

## Three-Year Follow-Up of the Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Multivessel Disease (ERACI)

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**Objectives.** The purpose of this study was to report the 3-year follow-up results of the ERACI trial (Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Multivessel Disease).

**Background.** Although coronary angioplasty has been used with increased frequency in patients with multivessel coronary artery disease, its value, compared with bypass graft surgery, has not been established. Thus, controlled, randomized clinical trials such as the ERACI are needed.

**Methods.** In this trial 127 patients who had multivessel coronary artery disease and clinical indication of myocardial revascularization were randomized to undergo coronary angioplasty (n = 63) or bypass surgery (n = 64). The primary end point of this study was event-free survival (survival with freedom from myocardial infarction, angina and new revascularization procedures) for both groups of patients at 1, 3 and 5 years of follow-up.

**Results.** Freedom from combined cardiac events (death, Q-wave myocardial infarction, angina and repeat revascularization pro-

cedures) was significantly greater for the bypass surgery group than the coronary angioplasty group (77% vs. 47%;  $p < 0.001$ ). There were no differences in overall (4.7% vs. 9.5%;  $p = 0.5$ ) and cardiac (4.7% vs. 4.7%;  $p = 1$ ) mortality or in the frequency of myocardial infarction (7.8% vs. 7.8%;  $p = 0.8$ ) between the two groups. However, patients who had bypass surgery were more frequently free of angina (79% vs. 57%;  $p < 0.001$ ) and required fewer additional reinterventions (6.3% vs. 37%;  $p < 0.001$ ) than patients who had coronary angioplasty.

**Conclusions.** 1) Freedom from combined cardiac events at 3-year follow-up was greater in patients who had bypass surgery than in those who had coronary angioplasty. 2) The coronary angioplasty group had a higher incidence of recurrence of angina and the need for repeat revascularization procedures. 3) Cumulative cost at 3-year follow-up was greater for the bypass surgery group than for the coronary angioplasty group.

(*J Am Coll Cardiol* 1996;27:1178-84)

Coronary artery bypass graft surgery and percutaneous transluminal coronary angioplasty are the most commonly used procedures to treat patients with coronary artery disease who require myocardial revascularization. Bypass surgery has been demonstrated to be effective in relieving angina, prolonging survival and decreasing coronary events in patients with multiple vessel disease (1,2). Although coronary angioplasty has been used with increased frequency with high success rates and low complications in patients with multivessel coronary artery

disease (3-8), its value, as compared with bypass surgery, has not been established. Several controlled, randomized clinical trials of coronary angioplasty versus bypass surgery in patients with multivessel coronary artery disease in North and South America and Europe have reported their partial or final results (9-14). We previously reported the immediate and first-year follow-up results of the ERACI (Argentine Randomized Trial of Percutaneous Transluminal Coronary Angioplasty Versus Coronary Artery Bypass Surgery in Multivessel Disease) patients who were considered good candidates for either procedure (9). In the present study we report the 3-year clinical follow-up of these patients.

### Methods

**Patients.** Details of the ERACI trial have been previously described (9). This trial included patients with multivessel coronary artery disease and clinical indication of myocardial revascularization in whom complete functional revasculariza-

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Manuscript received September 1, 1995; revised manuscript received November 21, 1995, accepted November 29, 1995.

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tion could be achieved by the treatment of coronary lesions amenable to both coronary angioplasty or bypass surgery. The patients were required to have  $\geq 70\%$  stenosis in more than one major epicardial coronary artery. Patients with severe main left trunk stenosis, poor left ventricular ejection fraction ( $\leq 35\%$ ), associated severe valvular or hypertrophic heart disease, or both, evolving acute myocardial infarction and limited life expectancy were excluded from the study (9). The primary end point of this study was to compare event-free survival (survival with freedom from myocardial infarction, angina and new revascularization procedures) between both groups of patients at 1, 3, and 5 years of follow-up. Secondary end points included 1) comparison of major in-hospital complications (death, Q-wave myocardial infarction and emergency revascularization procedures); 2) comparison of the completeness of revascularization as achieved by both methods; and 3) comparison of in-hospital and late costs of both revascularization techniques.

