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Percutaneous Coronary Interventions in Octogenarians in the American College of Cardiology–National Cardiovascular Data Registry

Development of a Nomogram Predictive of In-Hospital Mortality

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OBJECTIVES We sought to evaluate the results of percutaneous coronary intervention (PCI) in elderly patients in contemporary practice.

BACKGROUND Prior studies of PCI in the elderly population demonstrate increased in-hospital mortality, but these studies are limited by small population size.

METHODS Using the American College of Cardiology–National Cardiovascular Data Registry (ACC–NCDR) of 100,253 patients, the in-hospital outcomes in all 8,828 PCI procedures performed on octogenarians were evaluated. Patients underwent PCI between 1998 and 2000 at over 145 participating centers.

RESULTS The mean age was 83.72 ± 3.02 years, with female preponderance (53%). The PCI was considered angiographically successful in 93%, stents were placed in 75%, and the post-PCI length of stay was 3.3 ± 5.1 days. Overall in-hospital mortality was 3.77% but was only 1.35% in PCI without recent myocardial infarction (MI) within one week ($p < 0.0001$). Patients having PCI within 6 h of the onset of their MI had an increase in mortality tenfold (13.79%) compared with patients without a recent MI ($p < 0.0001$). All groups that were defined based on time of PCI after MI onset up to seven days had increased mortality (all $p < 0.0001$). Older age (odds ratio [OR] of 1.03 per incremental year), depressed ejection fraction (EF) (OR 0.69 per 10 points for EF <60%), and time of PCI after MI onset (<6 h, OR 6.87; 6 to 24 h, OR 5.66; 24 h to one week, OR 2.93) were most strongly predictive of outcome by multivariate analysis. The predicted mortality from the multivariate model correlated well with the observed in-hospital mortality up to 20% mortality. A 254-point nomogram was constructed employing the logistic model using a weighted point system.

CONCLUSIONS In patients ≥80 years old, PCI has good success and acceptable mortality. The presence of an acute or recent MI substantially increases the risk of in-hospital death. (J Am Coll Cardiol 2002;40:394–402) © 2002 by the American College of Cardiology Foundation

Octogenarians experience increased in-hospital complications and mortality after percutaneous coronary intervention (PCI) (1–3). The original National Heart, Lung and Blood Institute (NHLBI) studies (4–6) and the initial American Heart Association/American College of Cardiology (AHA/ACC) guidelines (7,8) noted that the very elderly constituted a special patient population with worse outcomes. Specifically, although PCI could be performed with a high success rate (85% to 90%) in the years 1985 to 1995 (1–3,9–13), the increased mortality (2% to 20%) and more frequent ischemic events observed (5% to 19%) mandated a more conservative approach to patient selection. However, given the 5% to 10% in-hospital mortality of coronary artery bypass graft (CABG) in this group, PCI has continued to be an acceptable option in selected patients, especially those with refractory angina. Recent progress in addressing the adverse lesion and patient characteristics commonly present in the elderly, such as calcified lesions, low ejection fraction (EF), prior myocardial infarction (MI), diffuse disease, and co-morbid conditions, is commonly believed to have significantly improved PCI outcomes in this patient group.

The goal of this study was to analyze the current experience in octogenarians (1998 to 2000) within the American College of Cardiology–National Cardiovascular Data Registry (ACC–NCDR) and to better understand the outcomes in this unique patient group in current practice. The in-hospital mortality in all 8,828 procedures in octogenarians contained in the registry was evaluated, and indices of severity of disease and co-morbid conditions predictive of outcome were assessed. Besides examining which clinical and procedural variables predict in-hospital mortality in current practice, a logistic model and nomogram were constructed that accurately predict risk.

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Abbreviations and Acronyms

ACC	= American College of Cardiology
AHA	= American Heart Association
CABG	= coronary artery bypass graft surgery
CVA	= cerebrovascular accident
EF	= ejection fraction
LV	= left ventricular
NCDR	= National Cardiovascular Data Registry
NHLBI	= National Heart, Lung, and Blood Institute
PCI	= percutaneous coronary intervention

METHODS

Data collection. The ACC–NCDR catalogs clinical data and outcomes in 100,253 PCI procedures, including the impact of current device use and adjunctive pharmacotherapy, collected prospectively from 145 institutions across the U.S. and entered in a common database format. The development of this national registry is described in a separate publication (14), as is a risk adjustment mortality model derived from these data (15).

The data are entered into various ACC-approved commercial or privately developed databases in sites at participating institutions. The data collected are exported in a standard format to Heart House (Bethesda, Maryland). Only institutions with submissions passing the inclusion/exclusion criteria for data completeness were included. The first PCI procedure performed in any individual patient during a qualifying hospitalization was chosen for analysis. In all, 100,253 patient procedures passed the screening for inclusion in the registry. This screening process required that 99% completeness be achieved in all outcome variables (14,15).

