

# Left internal thoracic artery–radial artery composite grafts as the technique of choice for myocardial revascularization in elderly patients: A prospective randomized evaluation

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**Objectives:** The technique of choice for myocardial revascularization in elderly patients remains a debated issue. We evaluated the potential advantages of the use of left internal thoracic artery–radial artery composite grafts compared with conventional coronary artery bypass grafts in elderly patients.

**Methods:** We prospectively enrolled 160 patients aged more than 70 years scheduled to undergo isolated myocardial revascularization. Patients were assigned at random to group 1, 80 patients undergoing total arterial revascularization (left internal thoracic artery on left anterior descending coronary artery plus radial artery), or group 2, 80 patients undergoing standard coronary artery bypass graft surgery (left internal thoracic artery on left anterior descending coronary artery plus saphenous veins). The radial artery was used in all cases as a composite Y-graft.

**Results:** Preoperative characteristics and risk factors (EuroSCORE: group 1 = 7.9 vs group 2 = 8.1), number of grafted coronary vessels (group 1 = 2.4 vs group 2 = 2.5), aortic crossclamping time (group 1 = 37 ± 7 minutes vs group 2 = 38 ± 7 minutes), ventilation time (group 1 = 22 ± 12 hours vs group 2 = 23 ± 11 hours), intensive care unit stay (group 1 = 39 ± 10 hours vs group 2 = 40 ± 9 hours), and hospital mortality (group 1 = 3.8% vs group 2 = 5%) were comparable between the groups. Comparison between the 2 groups in terms of early postoperative complications showed a higher incidence of cerebrovascular accidents in group 2 (group 1 = 0 patients vs group 2 = 4 patients, 5%). At a mean follow-up of 16 ± 3 months, patients in group 1 showed superior clinical results with a lower incidence of graft occlusion (group 1 = 2 vs group 2 = 11;  $P = .06$ ) and angina recurrence (group 1 = 2 patients vs group 2 = 12 patients;  $P = .03$ ). Multivariate analysis identified saphenous vein grafts as independent predictors for graft occlusion and angina recurrence.

**Conclusions:** Left internal thoracic artery–radial artery composite grafts proved to be a safe procedure in elderly patients. It improved the clinical outcome, providing a significantly higher graft patency rate and a lower incidence of late cardiac events.

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**A**steadily increasing number of patients aged more than 70 years are undergoing coronary artery bypass graft (CABG) surgery.<sup>1,2</sup> Many authors have reported improved outcomes and beneficial effects of surgical innovations, such as multivessel off-pump coronary surgery, performed in this subset of high-risk patients.<sup>3-6</sup> Nevertheless, most surgeons still consider saphenous vein grafts (SVGs) the conduits of choice in elderly patients despite the proven benefits of internal thoracic arteries on long-term outcome. Concerns about excessive surgical

invasiveness of arterial conduit harvesting and reduced life expectancy have hindered the diffuse use of arterial grafting in this high-risk subset of patients.

The use of the radial artery (RA) is progressively gaining popularity after its revival by Acar and colleagues and the favorable reports of several centers<sup>7-9</sup> describing its use as a composite Y/T-graft with the left internal thoracic artery (LITA). We therefore prospectively evaluated the clinical outcome of elderly patients undergoing total arterial revascularization with composite LITA-RA grafts compared with conventional CABG surgery.

## Methods

### Patient Selection

From October 2000 to January 2002, 160 patients aged more than 70 years and scheduled for on-pump isolated myocardial revascularization were prospectively enrolled after providing informed consent for the operation. The patients were then randomly assigned to group 1 (80 patients undergoing total arterial myocardial revascularization with composite LITA-RA grafts) or group 2 (80 patients undergoing conventional CABG surgery with LITA on left anterior descending [LAD] coronary artery and additional SVGs).

Exclusion criteria for enrollment included age less than 70 years of age, single-vessel disease, emergency operations, concomitant procedures other than coronary surgery, LV ejection fraction less than 20%, Euroscore greater than 10, and the presence of a positive Allen's test. The institutional review board approved the study protocol.

Patients undergoing RA harvesting were assessed with respect to their nondominant hand circulation by means of the Allen's test and oximetric plethysmography.