Of 1,409 patients with a presumptive clinical diagnosis of coronary artery disease who underwent coronary arteriography at the Anchorena Hospital between June 1988 and December 1990, revascularization was indicated in 748 patients. Entrance criteria for randomization were met by 302 patients. Of these 302 patients, 63 were randomized to coronary angioplasty and 64 to bypass surgery. Of the 175 patients with randomizable criteria but who were not randomized, 99 had coronary angioplasty and 76 had bypass surgery. The randomized group included 108 males and 19 females with a mean age of  $58 \pm 5$  years (range 33 to 76). The two randomized groups (bypass surgery and coronary angioplasty) were well matched for demographic, clinical, arteriographic and angiographic characteristics. There were no significant differences in the number of double (53.1% vs. 57.1%) and triple (46.9% vs. 42.9%) vessels or in left ventricular ejection fraction ( $62 \pm 12\%$  vs.  $59 \pm 12\%$ ) between the two groups (9). The major in-hospital complications and follow-up events of both revascularization modalities—mortality, Q-wave myocardial infarction, incidence of angina and the need for additional revascularization procedures (coronary angioplasty or bypass surgery)—were recorded. A trained staff was responsible for data collection of variables and clinical follow-up of patients (using tabulated forms). Patients were contacted every 6 months for follow-up information. 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.

**Statistical analysis.** Continuous variables are expressed as mean  $\pm$  SD. Differences in categorical variables between both groups of patients were determined using chi-square analysis. The Student *t* test or Wilcoxon two-sample test was used for comparison of continuous variables when appropriate. Overall survival and survival with freedom from combined cardiac events for both groups of patients at 3-year follow-up were determined using Kaplan-Meier curves and the log-rank test.

A *p* value  $< 0.05$  was considered statistically significant. As previously reported, the power of this study (estimating a combined event-free survival at 1, 3 and 5 years of follow-up of 75% to 85% in the bypass surgery group and 55% to 65% for the coronary angioplasty group) is 70% (9).

## Results

**Initial and 1-year follow-up.** The baseline clinical and angiographic characteristics and the in-hospital and 1-year follow-up results of the ERACI trial were previously reported (9). Coronary angioplasty and bypass surgery were associated with similar rates of in-hospital mortality (1.5% in coronary angioplasty vs. 4.6% in bypass surgery), periprocedural Q-wave myocardial infarction (6% in coronary angioplasty vs. 6% in bypass surgery) and incidence of urgent revascularization (1.5% in coronary angioplasty vs. 1.5% in bypass surgery). At 1-year follow-up there were no significant differences in mortality and incidence of Q-wave myocardial infarction between the two groups. However, patients who had bypass surgery were more frequently free of angina and were less likely to need additional revascularization procedures.

**Mortality.** In the bypass surgery group, three patients (4.7%) died during the 3 years of follow-up. All of deaths from bypass surgery occurred during the initial hospitalization and none occurred during the follow-up period.

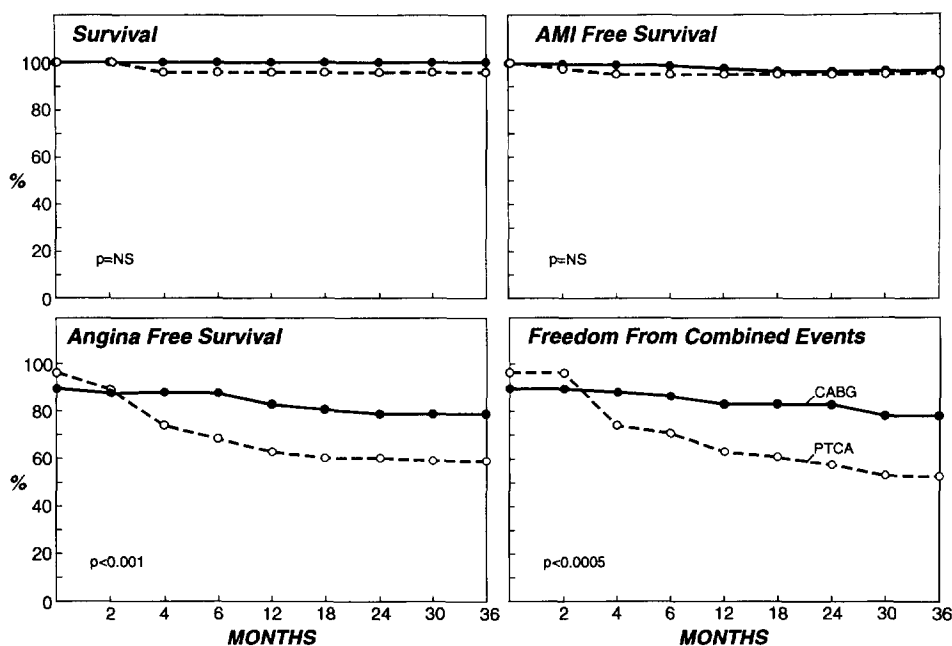
In the coronary angioplasty group, six patients (9.5%) died during the 3 years of follow-up. There were three cardiac (4.7%) and three noncardiac (4.7%) deaths. One cardiac death occurred during the initial hospitalization. Two additional cardiac deaths occurred during the follow-up period. The three noncardiac deaths included one patient who had undergone bypass surgery 2 months after coronary angioplasty and died of lung cancer at the beginning of the second year of follow-up; one patient maintained on long-term dialysis who died from meningitis; and one patient who died in an automobile accident.

