

# Relationship Between Procedure Indications and Outcomes of Percutaneous Coronary Interventions by American College of Cardiology/American Heart Association Task Force Guidelines

H. Vernon Anderson, MD; Richard E. Shaw, PhD; Ralph G. Brindis, MD; Lloyd W. Klein, MD; Charles R. McKay, MD; Michael A. Kutcher, MD; Ronald J. Krone, MD; Michael J. Wolk, MD; Sidney C. Smith, Jr, MD; William S. Weintraub, MD

**Background**—An American College of Cardiology/American Heart Association (ACC/AHA) Task Force periodically revises and publishes guidelines with evidence-based recommendations for appropriate use of percutaneous coronary intervention (PCI). Some studies have suggested that closer adherence to guidelines can reduce variations in care, can improve quality, and may ultimately result in better outcomes, but this finding is incompletely understood. Guidelines themselves must change to be responsive to continuously evolving clinical practice. Our goal here was to investigate whether any relationship existed between the most recent ACC/AHA recommended indications for PCI and short term in-hospital outcomes.

**Methods and Results**—We analyzed the ACC National Cardiovascular Data Registry for the period of January 1, 2001, through March 31, 2004. We excluded PCI procedures performed for acute myocardial infarction (ST-segment elevation myocardial infarction); all others were grouped by their indications according to the standard ACC/AHA scheme: Class I, evidence and/or agreement that PCI is useful and effective; Class IIa, conflicting evidence and/or divergent opinions, weight is in favor; Class IIb, usefulness/efficacy is less well established; and Class III, evidence and/or agreement that PCI is not useful or effective and may be harmful. Clinical success was defined as angiographic success ( $<20\%$  residual stenosis) at all lesions attempted without the adverse events of myocardial infarction, same-admission bypass surgery, or death. There were 412 617 PCI procedures included in the analysis. Frequency of indications was as follows: Class I, 64%; Class IIa, 21%; Class IIb, 7%; and Class III, 8%. Clinical success declined across the indications classes (92.8%, 91.7%, 89%, and 85.5%, respectively;  $P<0.001$ ), whereas adverse events increased.

**Conclusions**—In this large survey of contemporary PCI practice, most procedures were performed for Class I indications. A significant relationship between evidence-based indications recommended by the ACC/AHA Task Force and in-hospital outcomes was noted. (*Circulation*. 2005;112:2786-2791.)

**Key Words:** angioplasty ■ coronary disease ■ mortality ■ registries ■ stents

In 2001, the American College of Cardiology/American Heart Association (ACC/AHA) Task Force on Practice Guidelines published updated evidence-based recommendations concerning indications for percutaneous coronary intervention (PCI).<sup>1,2</sup> The purpose of these PCI guidelines is to help the individual operator formulate an evidence-based management strategy for patients with coronary disease, thereby assisting in the often complicated task of balancing the risks versus benefits of PCI in various clinical situations. Through the establishment of categories in which evidence suggests risks are lower and/or benefits are higher, and

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therefore PCI may appropriately be recommended, and other categories in which the converse is true (higher risks and/or lower potential benefits and thus PCI is not recommended), the hope is that careful application of these guidelines could be used to improve the quality of care. As yet, there have been no large-scale assessments of guidelines-based PCI practice. The ACC established the National Cardiovascular Data Registry (ACC-NCDR) several years ago, in part to provide an objective mechanism to examine this question.<sup>3,4</sup> Our goal in

