Interventional Cardiology

Argentine Randomized Study: Coronary Angioplasty With Stenting Versus Coronary Bypass Surgery in Patients With Multiple-Vessel Disease (ERACI II): 30-Day and One-Year Follow-up Results

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OBJECTIVES The purpose of this study was to compare percutaneous transluminal coronary revascularization (PTCR) employing stent implantation to conventional coronary artery bypass graft surgery (CABG) in symptomatic patients with multivessel coronary artery disease.

BACKGROUND Previous randomized studies comparing balloon angioplasty versus CABG have demonstrated equivalent safety results. However, CABG was associated with significantly fewer repeat revascularization procedures.

METHODS A total of 2759 patients with coronary artery disease were screened at seven clinical sites, and 450 patients were randomly assigned to undergo either PTCR (225 patients) or CABG (225 patients). Only patients with multivessel disease and indication for revascularization were enrolled.

RESULTS Both groups had similar clinical demographics: unstable angina in 92%; 38% were older than 65 years, and 23% had a history of peripheral vascular disease. During the first 30 days, PTCR patients had lower major adverse events (death, myocardial infarction, repeat revascularization procedures and stroke) compared with CABG patients (3.6% vs. 12.3%, p = 0.002). Death occurred in 0.9% of PTCR patients versus 5.7% in CABG patients, p < 0.013, and Q myocardial infarction (MI) occurred in 0.9% PTCR versus 5.7% of CABG patients, p < 0.013. At follow-up (mean 18.5 ± 6.4 months), survival was 96.9% in PTCR versus 92.5% in CABG, p < 0.017. Freedom from MI was also better in PTCR compared to CABG patients (97.7% vs. 93.4%, p < 0.017). Requirements for new revascularization procedures were higher in PTCR than in CABG patients (16.8% vs. 4.8%, p < 0.002).

CONCLUSIONS In this selected high-risk group of patients with multivessel disease, PTCR with stent implantation showed better survival and freedom from MI than did conventional surgery. Repeat revascularization procedures were higher in the PTCR group. (J Am Coll Cardiol 2001;37:51–8) © 2001 by the American College of Cardiology

Coronary artery bypass graft surgery (CABG) (1) and percutaneous transluminal coronary angioplasty (PTCA) (2) have been previously compared in several randomized studies. Seven controlled (3–9) trials comparing PTCA and CABG in multivessel disease were performed in North America (4,8), Europe (5–7,9), and South America (3,10). Less need for repeat procedures, less angina, and better survival in treated diabetic patients were major advantages of CABG over PTCA in these studies (8,11).

In recent years, stents have been shown to decrease acute complications (12), late restenosis, and need of repeat revascularization (13–15). Stent use has increased up to 60% to 70% in many interventional laboratories worldwide (16). We wished to compare current techniques in percutaneous transluminal coronary revascularization (PTCR) including free use of stents versus CABG in patients with multivessel disease. We hypothesized that stent use might significantly decrease early complications in comparison to CABG.

METHODS

Study population. A total of 5,619 patients underwent coronary angiography in the participating centers of the ERACI II (list appears in Appendix) between October 1996 and September 1998. Of this group, 2,759 patients had an indication for myocardial revascularization. There was no need for revascularization in the other 2,860 patients because of the presence of normal coronary artery disease, nonsignificant coronary artery disease or coronary artery

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disease amenable to medical therapy. From the 2,759 patients who required myocardial revascularization, 1,076 patients met the entrance criteria for randomization and 1,683 did not. From the 1,076 randomizable patients, 450 were randomized and are the subject of this study. Six-hundred and twenty-six patients with angiographic and clinical criteria for randomization were not randomized because they refused to be included in the study or because of physician reference preference (335 had PTCA and 291 CABG). The other 1,683 patients treated either with PTCA or CABG did not meet the randomization criteria and were included in the registry.

