Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Multivessel Disease (ERACI): In-Hospital Results and 1-Year Follow-Up

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Objectives. This study was designed to compare freedom from combined cardiac events (death, angina, myocardial infarction) at 1-, 3- and 5-year follow-up in patients with multivessel disease randomized to either percutaneous transluminal coronary angioplasty or coronary artery bypass graft surgery.

Background. Percutaneous transluminal coronary angioplasty has been an effective approach in patients with coronary artery disease, but its role in patients with multivessel coronary artery disease is still controversial.

Methods. One-hundred twenty-seven patients with multivessel disease and lesions suitable for either form of therapy were randomized to either coronary artery bypass grafting ($n = 64$) or coronary angioplasty ($n = 63$). In this study we report the immediate results and freedom from combined cardiac events at 1-year follow-up.

Results. Demographic, clinical and angiographic characteristics were similar in both groups. There were no differences in in-hospital deaths, frequency of periprocedure myocardial infarction or need for emergency revascularization procedures between the two groups. At 1-year follow-up, there were no differences in mortality or in the incidence of myocardial infarction between the groups. However, patients treated with coronary artery bypass grafting were more frequently free of angina, reinterventions and combined cardiac events than were patients treated with coronary angioplasty (83.5% vs. 63.7%, $p < 0.005$). In-hospital cost and cumulative cost at 1-year follow-up were greater for the coronary artery bypass grafting than for the coronary angioplasty group.

Conclusions. No significant differences were found in major in-hospital complications between patients treated with coronary artery bypass grafting or coronary angioplasty. Although at 1-year follow-up there were no differences in survival and freedom from myocardial infarction, patients in the coronary artery bypass grafting group were more frequently free from angina, reinterventions and combined events than were patients in the coronary angioplasty group.

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coronary angioplasty versus coronary artery bypass surgery in the treatment of this latter group of patients with multivessel disease in whom the revascularization approach remains open to question and in whom the lesions being considered in the revascularization strategy were amenable to both coronary angioplasty and coronary artery bypass surgery. In this initial communication we report the immediate and the 1st year follow-up results of this randomized trial.

Methods

Study patients. From a total of 1,409 patients with a presumptive clinical diagnosis of coronary artery disease who underwent coronary arteriography at the Anchorena Hospital between June of 1988 and December of 1990, 748 patients had an indication for revascularization. There was no need for revascularization in the other 661 patients because of the presence of normal coronary arteries, non-significant coronary artery disease or coronary disease amenable to medical therapy (Fig. 1).

From the 748 patients who required myocardial revascularization, 302 met the entrance criteria for randomization and 446 did not. In this latter group coronary angioplasty was performed in 309 patients and coronary artery bypass surgery in 137 (Fig. 1). Coronary angioplasty was performed in these 309 patients because of the following reasons: 1) presence of single-vessel coronary artery disease (72%), 2) two-vessel disease without significant involvement of the proximal left anterior descending coronary artery (9%), 3) prior history of coronary artery bypass surgery (10.9%), 4) evolving acute myocardial infarction or acute myocardial infarction associated with severe left ventricular dysfunction (7%), and 5) associated significant valvular heart disease (0.6%). Coronary artery bypass surgery was performed in the other 137 patients for one of the following reasons: 1) presence of severe triple-vessel disease with depressed left ventricular ejection fraction, 2) multivessel coronary artery disease with poor distal vessels and diffuse disease, and 3) significant left stenosis. This group also included five patients with single-vessel proximal left anterior descending coronary artery disease whose primary physician had a preference for a left internal mammary artery graft to the left anterior descending coronary artery.

From the 302 patients who met the entrance criteria for randomization, 127 were randomized (63 to coronary angioplasty and 64 to coronary artery bypass surgery) and 175 were not. From these latter 175 patients with randomizable criteria who were not randomized, 99 patients were treated with angioplasty and 76 patients with bypass grafting (Fig. 1).

In the randomized group, there were 108 men and 19 women with a mean age of 58 ± 5 (33 to 76) years. Both revascularization procedures (coronary angioplasty and coronary artery bypass surgery) were performed at the Anchorena Hospital in Buenos Aires, Argentina.

