Balloon Angioplasty Versus New Device Intervention: Clinical Outcomes

A Comparison of the NHLBI PTCA and NACI Registries

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Atlanta, Georgia; Pittsburgh, Pennsylvania; Boston, Massachusetts; Bethesda, Maryland; Rochester, Minnesota; Richmond, Virginia; Montreal, Quebec, Canada; and Miami, Florida

Objectives. We sought to compare outcomes of patients treated in the National Heart, Lung, and Blood Institute (NHLBI) Percutaneous Transluminal Coronary Angioplasty (PTCA) and New Approaches to Coronary Intervention (NACI) registries.

Background. Coronary angioplasty has numerous shortcomings. New devices for performing coronary interventions have been introduced in an effort to improve clinical outcomes.

Methods. Under the sponsorship of the NHLBI, a registry of consecutive patients treated with PTCA during 1985 to 1986 was established. In 1990, the NHLBI funded a second registry, the NACI. The two registries used the same data coordinating center to collect detailed baseline and follow-up information.

Results. Patients enrolled in the NACI registry were older, had undergone more previous bypass surgery procedures and had more stenoses located in bypass grafts than patients in the NHLBI PTCA registry. Procedural success was achieved in 72.1% and 82.6% of patients in the PTCA and NACI registries, respectively; however, in-hospital and 1-year mortality rates were 1.0% versus 1.8% and 3.1% versus 5.9% for the PTCA versus NACI registries, respectively. After risk adjustment, there was no difference in 1-year mortality. Rates of target lesion revascularization (TLR) were 21.5% for the PTCA registry and 24.2% for the NACI registry.

Conclusions. This comparative study found no overall superiority of these newer devices in terms of patient survival or freedom from TLR after adjustment for baseline risk profiles. Although technologic improvements (especially improved stenting) continue, these observations highlight the importance of careful assessment of clinical results in the broad population of patients in whom interventions are used.

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Multicenter registries of percutaneous coronary interventions first came into being at the urging of Andreas Gruentzig and others, under the sponsorship of the National Heart, Lung, and

Blood Institute (NHLBI), National Institutes of Health, Bethesda, Maryland. The first registry catalogued >3,000 consecutive patients undergoing percutaneous transluminal coronary angioplasty (PTCA) between 1977 and 1981. After some maturity of both the technique and technology, notably the development of steerable guide wires, a new registry (PTCA II) was sponsored by the NHLBI to enroll patients undergoing initial PTCA in 1985 and 1986 (1).

With the advent of new devices in the late 1980s, a third registry (New Approaches to Coronary Intervention [NACI]) of patients undergoing catheter-based interventions with these new devices between 1990 and 1994 was established with the assistance of the NHLBI (2). The existence of the PTCA II and NACI registries allows for a comparison of balloon angioplasty and new device angioplasty at a time when reasonable guide
catheter and guide wire technology was available and each method had achieved a modest degree of maturity.

**Methods**

**Patient selection.** A total of 2,431 patients from 16 centers were enrolled in the PTCA II registry, and 4,389 patients from 39 clinical sites were enrolled in the NACI registry. To facilitate comparisons, we focused on the elective use of planned devices as much as possible, limiting the analysis to patients not experiencing acute, evolving myocardial infarction (MI). In PTCA II, there were 2,311 such consecutive patients who underwent their first angioplasty. To make the NACI cohort comparable to the PTCA II cohort, we excluded 527 patients who were later enrolled separately at the end of the recruitment period, as well as those with a previous angioplasty and patients who had new devices used as a rescue strategy after failed angioplasty. Using these criteria, there were 1,985 patients in the NACI registry who had undergone procedures involving directional coronary atherectomy (DCA [n = 607]), transluminal extraction catheter (TEC [n = 255]), rotational atherectomy (ROTA [n = 228]), stents (n = 182), lasers (n = 581) and multiple new devices (n = 132).

**Definitions.** Myocardial infarction was defined in the PTCA II registry, as the presence of at least two of three criteria: clinical symptoms, Q waves on the electrocardiogram (Minnesota Code) or elevated cardiac enzyme levels (double the normal levels for creatine kinase or its MB fraction. However, the individual criteria for detecting MI were not available for events occurring after the index hospital period. In the NACI registry, MI included the presence of Q waves (two-step Q wave change defined by the Minnesota Code) and “other MI” criteria (doubling of creatine kinase or its MB fraction without Q waves). **Angiographic success** was defined as a reduction in percent stenosis of at least 20% and a residual stenosis <50% in all attempted lesions. **Procedural success** was defined as lesion success without in-hospital death, Q wave MI or coronary artery bypass graft surgery (CABG).