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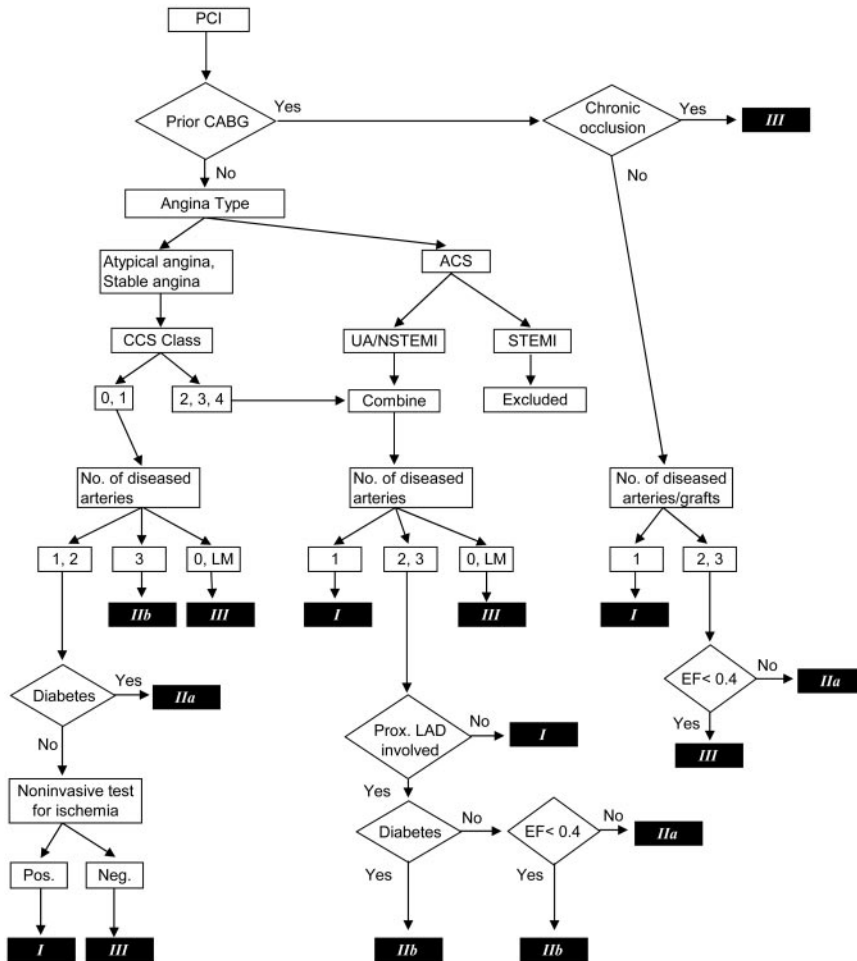
From the University of Texas Health Science Center, Houston, Tex (H.V.A.); Sutter Pacific Heart Center, San Francisco, Calif (R.E.S.); Kaiser Permanente Health System, Oakland, Calif (R.G.B.); Rush Medical College, Chicago, Ill (L.W.K.); Harbor-UCLA Medical Center, Torrance, Calif (C.R.M.); Wake Forest University, Winston-Salem, NC (M.A.K.); Washington University, St Louis, Mo (R.J.K.); Cornell Medical Center, New York, NY (M.J.W.); University of North Carolina, Chapel Hill, NC (S.C.S.); and Emory University, Atlanta, Ga (W.S.W.).

Correspondence to H. Vernon Anderson, MD, Cardiology Division, University of Texas Health Science Center Houston, 6431 Fannin, Suite 1.246, Houston, TX 77030. E-mail h.v.anderson@uth.tmc.edu

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**Figure 1.** Algorithm for assignment of PCI cases to ACC/AHA indications class. CCS indicates Canadian Cardiovascular Society; UA, unstable angina; ACS, acute coronary syndrome; Pos., positive; Neg., negative; EF, ejection fraction; and LAD, left anterior descending.

this study was to use the ACC-NCDR to investigate whether the indications for PCI according to the 2001 Task Force guidelines might be associated with differences in clinical outcomes.

## Methods

### Data Registry and Selection

The ACC-NCDR is a voluntary registry that receives data from >500 participating hospitals. There is a standard data set with written definitions, uniform data entry and transmission requirements, and data quality checks. Details on the data collection process have previously been published.<sup>5-7</sup> For the purpose of this study, we examined registry patients undergoing PCI procedures from January 1, 2001, through March 31, 2004. Patients who were undergoing PCI for ST-segment elevation acute myocardial infarction (STEMI) were excluded; all others were included.

### Indications Class

The 2001 ACC/AHA guidelines describe in detail the criteria to be applied in categorizing patients appropriately for PCI procedures.<sup>1</sup> As in past guideline documents, PCI indications are structured around 3 classes: I, II, and III, with Class II indications further subdivided into 2 subclasses. These are summarized as follows: Class I, conditions for which there is evidence for and/or general agreement that the procedure or treatment is useful and effective; Class II, conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness or efficacy of a procedure or treatment; Class IIa, weight of evidence/opinion is in favor of usefulness/efficacy; Class IIb, usefulness/efficacy is less well estab-

lished by evidence/opinion; and Class III, conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful or effective and in some cases may be harmful.