The strengths of this registry include the use of standardized data definitions, data completeness assessment and procedures, geographic and institutional diversity, and the large sample size over a relatively short, contemporary time frame (1998 to 2000). The complete definitions of all variables were prospectively defined by a committee of the ACC and are available at the ACC website (http://www.acc.org/ncdr/cathlab.htm).

Data analysis. The procedures in all 8,828 octogenarians in the registry were included in the analysis. Octogenarians were identified by comparing the date of birth field and procedure date, with inclusion of all patients 80 years of age and older. Over 70 data elements were selected for analysis, including patient demographic data (e.g., age, gender), risk factors (e.g., smoking, diabetes), medical history data (e.g., number of vessels diseased, prior MI, EF), PCI indications, PCI presentations, and angiographic findings as described previously (14,15). These data were then extracted from the registry and sent to the data analysis center in flat file format. The data were then entered into a dataframe in S-Plus for analysis. Multiple imputation was done in S-plus according to the method of Harrell (16,17). Data analysis was performed using both imputed data and non-imputed data. Multivariate models were derived for both, but the nomogram uses the imputed data. Fewer than 100 cases had data imputed in any field.

Continuous data are expressed as mean ± SD, and categorized data as proportions. Continuous data were compared by analysis of variance and categorized data by chi square (χ^2). A p value <0.05 was considered significant. Odds ratios (OR) and 95% confidence methods were calculated to assess predictive value. For modeling, multiple imputation was used to restore missing data. Correlates of binary events were determined by logistic regression with backward elimination. The discrimination of the model was assessed by the area under the receiver operating characteristic curves; the model was validated and calibrated according to the method of Harrell (16). A nomogram was then constructed from the model based on proportional linear weights.

RESULTS

Demographics. The mean age of the 8,828 octogenarians was 83.72 ± 3.02 years. There was a preponderance of women (53%). Indications for performing PCI were: stable angina, 945 (10.7%); unstable angina, 4,924 (55.8%); acute MI (within seven days), 2,901 (32.9%); and 58 were not characterized. In this patient group, 22% had diabetes, 35% had heart failure, 29% had prior MI, and 21% had prior CABG. The mean EF was 51 + 17% in 6,206 patients in whom ejection was calculated by concurrent contrast left ventriculography.

In-hospital outcome. The in-hospital mortality was 3.77% (333/8,828). In 93% of cases, PCI was considered angiographically successful, and the mean length of hospital stay was 3.33 ± 5.12 days. Stents were placed in 75% of procedures, and multi-site PCI was performed in 35% of cases. Other complications included Q-wave MI in 0.52%, cerebrovascular accidents (CVA) in 0.46%, renal failure in 2.15%, and major vascular complications in 3.73% of cases. Patients who died had a significantly longer hospital length of stay post PCI (5.3 ± 7.6 days) than those discharged alive (3.3 ± 5.0 days, $p < 0.0001$).

INFLUENCE OF OCCURRENCE AND TIMING OF PCI IN RELATION TO RECENT MYOCARDIAL INFARCTION. As illustrated in Tables 1 and 2, numerous clinical and procedural characteristics were strongly associated with the occurrence and timing of PCI in patients with acute MI. This association includes age, several conventional risk factors for coronary artery disease, prior revascularization procedures, presence of severe angina, heart failure, and shock. Age was also significantly associated with recent MI ($p < 0.001$) due to small differences in the mean age among groups. Diabetes ($p = 0.01$), hypertension ($p < 0.001$), and prior PCI or CABG (each $p < 0.001$) were also strongly associated with this factor. Consequently, because nearly all of the tested clinical and procedural variables were associated with MI,

Table 1. The Relationship of Clinical Variables to PCI in Patients With and Without an Acute MI

	Total (n = 8,828)	No MI (n = 5,927)	MI <6 h (n = 863)	MI 6–24 h (n = 679)	MI 1–7 days (n = 1,359)	p Value
Age	83.73 ± 3.02	83.58 ± 2.89	83.90 ± 3.17	84.10 ± 3.30	84.07 ± 3.25	<0.0001
Women	53%	51%	55%	56%	56%	0.002
Diabetes	22%	22%	18%	21%	24%	0.01
Hypertension	71%	73%	65%	64%	70%	<0.0001
History of renal failure	6.5%	6.5%	5.8%	5.8%	7.7%	0.24
Chronic lung disease	13%	13%	12%	12%	13%	0.62
Cerebrovascular disease	16%	16%	14%	14%	17%	0.12
Peripheral vascular disease	17%	17%	14%	14%	16%	0.008
Heart failure	35%	31%	36%	40%	46%	<0.0001
Class III–IV angina	66%	70%	51%	59%	60%	<0.0001
Previous MI	29%	32%	24%	23%	26%	<0.0001
Previous CABG	21%	24%	13%	15%	14%	<0.0001
Previous PCI	29%	23%	17%	20%	18%	<0.0001
Thrombolysis	5%	0%	13%	15%	14%	<0.0001
Acute MI indication	23%	2%	90%	75%	48%	<0.0001
Shock as indication	3%	0%	14%	8%	3%	<0.0001
Urgent/emergent/salvage	55%	68%	12%	22%	43%	<0.0001
Ejection fraction	51 ± 17 (n = 6,206)	53 ± 17 (n = 4,192)	45 ± 15 (n = 566)	46 ± 16 (n = 462)	48 ± 20 (n = 986)	<0.0001