**Target lesion revascularization** (TLR) was defined as either a repeat catheter-based procedure in the segment treated at baseline or any bypass surgery after hospital discharge for the original procedure. Data collected and their definitions were similar between the PTCA II and NACI registries, and the data coordinating center was the same. Although angiographic core laboratories provided readings for a subset of films in each registry, this report uses site-reported assessments for data comparability and completeness.

**Follow-up assessment.** Patients in both registries were contacted by the site coordinator 1 year after their index procedure. Information on vital status, hospital admission for MI or repeat revascularization, symptoms, activity level, employment status and medication use was collected on standard forms. In the PTCA II registry, patients reported the occurrence of angina during the 30 days before the interview; patients in the NACI registry reported angina during the previous 6 weeks. Lesion-specific information on repeat interventions was used to assess the outcome TLR.

**Statistical analysis.** Differences in proportions between subgroups were assessed by chi-square test or Fisher exact test, as appropriate. Differences in mean values of variables measured on a continuous scale were assessed by the Student t test; for variables with excessively skewed distributions, median values were compared using the Wilcoxon test. Life-table analysis with the product-limit method (3) was used to estimate event rates at 1 year. Cox regression analyses (4) were implemented to estimate crude and adjusted relative risks of an event for the NACI versus PTCA II registry. Baseline patient-specific factors, including age, gender, history of MI, hypertension, diabetes, congestive heart failure, number of diseased vessels, unstable angina, previous bypass surgery, severe, concomitant noncardiac disease and high surgical risk, were considered for adjustment in models of morbid events and repeat procedures. Also considered were baseline lesion factors, such as the presence of thrombus, calcium, eccentricity and total occlusion in any attempted lesion. For models of TLR, “vein graft attempt” was forced into each model, and “number of lesions attempted” was also considered.

To address potential confounding factors due to different centers and operators in the two registries, all comparisons are supplemented by identical analyses using only the five sites participating in both registries (Medical College of Virginia, Mayo Clinic, Emory University, Miami Heart Institute and Montreal Heart Institute).

**Results**

**Baseline characteristics.** Some of the numerous differences in patient baseline characteristics between the two registries (Table 1) reflect the later time frame of the NACI registry. NACI registry patients were 5 years older on average, and three times as many had undergone a previous CABG and had heart failure or severe concomitant disease. Diabetes was more prevalent in the NACI registry. Baseline anginal patterns were similar, with >50% of patients having unstable angina. Although the majority of patients in both registries had multivessel disease, the proportion was 10% higher in the
NACI registry. Mean left ventricular ejection fraction was 3% higher in the PTCA II registry. Although most baseline features were similar among the five common sites and the overall population in both registries, more patients from the common sites had multivessel disease.

Characteristics of attempted lesions. As shown in Table 2, slightly more patients in the PTCA II registry underwent multivessel and multilesion angioplasty. In contrast, vein grafts were attempted 10 times more in the NACI registry patients. Although single, discrete lesions were more commonly treated in the NACI registry, eccentric lesions and lesions containing thrombus or calcium were also reported more frequently. These variations may have reflected a closer scrutiny in evaluating patients for specific devices in the NACI registry. New device angioplasty created a larger lumen (final stenosis diameter 32.8% in PTCA II vs. 18.9% in NACI) and therefore had a higher lesion success rate.