For each procedure included in this study, registry data were examined to determine the corresponding ACC/AHA indication class. Briefly, the 2001 guidelines group the indications around certain clinical descriptors: Patients with asymptomatic or mild (Class I) angina, patients with Class II to IV or unstable angina, patients with STEMI, and patients with prior coronary bypass surgery (CABG).<sup>1</sup> Individual assignment into the appropriate indication class was made with an algorithm (Figure 1). Procedures with missing data elements that precluded classification were placed in a "not classified" category.

### Outcomes

The ACC-NCDR contains information on angiographic and clinical success of a procedure and adverse events up to hospital discharge. Angiographic success entails reducing a lesion to <20% stenosis, and clinical success is defined as angiographic success for all lesions attempted, along with no adverse events. All major adverse clinical events were included: Postprocedure MI, same-admission CABG, and death.

### Statistical Analysis

Categorical variables were compared by use of  $\chi^2$  tests and are presented as percentages. Continuous variables were compared by use of ANOVA and are presented as mean  $\pm$  SD.

## Results

There were 363 participating hospitals that submitted data on 509 766 procedures for the 39-month period of January 1,

**TABLE 1. Clinical and Procedural Characteristics and Outcomes for Classified and Not Classified Procedures**

|                                        | Not Classified<br>(n=50 471) | Classified<br>(n=412 617) | P       |
|----------------------------------------|------------------------------|---------------------------|---------|
| Age, y                                 | 63±12                        | 64±12                     | <0.0001 |
| Women, %                               | 31                           | 35                        | <0.0001 |
| Family history, %                      | 40                           | 39                        | <0.01   |
| Diabetes, %                            | 21                           | 31                        | <0.0001 |
| Hypertension, %                        | 65                           | 74                        | <0.0001 |
| Prior MI, %                            | 26                           | 31                        | <0.0001 |
| History CHF, %                         | 9                            | 11                        | <0.0001 |
| Prior PCI, %                           | 31                           | 38                        | <0.0001 |
| Prior CABG, %                          | 17                           | 22                        | <0.0001 |
| Renal disease, %                       | 3.9                          | 4.9                       | <0.0001 |
| Chronic lung disease, %                | 14                           | 15                        | <0.0001 |
| 3-Vessel CAD, %                        | 11                           | 20                        | <0.0001 |
| Class III–IV lesion, %*                | 17                           | 10                        | <0.0001 |
| Graft lesion treated, %                | 7.9                          | 8.6                       | <0.0001 |
| Stent, %                               |                              |                           |         |
| Any                                    | 82.4                         | 81.9                      | <0.001  |
| Bare metal                             | 66.8                         | 64.1                      | <0.0001 |
| Drug-eluting                           | 15.6                         | 17.8                      | <0.0001 |
| GP IIb/IIIa, %                         | 67                           | 67                        | 0.155   |
| Thrombolytics used during procedure, % | 34                           | 1.5                       | <0.0001 |
| IABP, %                                | 3.4                          | 1.3                       | <0.0001 |
| LVEF, %                                | 50±13                        | 53±14                     | <0.0001 |
| Clinical success, %                    | 91.8                         | 91.7                      | 0.967   |
| MI, %                                  | 0.9                          | 1.1                       | <0.001  |
| CABG, %                                | 0.7                          | 0.5                       | <0.001  |
| Death, %                               | 1.6                          | 0.7                       | <0.0001 |

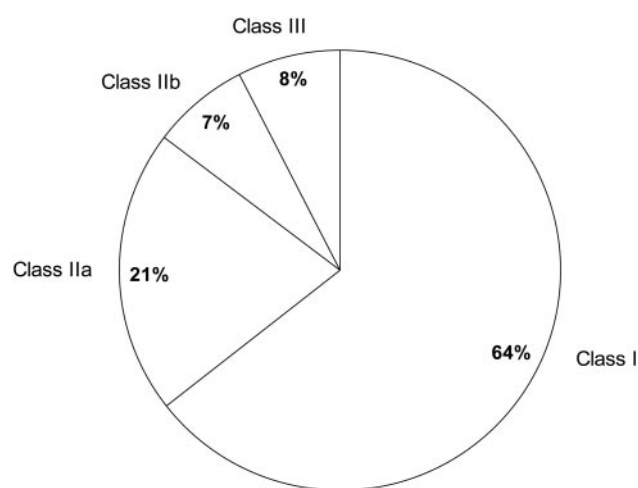
CHF indicates congestive heart failure; CAD, coronary artery disease; GP, glycoprotein; IABP, intra-aortic balloon pump; and LVEF, left ventricular ejection fraction.