CABG = coronary artery bypass graft surgery; MI = myocardial infarction; PCI = percutaneous coronary intervention.

multivariate analysis was crucial to the data analysis once the univariate predictors were identified.

As shown in Table 2, the incidence of most complications and length of hospital stay were closely associated with MI. A PCI done within 24 h of the onset of MI predicted the occurrence of CVA, renal failure, and vascular complications in addition to death. The incidence of Q-wave MI could not be shown to relate to the timing of PCI.

As shown in Figure 1, the occurrence and timing of MI was strongly predictive of mortality. If there was no MI within seven days of PCI, the mortality was 1.35%, but was 4.93% if an MI had occurred between 24 h and seven days prior to PCI, 9.87% if onset was within 6 to 24 h, and 13.79% if within the past 6 h ($p < 0.0001$). This latter point can be emphasized by noting that PCI done within 6 h of MI onset was associated with a tenfold increase in mortality compared with elective PCI. The presence of cardiogenic shock ($p < 0.0001$) and urgent/emergent/salvage indication ($p < 0.0001$) were strong covariant predictors in this group.

Shock was strongly predictive of outcome. Of the 240 (3%) octogenarians who underwent PCI who fulfilled the pre-specified shock definition in the ACC–NCDR (see Appendix), 104 (43%) died, while 136 (57%) were discharged alive. Of the 333 patients in the total group who died, shock was present in 31%, compared with an incidence of 2% of the 8,495 patients who survived ($p < 0.0001$). Urgent, emergent, or salvage indication was present in 45% of cases and was also highly predictive of outcome ($p < 0.0001$). Both of these situations were also highly co-linear with the MI variables, in particular the non-elective procedure indications.

Gender was not predictive of major adverse coronary events, including in-hospital mortality. Men experienced 3.63% mortality versus 3.94% mortality in women ($p = 0.48$). Similarly, gender did not predict Q-wave MI (0.53% vs. 0.49%, $p = 0.93$), CVA (0.33% vs. 0.60%, $p = 10$), or renal failure (2.36% vs. 1.94%, $p = 0.19$). However, women did suffer an increased incidence of major vascular complications (2.58% vs. 4.74%, $p < 0.0001$) and had longer post-procedure hospital length of stay (3.17 ± 5.25 days vs. 3.48 ± 4.99 days, $p = 0.003$) than men.

Unstable angina was not associated with worse outcomes compared with the stable angina cohort in the patients without an acute MI. There was no difference noted in

Table 2. The Relationship of Angiographic and Outcome Variables to PCI in Patients With and Without an Acute MI

	Total (n = 8,828)	No MI (n = 5,927)	MI <6 h (n = 863)	MI 6–24 h (n = 679)	MI 1–7 days (n = 1,359)	p Value
Multisite PCI	35%	35%	28%	36%	34%	0.0006
Stent placement performed	75%	75%	69%	77%	79%	<0.0001
Angiographic success	93%	94%	91%	92%	91%	0.0007
Post-PCI LOS	3.33 ± 5.12	2.64 ± 4.79	5.76 ± 6.70	4.85 ± 5.02	4.06 ± 4.67	<0.0001
Q-wave MI	0.52%	0.46%	0.93%	0.74%	0.44%	0.26
CVA	0.46%	0.34%	1.05%	0.89%	0.44%	0.01
Renal failure	2.15%	1.45%	3.6%	3.55%	3.61%	<0.0001
Vascular complications	3.73%	2.87%	6.72%	6.04%	4.42%	<0.0001

CVA = cerebrovascular accident; LOS = length of stay. Other abbreviations as in Table 1.