The study. Only patients with multivessel coronary artery disease with clinical indication for myocardial revascularization but in whom the choice of revascularization approach was open to question were included in this study. In these patients complete functional revascularization could be achieved by the treatment of multivessel coronary lesions amenable to either coronary angioplasty or coronary artery bypass surgery.

Patients signed a consent form reviewed and approved by the Committee of Human Studies of the Anchorena Hospital.

Aims of the study. The primary aim of the study was to compare freedom from combined coronary cardiac events (death, myocardial infarction, repeat revascularization procedures and angina) at 1-, 3- and 5-year follow-up between patients who underwent coronary artery bypass grafting or coronary angioplasty.

Secondary aims were 1) to compare major in-hospital complications (death, Q wave myocardial infarction and need for emergency revascularization procedures) between both revascularization modalities; 2) to compare completeness of revascularization achieved by both procedures; and 3) to compare in hospital and late costs of both techniques.

Randomization protocol. Before randomization, all patients were evaluated by the primary clinical cardiologist, a cardiac surgeon and an interventional cardiologist. Patients were randomized in the study only when both the cardiac surgeon and the interventional cardiologist believed that functional revascularization of the patient could be achieved by coronary artery bypass surgery or coronary angioplasty, respectively. Patients were excluded from randomization when there was agreement between the cardiac surgeon and the interventional cardiologist on one of the two revascularization modalities. This selection system allowed randomization of only those patients for whom the choice of coronary artery bypass surgery versus coronary angioplasty was open to question. In these patients, the lesions being considered in the functional revascularization strategy were suitable for both procedures.
Inclusion criteria. Patients were eligible for inclusion in the study if they had 1) severely limiting stable angina despite maximal medical therapy; 2) rest unstable angina refractory to maximal medical therapy; 3) no or minimal symptoms but with a large area of myocardium at risk identified by exercise testing. Patients were required to have angiographic evidence of severe coronary obstruction (≥70%) in more than one major epicardial coronary artery and all lesions included in the revascularization strategy were, from the angiographic point of view, amenable to both coronary angioplasty and coronary artery bypass surgery.

Exclusion criteria. Patients were excluded from the study if they had 1) dilated ischemic cardiomyopathy; 2) an indication for coronary artery bypass surgery but not for coronary angioplasty (patients in this category included those with a) severe left main trunk stenosis, b) severe three-vessel disease and depressed ejection fraction (≤35%), and c) associated severe valvular heart disease or hypertrophic heart disease, or both; 3) evolving acute myocardial infarction; 4) limited life expectancy due to terminal illness; or 5) not given consent.

Revascularization techniques. Coronary artery bypass surgery was performed with standard surgical techniques, under hypothermic arrest and using blood cardioplegia. Complete revascularization was performed when possible using reverse saphenous vein grafts and the left internal mammary artery as conduits. The left internal mammary artery was employed in 76.5% of the patients.

Coronary angioplasty was performed using standard techniques as previously described. Patients were pretreated with aspirin, 325 mg/day, and a calcium channel blocker for at least 24 h before angioplasty. A bolus of 10,000 U of intravenous heparin was administered at the beginning of the procedure and followed by a continuous infusion of heparin to maintain a therapeutic partial thromboplastin time (70 to 80 s) for an additional 24 h. Successful angioplasty was defined as a gain in lumen diameter ≥20% and a final residual stenosis <50%.

The strategy of revascularization with coronary angioplasty was carefully planned before the procedure to achieve complete functional revascularization. The identified culprit lesion was dilated first followed by angioplasty of the other critical lesions during the same procedure or in a second procedure. Only significant lesions (≥70% stenosis) with evidence of ischemia by noninvasive testing were dilated. Total occlusions were attempted only when there was evidence of viable or hibernating myocardium, or both, in the area supplied by the occluded vessel. Coronary angioplasty of chronically occluded vessels (>3 months) supplying akinetic left ventricular segments was not attempted.

Complete anatomic revascularization after coronary angioplasty was defined as no residual stenosis >50% in any major epicardial coronary artery. Complete functional revascularization after angioplasty was defined as no residual stenosis >50% in any major epicardial vessel supplying viable myocardium. Although the presence of a total chronic occlusion supplying a nonviable segment of the left ventricle represents "incomplete anatomic revascularization," it could be present in the presence of "complete functional revascularization" if the other arteries had <50% residual stenosis after angioplasty.