\*SCAI Lesion Classification.

2001, to March 31, 2004. We excluded 46 678 procedures performed for STEMI, leaving 463 088 procedures available for this study. The PCI procedures were done mostly at private community hospitals (94%); a few were done at university hospitals (6%). Approximately one half (47%) were done at teaching institutions. The community setting was urban for 57%, suburban for 27%, and rural for 16%. The average number of PCI procedures performed annually per institution was 1409±968 (range, 43 to 4706). Only 9% of the procedures were done in hospitals performing ≤400 PCIs per year, whereas 91% were done in hospitals performing >400 PCIs per year.

### Indications Class Frequencies

The initial population of 463 088 were classified as follows: Class I, 57% (n=265 788); Class IIa, 19% (n=86 070); Class IIb, 6% (n=29 716); Class III, 7% (n=31 043); and not classified, 11% (n=50 471). Some characteristics of classified and not classified procedures are shown in Table 1. Removing the not classified procedures resulted in a total of

**Figure 2.** Indications class frequencies.

412 617 procedures that could be analyzed. This final frequency distribution is shown in Figure 2: Class I, 64%; Class IIa, 21%; Class IIb, 7%; and Class III, 8%.

### Clinical Features and Outcomes

Profiles of the 4 different indications classes, along with their outcomes, are shown in Table 2 and Figure 3. Because of the large group sizes, all differences between classes were significant for every variable. However, no differences in clinical outcomes or adverse events were found for procedures done at hospitals performing ≤400 PCIs per year compared with those performing >400 PCIs per year. On the other hand, several important differences by indications class stand out (Table 2). This is expected, given the careful way in which the indications classes were originally constructed by the guidelines Task Force from extensive review of available evidence; ie, assignment to an indications class constitutes risk stratification and was not random but intentional. At one end of the spectrum, the procedures with Class I indications, the average patient age was the youngest, and this group had the lowest percentages of diabetes, 3-vessel coronary disease, prior MI, and renal disease. In contrast, at the other end of the spectrum, the procedures with Class III indications, the average patient age was the oldest and the percentage of women was the lowest, and this group had the highest percentages of prior MI, prior CABG, congestive heart failure, renal disease, and complex native vessel and graft lesions treated, and the lowest use of stents. Class II procedures were intermediate in these characteristics, with the notable exceptions that Class IIb had the highest percentages of diabetes and 3-vessel coronary disease and the absence of prior CABG. Clinical success declined modestly but successively across the 4 classes (Figure 3A), falling from 92.8% in Class I procedures to 91.7% in Class IIa, 89% in Class IIb, and 85.5% in Class III ( $P<0.0001$ ). Major adverse events increased (Figure 3B), with in-hospital mortality rising from 0.5% in Class I to 0.7% in Class IIa, 1.9% in Class IIb, and 1.7% in Class III ( $P<0.0001$ ). Interestingly, the rate of same-admission CABG increased from Class I to IIa to IIb