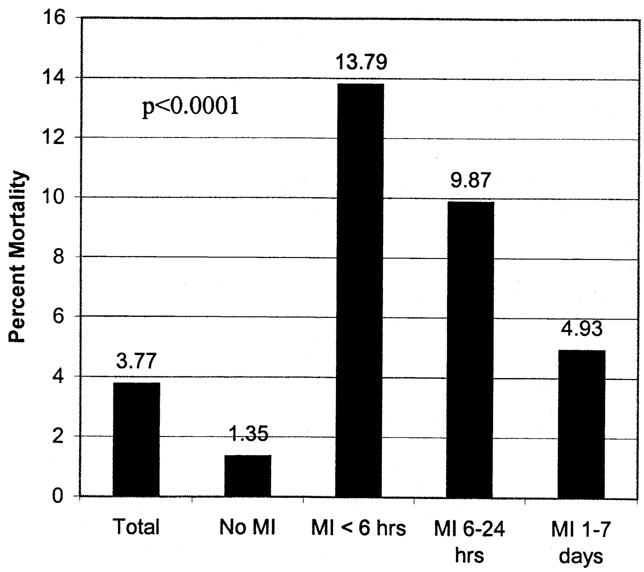

Figure 1. Mortality in all octogenarians, those without a prior acute myocardial infarction and those with a prior acute myocardial infarction (MI) within 6 h, 6 to 24 h and between one and seven days from the onset of the infarction to percutaneous coronary intervention.

death (1.2% vs. 1.8%, p = 0.18) or Q-wave MI (0.47% vs. 0.42%, p = 0.85). Surprisingly, patients with stable angina had a longer post-procedure hospital length of stay (3.15 ± 6.2 vs. 2.52 ± 4.1 days, p = 0.0001), despite similar angiographic success (95% vs. 91%, p = 0.13) and stent utilization (75% vs. 75%, p = 0.97).

Ejection fraction as evaluated by concurrent contrast left ventriculography was calculated in 6,206 patients of the 8,828 total patients (70.3%). This included 4,192/5,927 (70.7%) patients without concurrent MI, 566/863 (65.6%) patients with MI <6 h, 462/679 (68.0%) patients with MI 6 to 24 h, and 986/1,359 (72.6%) patients with MI one to seven days. Ejection fraction was 51 ± 17% in the total patient group but was 41 ± 36% in the 207 patients who had in-hospital death (62.1% of those who died) versus 51 ± 16% in the remainder (70.6% of those discharged) who survived. Ejection fraction was also strongly associated with recent MI; the "no recent MI" group who had left ventriculograms performed had an EF of 53 ± 17% compared with 45 ± 15% in the MI <6-h group, 46 ± 16% in the 6- to 24-h group, and 48 ± 20% in the one- to seven-day group (p < 0.0001).

AGE. Despite the fact that all patients in this study were age 80 or greater, age evaluated as a continuous variable was predictive of in-hospital mortality. Age was 84.38 ± 3.16 years in those who died and 83.70 ± 3.01 in those who were discharged alive (p < 0.0001).

POST-PCI HOSPITAL LENGTH OF STAY. Length of hospital stay after PCI has been shown to be a surrogate marker of cost. As shown in Table 2, length of stay was strongly correlated with recent acute MI (p < 0.0001). Patients who had PCI without MI in the previous seven days had a mean length of hospital stay of 2.64 ± 4.79 days compared with 5.76 ± 6.70 days in the MI <6-h group, 4.85 ± 5.02 days in the MI 6- to 24-h group, and 4.06 ± 4.67 in the MI one- to seven-day group. Additionally, length of stay was strongly predictive of in-hospital mortality: although the mean length of stay was 3.33 ± 5.11 days in all 8,828 patients, it was 5.31 ± 7.56 days in those who died versus 3.26 ± 4.98 days in those discharged alive (p < 0.0001).

COMPLICATIONS AND MORTALITY. Patients suffering procedural-related complications such as Q-wave MI, stroke, acute renal failure, or peripheral vascular complications had a higher in-hospital mortality (Table 3).

Table 3. The Relationship of PCI-Related Complications to In-Hospital Mortality

	Mortality Without Complication	Mortality With Complication	OR	p Value
Q-wave MI	3.72%	17.39%	5.45	<0.0001
Stroke	3.71%	16.67%	5.19	0.0001
Acute renal failure	3.23%	28.85%	12.21	<0.0001
Vascular complication	3.62%	8.16%	<0.0001	<0.0001

OR = odds ratio. Other abbreviations as in Table 1.

Multivariate analysis. Nine pre-procedure variables were shown to be multivariate predictors of in-hospital mortality. The variables associated with increased mortality were increasing age, recent MI and its timing relative to the PCI procedure, renal failure, lung disease, peripheral vascular disease, and EF <60%. Shock and acuteness (elective, urgent, emergent, or salvage) were excluded from the model due to co-linearity with acute MI. As can be seen in Table 4, the presence of a recent acute MI was clearly the single most predictive factor in determining risk of mortality. Also, the timing of the PCI after MI onset, especially in the first 24 h, was predictive. Prior PCI was found to be associated with a decreased likelihood of in-hospital mortality. The OR and 95% confidence interval (CI) for all multivariate predictors are shown in Table 4. Table 5 displays the data analysis for unimputed data.

