Association of a Continuous Quality Improvement Initiative With Practice and Outcome Variations of Contemporary Percutaneous Coronary Interventions

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Background—The objective of this study was to evaluate the association of a continuous quality improvement program with practice and outcome variations of percutaneous coronary intervention (PCI).

Methods and Results—Data on consecutive PCI were collected in a consortium of 5 hospitals; 3731 PCIs reflected care provided at baseline (January 1, 1998, to December 31, 1998), and 5901 PCIs reflected care provided after implementation of a continuous quality improvement intervention (January 1, 2002, to December 31, 2002). The intervention included feedback on outcomes, working group meetings, site visits, selection of quality indicators, and use of bedside tools for quality improvement and risk assessment. Postintervention data were compared with baseline and with 10 287 PCIs from 7 hospitals added to the consortium in 2002. Quality indicators included use of preprocedural aspirin or clopidogrel, use of glycoprotein IIb/IIIa receptor blockers and postprocedural heparin, and amount of contrast media per case. Outcomes selected included emergency CABG, contrast nephropathy, myocardial infarction, stroke, transfusion, and in-hospital death. Compared with baseline and the control group, the intervention group at follow-up had higher use of preprocedural aspirin and glycoprotein IIb/IIIa blockers, lower use of postprocedural heparin, and a lower amount of contrast media per case (P<0.05). These changes were associated with lower rates of transfusions, vascular complications, contrast nephropathy, stroke, transient ischemic attack, and combined end points (all P<0.05).

Conclusions—Our nonrandomized, observational data suggest that implementation of a regional continuous quality improvement program appears to be associated with enhanced adherence to quality indicators and improved outcomes of PCI. A randomized clinical trial is needed to determine whether this is a “causal” or a “casual” relationship. (Circulation. 2006;113:814-822.)

Key Words: coronary disease ■ outcome ■ percutaneous coronary intervention ■ quality improvement ■ revascularization

Advancements in catheter technology and improved operator techniques have resulted in the continuous growth of percutaneous coronary intervention (PCI).1,2 Despite these advances, the procedure is still associated with a small, but not insignificant, risk of morbidity and mortality and with high costs related to equipment use, professional fees, and need for hospitalization. Variations in practice and outcomes of PCI may depend on the characteristics of the patient population treated, on the operator’s skills, and on the care process of the institution at which the procedures are performed. Few studies have assessed outcomes of coronary interventions in community practice,3,4 and the impact of continuous quality improvement programs on practice variations and temporal trends of PCI remains to be determined. The objective of our study was to determine whether a regional collaborative continuous quality improvement program could reduce practice variations and improve outcomes

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of contemporary PCI. We describe here the development of the project and the initial results of our collaborative effort.

Methods

Development of the Consortium

In July 1996, 16 hospitals in the state of Michigan were invited to participate in a regional cardiovascular consortium. The goals of the project were to improve the quality of care of patients undergoing PCI through sharing of information and a continuous quality improvement process. Nine hospitals agreed to participate in the consortium. A common data collection form and a standard set of definitions were developed. The full project began in December 1997, after a 1-month pilot data collection phase, and has been ongoing since then. Of the 9 initial hospitals, 5 high-volume hospitals (1 academic hospital, 3 tertiary referral hospitals, and 1 community hospital performing >600 PCIs per year) had uninterrupted participation in the project over the entire 5-year time period. PCI care in these hospitals is the subject of this report. The registry has been incorporated into the quality assessment and quality improvement programs of participating institutions, and it was approved by the Institutional Review Board of the University of Michigan and by local institutional review boards.

Study Patients

The study sample consisted of 3731 PCIs reflecting care provided during the first year (January 1, 1998, to December 31, 1998) and 5901 consecutive PCIs reflecting care provided during the fifth year (January 1, 2002, to December 31, 2002), after implementation of the continuous quality improvement program. Temporal trends during the full duration of the study also were collected.

Control Group

To further assess the potential contribution of secular trends to observed rates of outcomes and quality indicators, data from the 5 intervention hospitals were compared with data from 7 high-volume hospitals (>600 procedures per year) added to the consortium during the second half of calendar year 2001 (10 287 procedures performed between January 1, 2002, and December 31, 2002). The control group included 5 tertiary referral hospitals and 2 large community hospitals.