**TABLE 2. Demographic and Clinical Profiles of Indications Classes**

|                         | Class I<br>(n=265 788) | Class IIa<br>(n=86 070) | Class IIb<br>(n=29 716) | Class III<br>(n=31 043) | P       |
|-------------------------|------------------------|-------------------------|-------------------------|-------------------------|---------|
| Age, y                  | 63±12                  | 66±11                   | 66±12                   | 67±11                   | <0.0001 |
| Women, %                | 36                     | 31                      | 37                      | 28                      | <0.0001 |
| Family history, %       | 39                     | 39                      | 35                      | 40                      | <0.0001 |
| Diabetes, %             | 26                     | 36                      | 63                      | 39                      | <0.0001 |
| Hypertension, %         | 72                     | 77                      | 78                      | 78                      | <0.0001 |
| Prior MI, %             | 27                     | 35                      | 33                      | 51                      | <0.0001 |
| History CHF, %          | 8                      | 8                       | 18                      | 29                      | <0.0001 |
| Prior PCI, %            | 37                     | 40                      | 34                      | 47                      | <0.0001 |
| Prior CABG, %           | 10                     | 48                      | 0                       | 72                      | <0.0001 |
| Renal disease, %        | 3.8                    | 5.5                     | 8.5                     | 9.0                     | <0.0001 |
| Chronic lung disease, % | 15                     | 14                      | 17                      | 17                      | <0.0001 |
| 3-Vessel CAD, %         | 8                      | 36                      | 59                      | 36                      | <0.0001 |
| Class III–IV lesion, %* | 9                      | 5                       | 13                      | 26                      | <0.0001 |
| Graft lesion treated, % | 4                      | 19                      | 0                       | 32                      | <0.0001 |
| Stent, %                |                        |                         |                         |                         |         |
| Any                     | 82                     | 83                      | 84                      | 76                      | <0.0001 |
| Bare metal              | 64                     | 64                      | 63                      | 64                      | <0.0001 |
| Drug-eluting            | 18                     | 19                      | 21                      | 12                      | <0.0001 |
| GP IIb/IIIa, %          | 68                     | 68                      | 69                      | 62                      | <0.0001 |
| IABP, %                 | 0.9                    | 1.1                     | 3.3                     | 2.8                     | <0.0001 |
| LVEF, %                 | 55±15                  | 57±10                   | 47±15                   | 39±14                   | <0.0001 |
| Clinical success, %     | 92.8                   | 91.7                    | 89.0                    | 85.5                    | <0.0001 |
| MI, %                   | 1.0                    | 1.3                     | 1.4                     | 1.5                     | <0.0001 |
| CABG, %                 | 0.5                    | 0.6                     | 0.8                     | 0.4                     | <0.0001 |
| Death, %                | 0.5                    | 0.7                     | 1.9                     | 1.7                     | <0.0001 |

Abbreviations as in Table 1.

\*SCAI Lesion Classification.

(0.5%, 0.6%, 0.8%, respectively) but then declined in Class III to the lowest rate observed (0.4%).

## Discussion

The 2001 ACC/AHA PCI guidelines gave suggested indications for PCI based on an extensive review of the evidence for clinical efficacy and risk. The present study shows that the guideline indications have both reflected clinical practice and correlated with clinical outcomes during the period we studied. This finding is not unexpected because these guidelines were carefully formulated to recommend PCI when evidence showed that clinical success could be readily achieved at lower risk, and conversely to recommend against PCI when the evidence did not favor it. Although the intent of practitioners to follow guidelines cannot be determined by these data, this study provides support for the concept that adherence to appropriately developed guidelines might be used to improve the quality of care in PCI by increasing success and reducing adverse events.

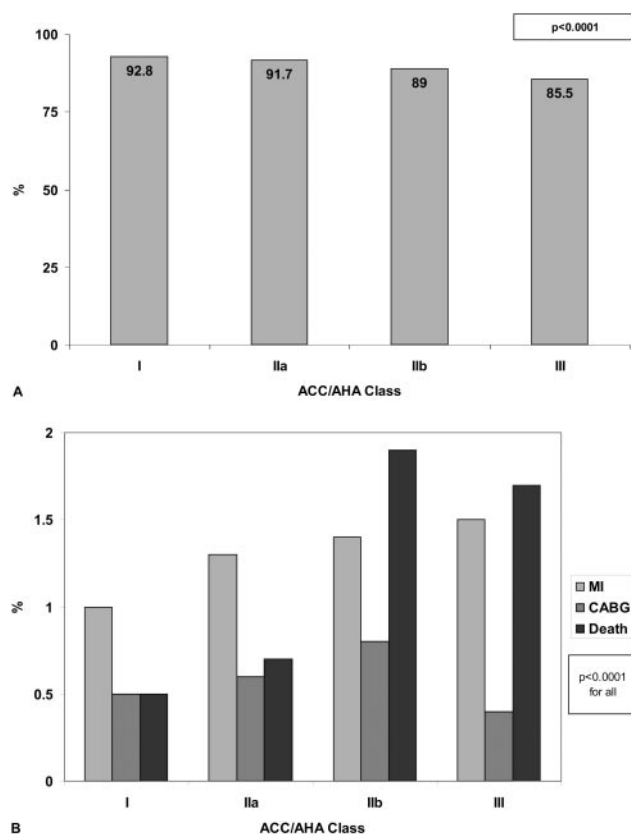
## Practice Guidelines and Quality of Care