The major in-hospital complications of both procedures: death, Q wave myocardial infarction and the need for emergency revascularization procedure (coronary angioplasty or coronary artery bypass surgery) were recorded. Randomization of patients fulfilling the inclusion criteria was performed by the coordinating center by 10 patient blocks. Forty patients were randomized in 1988, 37 patients in 1989 and 50 patients in 1990. Eight of the 64 patients assigned to bypass grafting (12.5%) crossed over to angioplasty and 8 (12.6%) of the 63 patients assigned to angioplasty crossed over to bypass grafting (p = NS). A trained staff was responsible for data collection of variables and clinical follow-up of patients (using tabulated forms). The organization and analysis of the results of the study were conducted by a central coordinating executive committee. The study was monitored by a Safety and Data Monitoring Committee.

Sample calculation. To estimate follow-up ischemic events (death, myocardial infarction and angina) related to coronary angioplasty or coronary artery bypass surgery in patients with multiple vessel coronary artery disease, previous published nonrandomized results were used. Estimating a combined event-free survival at 1-, 3- and 5-year follow-up of 75% to 85% in the group with bypass grafting and 53% to 65% in the group with angioplasty; the estimated sample was approximately 160 patients at an alpha value of 0.05 and a power of 80%. Because the sample was 127 patients, the power of this study is 70%.

Statistical analysis. Differences in baseline characteristics and in in-hospital complications between the two groups were determined using chi-square analysis. Event-free survival between the two groups at 1-year follow-up was compared using the Kaplan-Meier method and the log-rank test.

Results

Baseline characteristics. Clinical. Randomization resulted in balanced treatment groups. There were no differences in age, gender, history of smoking, diabetes, hypercholesterolemia and previous myocardial infarction between the two groups of patients. The incidence of unstable angina was high in the overall cohort of patients (83%) and was more frequent in the group with coronary artery bypass surgery than in the group with coronary angioplasty (89% vs. 76%, p < 0.05) (Table 1).

Angiographic. The two groups (angioplasty and bypass grafting) were also well matched for arteriographic and ventriculographic characteristics. There were no significant differences in the number of vessels, culprit arteries and left ventricular function between the two groups of patients (Table 1).
Table 1. Demographic and Angiographic Characteristics of the Randomized Patients

<table>
<thead>
<tr>
<th></th>
<th>CABG (n = 64)</th>
<th>PTCA (n = 63)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>65 ± 8</td>
<td>59 ± 2</td>
<td>NS</td>
</tr>
<tr>
<td>Men</td>
<td>57</td>
<td>51</td>
<td>NS</td>
</tr>
<tr>
<td>Women</td>
<td>7</td>
<td>12</td>
<td>NS</td>
</tr>
<tr>
<td>Smoking</td>
<td>45</td>
<td>39</td>
<td>NS</td>
</tr>
<tr>
<td>Hypertension</td>
<td>37</td>
<td>33</td>
<td>NS</td>
</tr>
<tr>
<td>Diabetes</td>
<td>7</td>
<td>7</td>
<td>NS</td>
</tr>
<tr>
<td>Hypercholesterolemia</td>
<td>39</td>
<td>35</td>
<td>NS</td>
</tr>
<tr>
<td>Hyperuricemia</td>
<td>7</td>
<td>7</td>
<td>NS</td>
</tr>
<tr>
<td>Old myocardial infarction</td>
<td>31</td>
<td>32</td>
<td>NS</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>57</td>
<td>48</td>
<td>&lt; 0.05</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>62 ± 12</td>
<td>59 ± 12</td>
<td>NS</td>
</tr>
<tr>
<td>Two vessels (%)</td>
<td>53.1</td>
<td>57.1</td>
<td>NS</td>
</tr>
<tr>
<td>Three vessels (%)</td>
<td>46.9</td>
<td>42.9</td>
<td>NS</td>
</tr>
<tr>
<td>Culprit artery</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAD (%)</td>
<td>36.9</td>
<td>37.9</td>
<td>NS</td>
</tr>
<tr>
<td>RCA (%)</td>
<td>33.6</td>
<td>28.7</td>
<td>NS</td>
</tr>
<tr>
<td>LCx (%)</td>
<td>29.5</td>
<td>33.4</td>
<td>NS</td>
</tr>
</tbody>
</table>

Data are expressed as mean value ± SD or number or percent of patients. CABG = coronary artery bypass graft surgery; LAD = left anterior descending coronary artery; LCx = left circumflex; coronary artery; LVEF = left ventricular ejection fraction; PTCA = coronary angioplasty; RCA = right coronary artery.

