of privileges is the responsibility of the governance of the local health care institution. The privileges of operators whose complication rates exceed benchmark rates (currently 4% for combined death and emergency CABG) should be reviewed carefully, with particular attention to case-mix-based risk adjustment and statistical power issues. Consideration should be given to not renewing privileges if an operator's complication rate exceeds benchmark rates over a 2-year monitoring period.

**4. Mentoring of operators.** Operators who perform <75 procedures/year should develop a defined mentoring relationship with a highly experienced operator who performs >150 procedures/year. The purpose of this relationship is to ensure that the operator's patients can benefit from the skills and knowledge of a more experienced physician and to facilitate the operator's acquisition of additional sophistication and skills. Elements of this relationship should include 1) consul-

tation with the mentor concerning case selection; 2) scrubbed assistance by the mentor for complex cases performed primarily by the low volume operator; 3) ready availability of the mentor to assist in the event of complications; and 4) scrubbing with the mentor on cases performed primarily by the mentor for the purpose of gaining additional experience.

## Appendix

### *Standards for Determining an Individual Physician-Operator's Case Load*

For the purposes of determining an operator's actual case load, the following standards should apply. For the purpose of counting the number of procedures, *an interventional procedure* is defined as a single session with a patient in the procedure room, irrespective of how many or what types of interventions are performed during the session. Only one physician may claim credit for a particular procedure. A physician-operator who claims credit for a procedure is the physician in charge of it. The participation of other physicians is often helpful when mentoring is needed or so that the additional physician may gain further experience. In an interventional cardiology fellowship program, the trainee will take an active role in the procedure under the direction of the supervising physician, who is responsible. However, the attending physician who takes primary responsibility for the procedure should be credited with performing it.

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