There were nonsignificant differences in overall (4.7% vs. 9.5% for bypass surgery and coronary angioplasty, respectively; *p* = 0.5) and cardiac (4.7% vs. 4.7% for bypass surgery and coronary angioplasty, respectively; *p* = 1) mortality between the coronary angioplasty and the bypass surgery groups. The corresponding actuarial survival curves during the 3 years of follow-up for these two groups of patients are shown in the right upper panel of Figure 1.

**Q-wave myocardial infarction.** In the bypass surgery group, five patients (7.8%) sustained a new nonfatal Q-wave myocardial infarction within the 3 years of follow-up, with three of them occurring during the initial hospitalization.

In the coronary angioplasty group, five patients (7.8%) sustained a new nonfatal Q-wave myocardial infarction within the 3 years of follow-up, with three of them occurring during the initial hospitalization.

There was no significant difference in the incidence of new



**Figure 1.** Comparison of overall survival (**upper left**), survival with freedom from Q-wave myocardial infarction (AMI) (**upper right**), survival with freedom from angina (**bottom left**) and survival with freedom from combined cardiac events (**bottom right**) in patients who had coronary artery bypass graft surgery (CABG) and percutaneous transluminal coronary angioplasty (PTCA).

nonfatal Q-wave myocardial infarction between the coronary angioplasty group and the bypass surgery group (7.8% vs. 7.8% for bypass surgery and coronary angioplasty, respectively;  $p = 0.8$ ). The corresponding actuarial survival with freedom from nonfatal Q-wave myocardial infarction curves during the 3 years of follow-up for these two groups of patients is shown in the left upper panel of Figure 1.

**Event-free survival (end point).** As shown in the left lower panels of Figure 1, the 3-year actuarial event-free survival (survival with freedom from nonfatal Q-wave myocardial infarction, angina and repeat revascularization procedures) was significantly greater in the bypass surgery group than in the coronary angioplasty group (77% vs. 47% for bypass surgery and coronary angioplasty, respectively;  $p < 0.0005$ ). As shown in the right lower panel of Figure 1, the 3-year actuarial survival with freedom from angina (79% vs. 56.5% for bypass surgery and coronary angioplasty, respectively;  $p < 0.001$ ) was significantly greater for the bypass surgery group. Patients who had coronary angioplasty had both a higher incidence of angina (43% vs. 21%;  $p < 0.001$ ) and a greater need for repeat revascularization procedures (37% vs. 6.3%;  $p < 0.001$ ) than those who had bypass surgery.

When considering the coronary angioplasty group alone, there were nonsignificant differences in freedom from combined cardiac events between those patients in whom coronary angioplasty resulted in "complete anatomic revascularization" and those in whom coronary angioplasty resulted in "complete functional revascularization."

**Incidence of angina.** Eleven patients in the bypass surgery group (18%) and 24 patients in the coronary angioplasty group (39%) had angina at the end of the first year.

Although the prevalence of angina was significantly higher

in the coronary angioplasty group during the initial 6 months of follow-up, this difference disappeared by the end of the third year of follow-up (4.8% for coronary angioplasty vs. 3.2% for bypass surgery;  $p = NS$ ).