Results of coronary angioplasty. The angiographic characteristics of the lesions in the coronary angioplasty group included 3.7% type A lesions, 83.5% type B lesions (33.1% type B1 and 50.4% type B2) and 12.8% type C lesions (Fig. 2).

The overall primary success rate of angioplasty per lesion was 91.7% (100 of 109): 100% in type A lesions, 95.6% in type B lesions and 64.2% in type C lesions (Fig. 2).

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As part of the revascularization strategy, coronary angioplasty was not attempted in 44 chronic total occlusions (in patients with a previous history of myocardial infarction)

Figure 2. Incidence of modified ACC/AHA score of 109 lesions treated with coronary angioplasty. ACC = American College of Cardiology; AHA = American Heart Association.

Table 2. Major In-Hospital Complications of the Randomized Group*

<table>
<thead>
<tr>
<th></th>
<th>CABG (n = 64)</th>
<th>PTCA (n = 63)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>4.6% (3/64)</td>
<td>1.5% (1/63)</td>
</tr>
<tr>
<td>AMI</td>
<td>6.2% (4/64)</td>
<td>6.3% (4/63)</td>
</tr>
<tr>
<td>Emergency CABG</td>
<td></td>
<td>1.5% (1/63)</td>
</tr>
<tr>
<td>Emergency PTCA</td>
<td>1.5% (1/64)</td>
<td></td>
</tr>
<tr>
<td>Stroke</td>
<td>3.1% (2/64)</td>
<td>1.5% (1/63)</td>
</tr>
</tbody>
</table>

*No differences between groups were significant. AMI = acute myocardial infarction; other abbreviations as in Table 1.

supplying an area of nonviable myocardium as determined by noninvasive testing.

In-hospital complications. There were no significant differences in major in-hospital complications between the two groups of patients. The in-hospital mortality rate of patients in the coronary artery bypass surgery group was 4.6% versus 1.5% in the group with coronary angioplasty; 6.2% of patients in the bypass grafting group had a Q wave myocardial infarction versus 6.3% in the angioplasty group; 1.5% of the patients in the bypass grafting group needed in-hospital angioplasty and 1.5% of patients in the angioplasty group needed emergency bypass grafting (Table 2). There were two strokes (3.1%) in the bypass grafting group and 1 stroke (1.5%) in the angioplasty group.

Complete revascularization. Complete anatomic revascularization was more frequently achieved in the group with coronary artery bypass surgery than in the group with coronary angioplasty (88% vs. 51%, p < 0.001). However, revascularization was functionally complete in 89.2% of the angioplasty group (Fig. 3).

Patients with randomizable criteria who were not random-ized. As described above, from the cohort of 175 patients with criteria of randomization who were not randomized, 99 patients were treated with coronary angioplasty and 76 patients with coronary artery bypass surgery. There were no significant differences in age, gender, history of smoking, diabetes, elevated cholesterol level and previous myocardial infarction between patients treated with angioplasty or with bypass grafting. The incidence of unstable angina was also similar between the two groups (76.7% vs. 72.3% for patients

Figure 3. Comparison of completeness of anatomic revascularization with coronary angioplasty and coronary artery bypass surgery. Completeness of functional revascularization achieved with angioplasty is also shown. Abbreviations as in Figure 1.
Table 3. Major In-Hospital Complications of Patients With Criteria for Randomization Who Were Not Randomized*

<table>
<thead>
<tr>
<th></th>
<th>CABG (n = 76)</th>
<th>PTCA (n = 99)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death (%)</td>
<td>5.2</td>
<td>2</td>
</tr>
<tr>
<td>AMI (%)</td>
<td>3.9</td>
<td>5</td>
</tr>
<tr>
<td>Emergency CABG (%)</td>
<td>—</td>
<td>2</td>
</tr>
<tr>
<td>Emergency PTCA (%)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Stroke (%)</td>
<td>2.6</td>
<td>0</td>
</tr>
</tbody>
</table>

*No differences between groups were significant. Abbreviations as in Tables 1 and 2.

