ORIGINAL ARTICLES

Percutaneous Transluminal Coronary Angioplasty:
Report of Complications from the National Heart,
Lung, and Blood Institute PTCA Registry

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SUMMARY The complications reported in the first 1500 patients enrolled in the National Heart, Lung,
and Blood Institute Percutaneous Transluminal Coronary Angioplasty (PTCA) Registry are analyzed. Data
were contributed from 73 centers between September 1977 and April 1981. PTCA was successful in 63% of
attempts. Five hundred forty-three in-hospital complications occurred in 314 patients (21%). The most
frequent complications were prolonged angina in 121, myocardial infarction (MI) in 72, and coronary
occlusion in 70. One hundred thirty-eight patients (9.2%) had major complications (MI, emergency
surgery or in-hospital death). One hundred two patients (6.8%) required emergency surgery, usually for
coronary dissection or coronary occlusion. Sixteen patients (1.1%) died in-hospital; the mortality rate was
0.85% in patients with one- vessel disease and 1.9% in those with multivessel disease. The mortality rate
was significantly higher in patients who had had bypass surgery ($p < 0.001$). Nonfatal complications were
significantly influenced by the presence of unstable angina ($p < 0.001$) and initial lesion severity $> 90$

diameter stenosis ($p < 0.001$). This report delineates and assesses the complications encountered with
PTCA during its initial $3\frac{1}{2}$-year clinical experience. These results support the relative safety of PTCA as a
method of nonsurgical myocardial revascularization in carefully selected patients.

PERCUTANEOUS transluminal coronary angioplasty
(PTCA) was introduced in 1977 and has received
widespread attention as a new approach to the manage-
ment of selected patients with symptomatic coronary
to occlusive disease. In March 1979, the National
Heart, Lung, and Blood Institute (NHLBI) established
an international registry of PTCA patients. The pur-
pose of the Registry was to accumulate baseline and
follow-up data to facilitate the evaluation of the safety,
efficacy and long-term effects of this technique. Al-
though previous reports indicate that PTCA is suc-
cessful in a majority of patients, the procedure has both
associated and inherent risks. In this report, we review
the NHLBI Registry data concerning complications in
the first 1500 patients entered into the Registry during
the first $3\frac{1}{2}$ years of clinical experience with PTCA.

Methods

The NHLBI PTCA Registry is a voluntary interna-
tional registry of PTCA procedures performed ac-

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The data presented here are from the first 1500
patients enrolled in the NHLBI PTCA Registry, and
were contributed from 73 participating centers from
September 1977 to April 21, 1981. The number of
cases from individual centers varied from one case to
188 cases, with a median of nine cases. Nine centers
had enrolled more than 50 patients each and 25 centers
had enrolled fewer than five patients. One-half of the
total population was contributed from eight centers.

Data collection forms were completed by the inves-
tigators at the clinical sites, then mailed to the Data
Coordinating Center at the University of Pittsburgh. At
the Data Coordinating Center, the forms were re-
viewed by a physician for completeness, accuracy and
consistency. When questions arose, the investigators
were consulted by telephone or by mail to resolve the
problem. On-line terminal entry was used to transmit
data to a data base management system (1022 DBMS)
for computer storage and analysis. The 1022 DBMS
has an inquiry system that permits interrogation of data
bases for simple statistics. This inquiry system was
used to examine occurrence of complications and the
association of these complications with the success of
the procedure as well as with numerous other factors
considered. The 1022 DBMS interfaces with SPSS
(Statistical Package for the Social Sciences). SPSS
was used for statistical tests and many multivariate
analyses.

The complications were defined according to the
PTCA Manual of Operations. Angina pectoris was