Over the past 20 years, the development and introduction of cardiovascular drugs, procedures, and devices have been astounding. Although numerous studies have investigated and

refined many of the clinical situations in which these innovations can be useful and effective, other studies, particularly those done over the past decade, have revealed that adoption of effective practices quite often can be scattered, inconsistent, and haphazard. This inconsistency has been shown to result in widespread variations in medication and procedure use for the same or similar clinical conditions. Furthermore, clinical outcomes also have been found to vary widely, and to some degree, this variation appears to correlate with the use of evidence-based protocols and guidelines. These issues of variations in quality and outcomes, and recommendations for addressing them, have been longstanding and widely discussed for acute ST segment elevation MI (STEMI). They are now being enlarged to encompass non-STEMI under the more broadly based heading of acute coronary syndromes in general.<sup>8–11</sup> Initiatives in other areas are also underway.

## PCI

Few or no data are available on the use of evidence-based guidelines for coronary intervention. Only 1 published study was found.<sup>12</sup> In it, the investigators examined a random sample of Medicare patients in 5 states for the years 1991 to 1992. There were 543 PCI procedures identified, and clinical data were obtained retrospectively from chart reviews. The



**Figure 3.** Clinical success and adverse events by indications class. A, Clinical success rates by indications class. B, Adverse event rates by indications class.

procedure indications were classified both by the 1988 and the 1993 ACC/AHA PCI guidelines. In contrast to our findings, this smaller, older investigation revealed that 19% to 20% had Class I indications, 51% to 56% had Class II indications, and 24% to 30% had Class III indications. The investigators concluded in part that clinical guidelines needed to evolve in parallel with clinical practices to be useful and that frequent revisions would be necessary to take into account new developments and technical improvements. This last point is consistent with another recent analysis of 17 different clinical practice guidelines by the Agency for Healthcare Research and Quality, which suggested an interval

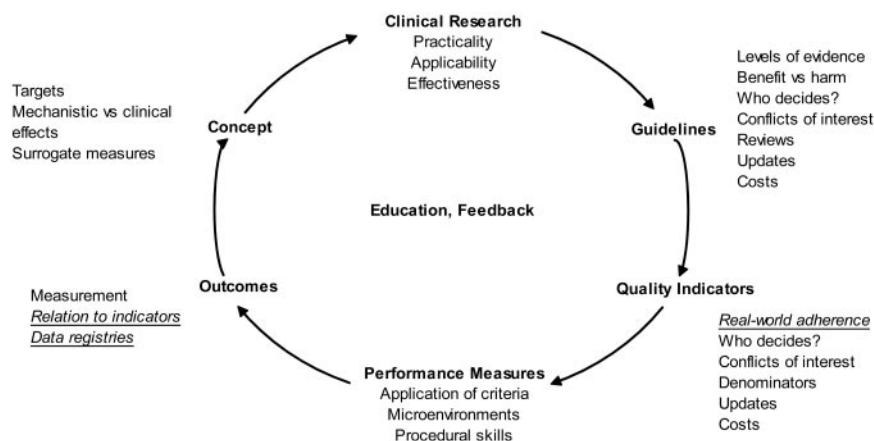
of 3 years for guideline revisions in general.<sup>13</sup> Whether 3 years would be an appropriate interval for PCI guidelines revisions still requires further research.