Data Collection and Validity

Each hospital agreed to allocate a dedicated staff member to the coordination and quality assurance of data collection. The data forms were processed by the coordinating center and individually evaluated for face validity and completeness. Incomplete forms were recoded by the participating hospitals and resubmitted to the coordinating center. Site visits were performed at each participating hospital twice a year by the coordinating center; site visits to the coordinating center were performed by one of the other participating hospitals. During the site visits, cardiac catheterization logs were compared with the database logs to ensure that all consecutive patients having PCI had been enrolled. Participating institutions were asked to submit forms for all missing cases. The medical records of any patient who died or who underwent coronary artery bypass surgery, history of prior myocardial infarction (MI), gender, and history of congestive heart failure,7,8 pressure, cardiogenic shock, history of prior coronary artery bypass surgery, history of prior myocardial infarction (MI), gender, and history of congestive heart failure.7,8

Quality Improvement Intervention

The collaborative process was similar to that of the Northern New England Cardiovascular Study Group for its quality improvement initiative in Coronary Artery Bypass Surgery.9-11 A preintervention period of data collection was followed by an intervention, including feedback on absolute and risk-adjusted outcomes through quarterly and annual reports to each hospital and individual operator, quarterly working group meetings, site visits for data quality assurance and feedback, grand rounds presentations, and the development of a newsletter and bedside tools for quality improvement and risk assessment. These included bedside tools for the prediction of in-hospital mortality after PCI15 and for the prediction and prevention of nephropathy requiring dialysis,16 as well as guidelines for appropriate blood transfusion.14

The grand rounds site visits were performed by the principal investigator (M.M.) and by a nurse-investigator expert in continuous quality improvement (C.M.). During these site visits, the project was presented to all participating physicians with discussion of site-specific practice and outcome variations.

A list of quality indicators and outcome measures was agreed on during working group meetings; it was distributed to participating centers at the end of the third year. Bedside tools developed on laminated index cards were distributed to all participating centers. The tools included risk prediction models for that particular outcome and suggestions on how to modify the process of care to improve outcome (Appendix I, found in the online-only Data Supplement). Each center was asked to focus on those quality indicators that offered the most opportunity for improvement at their institution. A written commitment with notification to the coordinating center of the quality indicators selected was requested from each participating center. Aggregate and blinded individual institution data were reviewed during the working group meetings, and lessons learned were shared among participants. Examples of interventions instituted in participating hospitals included incorporating routine administration of preprocedural aspirin before diagnostic cardiac catheterization as part of standard scheduling orders; instituting nursing protocols for assessment of pre–cardiac catheterization use of medications and delaying surgery in patients who had not received antiplatelet agents; instituting routine preprocedural hydration, bi-plane coronary angiography, and avoidance of unnecessary views, including left ventriculography in high-risk patients with renal insufficiency; and modifying of emergency room protocols for patients with acute coronary syndromes. In addition, each quarterly report provided by the coordinating center was used routinely for internal quality assurance and for morbidity-mortality conferences in participating hospitals.

Quarterly and Summary Reports

A 9-page report for individual operators and institutions was prepared by the coordinating center quarterly and mailed to the participating hospitals. A summary report was mailed at the end of each calendar year. The reports included comorbidities, resource use, indicators, procedure variables, and outcome variables. The report had 3 columns: individual operator summary statistics, institution summary statistics, and summary statistics from the consortium. The main purpose of the report was to allow individual operators to understand their practice and to “benchmark” their practice with their institution and the consortium.

Main Outcome Measures

Quality indicators selected included routine preprocedural aspirin use, glycoprotein (GP) IIb/IIIa receptor blocker use, avoidance of routine use of postprocedural intravenous heparin, and avoidance of exceeding a maximum weight-adjusted and creatinine-adjusted total amount of contrast media per case. Clinical outcomes measured included in-hospital death; emergency CABG; nephropathy requir-
ing dialysis; MI; stroke or transient ischemic attack; blood transfusion; vascular complications; a combined end point including any revascularization (emergency CABG or repeated PCI at the same site), death, and stroke or transient ischemic attack; and a combined end point including any revascularization (emergency CABG or repeated PCI at the same site), death, stroke or transient ischemic attack, and MI.