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classified according to the Canadian Heart Association classification. Myocardial infarction was diagnosed by the presence of two of the following three criteria: occurrence of prolonged chest pain, ECG criteria for infarction using the Minnesota Code, and elevation of creatine kinase (CK) or CK-MB to more than three times normal. Myocardial infarction was considered definite (Q-wave criteria) or probable (Q-wave criteria or ST-T-wave criteria) according to the Minnesota Code. Prolonged angina was defined as chest pain that persisted longer than usual angina or was not promptly relieved with sublingual or parenteral nitroglycerin. Coronary artery spasm was defined as sudden, transient vasoconstriction resulting in myocardial ischemia. Coronary artery dissection (intimal tear) was defined as the presence of angiographically evident intimal damage producing either an intraluminal filling defect or extraluminal extravasation of contrast material; coronary dissection was considered a complication of PTCA if it caused major luminal obstruction or was associated with coronary occlusion, myocardial infarction, or deterioration of flow necessitating emergency coronary bypass surgery. Hypotension was defined as a fall in systolic blood pressure of at least 30 mm Hg that lasted more than 30 minutes and required therapy. Bradycardia was reported if heart rate was less than 50 beats/min and required therapy. A central nervous system event was recorded if a transient or persistent neurologic deficit occurred. Ventricular tachycardia was reported as three or more consecutive premature ventricular complexes whether or not therapy was required. Vascular complications included arterial thrombosis, pseudoaneurysm, and significant hematoma formation.

Statistical analysis was performed using the chi-square significance test and linear regression analysis for trend in proportions.

**Clinical Characteristics**

The baseline clinical characteristics of the patients are shown in table 1.

**Results**

Complications were encountered in 314 patients (21%) and a total of 543 in-hospital complications were reported. The type and frequency of complications are listed in table 2. The most frequent complications were prolonged angina (n = 121, 22.3%), myocardial infarction (n = 72, 13.3%), coronary occlusion (n = 70, 12.9%), and coronary artery spasm (n = 63, 11.6%). A coronary artery dissection occurred in 43 patients (2.9%), hypotension in 31 (2.1%), bradycardia in 25 patients (1.7%) and ventricular fibrillation in 24 (1.6%); 16 patients died in-hospital (1.1%). Excessive blood loss, vascular complications requiring surgery, ventricular tachycardia, and coronary embolism each occurred in less than 1% of patients.

One hundred fifty-five patients (10.3%) suffered 217 significant complications. One hundred thirty-eight (9.2%) had major complications, which included nonfatal myocardial infarction (n = 63), emergency coronary bypass surgery (n = 59) and in-hospital death (n = 16). One hundred ninety-three of these 217 significant complications occurred in these 138 patients. Seventeen additional patients had a complication associated with significant morbidity (i.e., vascular complications requiring surgical repair, stroke, pulmonary edema, cardiac tamponade and pulmonary embolism).

**Myocardial Infarction**

There were 72 myocardial infarctions (4.8%). Twenty-seven infarctions occurred in the catheterization laboratory, 35 within 24 hours after PTCA and 10 between 24 hours and 1 week after PTCA. A myocardial infarction occurred in 40 of 102 patients (39%) who underwent emergency bypass surgery, in nine of 292 patients (3.1%) who had elective bypass surgery, and in 23 patients (2.1%) who did not undergo bypass surgery. Of the 23 patients who had a myocardial infarction after PTCA and did not undergo surgery, 17 had successful PTCA. Two of these 17 patients had an infarction in the catheterization laboratory associated with coronary spasm or prolonged angina and 13 had an infarction within 24 hours of the angioplasty (five without associated in-laboratory complications, five

<table>
<thead>
<tr>
<th>TABLE 1. Characteristics of the Patient Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of pts</td>
</tr>
<tr>
<td>Males</td>
</tr>
<tr>
<td>Age (years)</td>
</tr>
<tr>
<td>Mean</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td>Angina</td>
</tr>
<tr>
<td>Prior myocardial infarction</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Diabetes</td>
</tr>
<tr>
<td>Cholesterol ≥ 250 mg/dl</td>
</tr>
<tr>
<td>Extent of coronary artery disease</td>
</tr>
<tr>
<td>1 vessel</td>
</tr>
<tr>
<td>2 vessel</td>
</tr>
<tr>
<td>3 vessel</td>
</tr>
<tr>
<td>Left main</td>
</tr>
<tr>
<td>Angina class III or IV</td>
</tr>
<tr>
<td>Duration of angina</td>
</tr>
<tr>
<td>&lt; 6 months</td>
</tr>
<tr>
<td>6–12 months</td>
</tr>
<tr>
<td>Ejection fraction &gt; 50%</td>
</tr>
<tr>
<td>Vessels attempted</td>
</tr>
<tr>
<td>LAD</td>
</tr>
<tr>
<td>RCA</td>
</tr>
<tr>
<td>LCx</td>
</tr>
<tr>
<td>Left main</td>
</tr>
<tr>
<td>Bypass graft</td>
</tr>
</tbody>
</table>

PTCA was attempted in one lesion in 1421 patients, in two lesions in 72 patients and in three lesions in seven patients.