Patients treated with angioplasty and bypass grafting, respectively. Patients treated with bypass grafting had a higher incidence of three-vessel coronary artery disease than did patients treated with angioplasty (52.7% vs. 33%, respectively).

Major in-hospital complications in this cohort of patients with criteria for randomization who were not randomized are shown in Table 3. The in-hospital mortality rate was 2% for the 99 patients treated with coronary angioplasty and 5.2% for the 76 patients treated with coronary artery bypass surgery; the incidence of periprocedure myocardial infarction was 5% for the angioplasty group and 3.9% for the bypass grafting group, and the incidence of emergency bypass grafting in patients with coronary angioplasty was 2%. There were no strokes in the angioplasty group and two strokes (2.6%) in the bypass grafting group. These complications are similar to those occurring in the randomized group. Because in this cohort of patients the strategy of angioplasty was to treat the culprit artery, complete anatomic revascularization was significantly less in the angioplasty group than in the bypass grafting group (45.4% vs. 90.7%, respectively).

One-year follow-up data. At 1 year of follow-up, there were two deaths in the coronary angioplasty group (3.2%) versus none (0%) in the coronary artery bypass surgery group (p = NS). One patient died suddenly 4 months after successful angioplasty. The other patient had an anterior myocardial infarction after unsuccessful angioplasty and died of congestive heart failure 6 months later. Two patients (3.2%) in the angioplasty group had a new Q wave myocardial infarction versus one (1.8%) in the bypass grafting group (p = NS).

Figure 4 shows the 1-year survival, freedom from myocardial infarction, freedom from angina and freedom from combined coronary cardiac events for those patients treated with coronary angioplasty and coronary artery bypass surgery. Although there were no differences in survival and freedom from myocardial infarction between the two groups, freedom from angina, freedom from repeat revascularization procedures (angioplasty or bypass grafting), and freedom from combined events were higher in the bypass grafting group than in the angioplasty group. Patients treated with angioplasty had a greater incidence of angina and need for a repeat revascularization procedure (angioplasty or bypass grafting) than did patients treated with bypass grafting. Thirty-two percent of the patients (20 of 62) in the angioplasty group needed a second revascularization procedure: 9 had repeat angioplasty and 11 underwent bypass grafting) versus 3.2% of the patients (2 of 61) in the bypass grafting group (p < 0.001). However, after 6 months of follow-up (when patients treated with angioplasty had a second revascularization procedure) freedom from angina was similar in both groups.

As seen in Figure 5, at 1 year of follow-up there were nonsignificant differences in freedom from combined ischemic events between patients in whom coronary angioplasty resulted in complete functional revascularization and those in whom it resulted in complete anatomic revascularization. Ninety-six percent of the patients with complete functional revascularization became asymptomatic after successful coronary angioplasty.
In-hospital and late costs. In Argentina there is a cost (all costs in this section are in U.S. dollars) of $4,000 and $5,000 for uncomplicated and complicated coronary angioplasty, respectively, and of $12,000 and $15,000 for uncomplicated and complicated coronary artery bypass surgery, respectively. Hospital costs for the 64 patients with coronary angioplasty including their in-hospital complications (one emergency coronary artery bypass surgery) was $270,000. Hospital costs for the 64 patients with coronary artery bypass surgery of (52 uncomplicated and 12 complicated) was $820,000 (p < 0.01).

In the period of follow-up of 1 year in the coronary angioplasty group, there were 9 repeat angioplasty procedures and 11 coronary artery bypass surgery procedures because of restenosis, adding $160,000 to the coronary angioplasty cost. Consequently, the total cost of coronary angioplasty (in-hospital and 1st year follow-up) was $438,000. In contrast, in the coronary artery bypass surgery group two patients underwent angioplasty during the 1st year of follow-up, adding $8,000 to the bypass grafting group cost. Therefore, the total cost of the bypass grafting group (in-hospital and 1st year follow-up) was $828,000 (p < 0.01).