**Definitions**

Nephropathy requiring dialysis was defined as a decrease in renal function requiring peritoneal dialysis or hemodialysis. Contrast nephropathy was defined as an increase in serum creatinine ≥0.5 mg/dL over baseline; in-hospital death was defined as death from either a cardiac or noncardiac cause. Vascular complications were defined as any vascular complication, including pseudoaneurysm, AV fistula, femoral neuropathy, retroperitoneal hematoma, any complication requiring surgical repair, and hematoma requiring transfusion, prolonged hospital stay, or causing a drop in hemoglobin >3.0 gm/dL. Periprocedural MI was defined as non-Q-wave MI (any rise in creatine phosphokinase-MB fraction above the normal at 3.0 gm/dL). Periprocedural MI was defined as non–Q-wave MI (any rise in creatine phosphokinase-MB fraction above the normal at 3.0 gm/dL). Periprocedural MI was defined as non–Q-wave MI (any rise in creatine phosphokinase-MB fraction above the normal at 3.0 gm/dL). Periprocedural MI was defined as non–Q-wave MI (any rise in creatine phosphokinase-MB fraction above the normal at 3.0 gm/dL). Periprocedural MI was defined as non–Q-wave MI (any rise in creatine phosphokinase-MB fraction above the normal at 3.0 gm/dL). Periprocedural MI was defined as non–Q-wave MI (any rise in creatine phosphokinase-MB fraction above the normal at 3.0 gm/dL). Periprocedural MI was defined as non–Q-wave MI (any rise in creatine phosphokinase-MB fraction above the normal at 3.0 gm/dL). Periprocedural MI was defined as non–Q-wave MI (any rise in creatine phosphokinase-MB fraction above the normal at 3.0 gm/dL). Periprocedural MI was defined as non–Q-wave MI (any rise in creatine phosphokinase-MB fraction above the normal at 3.0 gm/dL).

**Statistical Analysis**

Summary statistics are presented as frequencies and percentages, as well as mean±SD. Associations of event rates by year of study enrollment were inferred by means of χ² tests for nominal variables, by the Student t test for continuous variables, and by the Cochran-Armitage trend test for nominal variables or regression for continuous variables as appropriate.

Iterative logistic regression modeling for adverse in-hospital outcomes was performed. Initial modeling used elements marginally associated with outcome (P<0.20). Two groups of models were fitted. In the first group, hospitals were considered fixed effects; in the second group, a random effect was included, assuming normal hospital-effect distributions (SAS PROC MIXED). Variables reviewed for testing included age, gender, current smoking, history of extracardiac vascular disease (history of peripheral vascular disease, stroke, or transient ischemic attack), hypertension, diabetes, congestive heart failure, renal failure requiring dialysis, gastrointestinal bleeding, cardiac arrest, prior history of PCI, prior history of CABG, etc.