Abbreviations: LAD = left anterior descending coronary artery; RCA = right coronary artery; LCx = left circumflex coronary artery.
with angiographic evidence of coronary dissection but no associated adverse effects in the laboratory, and three with an in-laboratory complication of coronary spasm or prolonged angina). Two patients in whom PTCA was successful and not associated with in-laboratory complications had a myocardial infarction 24 hours to 1 week after PTCA. Myocardial infarction occurred in six patients with an unsuccessful PTCA who did not undergo surgery: five had no in-laboratory complications and infarction occurred while awaiting elective bypass surgery (within 24 hours in four and between 24 hours and 1 week in one), and one patient had a myocardial infarction and subsequently died in the catheterization laboratory. Nine of 72 patients (12.5%) who sustained a myocardial infarction died.

**Emergency Coronary Bypass Surgery**

Emergency coronary bypass surgery was performed in 102 patients (6.8%). The indications for emergency surgery were coronary dissection in 32 patients (31%), coronary occlusion in 30 (29%), prolonged angina in 18 (17%), coronary artery spasm in 12 (12%), myocardial infarction in four (4%), coronary embolism in two (2%), and cardiac tamponade, coronary air embolism, ventricular fibrillation and hypotension in one patient each. Forty-three patients (42%) who underwent emergency surgery had an additional major complication (nonfatal myocardial infarction in 36 and death in seven [6.9%]).

Elective bypass surgery was performed in 292 patients after PTCA. Complications were reported in 44 of these patients (15%), including perioperative myocardial infarction in nine (3.1%) and in-hospital death in five (1.7%).

**In-hospital Deaths**

Sixteen patients (1.1%) (10 males and six females) died during the same hospitalization in which coronary angioplasty was attempted (tables 3 and 4). Ten patients with one-vessel disease died (0.9% mortality), including one patient who had bypass surgery. Six patients with multivessel disease died (1.6% mortality), and four had bypass surgery. Eleven patients with no prior bypass surgery died (0.8% mortality); nine had one-vessel disease and two had multivessel disease. Five patients (5%) with previous bypass surgery died: one patient had one-vessel disease (2.4%), and four patients had multivessel disease (6.9%). The mortality rate was significantly increased ($p < 0.001$) in patients who had bypass surgery.

The NHLBI PTCA Registry formed a committee of experts (not participating in the Registry) to study the data and narrative summaries of the patients who died and thereby assist in the analysis.

Eleven of the 16 deaths were related to PTCA. The related complications include Teflon guiding catheter dissection of the left main coronary artery, inadvertent omission of anticoagulation during the angioplasty procedure, probable coronary spasm, coronary artery dissection, coronary occlusion, prolonged angina, and myocardial revascularization in an unstable patient. Five patients died of events that were probably not related to PTCA. Three of these five patients had had bypass graft surgery; the causes of death in these five patients were disseminated intravascular coagulopathy after successful myocardial revascularization, technical complications during an elective second operation 72 hours after an unsuccessful PTCA, a myocardial infarction after postoperative saphenous vein graft occlusion, and an intraoperative myocardial infarction during elective surgery.

**Coronary Occlusion**

Coronary occlusion was reported in 69 patients (4.6%) after PTCA. A major complication occurred in 53 of these patients (77%): 25 (36%) had a myocardial infarction, 50 (72%) required emergency surgery and three (4.3%) suffered in-hospital death.

**Coronary Dissection**

A coronary dissection or intimal tear (remote or distal from the lesion) was recorded in 138 patients (9.2%) undergoing PTCA. Coronary artery dissection was a complication of PTCA in 43 patients (31%) who suffered a major associated complication: myocardial infarction, ventricular fibrillation, and hypotension in four patients each.
infarction in 16, emergency bypass surgery in 36 (26%), and in-hospital death in five (4%). There were three left main coronary dissections caused by the guiding catheter, two of which necessitated emergency bypass surgery. Neither of these patients survived the myocardial revascularization surgery. Sixty-nine percent of the patients with angiographic evidence of coronary dissection did not have any associated adverse effects or require emergency bypass surgery.

Coronary Artery Spasm
Coronary spasm occurred in 63 patients (4.2%). Coronary spasm was associated with major complications (not mutually exclusive) in 18 patients (29%): myocardial infarction in five, emergency bypass surgery in 14, and in-hospital death in two. No adverse effects were encountered with coronary spasm in 45 patients (71%). PTCA was successful in 28 patients and 17 patients underwent elective bypass surgery.