Discussion

The present randomized study of coronary angioplasty versus coronary artery bypass surgery in the treatment of patients with multivessel coronary artery disease showed no significant differences in major in-hospital complications (death, acute myocardial infarction and need for emergency revascularization procedure) between patients treated with bypass grafting or angioplasty. This study also shows that at 1 year of follow-up there were no significant differences in mortality and freedom from myocardial infarction between the two groups of patients. However, patients treated with bypass grafting were more frequently free of angina and combined ischemic events than were patients treated with angioplasty. Furthermore, although anatomic complete revascularization was achieved more frequently in patients treated with bypass grafting than with angioplasty, the incidence of patients achieving complete functional revascularization with angioplasty was similar to the incidence of complete anatomic revascularization achieved with bypass grafting. In addition in the present study in hospital cost and cumulative cost up to 1 year of follow-up were greater for the bypass grafting than for the angioplasty group.

In-hospital results. The incidence of major in-hospital complications was similar in both groups as reflected in similar rates for in-hospital mortality, incidence of acute myocardial infarction and the need for emergency revascularization procedure. Similar in-hospital results were obtained in the 175 patients (99 treated with coronary angioplasty and 76 with coronary artery bypass surgery) who met randomization criteria but were not randomized.

Our primary PTCA success rate is similar to that reported in other nonrandomized studies with similar patient cohorts (12,14). Both the higher mortality and the higher incidence of periprocedure acute myocardial infarction in our overall patient population are more likely to be related to patient baseline characteristics. A high incidence of unstable angina (83%) was present in our patients with multivessel disease. An increased mortality and a higher incidence of periprocedure myocardial infarction have been reported in patients with unstable angina treated with both bypass grafting and angioplasty (12,20). Furthermore, the success and complication rates of coronary angioplasty are related to the type of angiographic lesion (21). Our patients have a higher incidence of type B and C lesions and only a 3.7% incidence of a type A lesion. A higher incidence (11%) of in-hospital complications associated with angioplasty of type B or C lesions has been reported (21). The need for emergency surgery in our angioplasty group was similar to the incidence previously reported in nonrandomized trials (13,16,21).

The 4.6% in-hospital mortality rate and the 6.2% incidence of myocardial infarction in the bypass grafting group are similar to results reported in other series of patients with unstable angina and multivessel coronary artery disease. Perioperative mortality between 1.8% and 8.5% and perioperative incidence of myocardial infarction between 1.0% and 16.7% has been reported previously in patients with unstable angina (17,20,22,24).

Revascularization status. Complete revascularization is an important factor determining the long-term follow up of patients with multivessel disease who have undergone a revascularization procedure. Several studies have shown that patients who have undergone complete revascularization after coronary artery bypass surgery have improved survival at follow-up (25,27). Conversely, with coronary angioplasty this seems to be less evident (16,28). It is well known that in most patients with multivessel disease complete revascularization is infrequently achieved with angioplasty. Reasons for incomplete revascularization with angioplasty include chronic total occlusions and the strategy of not dilating coronary lesions that are not critical. It is well
known that complications with angioplasty are unpredictable and can occur with dilation of nonsignificant lesions. Furthermore, if restenosis occurs, the restenosis lesion often is more severe than the initial one.

Coronary angioplasty has been reported to achieve complete revascularization in <50% of the patients with multivessel coronary artery disease (3,4,7,16,28). However, incomplete angiographic anatomic revascularization is part of the strategy of coronary angioplasty. In our series "incomplete anatomic revascularization" was the result of total chronic occlusion in which the occluded artery was supplying areas of nonviable myocardium after an old myocardial infarction. However, in those patients "complete functional revascularization" was frequently achieved because all the vessels supplying viable areas had successful angioplasty. The concept of "functional revascularization" is supported by similar event-free survival rates early after angioplasty in patients with complete anatomic and complete functional revascularization. Furthermore, there were no differences between the latter two groups in the incidence of angina at 6 months of follow-up secondary to restenosis. The advantages of complete anatomic revascularization achieved with bypass grafting over complete functional revascularization obtained with coronary angioplasty are unknown. However, it is possible that revascularization of all the vessels is unnecessary when total chronic occlusions serving nonviable myocardium are present.