**TABLE 1. Baseline Demographic Data**

<table>
<thead>
<tr>
<th></th>
<th>Intervention Hospitals</th>
<th>Control Hospitals</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=3731)</td>
<td>(n=5901)</td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (mean±SD), y</td>
<td>61.7±12</td>
<td>63.0±12</td>
</tr>
<tr>
<td>Female gender, %</td>
<td>30.6</td>
<td>32.5</td>
</tr>
<tr>
<td>Smoking, %</td>
<td>27.7</td>
<td>26.2</td>
</tr>
<tr>
<td>Congestive heart failure, %</td>
<td>8.7</td>
<td>11.0</td>
</tr>
<tr>
<td>Hypertension, %</td>
<td>57</td>
<td>72.0</td>
</tr>
<tr>
<td>Extracardiac vascular disease, %</td>
<td>12.6</td>
<td>21.1</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>24.7</td>
<td>30.2</td>
</tr>
<tr>
<td>Creatinine ≥2.0 mg/dL, %</td>
<td>2.8</td>
<td>3.3</td>
</tr>
<tr>
<td>Renal failure on dialysis, %</td>
<td>1.2</td>
<td>1.4</td>
</tr>
<tr>
<td>Prior MI, %</td>
<td>33.8</td>
<td>33.8</td>
</tr>
<tr>
<td>Prior CABG, %</td>
<td>17.4</td>
<td>18.5</td>
</tr>
<tr>
<td>Prior PCI, %</td>
<td>31.4</td>
<td>36.0</td>
</tr>
<tr>
<td>Ejection fraction (mean±SD), %</td>
<td>53.0±11</td>
<td>52.1±11</td>
</tr>
<tr>
<td>Clinical presentation at time of PCI, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MI within 24 h</td>
<td>13.2</td>
<td>18.9</td>
</tr>
<tr>
<td>Rescue PCI</td>
<td>6.4</td>
<td>2.9</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>40.0</td>
<td>32.0</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
<td>2.4</td>
<td>2.3</td>
</tr>
<tr>
<td>Cardiac arrest</td>
<td>1.9</td>
<td>7.2</td>
</tr>
<tr>
<td>Procedural characteristics, %</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3-Vessel disease</td>
<td>19.7</td>
<td>20.6</td>
</tr>
<tr>
<td>Thrombus</td>
<td>18.1</td>
<td>25.3</td>
</tr>
<tr>
<td>Type C lesion</td>
<td>12.7</td>
<td>26.3</td>
</tr>
<tr>
<td>Severe calcification</td>
<td>16.4</td>
<td>18.9</td>
</tr>
<tr>
<td>Stent</td>
<td>71.6</td>
<td>84.0</td>
</tr>
</tbody>
</table>

*For comparison vs baseline.
†For comparison of intervention and control hospitals in 2002 (χ² test for nominal variables and Student’s t test for continuous variables).
emergency PCI, cardiac arrest, creatinine $\geq$ 2 mg/dL, left ventricular ejection fraction < 50%, cardiogenic shock, acute MI (< 24 hours), MI within 7 days, rescue PCI after failed thrombolysis, and acute MI complicated by ventricular tachycardia or fibrillation.

Diagnostic routines (Hosmer-Lemeshow test, deviance, likelihood ratio test) were used for final model selection. The effect of the quality improvement effort on clinical outcomes was evaluated by logistic regression, with covariates including age, gender, left ventricular ejection fraction, coronary artery disease, prior MI, congestive heart failure, and extracardiac vascular disease. The regression model was used to estimate adjusted odds ratios. Standardized event ratios (observed/predicted) and 95% CIs also were calculated.15 SAS 8.2 software was used for the analysis.

Results

Of the 9 hospitals that initially agreed to participate in the project, 4 hospitals dropped out during the study period: 2 during the first year, 1 during the third year, and 1 during the fourth year. Lack of hospital administration support for the project and for the internal data collection effort was the main reason why 2 institutions dropped out during the study period; lack of both physician leadership and administration support was the reason in 1 case; and loss of physician leadership was the reason in the fourth case. Of the 2 hospitals that dropped out in 1998, 1 hospital re-joined in 2000 but was unable to provide complete data in 2001 and in 2002; therefore, it was not included in the analysis. The second hospital re-joined during 2001 and was included in the control group. Thus, strong physician leadership and strong support from the hospital administrations were identified as key elements for successful continuous participation to the project.

Table 1 gives the clinical characteristics of patients undergoing PCI at baseline and at follow-up in the 5 study hospitals that are part of the intervention group and of patients undergoing PCI in the control group in the year 2002. Patients treated in the postintervention period were older ($P<0.0001$) and had a higher prevalence of hypertension, diabetes mellitus, congestive heart failure, and extracardiac vascular disease ($P<0.0001$). There were no significant differences in history of prior coronary artery bypass surgery and history of prior MI. Patients in the postintervention period were more likely to undergo PCI within 24 hours of an MI ($P<0.01$) and less likely to undergo rescue PCI after failed thrombolysis ($P<0.01$), possibly reflecting a change toward primary PCI as a treatment for acute MI.

Practice Variations and Quality Indicators

Table 2 shows practice and outcome variation among the 5 intervention hospitals at baseline and at follow-up. At baseline, there were large variations in the use of preprocedural aspirin, GP IIb/IIIa receptor blockers use, total amount of contrast per case, (mL), and use of postprocedural heparin. Striking variations also were observed in the frequency of each outcome measure selected. Overall, less variation and a lower number of outliers were observed in the postintervention period.
groups. Compared with the control group, in calendar year 2002, the intervention group had significantly higher use of preprocedural aspirin and GP receptor blockers, lower average amount of contrast per case, and a lower percentage of patients exceeding the maximum contrast dose (Table 2 and Figure 1). In addition, for each quality indicator, the control group in 2002 had average rates that were the same as or similar to the rates of the intervention group in 1998 (Figure 1).