In this latter group, coronary angioplasty was performed in 1,396 patients and CABG in 287 patients (Fig. 1). Angioplasty was performed in these 1,396 patients because of the following reasons: single-vessel disease in 67.5%, two-vessel disease not amenable for surgery in 1.5%, previous CABG in 5%, acute myocardial infarction (AMI) in 10%, and previous PTCA in 16%. From the 287 patients in the registry who had CABG, 16% were selected for a protocol of minimal invasive surgery, 27% had left main stenosis, 1.7% had previous surgery, 27% had poor left ventricular function, and 28.3% had multivessel disease not amenable for PTCA.

Randomization and study design. Randomization of patients fulfilling the inclusion criteria was performed by the Coordinating Center in 10 patient blocks. A randomization sequence was developed so that an equal number of patients were assigned to each treatment strategy at each center. Only patients with multivessel coronary artery disease with clinical indication for revascularization but in whom the choice of revascularization approach was open to question were included in the study.

In these patients, functional revascularization could be achieved by treatment of multivessel coronary lesions amenable to either current techniques of coronary angioplasty or CABG. Before randomization the clinical cardiologist, cardiac surgeon, and an interventionalist evaluated all patients. Patients were randomized in the study only when both the cardiac surgeon and the interventionalist believed that equivalent functional revascularization could be achieved by both techniques.

Randomization started in October 1996, and the last patient was randomized in September 1998. A trained staff was responsible for data collection of variables and clinical follow-up of patients using tabulated forms. An independent biostatistical center verified all data and provided reports to the Steering Committee. The organization and analysis of the results of the study were conducted by a Central Coordinating Steering Committee. The study was monitored by a Safety and Data Monitoring Committee.

All data was stored in a computerized database. Throughout the entire length of the trial all clinical investigators were unaware of the outcome data for the two treatment groups. The Steering Committee included in equal proportion interventional cardiologists, cardiovascular surgeons, and clinical cardiologists. The Clinical Events Committee reviewed the major adverse events and was blinded to the initial treatment strategy received. Patients signed a written consent form. The protocol of the study was approved by the Committee of Human Studies in each participation site of the trial.

Ascertainment of primary end point. The composite primary end point was occurrence of a major adverse cardiac events (MACE) defined as death, Q-wave MI or stroke within 30 days and need for emergency or elective repeat revascularization procedures at 30 days. Follow-up at one, three, and five years between patients who underwent CABG or coronary angioplasty was also obtained. Death included mortality from all causes. A Q-wave MI was defined as new pathologic Q-waves, or new left bundle branch block with >3 times creatine kinase, MB fraction (CK-MB) rise and was judged to be present on the basis of a review of all electrocardiograms (ECGs) obtained as part of the study protocol and other ECGs associated with admission.

The secondary end points included anginal status at one, three, and five years, completeness of revascularization

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**Figure 1.** Patient population of the ERACI II study.
anatomically judged by angiography or functionally as assessed by stress thallium at 30 days, and follow-up costs of both techniques.

**Inclusion criteria.** Patients were eligible for inclusion in the study if they had severely limiting stable angina (Canadian Cardiovascular Society class III–IV) despite maximal medical therapy and unstable angina, including post–acute myocardial infarction (AMI) angina. Patients with no angina or minimal symptoms but with a large area of myocardium at risk identified by exercise testing (two or more areas with perfusion defects) were also eligible. Unstable angina class was defined according to Braunwald’s criteria (17). Patients were required to have angiographic evidence of severe coronary obstruction (≥70% by visual estimation) in at least one major epicardial vessel and more than 50% in other vessels. At least one of the major epicardial vessels to be treated with PTCR should have ≥3.0 mm (visual estimation) as reference diameter suitable for stenting, and all lesions included in the revascularization strategy were from the angiographic point of view amenable to both coronary angioplasty and CABG. Patients with unprotected left main stenoses could be included if they were amenable to single-stent procedure according to the interventionalist point of view.

**Exclusion criteria.** Patients were excluded from the study if they had the following:

1. single-vessel disease
2. previous CABG
3. previous PTCA in the last year
4. previous stenting
5. acute myocardial infarction during the first 24 h
6. poor left ventricular function (ejection fraction ≤35%)
7. more than two chronic total occlusions
8. concomitant severe valvular heart disease
9. limited life expectancy because of older age or concomitant illness
10. lack of informed consent.