**Repeat revascularization procedures.** A total of 23 patients (37%) in the coronary angioplasty group and four patients (6.3%) in the bypass surgery group underwent a second revascularization procedure (coronary angioplasty or bypass surgery) during the 3 years of follow-up. In the first year of follow-up, 20 of the patients in the coronary angioplasty group underwent a second revascularization procedure (9 repeat angioplasties and 11 bypass surgeries) within 6 months of randomization. Three additional patients in the coronary angioplasty group underwent bypass surgery during the second and third years of follow-up.

Meanwhile, only three additional patients in the bypass surgery group required a repeat revascularization procedure during the 3 years of follow-up. Coronary angioplasty was performed in two of these patients in the first year of follow-up and in one other patient during the rest of the follow-up period. There was a significant difference in the incidence of repeat revascularization procedures between the coronary angioplasty and the bypass surgery groups (37% vs. 6.3% for coronary angioplasty and bypass surgery, respectively;  $p < 0.001$ ).

**Hospital cost.** Table 1 summarizes the cost of revascularization procedures for both groups of patients. An estimate of hospital cost per patient for both procedures was calculated using the payment (in U.S. currency) established by the medical system of Argentina (\$4,000 and \$5,000 for noncomplex and complex coronary angioplasty, respectively vs. \$12,000 and \$15,000 for noncomplex and complex bypass surgery, respectively). The estimated hospital cost for the 63 patients

**Table 1.** Cost of Revascularization Procedures

	PTCA (n = 63)	CABG (n = 64)	p Value
In hospital	\$270,000	\$820,000	0.01
Three-year follow-up*	\$204,000	\$12,000	0.01
Total	\$474,000	\$832,000	0.02

\*Includes only repeat revascularization procedures: coronary artery bypass graft surgery (CABG) or percutaneous transluminal coronary angioplasty (PTCA).

who had coronary angioplasty, including the in-hospital complications (one emergency bypass surgery), was \$270,000. The estimated hospital cost for the 64 patients who had bypass surgery (52 noncomplex and 12 complex) was \$820,000 ( $p = 0.01$ ). During the 3-year follow-up, 9 coronary angioplasties and 14 bypass surgeries were performed in the coronary angioplasty group because of restenosis. This implies an additional estimated cost of \$204,000 to the initial hospital cost of the coronary angioplasty cohort. Therefore, the total estimated cost of patients treated with coronary angioplasty (in-hospital and 3-year follow-up) was \$474,000. However, in the bypass surgery group, two patients underwent coronary angioplasty during the first year of follow-up and one patient during the rest of the follow-up, adding \$12,000 to the initial hospital cost. Thus, the total cost of patients who had bypass surgery (in-hospital and 3-year follow-up) of \$832,000 was significantly higher than the cost of patients who had coronary angioplasty of \$474,000 ( $p = 0.02$ ).

**Patients with randomizable criteria but who were not randomized.** As we previously described (9), 175 patients had criteria of randomization but were not randomized—99 were treated with coronary angioplasty and 76 with bypass surgery. The immediate and long-term results of this group of patients are shown in Table 2. Patients who had bypass surgery had a

**Table 2.** Immediate and Follow-Up Results of Nonrandomized (“registry”) Patients

	CABG (n = 76)	PTCA (n = 99)
Three-vessel CAD	52.7%	33%
In-hospital complications		
Mortality	5.2%	2%
Q-wave MI	3.9%	5%
Emergency CABG	—	2%
Stroke	2.6%	0%
Follow-up results (3 yr)		
Cardiac mortality	0%	2%
Noncardiac mortality	2.6%	0%
Q-wave MI	0%	1%
Angina (1 yr)	7.1%	20.4%
Angina (3 yr)	7.1%	12.2%
Repeat revascularization	0%	28.4%

CAD = coronary artery disease; MI = myocardial infarction; other abbreviations as in Table 1.