### Development Cycles

As noted, the development of practice guidelines, performance measures, and other aids that could help reduce care variation and improve quality also requires adequate feedback of clinical outcomes to truly effect positive change. The concept has been proposed for a “cycle” of therapeutic development (Figure 4).<sup>14,15</sup> The ACC-NCDR was envisioned from the very beginning to be used not only as an integral part of local hospital quality improvement programs but also as a tool for collecting clinical data and outcomes to aid the ACC/AHA Guidelines Committee in periodically reassessing and revising clinical practice guidelines. This present study is the first attempt to do so. As shown in Figure 4, this study most directly fits into the development cycle in 2 areas: Quality Indicators (as real-world adherence), and Outcomes (as relation to indicators and data registries). We observed that most PCI procedures were done for Class I indications (64%) and that only a small fraction were done against recommendations (Class III, 8%). This finding suggests that PCI practice conforms to the guidelines to a large extent. When taken further as a measure of the quality of clinical practice, adherence to the recommended indications for PCI was associated with better outcomes.

### Study Limitations

The major limitation of this study is the fact that the current version of the NCDR does not specifically capture procedure indications in an ACC/AHA guidelines format. Instead, indications were derived from collected clinical data. This may be either a strength or a weakness, depending on one’s perspective. A more formal approach to collecting data for indications is worth considering. It is also noteworthy that missing data precluded classification of 11% of procedures, which is not unreasonably large but might be reduced further with more stringent data completeness checks. An in-depth analysis of the not classified category was not undertaken because of incomplete data. The mortality rate in this group was 1.6% compared with only 0.7% in the classified group. The rates of MI and CABG were similar. If substantial



**Figure 4.** Integration into the cycle of therapeutic development. The present study fits into this cycle in at least 2 areas: quality indicators (as real-world adherence) and outcomes (as relation to indicators and data registries). Adapted from Reference 14, with permission from the American College of Cardiology Foundation.

numbers of these not classified procedures had been classifiable and turned out to be in the Class I or IIa group, then perhaps the mortality rates might not have been different, but this is speculative. The hospitals included in this voluntary database appear to be mostly large, busy, urban or suburban institutions with teaching programs. The degree to which these hospitals are representative of all facilities with PCI capability is unknown. Only 9% of the procedures were done in hospitals performing less than the guidelines-recommended volume of 400 PCIs per year, and individual operator volumes were not available. Although there were no apparent differences in the lower-volume hospitals, their numbers of procedures may not be sufficient to form valid comparisons. Finally, the ACC-NCDR is mainly a safety database with only the in-hospital events recorded, so there were no long-term outcomes beyond hospital discharge available for analysis. Although the guidelines are derived from evidenced-based analyses that take into account the long-term outcomes among other things, we do not know specifically how long-term outcomes varied with procedure indications in the patients studied here.

## Conclusions

This review of a large national PCI database found a relationship between procedure indications, clinical success, and adverse events. The implications of these findings are that a more careful consideration of procedures with Class IIb and III indications might improve clinical outcomes and by extension the quality of patient care. Although this hypothesis remains unproved at present, future studies may be able to test it. Alternatively, the Class IIb and III indications may need to be studied in more depth and their definitions revised on the basis of evolving technologies and practices. Understanding the reasons why PCI procedures are done against recommendations (the Class III procedures) may provide valuable clues and insights into new or developing approaches. Sometimes, this may be the only way to gain such insight. Importantly in this regard, we observed that same-admission CABG increased from Class I to IIa to IIb and then declined in Class III. This might have been due in part to the high percentage of prior CABG in Class III patients and the large number of graft lesions being treated, all suggesting that a decision had already been made against additional surgery for necessary revascularization. It is worth reemphasizing that no large-scale database like this one could ever hope to capture all aspects of clinical decision making, which is frequently quite complex and nuanced.

Even though a change in focus to develop disease-oriented guidelines in preference to procedure-oriented guidelines has been suggested and likely is a more desirable approach, it will still always be necessary to maintain and update existing procedure-based guidelines. Discrepancies between the 2 viewpoints should be monitored and resolved as much as possible to ensure consistency in recommendations for clinical care. It is also vitally necessary to review frequently the clinical descriptors, and in our case the algorithm, used to assign the indications classes to be certain that new developments are adequately and properly addressed. It seems likely that much better clinical risk stratification should be achiev-

able than the modest differences we observed using the present scheme. Finally, we believe the findings of our study will be of interest to clinicians, members of guidelines committees, and all others concerned with issues of quality of care.