CONSTRUCTION OF THE NOMOGRAM. A nomogram was constructed using the correlation coefficients in Table 4 as weights. The point value was derived from the statistical

Table 4. Multivariate Correlates of In-Hospital Mortality

	OR	95% CI	p Value
Age (per year)	1.03	1.00–1.07	0.0680
Acute MI <6 h	6.87	5.02–9.40	<0.0001
Acute MI 6–24 h	5.66	3.97–8.07	<0.0001
Acute MI 1–7 days	2.93	2.09–4.11	<0.0001
Renal failure	1.87	1.32–2.66	0.0005
Chronic obstructive pulmonary disease	1.27	0.93–1.73	0.1307
Peripheral vascular disease	1.44	1.08–1.94	0.0146
Ejection fraction (for every 10-point decrement, below 60%)	0.69	0.65–0.73	0.0000
Prior PCI	0.62	0.46–0.84	0.0022

ROC = 0.829, corrected ROC = 0.823. Abbreviations as in Table 1.

Table 5. Unimputed Multivariate Model

Variable	OR	95% CI	p Value
Age	1.05	1.01–1.11	0.017
Acute MI <6 h	7.87	5.31–11.62	<0.0001
Acute MI 6–24 h	5.46	3.51–8.48	<0.0001
Acute MI 1–7 days	2.91	1.90–4.54	<0.0001
Renal failure	2.94	1.90–4.54	<0.0001
COPD	1.13	0.75–1.70	0.5467
PVD	1.38	0.95–1.99	0.0887
EF	0.74	0.67–0.81	<0.0001
Prior PCI	0.74	0.51–1.09	0.1272

COPD = chronic obstructive pulmonary disease; EF = ejection fraction; PVD = peripheral vascular disease; ROC = 0.801, corrected ROC = 0.793. Other abbreviations as in Table 1.

analysis for each predictive variable. The ability to predict mortality accurately depends on the model's being calibrated to function well over a range of probabilities of mortality. Figure 2 is a graphical display of actual versus predicted probability of mortality in this patient group, based on the logistic model. Figure 2 illustrates that the calibration of the model is very strongly and accurately predictive up to a 20% mortality, with a mean absolute error of 0.003, demonstrating that it is an excellent model up to that level of risk. For the smaller number of patients with very high mortality risk, the model is no longer accurate in assessing precise risk (other than to predict that it is very high and >20%). Figure 3 shows a similar graphic for unimputed data.

The nomogram incorporated seven variables (including the three based on timing of PCI relative to MI onset as one variable) using a point score system of 0 to 254 points. Table 6 displays the point value assigned to each predictive value. Table 7 shows the correlation of total points to prediction of in-hospital mortality.

Specific patient examples using the nomogram are enumerated below:

1. An 84-year-old man admitted without an acute MI and an EF of 61% with no prior cardiac or medical illnesses and a 90% left anterior descending coronary stenosis: 56 points, <1% likelihood of death.
2. An 88-year-old man one week after an anterior wall MI treated with thrombolysis, EF of 20%: 6 + 79 + 36 = 121 points, 6% likelihood of death.
3. An 82-year-old woman with ST elevation in the inferior leads and chest pain <6 h duration, EF of 30%, with creatinine 2.5 and known peripheral vascular disease:

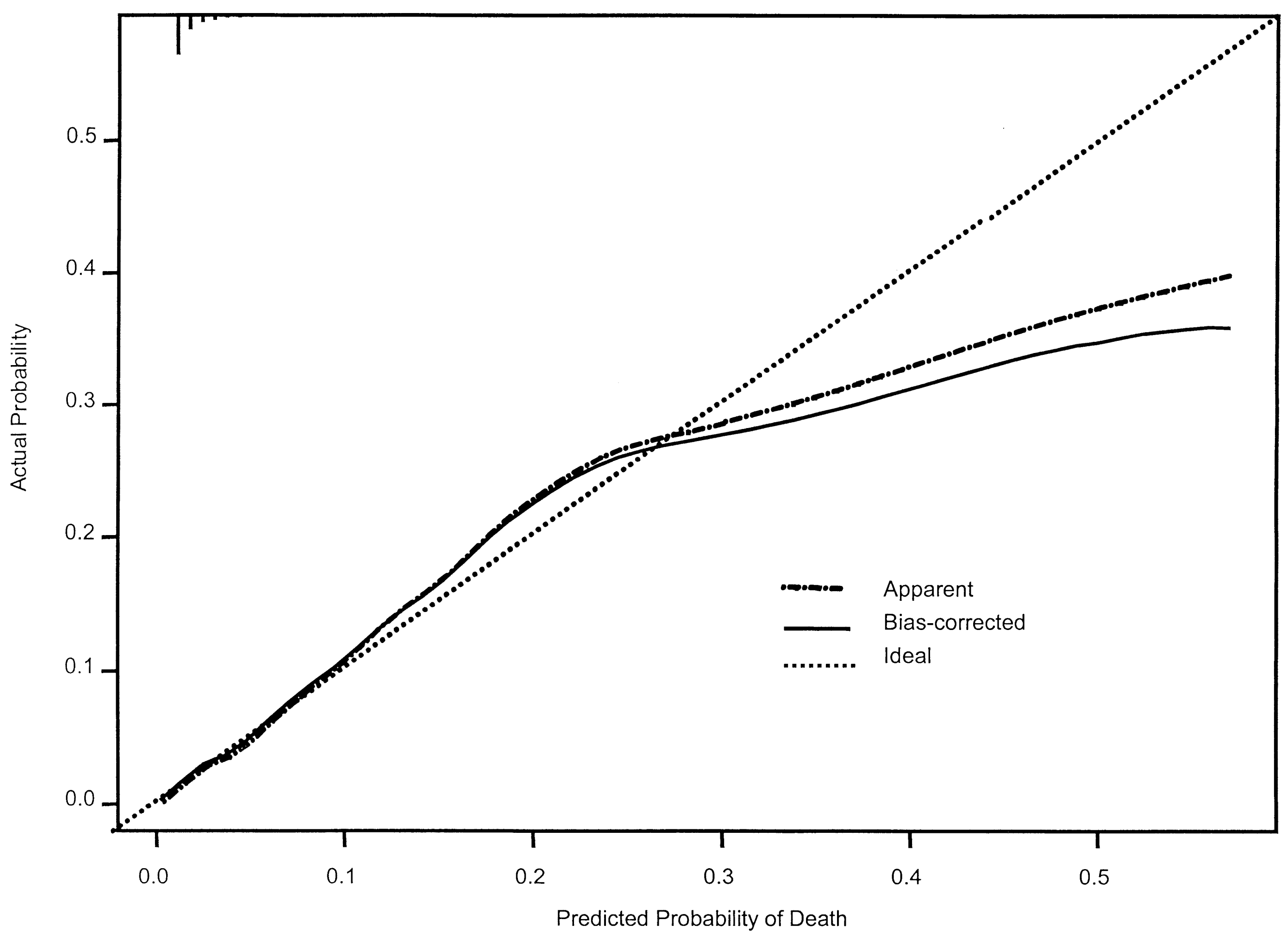

Figure 2. Correlation of the predicted probability of death from the logistic model with the observed probability of death.