Clinical Outcomes at Baseline and After Intervention
As shown in Table 2, compared with the preintervention period, the postintervention period was associated with lower crude rates of in-hospital death, emergency CABG, nephropathy requiring dialysis, MI, stroke, and combined end points. Similar trends were observed when the intervention group was compared with the control group. There was, however, a trend toward a lower incidence of postprocedural MI in the control group compared with the intervention group. This trend was driven by an overall higher reporting of postprocedural MI in 2 institutions in the intervention group (hospitals 3 and 5, Table 2) that had systematic assessment of postprocedural markers of myocardial necrosis (creatine phosphokinase-MB and troponin I).

After multivariate risk adjustment, the postintervention period was associated with a decreased risk of death, emergency CABG, nephropathy requiring dialysis, stroke or transient ischemic attack, and combined end points. A nonsignificant trend toward a relative risk reduction was observed for postprocedural MI (Table 3).

Use of stents was high at baseline (72%) and increased in the postintervention period (84%) (Table 1). To determine whether the change in risk-adjusted outcomes was due to the higher use of coronary stents, a second set of models was developed with coronary stenting included as an explanatory variable. In these models, after adjustment for comorbidities and stent use, the postintervention period remained an independent predictor of a lower risk of in-hospital death ($P=0.003$), nephropathy requiring dialysis ($P=0.003$), stroke or transient ischemic attack ($P=0.002$), emergency CABG ($P=0.02$), and combined end points ($P<0.0001$), consistent with the fact that differences in stent use alone could not account completely for the observed differences in clinical outcomes (Table 3).
Figure 2 shows yearly trends in the incidence of nephropathy requiring dialysis (Figure 2A) and the percentage of patients exceeding the maximum weight- and creatinine-adjusted contrast dose (Figure 2B) (Cochran-Armitage trend, $P_{\text{H11005}} < 0.0001$ and $P_{\text{H11021}} < 0.0001$, respectively). There was a correlation between percentages of patients exceeding this contrast dose and percentage of patients developing nephropathy requiring dialysis ($r_{\text{H11005}} = 0.70$, $P_{\text{H11005}} = 0.19$). Importantly, there was a decrease in the frequency of patients exceeding the contrast dose and in the frequency of nephropathy requiring dialysis in the year 2001, after the relationship was reported to the hospitals and at a national meeting in abstract format. There was a further decrease in the year 2002, after the bedside tool (Appendix I) was prepared and disseminated to all participating providers. In contrast, no changes were observed in 1999 and 2000, before implementation of the quality improvement phase. The observed reduction in the incidence of nephropathy requiring dialysis in the postintervention period was associated with a significant reduction in in-hospital death in patients with creatinine $\geq 2.0$ mg/dL (1998 death rate of 11.7% versus 2002 death rate of 2.6%; $P_{\text{H11001}} = 0.0014$).

Standardized ratios and 95% CIs for each outcome and for the combined major adverse cardiovascular event end point in the 2 time periods in the intervention group and in the year 2002 for the control group are shown in Figure 3. A significant reduction in most adverse events was observed in 2002 compared with 1998. In addition, compared with the control group, in 2002, the intervention group had significantly lower standardized ratios of blood transfusion, vascular complications, stroke, contrast nephropathy, and combined end points. Nonsignificant trends toward lower standardized ratios of nephropathy requiring dialysis and death were also observed.

**Discussion**

Our report illustrates the effect of a collaborative quality improvement program on practice and outcome variations of contemporary PCI. The past decade has been characterized by increased scrutiny of outcomes of surgical procedures and PCI. This increased scrutiny has led to the development of regional, state, and national databases for outcome assessment and for public reporting. In an attempt to improve the quality of care for patients undergoing PCI, our group of hospitals agreed to create a regional collaborative consortium to develop a quality improvement program in interventional cardiology. Although the success of this type of approach has previously been reported for coronary artery bypass surgery and in other areas of cardiac care, its validity in the context of PCI requires further investigation.