**Surgical techniques.** The CABG was performed with standard surgical techniques. Complete revascularization was performed when possible using arterial conduits or reverse saphenous vein graft (3–9).

**Coronary angioplasty and stent deployment.** Coronary angioplasty was performed using standard techniques as previously described (3). Patients were pretreated with aspirin 325 mg daily and ticlopidine 500 mg daily when possible 24 h before the procedure. A weight-based intravenous (IV) heparin bolus was given, to achieve an activated clotting time greater than 280 during the procedure. Patients with rest pain in the last 48 h or post-MI angina were recommended to undergo bolus and infusion of abciximab. Stenting of the target lesions was accomplished using the Gianturco Roubin II stent (COOK, Bloomington, Indiana) as the primary device (18–20) (20 and 12 mm of length). Elective vessel stenting was allowed only with a reference diameter ≥3 mm by visual estimation.

The strategy of revascularization with coronary angioplasty was carefully planned before the procedure to achieve complete functional revascularization. The identified culprit lesion in the main vessel was treated first followed by angioplasty of the other vessels. Coronary angioplasty of chronically occluded vessels supplying akinetic left ventricular segments was usually not attempted.

Intermediate lesions >50% to <70% were treated with PTCR under each physician criteria. Complete anatomic revascularization was defined angiographically after PTCR as the absence of a severe (≥70%) residual stenosis in any major epicardial vessel and for surgery according to the number of distal anastomoses in the disease vessels judged by surgical protocol. Complete functional revascularization was defined using clinical functional criteria with stress thallium performed in the first month after both procedures.

**Sample size.** A 10% to 12% incidence of MACE in patients treated with CABG has remained unchanged during the last decade (3,21–24). In our first randomized ERACI I (Argentine Randomized Study: Coronary Angioplasty vs. Coronary Bypass Surgery in Multivessel Disease) study, hospital MACE with surgery was 11%, and this is in agreement with the current practice of CABG in Argentina (21). Other international studies with surgery had similar results (7,24,25). In contrast, the incidence of hospital and 30-day MACE with current PTCA techniques may be significantly reduced. The estimated rates were 3% to 4% according to recently published data (18,20,26,27). On the assumption that either death, myocardial infarction, repeat procedures or stroke would occur during hospitalization in 10% to 12% of the patients assigned to CABG and in 3% to 4% in patients assigned to PTCA, for a power of 0.90 and an alpha error of 0.05, the estimated sample size will be 230 patients in each group.

**Statistics.** The primary analysis of angiographic and clinical outcomes was based on the intention-to-treat principle. The results are expressed as mean ± SD. For comparison of continuous variables between the two treatments groups, the unpaired two-tailed Student t-test was used. Comparison of categorical variables and the 30-day composite end point between the two groups was performed using the chi-square method. Comparison of the composite clinical end point during the follow-up period was performed using the Kaplan–Meier and Wilcoxon tests (28) with p values calculated according to the log-rank test. All tests were two-tailed, and a p value of <0.05 was considered to indicate statistical significance. Multivariate logistic regression analysis was used to identify independent predictors of worse outcome at 30 days. In the regression model for predictors, a backward stepwise program was used to select co-variates. Enrollment of the patients randomized could be terminated if the interim analysis showed significant differences (p < 0.05) between both groups in the composite primary end point (death + MI + repeat procedures + stroke).
RESULTS

Clinical outcome. Randomization of the 450 patients (225 in PTCR and 225 in CABG) resulted in balanced treatment groups. No differences existed in age, gender, current smokers, diabetes, hypercholesterolemia, and previous infarction between the two groups of patients. The incidence of unstable angina class IIb, IIb, and C was high in the overall cohort of patients (91.1%), and was similar between the PTCA (92%) and the CABG (90.7%) group, with 10% of patients having class C angina in both groups (Table 1). Time between randomization to assigned treatment was lower in the PTCA than in the CABG group (4.2 ± 1.5 vs. 13.2 ± 32 days, respectively, p = 0.0002). Twenty-eight percent of patients included in PTCR had a bolus and infusion of abciximab during the procedure.