### Surgical Strategy

Radial artery Y/T end-to-side anastomosis was performed on the fascial side of the LITA with an 8-0 polypropylene running suture before cardiopulmonary bypass institution. We previously described our technique for the arrangement of composite arterial grafts according to target stenosis and coronary vessels anatomy.<sup>10</sup> In particular, in this subset of patients, we used only configuration types 2 and 3. In configuration type 2, the RA was anastomosed end-to-side to the in situ LITA in a Y/T-graft fashion, whereas in configuration type 3, the RA was first divided into 2 segments and then anastomosed end-to-side on the LITA in a double Y-graft fashion. The RA and the SVGs were routinely used to bypass native coronary vessels with a target stenosis of at least 70%, whereas a coronary artery stenosis of 60% was considered to be the threshold value when using the LITA.

Two surgeons performed all of the operations in the present study and were equally represented in both the SVG and LITA-RA groups.

### Postoperative Medications

In patients scheduled to receive the RA grafts, oral diltiazem was given the day before operation at a dose of 60 mg every 8 hours. Intravenous diltiazem infusion (mean dose: 0.5-1.5  $\mu\text{g} \cdot \text{kg} \cdot \text{min}$ ) was administered throughout the operation and during the first 48

hours after surgery. Thereafter, diltiazem oral therapy ( $\geq 120$  mg/day) was continued for at least 6 months.

### Follow-up

Follow-up visits were performed at 1, 6, and 12 months. Additional clinical data were collected from patients' cardiologists and home physicians. We evaluated the outcome of the patients enrolled in the present study with respect to early postoperative complications (short-term), hospital mortality, and occurrence of late cardiac-related events (recurrence of angina/myocardial infarction, graft occlusion, need of percutaneous transluminal coronary angioplasty [PTCA] reintervention, and death). At angiography, graft patency was defined according to Fitzgibbon classification, that is, grade A (unimpaired graft run-off), grade B (reduced graft caliber  $< 50\%$  of the grafted coronary artery), and grade C (occluded graft).

### Statistical Analysis

The  $\chi^2$  test was used to analyze preoperative and postoperative discrete variables, and the unpaired *t* test or the Mann-Whitney test was used for continuous variables (expressed as mean  $\pm$  SD). Multivariate analysis was performed using the Cox regression model for angina recurrence (time-dependent variable), and multivariate stepwise logistic regression was used for graft occlusion (time-independent variable). Survival curves were calculated with the Kaplan-Meier method. SPSS software was used for statistical analysis (SPSS 11.5, SPSS Inc, Chicago, Ill).

### Preoperative and Perioperative Data

There were no significant differences between the groups in the preoperative variables, such as age (group 1:  $77.3 \pm 3$  years vs group 2:  $76.8 \pm 2$  years,  $P = .217$ ), female gender (group 1: 43.7% vs group 2: 46.2%,  $P = .874$ ), and preoperative risk factors (EuroSCORE: group 1 =  $7.9 \pm 2.1$  vs group 2:  $8.1 \pm 2.5$ ,  $P = .585$ ); in particular, the prevalence of diabetes was 48.7% and 45% in groups 1 and 2, respectively. Five patients initially randomized in group 1 were excluded from the study because of a positive Allen test (3 patients) and significant atherosclerotic lesions of the RA (2 patients). However, a minimal atherosclerotic wall involvement of the RA did not jeopardize its use.

Double-vessel disease was observed in 36 patients (45%) in group 1 and in 38 patients (47.5%) in group 2 ( $P = .87$ ), and triple-vessel disease was found in 39 patients (48.7%) in group 1 and in 37 patients (46.2%) in group 2 ( $P = .87$ ). Moreover, 5 patients (6.2%) in groups 1 and 2 had left main stem stenosis ( $P = .74$ ). Patients in both groups demonstrated a similar distribution of target coronary vessels (group 1: LITA-LAD = 80, RA-diagonal = 12, RA-circumflex = 57, RA-right coronary artery = 43 vs group 2: LITA-LAD = 80, SVG-diagonal = 14, SVG-circumflex = 62, SVG-right coronary artery = 44) and received a similar number of graft anastomoses (mean number of anastomoses in group 1:  $2.4 \pm 0.5$  vs group 2:  $2.5 \pm 0.2$ ,  $P = .408$ ). The LITAs and the SVGs were used as single grafts in the majority of cases (LITA: 80/80 anastomoses, 100%; SVG: 196/200 anastomoses, 98%), whereas the RA was more extensively used for sequential anastomoses (32/192 anastomoses, 16.6%). Table 1 illustrates additional intraoperative and perioperative data.