**Table 3. Unadjusted Odds Ratios and Adjusted Odds Ratios for Adverse Outcomes in 2002 Versus 1998 in the Intervention Group**

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Unadjusted OR</th>
<th>Fixed-Effects Morbidity–Adjusted OR</th>
<th>Random-Effects Morbidity–Adjusted OR</th>
<th>Random-Effects Morbidity–Stent–Adjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transfusion</td>
<td>1.20</td>
<td>0.99 (0.99–1.46)</td>
<td>0.99 (0.79–1.23)</td>
<td>0.99 (0.80–1.24)</td>
</tr>
<tr>
<td>Contrast nephropathy</td>
<td>0.61</td>
<td>0.51 (0.48–0.77)</td>
<td>0.51 (0.39–0.67)</td>
<td>0.58 (0.45–0.75)</td>
</tr>
<tr>
<td>Nephropathy requiring dialysis</td>
<td>0.42</td>
<td>0.34 (0.19–0.94)</td>
<td>0.34 (0.15–0.80)</td>
<td>0.37 (0.19–0.72)</td>
</tr>
<tr>
<td>MI</td>
<td>0.81</td>
<td>0.72 (0.60–1.10)</td>
<td>0.72 (0.53–0.99)</td>
<td>0.80 (0.58–1.09)</td>
</tr>
<tr>
<td>Stroke or TIA</td>
<td>0.49</td>
<td>0.36 (0.24–0.99)</td>
<td>0.36 (0.17–0.77)</td>
<td>0.36 (0.18–0.74)</td>
</tr>
<tr>
<td>Emergency CABG</td>
<td>0.50</td>
<td>0.40 (0.31–0.80)</td>
<td>0.40 (0.24–0.67)</td>
<td>0.43 (0.27–0.69)</td>
</tr>
<tr>
<td>Death</td>
<td>0.73</td>
<td>0.52 (0.52–1.02)</td>
<td>0.52 (0.34–0.78)</td>
<td>0.54 (0.38–0.78)</td>
</tr>
<tr>
<td>Emergency CABG/repeated PCI/stroke/death</td>
<td>0.59</td>
<td>0.44 (0.47–0.75)</td>
<td>0.44 (0.33–0.58)</td>
<td>0.44 (0.33–0.58)</td>
</tr>
<tr>
<td>Emergency CABG/repeated PCI/MI/stroke/death</td>
<td>0.70</td>
<td>0.56 (0.57–0.85)</td>
<td>0.56 (0.45–0.69)</td>
<td>0.58 (0.47–0.73)</td>
</tr>
</tbody>
</table>

OR indicates odds ratio; TIA, transient ischemic attack.
improving outcomes of PCI beyond the barriers of regional and market competition remained to be determined.

In our initial analysis, we identified significant practice and outcome variations among the participating hospitals. The significant variations in postprocedural heparin use, despite evidence of a lack of benefit from its use after uncomplicated PCI, and the variations in transfusion practices, contrast use, GP IIb/IIIa receptor blocker use, and other outcomes were surprising and were the trigger for the selection of the quality indicators for the quality improvement effort. Several additional factors influenced the final selection. Preprocedural aspirin is considered standard care for patients undergoing PCI, and except for the small percentage of patients with a true aspirin allergy, any patient undergoing PCI should receive aspirin before the procedure. Although the underuse of aspirin observed during the initial data collection might have been due at least in part to inadequate documentation, some eligible patients still were not receiving aspirin before the procedure.

GP IIb/IIIa blockers have consistently been found to decrease the risk of ischemic complications after elective or emergency PCI, particularly in patients with acute MI. Thus, given the significant variation in use observed, it was felt important to include them in the list of quality indicators. Finally, additional quality indicators such as contrast nephropathy, nephropathy requiring dialysis, and total amount of contrast per case were selected on the basis of analyses aimed at identifying procedure variables linked to poor outcomes.13,25,26 We observed an improvement in all the quality indicators selected, and this improvement was associated with an improvement in clinical outcomes and with a reduction in practice variation at follow-up.