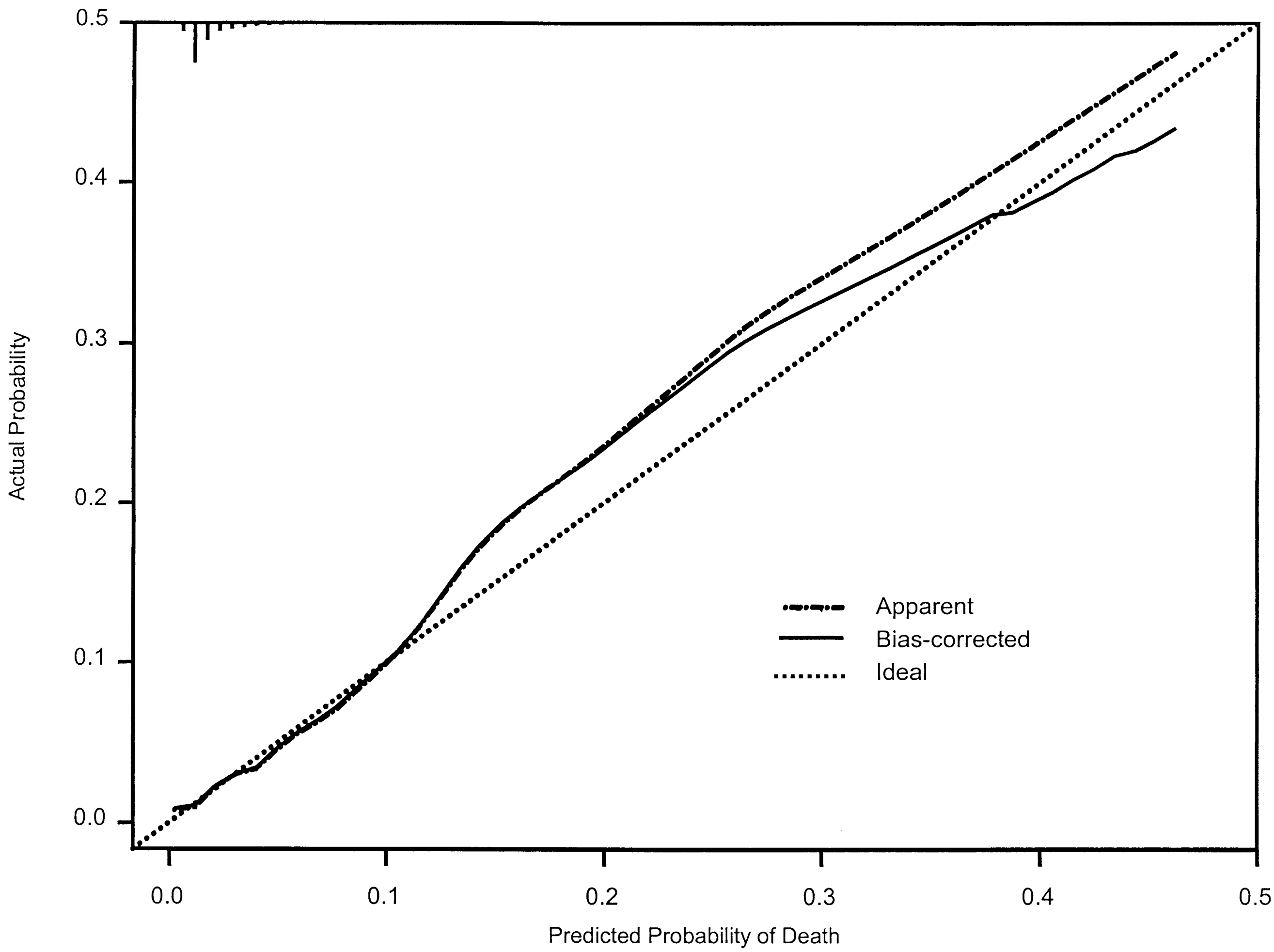

Figure 3. Correlation between predicted probability of mortality and actual mortality risk—unimputed data model.

2 + 100 + 27 + 15 + 9 = 153 points, 20% likelihood of death.

DISCUSSION

The decision to proceed with a percutaneous revascularization procedure in octogenarians is influenced by numerous factors. Important non-cardiac considerations to consider include baseline mental status, nutritional status, and coexisting renal, cerebral, pulmonary, and vascular diseases. Additionally, elderly patients are more often women, are more likely to present with acute coronary syndromes, and frequently have adverse coronary morphologic features, all of which predispose to more acute complications of intervention. Nevertheless, percutaneous revascularization can usually be performed with acceptable results. Additionally, the elderly are at increased risk of death after acute vessel closure, and there is an increased rate of vascular complications (1–13,18). The interventionist must closely monitor volume status, contrast load, urine output, bleeding, and vascular integrity during and immediately after the procedure to minimize adverse events in this often brittle patient population.

Current study. This report from the ACC–NCDR Registry analyzes data from the largest published series of contemporary octogenarians undergoing coronary intervention. Because the cases were performed in the years from 1998 to 2000, the results reflect current practice, including case selection, device use, antiplatelet therapies, and complication rates. The 8,828 procedures analyzed represent 8.8% of all cases in the registry and are confirmed to be consecutively collected.

The results of this study not only quantitate the effect of several variables long associated with mortality and adverse outcomes in this patient population but also identify some new features to consider. The most important clinical predictors of in-hospital mortality were the presence of an acute MI and the time after onset of the infarction. Numerous clinical characteristics known to be univariate predictors of mortality were strongly associated with timing of PCI after acute MI onset, a feature not previously emphasized.

Implications for practice. The optimal treatment of acute MI in the elderly remains an unsettled issue, and the data in this registry reveal important new information. Performing

Table 6. Nomogram to Predict Death

	Points
Age	
80	0
82	2
84	3
86	5
88	6
90	8
Ejection fraction	Points
20	36
30	27
40	18
50	9
60	0
70	1
Acute MI	Points
No MI	53
<6 h	100
6–24 h	95
1–7 days	79
Prior PCI	Points
Yes	−12
No	0
Renal failure	Points
Yes	15
No	0
COPD	Points
Yes	6
No	0
PVD	Points
Yes	9
No	0

Other abbreviations as in Tables 1 and 5.

PCI in elderly patients has been shown to be effective in opening the infarct-related vessel and reducing in-hospital mortality without the hemorrhagic complications associated with thrombolysis (18–23). The current study suggests that PCI is highly effective in this population as measured by angiographic success, but worse clinical outcomes than expected in elective procedures can be anticipated. Several population-based observational studies comparing the outcomes of thrombolysis and primary PCI in elderly patients with acute MI have had mixed results (24–26). In the SHOCK trial (27), patients over age 75 who underwent emergent revascularization with cardiogenic shock had a 41% higher mortality than patients who received aggressive medical therapy including intra-aortic balloon pump. Small observational studies in the shock subgroup also consistently demonstrate that PCI in elderly patients in shock has a high in-hospital mortality (28), a finding demonstrated in detail in the current study.