## References

1. Smith SC, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA guidelines for percutaneous coronary intervention: executive summary and recommendations: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty). *J Am Coll Cardiol*. 2001;37:2215–2238.
2. Gibbons RJ, Smith S, Antman E. American College of Cardiology/American Heart Association clinical practice guidelines, part I: where do they come from? *Circulation*. 2003;107:2979–2986.
3. Brindis RG, Fitzgerald S, Anderson HV, Shaw RE, Weintraub WS, Williams JF. The American College of Cardiology–National Cardiovascular Data Registry (ACC-NCDR): building a national clinical data repository. *J Am Coll Cardiol*. 2001;37:2240–2245.
4. Wolk MJ, Peterson E, Brindis R, Eagle K. The appropriate cardiologist: responsible stewardship in a golden era of cardiology. *J Am Coll Cardiol*. 2004;44:933–935.
5. Anderson HV, Shaw RE, Brindis RG, Hewitt K, Krone RJ, Block PC, McKay CR, Weintraub WS. A contemporary overview of percutaneous coronary interventions. *J Am Coll Cardiol*. 2002;39:1096–1103.
6. Shaw RE, Anderson HV, Brindis RG, Krone RJ, Klein LW, McKay CR, Block PC, Shaw LJ, Hewitt K, Weintraub WS. Development of a risk adjustment mortality model using the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR) experience: 1998–2000. *J Am Coll Cardiol*. 2002;39:1104–1112.
7. Shaw RE, Anderson HV, Brindis RG, Krone RJ, Klein LW, McKay CR, Block PC, Shaw LJ, Hewitt K, Weintraub WS. Updated risk adjustment mortality model using the complete 1.1 dataset from the American College of Cardiology National Cardiovascular Data Registry (ACC-NCDR). *J Invas Cardiol*. 2003;15:578–580.
8. Spertus JA, Radford MJ, Every NR, Ellerbeck EF, Peterson ED, Krumholz HM. Challenges and opportunities in quantifying the quality of care for acute myocardial infarction. *J Am Coll Cardiol*. 2003;41:1653–1663.
9. Mehta RH, Montoye CK, Faul J, Nagle DJ, Kure J, Raj E, Fattal P, Shariff S, Amlani M, Changezi HU, Skorcz S, Bailey N, Bourque T, LaTarte M, McLean D, Savoy S, Werner P, Baker PL, DeFranco A, Eagle KA. Enhancing quality of care for acute myocardial infarction: shifting the focus of improvement from key indicators to process of care and tool use. *J Am Coll Cardiol*. 2004;43:2166–2173.
10. Bhatt DL, Roe MT, Peterson ED, Li Y, Chen AY, Harrington RA, Greenbaum AB, Berger PB, Cannon CP, Cohen DJ, Gibbons CM, Saucedo JF, Kleiman NS, Hochman JS, Boden WE, Brindis RG, Peacock WF, Smith SC, Pollack CV, Gibler WB, Ohman EM. Utilization of early invasive management strategies for high-risk patients with non-ST-segment elevation acute coronary syndromes: results from the CRUSADE quality improvement initiative. *JAMA*. 2004;292:2096–2104.
11. Stukel TA, Lucas FL, Wennberg DE. Long-term outcomes of regional variations in intensity of invasive vs medical management of Medicare patients with acute myocardial infarction. *JAMA*. 2005;293:1329–1337.
12. Leape LL, Weissman JS, Schneider EC, Piana RN, Gatsonis C, Epstein AM. Adherence to practice guidelines: the role of specialty society guidelines. *Am Heart J*. 2003;145:19–26.
13. Shekelle PG, Ortiz E, Rhodes S, Morton SC, Eccles MO, Grimshaw JM, Woolf SH. Validity of the Agency for Healthcare Research and Quality Clinical Practice Guidelines. *JAMA*. 2001;286:1461–1467.
14. Califf RM, Peterson ED, Gibbons RJ, Garson A, Brindis RG, Beller GA, Smith SC. Integrating quality into the cycle of therapeutic development. *J Am Coll Cardiol*. 2002;40:1895–1901.
15. Gibbons RJ, Smith SC, Antman E. American College of Cardiology/American Heart Association clinical practice guidelines, part II: evolutionary changes in a continuous quality improvement project. *Circulation*. 2003;107:3101–3107.