Outcome. The angiographic success rate was 75% in PTCA II registry patients and 86% in the NACI registry patients (Table 3). The incidence of in-hospital major complications (death, Q wave MI or CABG) was lower and procedural success rate higher in the NACI registry. Subsequent CABG was more common in the PTCA registry, whereas repeat percutaneous intervention was more com-

### Table 1. Characteristics of Patients by Study Period

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>All Sites</th>
<th>Common Sites*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PTCA II</td>
<td>NACI</td>
</tr>
<tr>
<td></td>
<td>(n = 2,311)</td>
<td>(n = 1,985)</td>
</tr>
<tr>
<td>Mean age (yr)†‡</td>
<td>58.2</td>
<td>63.5</td>
</tr>
<tr>
<td>Age ≥ 65 yr†</td>
<td>27.2%</td>
<td>48.6%</td>
</tr>
<tr>
<td>Male†</td>
<td>74.3%</td>
<td>70.2%</td>
</tr>
<tr>
<td>Median time from chest pain (mo)†‡</td>
<td>6.0%</td>
<td>12.9%</td>
</tr>
<tr>
<td>Previous CABG‡</td>
<td>11.5%</td>
<td>37.5%</td>
</tr>
<tr>
<td>Hx of MI‡</td>
<td>43.6%</td>
<td>44.7%</td>
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<tr>
<td>Hx of CHF‡</td>
<td>5.6%</td>
<td>14.3%</td>
</tr>
<tr>
<td>Severe, concomitant disease‡</td>
<td>5.8%</td>
<td>13.6%</td>
</tr>
<tr>
<td>Inoperable/high risk†‡</td>
<td>8.1%</td>
<td>20.7%</td>
</tr>
<tr>
<td>Hx of diabetes‡</td>
<td>13.4%</td>
<td>20.9%</td>
</tr>
<tr>
<td>Hx of hypertension‡</td>
<td>45.7%</td>
<td>52.7%</td>
</tr>
<tr>
<td>Hx of hypercholesterolemia</td>
<td></td>
<td></td>
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<tr>
<td>&gt; 250 mg/100 ml</td>
<td>33.3%</td>
<td>—</td>
</tr>
<tr>
<td>&gt; 240 mg/100 ml</td>
<td>—</td>
<td>56.1%</td>
</tr>
<tr>
<td>Smoking‡</td>
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<tr>
<td>Present</td>
<td>30.2%</td>
<td>18.4%</td>
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<tr>
<td>Past</td>
<td>40.2%</td>
<td>43.7%</td>
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<tr>
<td>Never</td>
<td>29.5%</td>
<td>37.9%</td>
</tr>
<tr>
<td>Angina‡</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>3.5%</td>
<td>6.5%</td>
</tr>
<tr>
<td>Stable</td>
<td>42.5%</td>
<td>30.0%</td>
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<tr>
<td>Unstable</td>
<td>54.0%</td>
<td>57.5%</td>
</tr>
<tr>
<td>Only with MI</td>
<td>0</td>
<td>6.0%</td>
</tr>
<tr>
<td>Primary reason for revasc†</td>
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</tr>
<tr>
<td>Angina</td>
<td>89.5%</td>
<td>83.9%</td>
</tr>
<tr>
<td>Silent ischemia</td>
<td>2.8%</td>
<td>4.3%</td>
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<tr>
<td>Acute MI</td>
<td>5.5%</td>
<td>7.3%</td>
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<tr>
<td>Other</td>
<td>2.2%</td>
<td>4.5%</td>
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<tr>
<td>Vessel disease†</td>
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<tr>
<td>Single</td>
<td>47.9%</td>
<td>38.1%</td>
</tr>
<tr>
<td>Double</td>
<td>31.8%</td>
<td>26.6%</td>
</tr>
<tr>
<td>Triple</td>
<td>20.3%</td>
<td>55.3%</td>
</tr>
<tr>
<td>LMCA stenosis ≥ 50%‡</td>
<td>1.7%</td>
<td>9.8%</td>
</tr>
<tr>
<td>Average LVEF‡</td>
<td>58.4%</td>
<td>55.2%</td>
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</tbody>
</table>

*Medical College of Virginia, Mayo Clinic, Emory University, Miami Heart Institute and Montreal Heart Institute.
†‡ < 0.001 between PTCA II and NACI registries for all sites. †Testing for angina status between the two registries was not performed because of different categories in the two registries. Data are percent of patients, unless otherwise indicated. CABG = coronary artery bypass graft surgery; CHF = congestive heart failure; Hx = history; LVEF = left ventricular ejection fraction; LMCA = left main coronary artery; MI = myocardial infarction; N/A = not applicable; NACI = New Approaches to Coronary Interventions registry; PTCA = Percutaneous Transluminal Coronary Angioplasty registry; revasc = revascularization.
mon in the NACI registry. These trends were similar among common sites.