Late follow-up. Our study shows a higher event-free survival rate (p < 0.005) in the group with coronary artery bypass surgery than in the group with coronary angioplasty (83.5% vs. 63.7%) (Fig. 4). The difference is due only to a higher incidence of recurrence of angina and need for repeat revascularization procedures. Mortality and freedom from myocardial infarction were similar in both groups. The higher incidence rates of angina in the angioplasty group, at 1 year of follow-up, occurred during the 1st 6 months and represent restenosis after successful angioplasty. As a result of restenosis, 32% of patients in the angioplasty group were subjected to a repeat revascularization procedure, 55% (11 of 20) of them to bypass grafting and 45% (9 of 20) to repeat angioplasty. A decision to perform either bypass grafting or angioplasty as a repeat revascularization procedure was made by the cardiologist responsible for the patient care.

Event-free survival rates after 6 months (after repeat intervention for restenosis) were similar in both groups of patients. Our study is in agreement with previously reported nonrandomized studies (3,6,8,16,28,29) in patients with multivessel coronary artery disease showing a restenosis rate of 30% to 40% requiring repeat coronary angioplasty or coronary artery bypass surgery during follow-up. Restenosis after angioplasty remains the main limitation of this procedure in the treatment of patients with multivessel disease. Our practice has been to recommend bypass grafting when all lesions previously dilated develop restenosis at follow-up. However, if restenosis occurs in only one or two vessels, we recommend repeat angioplasty as a repeat revascularization procedure at follow-up.

Study limitations. Our study sample is small but it is sufficiently large to achieve our primary aim of comparing freedom from combined coronary events at follow-up with both forms of therapy in patients with multiple vessel disease requiring a revascularization procedure. Our data are further strengthened by similar results obtained in the additional 175 patients (99 treated with coronary angioplasty and 76 with coronary artery bypass surgery) with criteria for randomization who were not randomized. In the present study, a high prevalence rate of unstable angina was present in our cohort of patients with multivessel disease. It has been well established that the complications of revascularization procedures (12,16,21) are more frequent in patients with unstable angina; it is possible that results would be different in a cohort of patients with chronic stable angina. Other randomized studies (30) in progress in the United States and in Europe are evaluating coronary artery bypass surgery versus coronary angioplasty in patients with multivessel disease in a large cohort of patients and with a lower incidence of unstable angina.

Conclusions. Our study found no significant differences in in-hospital major complications between patients treated with coronary artery bypass surgery and coronary angioplasty.

Although complete anatomic revascularization was more frequently achieved in the bypass grafting than in the angioplasty group, complete functional revascularization was similar in both. At 1-year follow-up, there were no differences between survival and freedom from myocardial infarction; however, patients in the bypass grafting group were more frequently free of angina and from combined events than were patients in the angioplasty group. In-hospital cost and cumulative cost at 1-year of follow-up were greater for the bypass grafting than for the angioplasty group.

We thank Jose Luis Palazzo, MD and the Anchorena Foundation for their support in this trial.

Appendix

Study Organization and Participants

Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Multivessel Disease (ERACIk)

Organization and Executive Committee: Cardiac Unit, Hospital Anchoarena, Buenos Aires, Argentina

Clinical Cardiology Group: Nestor Perez Balitto, MD, FACC; Maria Ines Sosa Liprandi, MD; Eduardo Mele, MD; Ernesto Paiernge, MD; Claudia Pavlovic, MD; Rafael Diaz, MD; Maria Luganes, MD

Interventional Cardiology and Catheterization Laboratory Group: Alfredo Rodriguez, MD; Omar Aribad Santanera, MD; Gustavo Risau, MD; Mario Fernandez, MD; Mario Szejnell, MD

Cardiovascular Surgery Group: Fernando Bouillon, MD; Pablo Ahiulli, MD; Gustavo Vitale, MD
CORONARY ANGIOPLASTY VERSUS CORONARY BYPASS SURGERY

References