Prolonged Angina
Prolonged angina was the most frequent complication reported: 121 episodes in 109 patients (7.9% of patients). Prolonged angina was associated with major complications in 58 of these patients: myocardial infarction in 28, emergency surgery in 49, and in-hospital death in six. No sequelae were encountered in 51 patients after an episode of prolonged angina. PTCA was successful in 34 patients (31% of all patients with prolonged angina), and 17 patients subsequently underwent elective bypass surgery.

Ventricular Fibrillation
Ventricular fibrillation occurred in 24 patients (1.6%). Major complications occurred in eight patients who had ventricular fibrillation: myocardial infarction in four, emergency bypass surgery in three, and in-hospital death in one. No associated adverse effects occurred in 16 patients with ventricular fibrillation. PTCA was successful in 12 and unsuccessful in four, who subsequently had elective bypass surgery.

Vascular Complications
Vascular complications at the catheter induction site in the femoral or brachial artery occurred in 22 patients (1.5%): arterial thrombosis requiring surgery in 10, hematoma in five, pseudoaneurysm in two, thrombosis not requiring surgery in two, and femoral aneurysm, femoral arteriovenous fistula, and arterial laceration requiring repair in one patient each. Fourteen vascular complications caused significant morbidity.

Other Complications
Thirty-two miscellaneous complications were reported: five conduction defects (three transient right bundle branch block, one transient left bundle branch block, one persistent right bundle branch block), five neurologic events (one cerebrovascular accident, three transient neurologic deficits, one anoxic encephalopathy), and three arrhythmias (one atrial fibrillation, two ventricular premature beats). The additional other complications are listed in table 2. Ten of these complications were classified as major complications (i.e., cerebrovascular accident, anoxic encephalopathy, respiratory arrest, cardiac tamponade, pulmonary embolus, coronary air embolus, and pulmonary edema).

Factors Influencing the Occurrence of Complications
Analysis of the occurrence of nonfatal complications with respect to baseline clinical characteristics

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**Table 3. In-hospital Deaths**

<table>
<thead>
<tr>
<th>Mortality Statistics</th>
<th>One-vessel disease</th>
<th>Multivessel disease</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. All deaths</td>
<td>10/1177 (0.85%)</td>
<td>6/320 (1.9%)</td>
<td>16/1497 (1.1%)</td>
</tr>
<tr>
<td>2. Patients without previous</td>
<td>9/1135 (0.8%)</td>
<td>2/262 (0.8%)</td>
<td>11/1397 (0.8%)</td>
</tr>
<tr>
<td>bypass surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Patients with previous bypass</td>
<td>1/42 (2.4%)</td>
<td>4/58 (6.9%)</td>
<td>5/100 (5.0%)</td>
</tr>
<tr>
<td>surgery</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Relationship of the 16 deaths to PTCA

**Causes of death**

1. Related (11 patients)
   - Guiding catheter dissection of the left main coronary
   - Failure to administer anticoagulation
   - Probable coronary spasm
   - Myocardial revascularization in an unstable patient
   - Coronary artery dissection
   - Coronary occlusion
   - Prolonged angina

2. Probably not related (5 patients)
   - Disseminated intravascular coagulopathy
   - Perioperative myocardial infarction during elective surgery
   - A difficult elective second CABG

Abbreviations: CABG = coronary artery bypass grafting; PTCA = percutaneous transluminal coronary angioplasty.
Table 4. **In-hospital Deaths**