There was little difference in angina status at 1-year follow-up. One-year physical activity levels favored the NACI registry; 59% of NACI and 46% of PTCA II registry patients reported engaging in moderate or strenuous activity. However, similar proportions were as limited as before the intervention (19% for PTCA vs. 18% for NACI). Table 4 shows that angina-free status was achieved with similar numbers of subsequent interventions. In patients without angina, no additional procedure was performed in 73% in the PTCA registry and 68% in the NACI registry, whereas subsequent percutaneous procedures were performed in 14% and 20% and CABG in 13% and 12%, respectively.

Risk-adjusted composite adverse events at 1 year. Table 5 shows the unadjusted and adjusted event rates at 1 year. Although the cumulative 1-year mortality rate was twice as high in the NACI registry (crude relative risk for mortality 1.96 for NACI registry patients vs. PTCA II registry patients), the relative risk for mortality was no longer significant after risk adjustment for other baseline characteristics associated with mortality (Table 5). For the combined end point of death, MI or any repeat revascularization, as well as the end point of death, infarction or bypass surgery, the excess risk for NACI registry patients remained significant even after adjustment. Likewise, when TLR was adjusted for factors potentially confounding comparison of the two registries (multiple-lesion attempts during baseline procedure and routine follow-up angiography), a significant excess risk remained in the NACI registry.

The same analysis, restricted to patients from the five common centers, revealed that after adjustment there was no

**Table 2. Characteristics of Lesions (site assessment) by Study Period**

<table>
<thead>
<tr>
<th></th>
<th>All Sites</th>
<th>Common Sites*</th>
<th>PTCA II (n = 3,611)</th>
<th>NACI (n = 2,313)</th>
<th>PTCA II (n = 1,620)</th>
<th>NACI (n = 555)</th>
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<tbody>
<tr>
<td>No. of vessels attempted†</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>79.2%</td>
<td>84.7%</td>
<td>80.7%</td>
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<td>2</td>
<td>18.2%</td>
<td>13.8%</td>
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<tr>
<td>3</td>
<td>2.6%</td>
<td>1.5%</td>
<td>2.3%</td>
<td>4.4%</td>
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<td></td>
</tr>
<tr>
<td>No. of lesions attempted†</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>62.1%</td>
<td>69.5%</td>
<td>61.9%</td>
<td>60.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>25.4%</td>
<td>21.3%</td>
<td>25.6%</td>
<td>24.9%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>8.2%</td>
<td>6.8%</td>
<td>7.3%</td>
<td>9.0%</td>
<td></td>
<td></td>
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<tr>
<td>&gt;3</td>
<td>4.3%</td>
<td>2.5%</td>
<td>5.2%</td>
<td>5.5%</td>
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<tr>
<td>Use of adjunctive balloon</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td></td>
<td>N/A</td>
<td>77.7%</td>
<td>N/A</td>
<td>69.7%</td>
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<tr>
<td>Target vessel†</td>
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<tr>
<td>RCA</td>
<td>29.2%</td>
<td>24.3%</td>
<td>30.2%</td>
<td>27.0%</td>
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<td></td>
</tr>
<tr>
<td>LMCA</td>
<td>0.4%</td>
<td>2.3%</td>
<td>0.2%</td>
<td>3.6%</td>
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<td></td>
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<tr>
<td>LAD</td>
<td>45.3%</td>
<td>35.8%</td>
<td>44.9%</td>
<td>32.8%</td>
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<td></td>
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<tr>
<td>LCx</td>
<td>21.7%</td>
<td>8.7%</td>
<td>21.6%</td>
<td>9.2%</td>
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<tr>
<td>CABG</td>
<td>3.4%</td>
<td>28.8%</td>
<td>3.1%</td>
<td>27.4%</td>
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<tr>
<td>Lesion morphology†</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Single discrete</td>
<td>54.8%</td>
<td>63.5%</td>
<td>55.8%</td>
<td>68.6%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple discrete</td>
<td>8.8%</td>
<td>5.1%</td>
<td>5.4%</td>
<td>5.1%</td>
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<tr>
<td>Diffuse</td>
<td>11.4%</td>
<td>16.8%</td>
<td>10.5%</td>
<td>10.6%</td>
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<tr>
<td>Tubular</td>
<td>19.2%</td>
<td>9.2%</td>
<td>23.2%</td>
<td>13.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not visible</td>
<td>5.8%</td>
<td>5.5%</td>
<td>5.1%</td>
<td>2.2%</td>
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<td></td>
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<tr>
<td>Thrombus†</td>
<td>8.6%</td>
<td>15.3%</td>
<td>10.2%</td>
<td>13.9%</td>
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<td></td>
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<tr>
<td>Eccentric†</td>
<td>45.9%</td>
<td>71.9%</td>
<td>40.6%</td>
<td>75.8%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium†</td>
<td>11.1%</td>
<td>24.7%</td>
<td>10.1%</td>
<td>23.8%</td>
<td></td>
<td></td>
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<tr>
<td>Supplies collateral‡</td>
<td>8.4%</td>
<td>11.2%</td>
<td>6.0%</td>
<td>5.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Receives collateral†</td>
<td>20.3%</td>
<td>12.9%</td>
<td>19.3%</td>
<td>5.0%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total occlusion§</td>
<td>10.2%</td>
<td>8.6%</td>
<td>8.1%</td>
<td>4.5%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion length</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10 mm</td>
<td>N/A</td>
<td>71.5%</td>
<td>N/A</td>
<td>80.9%</td>
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<td></td>
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<tr>
<td>≥10 mm</td>
<td>N/A</td>
<td>28.5%</td>
<td>N/A</td>
<td>19.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean % stenosis before Tx†</td>
<td>82.0%</td>
<td>78.9%</td>
<td>82.6%</td>
<td>73.7%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean final % stenosis†</td>
<td>32.8%</td>
<td>18.9%</td>
<td>35.4%</td>
<td>21.0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Medical College of Virginia, Mayo Clinic, Emory University, Miami Heart Institute and Montreal Heart Institute.
fp < 0.001, ‡p < 0.01 and §p < 0.05 between PTCA II and NACI registries for all sites. Data presented are percent of patients. LAD = left anterior descending coronary artery; LCx = left circumflex artery; RCA = right coronary artery; other abbreviations as in Table 1.
significant excess mortality, but the end point of death or MI was higher in the NACI registry (relative risk 1.67, 95% confidence interval 1.16 to 2.38). However, the elevated TLR risk in the NACI registry seen in the overall analysis was not found in this subgroup.