**TABLE 1. Intraoperative and perioperative data**

	Group 1	Group 2	P
No. of grafted vessels*	2.47 ± 0.5	2.52 ± 0.2	.408
Aortic crossclamping time (min)*	37 ± 7	38 ± 7	.368
CPB time (min)*	56 ± 14	70 ± 11	<.001
Mechanical ventilation time (h)*	22 ± 12	23 ± 11	.583
ICU stay (h)*	39 ± 10	40 ± 9	.507
Postoperative hospital stay (d)*	7 ± 1	7 ± 2	1
Hospital mortality (%)	3 (3.75%)	4 (5%)	1

Group 1, total arterial revascularization; group 2, conventional revascularization. CPB, Cardiopulmonary bypass; ICU, intensive care unit.

\*Values are expressed as mean ± SD.

### Early Postoperative Results

The early postoperative outcome was similar between the groups in terms of mechanical ventilation time, intensive care unit stay, and hospital postoperative stay (Table 1). Patients in both groups demonstrated a similar incidence of postoperative complications, such as atrial fibrillation (group 1: 37.5% vs group 2: 40%,  $P = .871$ ), respiratory insufficiency (group 1: 7.5% vs group 2: 8.7%,  $P = 1$ ), renal failure (group 1: 6.2% vs group 2: 8.7%,  $P = .764$ ), perioperative myocardial infarction (group 1: 1.25% vs group 2: 1.25%,  $P = .477$ ), sternal wound infection (group 1: 1.25% vs group 2: 1.25%,  $P = .477$ ), and reoperation for bleeding (group 1: 2.5% vs group 2: 1.25%,  $P = 1$ ). Conversely, we observed the occurrence of cerebrovascular accidents only in patients ( $n = 4$ ) undergoing conventional coronary surgery (group 1: 0% vs group 2: 5%,  $P = .129$ ). Moreover, 7 patients had wound complications at the site of saphenous vein harvesting (8.75%), whereas no arm wound complication was detected in patients who had RA harvesting ( $P = .019$ ), despite a similar prevalence of preoperative risk factors (eg, diabetes).

Hospital mortality was similar in the 2 groups (Table 1). A total of 3 patients in each group died of sepsis and multiorgan failure, and 1 patient in group 2 died of intractable arrhythmia.

### Follow-up

We evaluated 76 patients (98%) in group 1 and 76 patients (100%) in group 2 by means of clinical visits and cycloergometric tests.

Recurrence of angina (defined as chest pain of Canadian Cardiovascular Society class II or higher) was detected in 2 patients in group 1 and 10 patients in group 2 ( $P = .03$ ), new onset of myocardial infarction (defined as an abnormal increase in cardiac-specific enzyme values, eg, CK-MB and troponin I) occurred in 1 patient in group 1 and 7 patients in group 2 ( $P = .06$ ), need of PTCA reintervention was observed only in patients receiving SVGs (group 1: 0 patients vs group 2: 8 patients,  $P = .01$ ), and late mortality was similar between the 2 groups (group 1 = 2 patients vs group 2 = 3 patients;  $P = .98$ ).

Angiographic evaluation was performed in 89.6% and 88.1% of hospital survivors in groups 1 and 2, respectively, after a mean period of  $16 \pm 3$  months. Table 2 provides a detailed outline of target coronary artery vessels, depicting a similar distribution between the groups. Angiography demonstrated a graft patency rate of 100% and 98.5% for the LITA in groups 1 and 2 (Fitzgibbon grade A), respectively. RA grade A patency rates (98.6%) were significantly higher ( $P = .033$ ) when compared with SVG

**TABLE 2. Angiographic results**

		Group 1	Group 2
LAD-LITA	Evaluated	69	67
	Occluded	0	1 (1.4%)
Diag-RA/SVG	Evaluated	10	10
	Occluded	0	2 (20%)
Cx-RA/SVG	Evaluated	47	50
	Occluded	1	5 (10%)
RCA-RA/SVG	Evaluated	37	36
	Occluded	0	4 (11.1%)

Group 1, total arterial revascularization; group 2, conventional revascularization. LAD, Left anterior descending; LITA, left internal thoracic artery; Diag, diagonal; Cx, circumflex artery; RCA, right coronary artery; RA, radial artery; SVG, saphenous vein graft.

grade A patency rates (88.5%). Therefore, 1 RA and 11 SVGs were classified as Fitzgibbon grade C.