higher incidence of three-vessel coronary artery disease than patients who had coronary angioplasty (52.7% vs. 33%, respectively). Major in-hospital complications of this cohort of patients with criteria of randomization but who were not randomized included an in-hospital mortality rate of 2% for the coronary angioplasty group and 5.2% for the bypass surgery group and an incidence rate of periprocedure Q-wave myocardial infarction of 5% for the coronary angioplasty group and 3.9% for the bypass surgery group. The incidence rate of emergency bypass surgery with coronary angioplasty was 2%. There were no strokes in the coronary angioplasty group and two strokes (2.6%) in the bypass surgery group. During the 3-year follow-up of patients with randomizable criteria but who were not randomized, no one died during the first year in either group. At the end of the 3 years of follow-up, the coronary angioplasty cardiac mortality rate was 2%. Although there were no additional cardiac deaths in the bypass surgery group during the rest of the follow-up period, there was a 2.6% noncardiac mortality rate in this patient cohort by the end of the 3-year follow-up. Nonfatal Q-wave myocardial infarction occurred in 1% of the patients who had coronary angioplasty and in none of the patients who had bypass surgery during the 3-year follow-up. During the first year of follow-up, 20.4% of the patients who had coronary angioplasty and 7.1% of the patients who had bypass surgery developed angina. At the end of the 3-year follow-up, angina was present in 12.2% of the patients who had coronary angioplasty and in 7.1% of the patients who had bypass surgery. Repeat revascularization procedures were required in 28.4% of the coronary angioplasty group (50% needed another coronary angioplasty and 50% needed bypass surgery) and in none of the patients in the bypass surgery group.

## Discussion

A 3-year follow-up of the ERACI trial (a randomized study of coronary angioplasty versus bypass surgery in the treatment of patients with multiple vessel disease and a high prevalence of unstable angina) showed a greater event-free survival for patients treated with bypass surgery than for those treated with coronary angioplasty (77% vs. 47%, respectively). Because there were no significant differences in overall survival and survival with freedom from nonfatal Q-wave myocardial infarction between both groups of patients, this difference is solely the result of a higher incidence of recurrence of angina and the need for additional revascularization procedures in the coronary angioplasty group. Furthermore, this study showed that the cost (according to the modules of practices of the Social Security System of Argentina) at 3-year follow-up, including the new revascularization requirements, was significantly higher for the cohort of patients who underwent bypass surgery than for those who underwent coronary angioplasty.

**Prevalence of angina at follow-up.** Patients who had bypass surgery were more frequently free of angina during follow-up

than those who had coronary angioplasty (79% vs. 57%, respectively). The rate of angina in the coronary angioplasty group was higher during the first year of follow-up (39% vs. 18% for coronary angioplasty and bypass surgery, respectively), reflecting restenosis and incomplete revascularization in the coronary angioplasty group. However, this difference is attenuated during later follow-up, so that by the end of the third year of follow-up the prevalence of angina was similar in both groups of patients—a consequence of both a higher rate of additional coronary revascularization procedures during the follow-up period in the coronary angioplasty group (37% vs. 6.3% for coronary angioplasty and bypass surgery, respectively) and graft disease in the bypass surgery group. During follow-up, 22% of the patients who initially underwent coronary angioplasty later needed bypass surgery, whereas only 6.3% of the patients who initially underwent bypass surgery later needed coronary angioplasty. With coronary angioplasty there is a high incidence of early events owing to restenosis and repeat revascularization procedures; however, with bypass surgery there is a low incidence of early events but a significant incidence of late events owing to graft disease. Therefore, longer follow-up studies are required.

The completeness of myocardial revascularization achieved during bypass surgery in patients with multiple vessel disease is an important determinant of the incidence of cardiac events at follow-up (15–19). However, the impact of incomplete revascularization in patients with multiple vessel coronary artery disease treated with coronary angioplasty has not been well established. Incomplete angiographic revascularization is part of the strategy in patients with multiple vessel disease undergoing coronary angioplasty of the culprit lesions. As we reported previously, “incomplete anatomic revascularization” resulting from the presence of total chronic occlusions was greater in the coronary angioplasty group than in the bypass surgery group. However, “complete functional revascularization” was similar in both groups of patients (9). Because the event-free survival was similar in the coronary angioplasty group of patients with “complete anatomic” revascularization and in those with “complete functional revascularization,” it remains unknown whether revascularization of total chronic occlusions of vessels irrigating areas of nonviable myocardium is necessary when treating patients with multiple vessel disease with coronary angioplasty.