<table>
<thead>
<tr>
<th>Related to PTCA</th>
<th>Age (years)</th>
<th>Sex</th>
<th>CAD</th>
<th>Prior CABG</th>
<th>Site of PTCA</th>
<th>Complications</th>
<th>Surgery after PTCA</th>
<th>Cause of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>38</td>
<td>F</td>
<td>MVD</td>
<td>No</td>
<td>LAD</td>
<td>LMCA dissection</td>
<td>Emergency</td>
<td>LMCA occlusion (died during surgery)</td>
</tr>
<tr>
<td>2.</td>
<td>49</td>
<td>M</td>
<td>MVD</td>
<td>Yes</td>
<td>LMCA</td>
<td>Cardiogenic shock</td>
<td>None</td>
<td>Probable coronary spasm (died in cath lab)</td>
</tr>
<tr>
<td>3.</td>
<td>56</td>
<td>M</td>
<td>SVD</td>
<td>No</td>
<td>LAD</td>
<td>Cardiac arrest, AMI</td>
<td>Emergency</td>
<td>AMI, no anticoagulant (died 8 days p/o)</td>
</tr>
<tr>
<td>4.</td>
<td>64</td>
<td>F</td>
<td>SVD</td>
<td>No</td>
<td>LCx</td>
<td>Cardiac arrest</td>
<td>Open-chest massage</td>
<td>Autopsy: LMCA thrombus, no anticoagulant (died in cath lab)</td>
</tr>
<tr>
<td>5.</td>
<td>40</td>
<td>F</td>
<td>SVD</td>
<td>No</td>
<td>LAD</td>
<td>LMCA dissection</td>
<td>Emergency</td>
<td>LMCA occlusion (died during surgery)</td>
</tr>
<tr>
<td>6.</td>
<td>49</td>
<td>F</td>
<td>SVD</td>
<td>Yes</td>
<td>LAD</td>
<td>Dissection, MI</td>
<td>Elective (&lt; 24 hours)</td>
<td>Cardiac arrest at surgery (died 2 days p/o)</td>
</tr>
<tr>
<td>7.</td>
<td>49</td>
<td>F</td>
<td>SVD</td>
<td>No</td>
<td>RCA</td>
<td>Occlusion</td>
<td>Emergency</td>
<td>Coronary spasm, probable (died 6 hours p/o)</td>
</tr>
<tr>
<td>8.</td>
<td>55</td>
<td>M</td>
<td>SVD</td>
<td>No</td>
<td>RCA</td>
<td>Dissection</td>
<td>Emergency</td>
<td>Coronary spasm, probable refractory VF (died 8 hours p/o)</td>
</tr>
<tr>
<td>9.</td>
<td>54</td>
<td>M</td>
<td>SVD</td>
<td>No</td>
<td>LAD</td>
<td>Dissection, CHF</td>
<td>Emergency</td>
<td>MI and CHF (died 14 days p/o)</td>
</tr>
<tr>
<td>10.</td>
<td>71</td>
<td>M</td>
<td>SVD</td>
<td>No</td>
<td>LAD</td>
<td>Coronary spasm, MI, arterial repair</td>
<td>No</td>
<td>Pulmonary embolism (died 33 days p/PTCA)</td>
</tr>
<tr>
<td>11.</td>
<td>53</td>
<td>M</td>
<td>SVD</td>
<td>No</td>
<td>RCA</td>
<td>Occlusion</td>
<td>Emergency</td>
<td>p/o MI, sepsis (died 19 days p/o)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Probably not related to PTCA</th>
<th>Age (years)</th>
<th>Sex</th>
<th>CAD</th>
<th>Prior CABG</th>
<th>Site of PTCA</th>
<th>Complications</th>
<th>Surgery after PTCA</th>
<th>Cause of Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>56</td>
<td>F</td>
<td>MVD</td>
<td>Yes</td>
<td>RCA</td>
<td>None</td>
<td>Elective (&gt; 24 hours)</td>
<td>Surgical complication (died during surgery)</td>
</tr>
<tr>
<td>2.</td>
<td>57</td>
<td>M</td>
<td>MVD</td>
<td>Yes</td>
<td>LAD</td>
<td>None</td>
<td>Elective (&lt; 24 hours)</td>
<td>MI 2nd occluded SVG (died 12 days p/o)</td>
</tr>
<tr>
<td>3.</td>
<td>46</td>
<td>M</td>
<td>MVD</td>
<td>No</td>
<td>LAD</td>
<td>None</td>
<td>Elective (&gt; 24 hours)</td>
<td>DIC (died &lt; 24 hours p/o)</td>
</tr>
<tr>
<td>4.</td>
<td>62</td>
<td>M</td>
<td>SVD</td>
<td>No</td>
<td>LAD</td>
<td>Prolonged angina</td>
<td>Elective (&gt; 24 hours)</td>
<td>MI during CAGB (died during surgery)</td>
</tr>
<tr>
<td>5.</td>
<td>62</td>
<td>M</td>
<td>MVD</td>
<td>Yes</td>
<td>SVG</td>
<td>Blood loss</td>
<td>Elective (&lt; 24 hours)</td>
<td>MI with induction (died during surgery)</td>
</tr>
</tbody>
</table>