When we performed a multivariate risk factor analysis on the predictors of late cardiac-related events, the only independent predictors of recurrent angina and graft occlusion were diabetes, the use of SVGs, and hyperlipidemia (Figure 1).

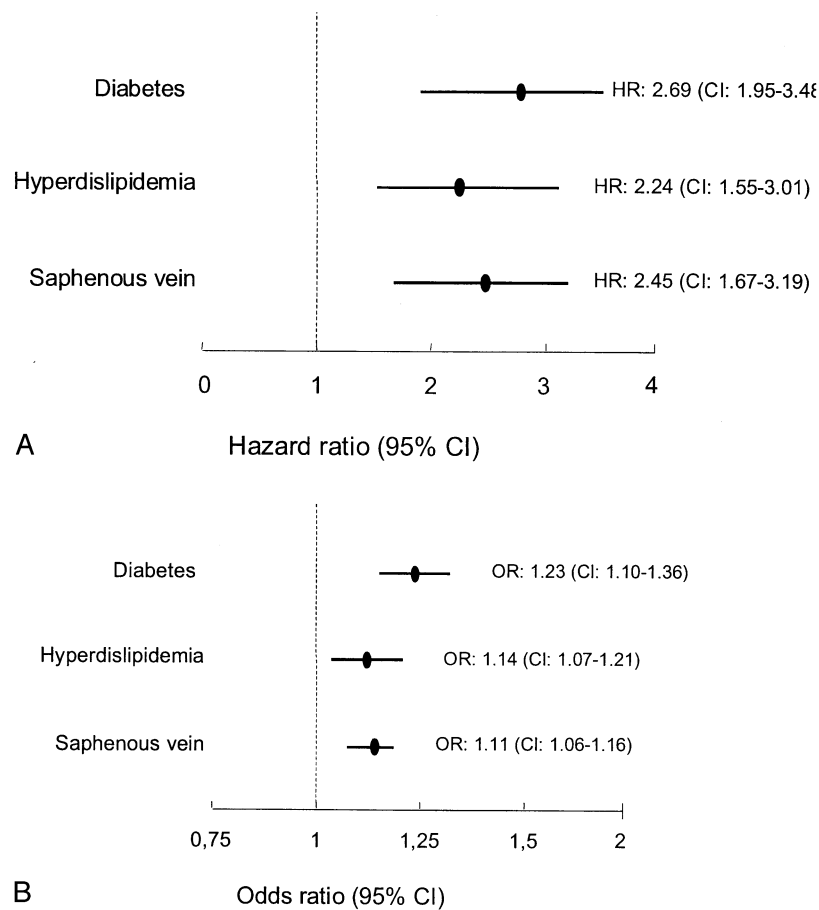
### Discussion

As the population of patients undergoing coronary surgery steadily ages, the impact of surgical innovations (eg, total arterial myocardial revascularization) in this high-risk subset of patients needs to be extensively evaluated. After the revival of the RA as a conduit for CABG by Acar and colleagues,<sup>7</sup> other authors<sup>8,9</sup> reported the favorable impact of this arterial conduit when used as a composite Y/T-graft with the LITA.

However, despite recent studies demonstrating the beneficial effects of total arterial grafting in the younger population,<sup>10,11</sup> most surgeons still consider SVGs as the conduits of choice for myocardial revascularization in elderly patients. This is because of the belief that arterial grafting in elderly patients may be associated with a higher perioperative morbidity and mortality when compared with younger patients.<sup>4</sup>

Because both advanced age and the presence of several comorbidities<sup>12</sup> may significantly affect the quality of the saphenous vein conduit and the degree of native coronary vessel disease, we evaluated in a prospective and randomized study the impact of total arterial revascularization with composite LITA-RA grafts in elderly patients. As outlined in the *Methods* section, we adopted only a few exclusion criteria to minimize the disproportionate distribution of high-risk patients into 1 particular group, the impact of selection bias and the effect of randomization.