Angiographic characteristics. The two groups were also well matched for angiographic characteristics. No significant differences were seen in the number of vessels, culprit arteries, and left ventricular function between the two groups of patients. Prevalence of stenosis in the proximal left anterior descending (LAD) artery was also similar in PTCR and CABG groups (Table 1).

Results of coronary angioplasty. Clinical evidence of successful revascularization defined as dilation of at least one major epicardial vessel (residual stenosis equal to or less than 30% either with balloon angioplasty or stenting) without occurrence of death, Q-wave MI, or emergent in hospital CABG, was achieved in 98.2% of the PTCR patients. At least 99% of the patients had one vessel successfully treated; two vessels were successfully treated in 80.5% of the patients, whereas 91.5% of planned vessels were successfully treated. Excluding those patients with chronic total occlusion, only 8.8% of the patients had severe residual stenosis in one major epicardial vessel after the PTCA procedure.

As part of the revascularization strategy, angioplasty was not attempted in 52 chronic total occlusions (23.4%) in patients with previous history of MI. The occluded artery supplied an area of nonviable myocardium determined by thallium stress test. Complete anatomic revascularization was more frequently achieved in the CABG group than in the coronary angioplasty group (85% vs. 50.2%, respectively, p = 0.002). However, similar functional completeness of revascularization was achieved in both groups. Dipyridamole thallium scintigraphy was performed within 30 days after the PTCA and CABG procedures, and it showed equivalent evidence of normal or nonreversible thallium perfusion areas (83.5% in PTCA vs. 85.1 in CABG patients, respectively, p = NS). After randomization, 3 patients in the PTCR group crossed over to CABG, whereas 16 patients in CABG crossed over to PTCR (1.4% vs. 7.6%, p = 0.04). The left internal mammary artery in the surgical group was used in 88.5% of the patients. In the PTCR group, 1.4 stents per patient were used and 92% of them were Gianturco Roubin II design (Table 2).

Hospital and 30-day outcome. Significant differences were seen in hospital and 30-day outcome between both strategies of revascularization. Mortality was 0.9 in PTCA (2/225) versus 5.7% in CABG patients (13/225), p < 0.013. Nonfatal Q-wave MI was 0.9% in PTCA versus 5.7% in CABG patients (13/225), p < 0.013.

The composite end point (death + MI) was significantly lower in the PTCR group than in the CABG group (1.8% vs. 11.4%, respectively, p = 0.0002). No patient died during the procedure in PTCR, whereas three patients died in the surgical procedure. One patient in PTCR versus six patients in CABG died during the first week. One additional patient in PTCR died after the first week versus three patients in the CABG group. One patient in the surgical group died before the assigned procedure was performed. In the surgical group, mortality related to cardiac failure was 4%. A large MI after unsuccessful PTCR was the cause of death in both patients dying after PTCR.
Two additional surgical patients had a nonfatal stroke during hospitalization (0.9%). No patient in the PTCR group needed emergent CABG; however, emergent angioplasty was required in three patients, and one additional patient after discharge required an elective PTCR during the first 30 days (1.8% in PTCR vs. 0% in CABG). Thus, the composite end point of death, Q-wave MI, repeat PTCA/CABG, and stroke were significantly lower in the PTCR/CABG patients (3.6% vs. 12.3%, respectively, p = 0.002) (Table 2). No significant differences existed in MACE during hospitalization among the participating trial centers. Although this study was not designed to assess outcome according to angina class at presentation, there was a trend for a higher 30-day mortality rate in patients with unstable angina randomized to surgery. As shown in Table 3, in-hospital mortality of surgically randomized patients were 0% (0/21), 5.6% (8/141) and 7.9% (5/63)* for patients with chronic stable angina, unstable angina class II, and unstable angina class III + C, respectively. Furthermore, when compared with PTCR, surgically treated patients with unstable angina class III + C have a greater inhospital mortality (p = 0.06 in favor of PTCR) (Table 3). The hospital mortality and the incidence of MI in eligible but nonrandomized patients were similar to randomized patients (death 11.1% vs. 5.1%, Q-wave AMI 0.7% vs. 5.2% for PTCR and CABG patients, respectively).