Table 7. Correlation of Score Based on Nomogram With Predicted Probability of In-Hospital Mortality

Total Points	Probability of Death
<62	0.006
69	0.008
75	0.010
92	0.020
102	0.030
109	0.040
115	0.050
120	0.060
127	0.080
133	0.100
145	0.150
153	0.200
>153	>0.200

Of note is the finding that elderly patients with unstable angina are not at increased risk for post-PCI in-hospital mortality, supporting the contemporary practice of considering this indication one of the most compelling for revascularization in elderly patients (12,18–20). Additionally, the efficacy of PCI in elderly patients with multivessel disease undergoing elective procedures as an alternative top bypass surgery demonstrates also that its employment in carefully selected patients has merit.

Study limitations. The limitations of this study are those of any multi-center registry. As previously described (11,12), the ACC–NCDR database fields were developed with input from over 50 physicians over a three-year period. Every variable definition was considered in depth before data collection began and collected in a data dictionary present at all sites for reference. Nevertheless, it is impossible to presume that every center and every operator interpreted clinical and angiographic variables in the same way. Similarly, there is no way to determine inter-observer and inter-center differences in denoting any particular variable. However, these definitions are a standard used in interventional practice and were originally designed to be intuitively applied by the clinician.

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APPENDIX

1. Renal Failure

   Indicate whether the patient has any documented history of renal (kidney) failure diagnosed and treated with medication, low protein diet, or dialysis by a physician. It is diagnostic if a baseline creatinine ≥2.0 mg/dl is significant.

2. Chronic Lung Disease

   Indicate whether the patient has a documented history of chronic lung disease. The patient should be on pharmacologic therapy (inhalers, theophylline, minophylline, or steroids) and/or have a forced expiratory volume at 1 s <75%, room air oxygen pressure <60% or room air carbon dioxide pressure >50.

3. Cardiogenic Shock

   Indicate whether the patient experienced cardiogenic shock at the time of the procedure. Cardiogenic shock is a clinical state of hyperfusion characterized by systolic pressure <80 mm Hg and central filling pressure >20 mm Hg, or a cardiac index <1.8 l/min/m^2. Shock is also considered present if intravenous inotropes and/or intra-aortic balloon pump are needed to maintain a systolic blood pressure >80 mm Hg and a cardiac index of >1.8 l/min/m^2.

4. Emergent/Urgent/Salvage Indication

   Urgency

   Indicate the status of the current procedure:

   Elective: The procedure could be deferred without increased risk of compromised cardiac outcome.

   Urgent: Not elective and not emergent. The procedure is required during the same hospitalization in order to minimize chance of further clinical deterioration. Worsening sudden chest pain, congestive heart failure (CHF), acute myocardial infarction (MI), anatomy, intra-aortic balloon pump, unstable angina with intravenous nitroglycerin, or rest angina may be included.

   Emergent: Ongoing ischemia including rest angina despite maximal therapy (medical or intra-aortic balloon pump) or acute evolving MI within 24 h prior to surgery. Pulmonary edema requiring intubation. Also, hemodynamic instability, which includes shock with or without circulatory support.

   Salvage: The procedure is required due to cardiac arrest with cardiopulmonary resuscitation immediately prior to entering the operating room or catheterization laboratory.

5. Number of Lesions Successfully Dilated

   Indicate the number of lesions where the residual post-intervention stenosis is <50% of the arterial luminal diameter, Thrombolysis In Myocardial Infarction flow grade is 3 and the minimal decrease in stenosis is 20%.

6. Vascular Complications

Vascular complications include:

- *Pseudoaneurysm*. The occurrence of an aneurysmal dilation of the artery at the site of catheter entry demonstrated by arteriography or ultrasound.
- *Bleeding*. Blood loss at the site of arterial or venous access or due to perforation of a traversed artery or vein requiring transfusion and/or prolonging the hospital stay, and/or causing a drop in hemoglobin-E 3.0 g/dl. Bleeding attributable to the vascular site could be retroperitoneal, a local hematoma E 10 cm diameter, or external.
- *Occlusion*. Total obstruction of the artery usually at the site of access requiring surgical repair.
- *Loss of distal pulse requiring therapy*.
- *AV fistula*. A connection between the femoral artery and femoral vein that is demonstrated by arteriography or ultrasound.
- *Dissection*.

7. Congestive Heart Failure

Physical should have CHF documented in the record or there should be a history of fluid retention during that same period, although this is not an absolute requirement. Patient should have received diuretics or cardiac medication to treat the failure. There should be a history of one or more of the following: paroxysmal nocturnal dyspnea, dyspnea on exertion due to heart failure, pulmonary congestion on x-ray, or ventricular S3 gallop. Bilateral pedal edema or dyspnea alone is not diagnostic.