TLR in patients with core laboratory readings. A subsample of baseline angiographic films from six centers (658 NACI and 263 PTCA II films selected to provide a large proportion of procedures involving vein graft angioplasty) were analyzed in 1993 by the NACI core laboratory at Washington Hospital Center. In this subgroup of patients with core laboratory readings, the adjusted relative risk of TLR for PTCA II versus NACI was essentially the same (1.02).

Table 3. In-Hospital Outcome and Follow-Up Events at 1 Year by Study Period

<table>
<thead>
<tr>
<th></th>
<th>All Sites</th>
<th>Common Sites*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PTCA II (n = 2,311)</td>
<td>NACI (n = 1,985)</td>
</tr>
<tr>
<td>Angiographic success</td>
<td>1,727 (74.7)</td>
<td>1,704 (85.8)</td>
</tr>
<tr>
<td>Major complications (death, Q wave MI or CABG)</td>
<td>190 (8.2)</td>
<td>116 (5.8)</td>
</tr>
<tr>
<td>Procedural success</td>
<td>1,667 (72.1)</td>
<td>1,640 (82.6)</td>
</tr>
<tr>
<td>Death</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-hospital</td>
<td>23 (1.0)</td>
<td>36 (1.8)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>48 (2.1)</td>
<td>81 (4.1)</td>
</tr>
<tr>
<td>1 year</td>
<td>71 (3.1)</td>
<td>117 (5.9)</td>
</tr>
<tr>
<td>Q wave MI†</td>
<td></td>
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</tr>
<tr>
<td>In-hospital</td>
<td>77 (3.3)</td>
<td>29 (1.5)</td>
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<tr>
<td>Any MI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-hospital</td>
<td>112 (4.8)</td>
<td>161 (8.1)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>63 (2.7)</td>
<td>84 (4.2)</td>
</tr>
<tr>
<td>1 year</td>
<td>172 (7.4)</td>
<td>233 (11.7)</td>
</tr>
<tr>
<td>Any CABG</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-hospital</td>
<td>134 (5.8)</td>
<td>70 (3.5)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>154 (6.7)</td>
<td>164 (8.3)</td>
</tr>
<tr>
<td>1 year</td>
<td>286 (12.4)</td>
<td>234 (11.8)</td>
</tr>
<tr>
<td>Repeat percutaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-hospital</td>
<td>45 (1.9)†</td>
<td>47 (2.4)</td>
</tr>
<tr>
<td>Follow-up</td>
<td>424 (18.3)</td>
<td>428 (21.6)</td>
</tr>
<tr>
<td>1 year</td>
<td>468 (20.3)</td>
<td>468 (23.6)</td>
</tr>
</tbody>
</table>