Abbreviations: SVD = single-vessel disease; MVD = multivessel disease; LMCA = left main coronary artery; LAD = left anterior descending artery; RCA = right coronary artery; LCx = left circumflex artery; AMI = anterior myocardial infarction; MI = myocardial infarction; SVG = saphenous vein graft; CABG = coronary artery bypass graft surgery; p/o = postoperatively; VF = ventricular fibrillation; DIC = disseminated intravascular coagulopathy.

revealed no significant difference in the frequency of nonfatal complications with respect to age, sex, extent of coronary artery disease, history of bypass surgery, the coronary vessel in which PTCA was attempted, the functional class of angina, duration of symptoms, history of hypertension, presence of diabetes mellitus, cholesterol level, or smoking status. The presence of unstable angina pectoris correlated significantly with an increased incidence of complications (26% with unstable angina vs 17% with stable angina, p < 0.001). A significant correlation was present for initial lesion severity and incidence of complications (18% of patients with a stenosis < 90% vs 24% in patients with a stenosis ≥ 90%, p < 0.001). The success of PTCA also significantly affected the complication rate: only 16% of patients in whom PTCA was successful had a complication, whereas 32% of patients in whom PTCA was unsuccessful had complications (p < 0.001).

**Fatal Complications**

Analysis of the occurrence of fatal complications with respect to the patient baseline characteristics revealed a significant increase in mortality only in patients with previous bypass surgery (5% with previous surgery vs 0.8% without previous bypass surgery, p < 0.001). No significant difference in mortality rate was identified with the patient’s sex, extent of coronary disease age, vessel in which PTCA was attempted, functional class of angina, duration of symptoms, or other baseline characteristics.

**Investigator Experience**

The investigator’s experience with technical proce-
dures of PTCA influenced the frequency of complications. For each angiographer, procedures were ordered chronologically. Table 5 shows the rate of all complications and the rate of major complications (death, myocardial infarction, or emergency surgery) by the sequence of performance. The first 10 cases of all investigators were combined, as were their second 10 cases, and so forth. These groupings were then related to the complications. Thus, the combined experience for all investigators produced 471 procedures with sequence performance numbers 10 or less; there were 126 complications, of which 62 were major complications. Statistical analysis for a linear trend indicates that the proportion of complications diminished as the investigator experience increased. Models were created to estimate the chance of a complication occurring as a function of the sequential number of the procedure being performed by the angiographer. The results are:

\[ P_c = 0.252 - 0.00118i \]

and

\[ P_m = 0.121 - 0.000545i, \]

where \( P_c \) is the chance of any complication, \( P_m \) is the chance of a major complication, and \( i \) is the sequence number. A chi-square test of significance for the slope (which increases the relationship between complication rate and experience) yields \( p < 0.01 \) for all complications, and \( p < 0.05 \) for major complications.

**Discussion**

This collaborative report from the NHLBI PTCA Registry reviews complications encountered in the first 1500 patients enrolled in the Registry and represents the largest source of information concerning this procedure. The baseline clinical characteristics and angiographic success rate in these patients do not differ from a previous NHLBI PTCA Registry report of 631 patients. Since this earlier report, the number of participating centers has increased to more than 100 institutions; the data presented here were from 73 centers.

One or more complications were reported in 21% of patients during or after attempted PTCA. Major complications occurred in 10% of patients: 9% of patients suffered nonfatal myocardial infarction, complications requiring emergency coronary bypass surgery, or died in hospital and 1% had other important cardiac or vascular complications.

Nonfatal myocardial infarction occurred in 4.2% of patients. Infarction occurred most frequently in patients who had other important complications that necessitated emergency bypass surgery. However, a myocardial infarction also occurred in 3.1% of patients who underwent elective bypass surgery after unsuccessful angioplasty, and in some patients who had successful PTCA without any surgery. Although a myocardial infarction occurred in only 0.2% of patients in whom PTCA was successful, these infarctions constituted nearly one-fourth of all those encountered in this study. The majority of these patients had an infarction within 24 hours after PTCA. This fact substantiates the need for patient monitoring early after successful PTCA. The hospital mortality rate of 12.5% in patients with myocardial infarction after PTCA is similar to the mortality rate associated with myocardial infarction in most coronary care units, and underscores the severity of this complication.