**Multivariate predictors of 30-day outcome.** A multivariate analysis of the overall population identified CABG treatment as the only independent predictor of 30-day MACE (odds ratio [OR] 3.91; 95% confidence interval [CI] 1.71–8.89, p < 0.0012). A second multivariate analysis performed in the male population alone identified CABG treatment (OR: 5.76; CI: 2.08–15.9; p < 0.0008) and age > 65 years (OR: 2.22, CI: 1.00–4.95; p < 0.05) as independent predictors of 30-day MACE in the male population (Table 4). According to the above figures, the power of the study to identify differences between groups was 90.0% for p < 0.05.

**Late clinical follow-up.** A mean clinical follow-up of 18.5 ± 6.4 months (range, 9 to 33 months) was completed in all patients. The Kaplan-Meier survival curves of follow-up at 900 days showed better survival in the PTCR group compared with the CABG group (96.9% vs. 92.5%, respectively, p < 0.017). There were more deaths during the first 30-day period in the surgical group. After one month, similar numbers of patients (5 in PTCR and 4 in CABG) died in each group (Fig. 2). Kaplan-Meier freedom from myocardial infarction was also better in the PTCR group than the surgery group (97.7% vs. 93.7%, respectively, p < 0.017) (Fig. 3). In contrast, freedom from requirement of new revascularization procedures were significantly better with CABG patients (95.22% vs. 83.2%, p < 0.001) (Fig. 4). Eleven PTCR patients (4.8%) crossed over to CABG during the follow-up period. Patients assigned to CABG were also more frequently free of angina than were patients assigned to PTCR (92% vs. 84.5%, respectively, p = 0.01). Event-free survival (death, myocardial infarction, and repeat PTCA/CABG) was similar in both groups.

**Hospital and follow-up costs.** Because analysis was performed by intention to treat, charges included those patients in each group crossing over to the other revascularization strategy. In Argentina there is an average cost (all amounts

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**Table 3. Thirty-Day Mortality in Patients Randomized to PTCR or CABG According to Angina Class**

<table>
<thead>
<tr>
<th>Angina Class</th>
<th>PTCR</th>
<th>CABG</th>
</tr>
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<tbody>
<tr>
<td>Stable (38)</td>
<td>0%  (0/17)</td>
<td>0%  (0/21)</td>
</tr>
<tr>
<td>Unstable Class II (279)</td>
<td>1.4% (2/138)</td>
<td>5.6% (8/141)</td>
</tr>
<tr>
<td>Unstable Class III + C (133)</td>
<td>0% (0/70)*</td>
<td>7.9% (5/63)*</td>
</tr>
</tbody>
</table>

*p = 0.06.

CABG = coronary artery bypass graft surgery; PTCR = percutaneous transluminal coronary revascularization.

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**Table 4. Multiple Stepwise Logistic Regression Analysis of MACE (Death, Myocardial Infarction, Stroke, Repeat Procedures)**

<table>
<thead>
<tr>
<th>Event-Free Survival Value</th>
<th>OR</th>
<th>CI</th>
</tr>
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<tbody>
<tr>
<td>Overall Population</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age &gt;65 years</td>
<td>0.19</td>
<td>1.61</td>
</tr>
<tr>
<td>Diabetic</td>
<td>0.61</td>
<td>1.26</td>
</tr>
<tr>
<td>Gender</td>
<td>0.71</td>
<td>1.18</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>0.96</td>
<td>0.98</td>
</tr>
<tr>
<td>Class C angina</td>
<td>0.63</td>
<td>0.67</td>
</tr>
<tr>
<td>Three vessels</td>
<td>0.16</td>
<td>0.61</td>
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<table>
<thead>
<tr>
<th>Male Population</th>
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<tbody>
<tr>
<td>CABG</td>
<td>&lt;0.0008</td>
<td>5.76</td>
</tr>
<tr>
<td>Age &gt;65 years</td>
<td>0.050</td>
<td>2.22</td>
</tr>
<tr>
<td>Diabetic</td>
<td>0.61</td>
<td>1.97</td>
</tr>
<tr>
<td>Class C angina</td>
<td>0.85</td>
<td>0.86</td>
</tr>
<tr>
<td>Unstable angina</td>
<td>0.65</td>
<td>0.81</td>
</tr>
<tr>
<td>Three vessels</td>
<td>0.33</td>
<td>0.68</td>
</tr>
</tbody>
</table>