*Medical College of Virginia, Mayo Clinic, Emory University, Miami Heart Institute and Montreal Heart Institute. †Q wave myocardial infarction data at follow-up were not available for the PTCA registry. ‡Rate of in-hospital repeat PTCA was reported if it was associated with abrupt closure. Data are presented as number (%) of patients. Abbreviations as in Table 1.

Table 4. Most Aggressive Therapy* by Study Period for Patients Who Were Alive and Angina Free at 1 Year

<table>
<thead>
<tr>
<th></th>
<th>All Sites</th>
<th>Common Sites†</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PTCA II (n = 1,391)</td>
<td>NACI (n = 1,221)</td>
</tr>
<tr>
<td>None or medication only</td>
<td>73.2%</td>
<td>67.9%</td>
</tr>
<tr>
<td>Repeat percutaneous intervention only</td>
<td>14.2%</td>
<td>19.7%</td>
</tr>
<tr>
<td>CABG only</td>
<td>10.1%</td>
<td>9.0%</td>
</tr>
<tr>
<td>CABG and repeat percutaneous intervention</td>
<td>2.6%</td>
<td>3.4%</td>
</tr>
</tbody>
</table>

*Level of therapy was classified hierarchically from least to most aggressive. †Medical College of Virginia, Mayo Clinic, Emory University, Miami Heart Institute and Montreal Heart Institute. Date presented are percent of patients. Abbreviations as in Table 1.
Table 5. Rates and Relative Risks of Events at 1 Year: Comparison of the NHLBI PTCA II and NACI Registries

<table>
<thead>
<tr>
<th>Event</th>
<th>PTCA II</th>
<th>NACI</th>
<th>RR (95% CI) for NACI vs. PTCA II</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unadjusted</td>
<td>Adjusted</td>
<td></td>
</tr>
<tr>
<td>Death*</td>
<td>3.1</td>
<td>5.9</td>
<td>1.96 (1.47–2.63) 1.00 (0.69–1.43)</td>
</tr>
<tr>
<td>Death/MI†</td>
<td>9.7</td>
<td>16.1</td>
<td>1.72 (1.45–2.04) 1.20 (0.98–1.49)</td>
</tr>
<tr>
<td>Death/MI/any repeat revasc‡</td>
<td>33.5</td>
<td>41.6</td>
<td>1.32 (1.19–1.45) 1.23 (1.10–1.37)</td>
</tr>
<tr>
<td>Death/MI/CABG§</td>
<td>18.6</td>
<td>24.6</td>
<td>1.37 (1.20–1.56) 1.25 (1.08–1.45)</td>
</tr>
<tr>
<td>Death/CABG‖</td>
<td>14.6</td>
<td>16.8</td>
<td>1.16 (1.00–1.35) 1.01 (0.85–1.20)</td>
</tr>
<tr>
<td>TLR®</td>
<td>21.5</td>
<td>24.2</td>
<td>1.11 (0.98–1.25) 1.28 (1.11–1.49)</td>
</tr>
</tbody>
</table>