Emergency surgery for complications encountered with coronary angioplasty was performed in 6.8% of patients. Surgery was performed in these patients for severe myocardial ischemia, usually as a result of coronary dissection, coronary occlusion, or coronary artery spasm. Emergency coronary bypass surgery was associated with a mortality rate of 6.9% and a high incidence (38%) of perioperative, nonfatal myocardial infarction. However, in the majority of patients with myocardial infarction and emergency surgery, the infarction occurred in the catheterization laboratory. The emergency surgery was performed for and during the evolving myocardial infarction. This may be an important factor relating to the increased mortality associated with emergency surgery. An increased risk has been reported in other studies in which coronary artery bypass surgery was performed in patients with acute myocardial infarction. However, this problem must be contrasted with the fact that the majority of patients in whom emergency surgery was performed did not develop evidence of myocardial infarction and had no significant perioperative complications. Studies of reperfusion after experimental coronary occlusion would support a role for acute revascularization in this setting.

During the hospitalization in which PTCA was attempted, 1.1% of the patients died. Two patients died in the catheterization laboratory and nine died after operations (seven emergency and two elective) precipitated by complications during PTCA. One patient did not undergo surgery but died of complications that occurred during and after PTCA. The four other patients who died had undergone elective surgery, three more than 24 hours after unsuccessful PTCA. Patients who had undergone bypass surgery had a higher risk at

**Table 5. Complications by Patient Sequence**

<table>
<thead>
<tr>
<th>Patient sequence no.</th>
<th>No. of pts</th>
<th>All complications</th>
<th>Major complications*</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>n</td>
<td>%</td>
<td>n</td>
</tr>
<tr>
<td>1–10</td>
<td>471</td>
<td>126</td>
<td>62</td>
</tr>
<tr>
<td>11–20</td>
<td>230</td>
<td>50</td>
<td>19</td>
</tr>
<tr>
<td>21–30</td>
<td>172</td>
<td>32</td>
<td>18</td>
</tr>
<tr>
<td>31–40</td>
<td>129</td>
<td>24</td>
<td>10</td>
</tr>
<tr>
<td>41–50</td>
<td>97</td>
<td>16</td>
<td>8</td>
</tr>
<tr>
<td>51–60</td>
<td>77</td>
<td>15</td>
<td>7</td>
</tr>
<tr>
<td>61–70</td>
<td>56</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>71+</td>
<td>268</td>
<td>37</td>
<td>17</td>
</tr>
<tr>
<td>Total</td>
<td>1500</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Death, myocardial infarction, or emergency surgery.

This table shows the rate of all complications and the rate of major complications (death, myocardial infarction, or emergency surgery) by the sequence of performance. The first 10 cases of all investigators were combined, as were their second 10 cases, etc. These groupings were then related to the complications.
emergency surgery than those who had not. The factors responsible for this increased risk are not entirely clear. However, reoperation appears to have played a role in the increased risk, for a reoperation was performed in four of the five patients who died. Emergency surgery was not a factor in these deaths, for each of these patients underwent an elective operation. Reoperation is technically more difficult than initial bypass surgery and has been associated with greater morbidity and mortality than the initial operation.\textsuperscript{12, 13} Mortality after PTCA in patients without prior coronary bypass surgery was 0.8% for patients with both one-vessel and multivessel disease, which is comparable to the mortality reported with elective operative revascularization.

Registry data indicate that coronary artery dissection is not uncommon with PTCA. A dissection was detected angiographically in 9.2% of patients. Although coronary dissection was an important complication and the most common indication for emergency surgery, angiographic evidence of coronary dissection was not associated with adverse effects in more than two-thirds of patients. A coronary dissection defined angiographically did not represent a complication in the majority of patients in whom it was identified.\textsuperscript{14} When a dissection did represent a significant complication, the adverse effects were usually manifest promptly. The recognition of coronary dissection after PTCA warrants careful patient monitoring early after PTCA. In the absence of early adverse effects, angiographically apparent coronary dissection does not usually represent a complication of PTCA.