**Other randomized trials of coronary angioplasty versus bypass surgery for multiple-vessel coronary artery disease.** The results of our study are in agreement with those of other controlled randomized trials of coronary angioplasty versus bypass surgery in patients with multiple vessel disease (10–14). Although there are important differences in the design and end points in these trials, their results have shown nonsignificant differences in in-hospital complications (mortality and Q-wave myocardial infarction) and no significant differences in survival and incidence of nonfatal myocardial infarction at follow-up. However, compared with patients undergoing bypass surgery, those undergoing coronary angioplasty were more likely to

have angina and to undergo additional coronary revascularization procedures at follow-up. Our 3-year follow-up results of 6.3% versus 37% of repeat revascularization for bypass surgery and coronary angioplasty, respectively, are similar to those reported by the Randomized Intervention Treatment of Angina (RITA) at 2.5-year follow-up in 1,011 patients (11% vs. 38%); the German Angioplasty Bypass Investigation (GABI) at 1-year follow-up in 359 patients (6.7% vs. 46.5%); the Emory Angioplasty Surgery Trial (EAST) at 3-year follow-up in 392 patients (13% vs. 54%); and the Coronary Artery Bypass Revascularization Investigation (CABRI) at 1-year follow-up in 1,054 patients (3.5% vs. 36.5%). The results of the National Heart, Lung, and Blood Institute (NHLBI)-sponsored Bypass Angioplasty Revascularization Investigation (BARI) in >1,800 patients will not be available until completion of the 5-year follow-up period.

Furthermore, similar to these randomized trials (10–14), in our study the randomized patients represent only a small proportion of the total number of patients who were screened for the study. Many patients with multivessel disease are not candidates for coronary angioplasty because of significant left main coronary artery stenosis, chronic occlusions, complex anatomy or diffuse disease. However, other important information can be derived from those patients with criteria of randomization but who were not randomized. The in-hospital and 3-year follow-up results of our 175 patients with criteria of randomization but who were not randomized are similar to those of our randomized patients. These results further support our findings that the initial form of revascularization, either coronary angioplasty or bypass surgery, does not affect the prognosis of patients with multivessel disease who have lesions that are suitable to treatment with bypass surgery or coronary angioplasty. The lack of significant differences in mortality and incidence of myocardial infarction between the two forms of revascularization demonstrates that the prognosis of both techniques is similar in patients with multivessel coronary artery disease suitable to treatment with either coronary angioplasty or bypass surgery. Although clearly a difference exists between the two forms of revascularization in terms of angina and repeat revascularization procedures, the selection of the revascularization strategy should be determined by the patient and the clinician, the available facilities and the cost of the procedure. Although coronary angioplasty is less expensive initially, the additional revascularization procedures in patients who had coronary angioplasty decrease the cost advantage of coronary angioplasty at follow-up. In our study the cumulative cost (according to the modules of practices of the Social Security System of Argentina) at 3-year follow-up, including the new revascularization requirements, was significantly higher for the bypass surgery group than for the coronary angioplasty group.

**Study limitations.** As we previously cited, our study sample size is small but appropriate to reach our primary aim of comparing bypass surgery and coronary angioplasty in patients with multiple vessel disease who needed revascularization. The

results reported by other randomized studies with a larger number of patients, such as EAST, RITA, GABI and CABRI, are in agreement with the results of our study (10-14).

A higher incidence of unstable angina was present in the patients in our study. It has been well established that in-hospital complications and the incidence of restenosis after angioplasty are greater in patients with unstable angina (20-23). Thus, it is possible that results could be different when comparing patients with chronic stable angina.

Our discussion of cost actually is an estimate rather than total cost and is based on flat rates for both initial and follow-up procedures. Other incurred costs, including physician visits, clinic visits, hospital admissions, medications, use of multiple catheters, physician fees and the level of disability and return to work, were not included in the cost analysis. Although the cost of medical therapy and more intensive follow-up in the patients with recurrent ischemia would need to be added to the cost of each group, we do not believe that the total cost of the coronary angioplasty group will come close to the bypass surgery group. It will be interesting to see if they are close at the 5-year follow-up.

Finally, in our study, percutaneous revascularization was achieved by the use of balloon angioplasty only. The use of the second generation of interventional devices that produce debulking and scaffolding of the coronary stenosis increase the success rate, decrease the incidence of acute complications and decrease the incidence of restenosis in the coronary angioplasty group (24-33). Thus, further studies are necessary to compare coronary artery bypass graft surgery with percutaneous catheter revascularization using coronary angioplasty and the second generation of interventional devices.

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

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