CABG = coronary artery bypass graft surgery; CI = confidence intervals; MACE = major adverse cardiac events.

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**Figure 2.** Kaplan-Meier curve. Freedom from death.
in this section are in U.S. dollars) of $4,500 for uncomplicated balloon angioplasty and $11,000 for uncomplicated CABG according to an agreement between the National Social Security System and each hospital participating in the ERACII (Argentine Randomized Study: Coronary Angioplasty with Stenting vs. Coronary Bypass Surgery in Multivessel Disease) trials. These costs included hospital charges, fees, and honorarium for both procedures.

The cost of the first stent was $3,000, and the cost of each additional stent was $2,800. In PTCR, these included two days of hospitalization and nine days of hospitalization in the CABG group. For each additional day in the Coronary Care Unit add a cost of $1,080. The bolus use of abciximab also adds a cost per bolus of $991, and for bolus and 12 hours of infusion, $2,974. The hospital stay in the PTCR group was shorter than in the CABG group (4.9 ± 4.5 vs. 9 ± 6.4 days, respectively, p = 0.0002). Taking into account the above numbers and related procedural resources, hospital complications and 30-day outcome, the final 30-day costs of both techniques were similar ($2,548,615 in PTCR vs. $2,415,500 in CABG, p = 0.9). During follow-up requirements of revascularization procedures, add a cost of $223,500 for PTCR and $95,500 for CABG. Thus, the overall cost per patient did not show a significant difference between PTCA and CABG ($12,320 vs. $11,160, respectively) (Table 5).

DISCUSSION

This prospective, multicenter, randomized study reveals that current techniques of PTCR with stent usage result in a significantly lower incidence of death and Q-wave MI during hospitalization and at 30 days when compared to conventional techniques of CABG in patients with multivessel disease. During the first month, the MACE factors were also significantly lower in the PTCR group. Patients treated with PTCR had significantly higher need of repeat revascularization procedures compared to surgery.

Comparison with previous studies. The rate of death and MI during hospitalization in this study in the surgical group is in agreement with randomized trials and registries previously published (3,10,21–25,29–31). In the ERACI I trial, 30-day mortality and MI rates with CABG were 4.7% and 6.2%, respectively (3,10). This mortality occurred even though there were fewer patients with unstable angina, no incidence of associated peripheral vascular disease, and no evidence of main left disease in the ERACI I than in the present ERACII study (3,10).

In the recently published VANQWISH (Estudio Randomizado Argentino Cirugia Angioplastia) trial, overall mortality at 30 days with surgery was 7.7%. Furthermore, it was 11.6% for patients in the invasive arm undergoing surgery (24). This high mortality in the VANQWISH trial occurred despite the fact that only low-risk patients with non Q-wave MI were randomized. Patients with hemodynamic instability and those with recurrent ischemia were excluded from this trial. Our patient population has had several factors associated with higher surgical risk, such as older age, peripheral or cerebral disease, unstable angina, and class C angina. A recent study of 5,517 patients who underwent CABG (22) showed that in-hospital mortality was higher among patients who underwent surgery if they had been treated after seven days for MI (13%), had peripheral or cerebral vascular concomitant disease (8%), were 65 years of age or older (4%), or had class 4 angina (5%).