The incidence of certain implications with PTCA, particularly noncardiac and peripheral vascular complications, ventricular fibrillation, central nervous system deficits, conduction disturbances and other miscellaneous complications, approximates the frequency of these events with diagnostic angiography.\textsuperscript{15, 16} However, the incidence of major complications producing severe myocardial ischemia or resulting in myocardial infarction or death is considerably higher and approximates that of coronary artery bypass surgery.\textsuperscript{17-19}

Analysis of factors influencing the frequency of complications with PTCA demonstrated a significant correlation with several baseline patient clinical and angiographic characteristics, as well as with investigator experience with PTCA. The presence of unstable angina pectoris correlated significantly with an increased incidence of nonfatal complications. Unstable angina has also been associated with increased risk in patients undergoing coronary angiography and with coronary artery bypass surgery.\textsuperscript{20-22} In addition, the frequency of complications was significantly higher in patients with severely stenotic lesions (≥ 90%) than in patients with less severe coronary narrowing. Analysis of factors influencing mortality revealed a significant relationship only for previous coronary bypass surgery. Another factor influencing the complication rate with PTCA is investigator experience. The frequency of all complications and of major complications declined with increasing patient sequence number at individual institutions. These data confirm the existence of a learning curve for PTCA and indicate that the complication frequency should continue to decline with increasing investigator experience.

These Registry data represent the combined results of many centers and reflect wide variation in experience in individual centers. (The number of cases from each center varies from one to 188 patients.) The median case frequency in this report is nine patients, and more than one half of all patients were among the first 25 cases done in each institution. Therefore, these results include the initial experience at all centers and represent a very limited experience at many of the centers and a more extensive experience at only relatively few centers. Moreover, during the course of this data collection, the catheter equipment and materials have improved and additional catheter systems have become available. Nevertheless, these data are probably representative of the results that may be expected at many independent centers that are performing or will be performing PTCA.

The acute morbidity and mortality statistics are impressive considering the age of this therapeutic procedure and appear certainly comparable to other therapeutic modalities. The long-term morbidity and mortality rates are not yet available from the PTCA Registry, and have not been addressed in this report. Nevertheless, these results appear to establish the relative safety and efficacy of PTCA as a nonoperative method of myocardial revascularization in carefully selected patients and should serve as a useful reference for additional studies.

References
SUMMARY

The relationships of total cholesterol and the proportion of cholesterol in individual lipoprotein classes to coronary heart disease are complex. To help simplify these relationships, cholesterol values are often combined into one summary estimate to form a single risk factor with a relationship to disease that is more easily described. Although summary estimates result in convenient expressions relating cholesterols to coronary heart disease, there is the potential for sacrificing information by ignoring the joint configuration of cholesterols that make up these estimates. We investigated the extent of this possibility for the ratio of total cholesterol to high-density lipoprotein cholesterol and the ratio of low-density lipoprotein cholesterol to high-density lipoprotein cholesterol. The findings suggest that the summary estimates are useful expressions for combining cholesterol information and are strong predictors of coronary heart disease. Clinicians who choose to use a summary estimate for screening purposes should recognize that a single ratio estimate is not always as informative as the joint configuration of the cholesterols that make up the estimate. This possibility is most clearly exhibited for the ratio of low-density lipoprotein cholesterol to high-density lipoprotein cholesterol, and it may become more apparent in future studies as the capabilities of exploring lipoprotein cholesterol relationships improve.

TOTAL CHOLESTEROL (T-C) and the amount of cholesterol in individual lipoprotein density classes have been shown to be related to the development of coronary heart disease (CHD). With the discovery of these relationships, attempts have often been made to reduce the complex explanations of causality among the lipoprotein density classes. These attempts have resulted in the derivation of summary estimates, which combine information contained in more than one cholesterol value. The summary estimates are not intended to replace the need to jointly consider individual pieces of information concerning lipid profiles. Rather, they are convenient measures of disease risk because they provide a single value that quantifies the potential for developing CHD that can be compared to an easily remembered scale.

Although summary estimates of lipids have been used in studies of the epidemiology of cardiovascular disease, an assessment of how well they predict CHD compared with the joint configuration of individual lipoprotein cholesterol levels has not been provided. Combining cholesterol levels into one summary estimate might eliminate important information available when individual cholesterol values are considered together.

In this report, we analyze data from the Framingham Heart Study and evaluate how well two summary estimates predict total CHD when compared with the information available by jointly considering individual levels of the cholesterol values that make up these estimates. The issue considered in this presentation is not intended to emphasize the importance of individual lipoprotein cholesterols, but to examine the summary estimates and determine whether important information that could help describe CHD risk is lost. The summary estimates examined are the ratio of T-C to