*Cox model, adjusted for vein graft attempt (relative risk [RR] 1.1), age ≥65 years (RR 2.4), congestive heart failure (CHF) (RR 2.99), severe, concomitant noncardiac disease (RR 1.8), high surgical risk (RR 3.0) and presence of thrombus (RR 1.6) in attempted lesion. †Cox model adjusted for vein graft attempt (RR 0.99), age ≥65 years (RR 1.2), CHF (RR 1.8), severe, concomitant noncardiac disease (RR 1.3), high surgical risk (RR 1.6), unstable angina (RR 1.2), multivessel disease (RR 1.4), presence of thrombus (RR 1.5) in attempted lesion, eccentric lesion (RR 1.2) and receives collateral vessels (RR 0.6). ¶Cox model adjusted for vein graft attempt (RR 0.99), CHF (RR 1.2), diabetes (RR 1.2), unstable angina (RR 1.1), multivessel disease (RR 1.3) and presence of calcium (RR 1.2) in attempted lesion. §Cox model adjusted for vein graft attempt (RR 1.3), previous CABG (RR 0.6), CHF (RR 1.5), high surgical risk (RR 1.4), unstable angina (RR 1.3), multivessel disease (RR 1.5) and presence of calcium (RR 1.3) in attempted lesion. †Cox model adjusted for vein graft attempt (RR 0.7), age ≥65 years (RR 1.2), CHF (RR 1.6), high surgical risk (RR 1.5), unstable angina (RR 1.2), multivessel disease (RR 1.5), multivessel attempt (RR 0.6) presence of calcium (RR 1.4) and total occlusion (RR 1.3) in attempted lesion. ‡Cox model adjusted for vein graft attempt (RR 0.6), smoking at baseline (RR 0.8), multilession attempt (RR 1.1), presence of calcium (RR 1.2) in attempted lesion, receives collateral vessels (RR 1.1) and routine follow-up angiograms (RR 0.7). CI = confidence interval; TLR = target lesion revascularization, defined as repeat percutaneous intervention in target segment after hospital discharge or any coronary artery bypass graft surgery (CABG).

the small numbers of each), however, were higher in the NACI registry than in the PTCA II registry.

After adjustment for characteristics affecting the likelihood of TLR, such as vein graft and multiple-lesion attempts and routine (nonsymptom related) angiography during follow-up, the lower risk of TLR in NACI registry patients treated with TEC and Palmaz-Schatz stents (compared with the reference category of PTCA II registry patients) was not statistically significant. The increased risk of TLR in patients treated with other single or multiple devices remained significant after adjustment.

The previous analysis of TLR was also carried out for procedures limited to native coronary arteries (2,210 for PTCA II, 1,399 for NACI), because it is possible that the large disparity in vein graft revascularizations between the two registries may have not been sufficiently compensated for by statistical adjustment. Figure 1B displays freedom from TLR curves for this analysis. The rate of TLR was 21.5% in the PTCA II registry and 28% in the NACI registry. As in the overall analysis, the higher risk in the NACI registry patients remained statistically significant after adjustment.

Discussion

In the mid to late 1980s, the limitations of balloon angioplasty became apparent. Some major problems were identified: 1) inability to cross lesions, especially chronic total occlusions; 2) inability to dilate resistant, elastic or diffuse lesions; 3) difficulty in controlling or preventing arterial dissection, which frequently led to abrupt closure; and 4) inability to control restenosis (5). These shortcomings of PTCA led to a proliferation of new devices designed to address the problems. As devices entered clinical testing, data were collected by the sponsoring companies for Food and Drug Administration submission, without balloon angioplasty control groups. To facilitate a better understanding of the results with these new devices, the NHLBI funded a new registry to provide common definitions for baseline and outcome variables, ensure independent data collection and core data center analysis and compare the new data with similar data collected for balloon angioplasty in the previous NHLBI registries.

It was hoped in the late 1980s and early 1990s that these new devices might replace balloon angioplasty or at least fill many of the clinical niches where standard balloon angioplasty was thought to be inadequate (6). The lack of demonstrable improvement in 1-year outcome with the new devices in the NACI registry compared with PTCA alone was hardly expected in the optimistic days of the early 1990s. This failure is particularly disappointing in light of the improved acute success and lower residual stenosis seen in the NACI registry and the benefits of new devices over PTCA observed in the randomized trials of stenting—Stent Restenosis Study (STRESS) (7), the Belgian Netherlands Stent study (BENESTENT) (8) and the Saphenous Vein De Novo (SAVED) (9) study—and DCA—the Balloon Versus Optimal Atherectomy Trial (BOAT) (10) but not the Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT) (11) or the Canadian Coronary Atherectomy Trial (CCAT) (12).