Recent studies have shown that advances in technology, particularly the introduction of coronary stents, have resulted in an overall improvement of outcomes of PCI.1,2,27 Our study period was characterized by the introduction of improved stent technology, by new findings on the efficacy of GP receptor blockers and of other antiplatelet agents, and by an increased awareness of quality issues surrounding cardiac care. Therefore, it is likely that secular trends also contributed to the observed improvement in quality indicators and outcomes. Our analysis of the relationship between the increased use of coronary stents and the incidence of emergency CABG supports this hypothesis. In addition, the control group in this study had overall better outcomes in 2002 compared with the intervention group in 1998, thus supporting a role for temporal trends. Nonetheless, the observed changes in quality indicators, in association with the beginning of the intensive quality improvement program in the intervention group, the observed reduction in practice and outcome variations, and the differences in quality indicators and risk adjusted outcomes between the intervention group and control group in 2002, suggest the possibility that the intervention itself might have been a contributing factor in the overall improvement. However, our study does not provide direct proof for that but rather highlights some of the current challenges surrounding the assessment of the effect of quality improvement efforts on practice and outcome variations. These challenges include the evaluation of the effect of temporal trends, the evaluation of selection bias, and how to differentiate between temporal trends and true effects of quality improvement interventions in registry analysis. As the science of randomized clinical trials continues to evolve and expands to the field of quality

![Figure 3. Standardized event ratios (SERs) in the preintervention period (diagonal bars; 1998) and in the postintervention period (grid bars; 2002) in the intervention group. The open bars represent standardized event ratios in 2002 in the control group. *Significant difference in preintervention and postintervention SERs. †Significant SER difference in postintervention 2002 patients vs control 2002 patients.](http://circ.ahajournals.org/)}
improvement, it is likely that our ability to accurately differentiate between “casual” and “causal” association in quality improvement interventions will be enhanced by the application of the randomized clinical trial study design.

Our study has several additional limitations. Data were collected by study participants rather than independently abstracted. However, the study did include systematic, independent data auditing, and the audit ensured that every PCI at participating institutions was included. In addition, although there was a physician champion in each participating institution, we cannot determine to what extent individual operators were influenced by the intervention. Second, postprocedural MI was one of the clinical end points measured, but collection of postprocedural biomarkers of myocardial necrosis was left to the discretion of participating institutions. Thus, it is likely that we underestimated the true incidence of MI, particularly clinically silent postprocedural elevation of biomarkers of myocardial necrosis. In addition, risk adjustment was used to evaluate clinical outcomes. Although a rigorous analysis was performed to adjust for confounders, we cannot rule out the possibility that we were unable to adjust for other unknown confounders. Finally, our report is based on changes that occurred at 5 hospitals. Given that these were the hospitals that participated in the program uninterruptedly from the beginning, the possibility of a selection bias cannot be excluded. In addition, it remains to be determined whether our results can be generalized to community practice nationwide.

In conclusion, our nonrandomized, observational data suggest that implementation of a regional continual quality improvement program appears to be associated with enhanced adherence to quality indicators and improved outcomes of PCI. A randomized clinical trial is needed to determine whether this is a causal or a casual relationship.

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Disclosures

Dr Moscucci has received grant support and salary support from Blue Cross Blue Shield of Michigan. The other authors report no conflicts.

References


**CLINICAL PERSPECTIVE**

This study evaluated the association of a continuous quality improvement intervention with practice variations of PCI. Baseline data (3731 PCIs) from a consortium of 5 hospitals were compared with postintervention data (5901 PCIs) and with 10,287 PCIs from 7 hospitals added to the consortium in 2002 (control group). Compared with baseline and the control group, the intervention group at follow-up had higher use of preprocedural aspirin and GP IIb/IIIa blockers and lower use of postprocedural heparin and contrast media per case ($P<0.05$). These changes were associated with lower rates of transfusions, vascular complications, contrast nephropathy, and combined end points (all $P<0.05$). Although the observational nonrandomized study design represents an important limitation in the interpretation of the results, the data presented highlight the presence of practice and outcome variations with contemporary PCI and suggest the possibility that the development of a collaborative quality improvement program might be associated with a reduction in those variations and improved outcomes. A randomized clinical trial is needed to determine whether this is a causal or a casual relationship.
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