These characteristics were common among our patients, as shown in Table 1. Although the surgical hospital mortality in the ERACII study is higher than those showed by

<table>
<thead>
<tr>
<th>Table 5. Cost of Revascularization Procedures</th>
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<tbody>
<tr>
<td>PTCR (225 Patients)</td>
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<tr>
<td>----------------------</td>
</tr>
<tr>
<td>In-hospital*</td>
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<tr>
<td>Follow-up (18.5 ± 6.4 months)*</td>
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<tr>
<td>Overall</td>
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<td>Per patient</td>
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*Includes hospital charges, procedural resources (stents, abciximab, etc.) and honorarium for both techniques. CABG = coronary artery bypass graft surgery; PTCR = percutaneous transluminal coronary revascularization.
the RITA (Randomized Intervention Treatment of Angina), CABRI (Coronary Angioplasty vs. Bypass Revascularization Investigation) BARI (Bypass Angioplasty Revascularization Investigation), and EAST (Emory Angioplasty versus Surgery Trial) (4–6,8,14,16,19,32). Furthermore, ERACI II had a larger cohort of patients with unstable and post-MI angina than did the two aforementioned studies (4,7) (Table 6). The high in-hospital mortality with CABG in unstable patients has been recognized (among 4% to 7%) in a review article recently published by the ACC/AHA (American College of Cardiology/American Heart Association) Task Force for Coronary Bypass Surgery (25). Concomitant peripheral disease, present in 27% in our surgical group, was also associated with high hospital MACE (21%) in the BARI trial (29). These data further strengthen our hypothesis that these unfavorable associated comorbid conditions are responsible for the high surgical mortality rate seen in the ERACI II trial.

The role of coronary stenting. The use of stents during coronary angioplasty has been demonstrated in reduced acute complications during the initial procedure (12,18,19,26,27,32). The use of stents in this study explains why emergent CABG and acute closure were significantly lower than in previous randomized studies with conventional balloon angioplasty (between 30% to 40%) (11). Furthermore, only 4.8% of the patients in the PTCR group have crossed over to CABG during the follow-up period (18% in previous trials) (3–11). Finally, the overall cost for each procedure in Argentina was similar, suggesting a significant increase in the cost of coronary angioplasty compared with previous analysis performed several years ago (10). Longer follow-up will be needed to address the long-term comparative efficacy and cost of PTCR versus surgery.

Study limitations. The study involved a large cohort of patients, with higher risk of in-hospital surgical morbidity and mortality. Because the differences in major events (death or MI) largely occurred during the hospital period and mainly in patients with more severe unstable angina. Therefore, these results could change if the patient population treated had different baseline clinical characteristics or if technical proficiency for either treatment was altered. In addition, the use of GRII (Gianturco-Roubin II) stents has been associated with high requirements of repeat procedures (36), thus, long-term outcome could have had better results than with other stent designs. Finally, only 16% of the screened patients were randomized, and this could bias the study; however, it is a common finding in all randomized trials comparing PTCA and CABG.

Conclusions. This multicenter randomized study demonstrates that symptomatic patients with multivessel coronary artery disease incur a lower risk of death or MI at 30 days when treated with routine stent therapy compared to conventional coronary bypass. These initial safety advantages are maintained at one-year follow-up.

APPENDIX

STUDY ORGANIZATION AND PARTICIPANTS:

Steering Committee: Alfredo Rodriguez, MD, PhD, FACC; William O’Neill, MD, FACC; Igor Palacios, MD, FACC; Liliana Grinfeld, MD, FACC; Jose Navia, MD, FACC; Raúl Oliveri, MD; Néstor Pérez Balíño, MD, FACC; Julio Baldi, MD.

Safety Committee: Marcelo Elizari, MD, FACC; Jorge Lerman, MD, FACC.

Coordinating Center: CECI: Alfredo Rodriguez, MD, PhD, FACC; Victor Bernardi, MD; Sandra Saavedra, MD; Máximo Rodriguez Alemparde, MD; Cecilia Espinosa, BS.

Core Laboratory: Carlos Fernández Pereira, MD; Omar Santaera, MD.

Statistics: Ulises Questa, MD, PhD; Larry Harrell, BS.

Clinical Events Committee: Raúl Oliveri, MD; Néstor
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