Randomized trials remain the reference standard for comparing new therapies. However, randomized trials seek relatively homogeneous populations and thus have many clinical and angiographic exclusions, whereas registries tend to offer a
broader, more generalizable observation of device results. The randomized trials have studied only a subset of patients. For example, only 10% of the NACI registry patients treated with Palmaz-Schatz stents would have met the inclusion criteria of the STRESS study (7). Sawada et al. (13) reported 6-month results for the majority of their patients whose baseline angiographic characteristics fell outside the category of discrete lesions studied in the STRESS and BENESTENT trials. For patients with small vessels, long lesions, ostial disease, vein grafts and restenotic lesions, the rate of restenosis at 6 months ranged from 27% to 40% (13), twice that seen in “STRESS”-like lesions. Colombo et al. (14,15) reported significantly

Figure 1. A, Freedom from TLR by study period and device used in the NACI registry. B, Freedom from TLR by study period for subgroups of patients with only native vessel attempted (2,210 for PTCA II, 1,399 for NACI). Other device = Rotablator, lasers and multiple devices; PSS = Palmaz-Schatz stent.
higher restenosis rates for bifurcation and ostial lesions. Kimura et al. (16) reported the 3-year follow-up data in a diverse group of patients with native coronary artery stenting, and Lafram et al. (17) recently reported 4- to 6-year clinical data in patients with both native and saphenous vein graft stenting. Although these reports are encouraging regarding the question of late stent restenosis and stent-related clinical problems, the 3-year survival rate of 90.8% (16) is not superior to that in the PTCA II registry or the PTCA arms of the randomized Emory Angioplasty Surgery Trial (EAST) (18) and Bypass Angioplasty Revascularization Investigation (BARI) (19) in patients with multivessel disease. The decreased complication rates shown in the BENESTENT II trial (20) may reflect improved techniques of balloon angioplasty and stenting (high pressure balloon inflation after dilation) and changes in anticoagulation regimens (aspirin and Ticlid) not used in the NACI registry. Most of the devices other than stents have been used for important niche applications, and trials continue in an effort to define their best use. The lowest TLR rate seen with TEC reflects its principal use in diffuse vein graft disease, a subset frequently not undergoing reintervention, even if closure recurs.

**Study limitations.** Comparison of registries of different time frames prevents definitive conclusions because device usage patterns, clinical and angiographic characteristics and techniques have changed. The techniques for using new devices have, in most cases, undergone more prolonged evolution than the use of balloon angioplasty. Compared with current catheters, the balloons used in the PTCA II registry were larger in deflated profile and capable of less pressure and utilized over the wire designs introduced ~2 years before collection of the present series. The mix of devices and techniques studied in the NACI registry reflects practice from 1990 through 1994 and is not fully representative of the mix of devices currently used. In the present report, we focused on aggregation of the NACI registry devices for the principal comparisons, and therefore the potential benefits of one or two devices, such as the trend toward decreased TLR associated with Palmaz-Schatz stents, were not addressed in detail. Such individual device assessments will be the subject of subsequent reports.

Although adjustment for risk factors and analysis using core laboratory data supported our main findings, these analyses may still have failed to fully correct for the differences in lesion and patient characteristics between the two registries. There is also the possibility that the site-reported TLR rates could have been affected by follow-up factors other than the routine follow-up angiography for which information was not available. Finally, although this study of two relatively large groups had >90% power to detect a ≥5% difference in overall TLR rates between the two registries, a 10% difference would be required for the same power in smaller device-specific subgroups (n = 200).

**Conclusions.** The present comparative study shows that after adjustment for baseline patient risk profile, no overall superiority of the new devices was seen in terms of patient survival. Patients in the NACI registry did not have reduced rates of MI or TLR compared with patients in the PTCA II registry, even after adjusting for differences in patient and lesion characteristics. Target lesion revascularization rates varied by device, with NACI registry patients who underwent Palmaz-Schatz stenting showing somewhat lower rates than PTCA II registry patients. Although continued technologic and procedural changes are significantly altering the early angiographic results of intervention, the magnitude of their effect on long-term clinical outcome remains unclear. Additional randomized comparisons must be carried out when appropriately targeted subsets can be defined. However, before we fully embrace the across the board superiority of new technology over established and more extensively observed interventions (including medical and surgical), it will be prudent to examine, through carefully controlled registries, the follow-up clinical outcomes in the broad population of patients in whom these technologies are presently being used.

**References**