In our study, patients receiving total arterial revascularization LITA-RA composite grafts did not show any increase in terms of perioperative morbidity and mortality when compared with the conventional group, demonstrating that total arterial grafting can be safely performed in elderly patients; conversely, the postoperative incidence of leg wound infections (because of an impaired healing process in this subset of patients) and cerebrovascular accidents was considerably higher in patients receiving SVGs. These results highlight the importance of reducing the degree of ascending aortic manipulation in this high-risk group of patients. Even if the differences did not reach a significant value, it should



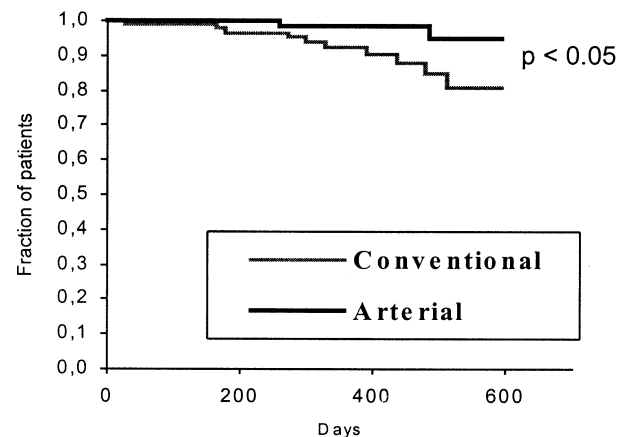
**Figure 1. Independent predictors of angina recurrence (Cox proportional hazard model, A) and graft occlusion (multivariate stepwise logistic regression, B) at multivariate analysis. CI, Confidence interval; OR, odds ratio.**

be noted that all the cerebrovascular accidents occurred in group 2. We therefore foresee that this difference would become significant in a larger cohort of patients.

Moreover, the major advantages of total arterial revascularization were particularly evident at mid-term: Sixteen months post-operatively, patients with LITA-RA composite grafts showed a significantly better clinical outcome with a lower incidence of angina and myocardial infarction recurrence (angina: group 1 = 2 patients vs group 2 = 10 patients,  $P = .03$ ; myocardial infarction: group 1 = 1 patient vs group 2 = 7 patients,  $P = .06$ ). In addition, no patient in group 1 needed coronary reintervention, whereas 8 patients in group 2 underwent PTCA ( $P = .01$ ).

Angiographic evaluation confirmed the clinical results, demonstrating significantly higher graft patency rates of the RA when compared with saphenous veins, regardless of the target coronary arteries.

Multivariate analysis identified SVGs, diabetes, and hyperlipidemia as independent predictors for angina recurrence and graft occlusion. In the Cox regression model, patients receiving SVGs demonstrated a higher risk of developing angina recurrence (hazard ratio of 2.3). As a consequence, the actuarial event-free survival was significantly better in patients receiving LITA-RA composite grafts (Figure 2).



**Figure 2. Event-free (no recurrence of angina, myocardial infarction, PTCA reintervention, death) survival curves for patients undergoing total arterial myocardial revascularization (group 1) and conventional coronary surgery (group 2). The difference between the conventional and arterial groups was significant.**

## Conclusion

This study confirms the safety and efficacy of total arterial grafting in elderly patients. Moreover, the randomized comparison clearly shows that patients receiving total arterial grafting had significantly better clinical outcome when compared with patients receiving SVGs. In the elderly population, the presence of extremely diseased coronary arteries and poor quality veins may significantly affect the patency of SVGs. In this subset population, LITA-RA grafts improve the clinical benefits of coronary surgery.

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## Discussion

**Dr Brian F. Buxton (Heidelberg, Australia).** Dr Muneretto, thank you for your excellent presentation this morning. I congratulate you and your colleagues on undertaking this prospective randomized trial in such an elderly group of patients.

There are a few exclusions in your entry criteria; therefore, the results are widely applicable and of interest to most adult cardiac surgeons. It should be emphasized, however, that the follow-up, defined as mid-term, is only 16 months. The surgical mortality and morbidity are low in both groups, indicating a very high quality of surgery.

A major strength of this article is the very high proportion of angiograms performed in both groups. If we focus on the secondary graft patency (non-LITA), there were 1 of 75 radial failures compared with 11 of 100 SVG failures. This

is a very large difference, as you indicated, in your study. It raises, in my mind, 2 questions.

I noted in your article that the preparation of the RA grafts was performed very carefully using calcium channel blockers, and that this was continued into the postoperative period. I am wondering whether the SVGs were afforded the same level of protection as the RA grafts because this may be a factor?

Second, were the trial surgeons equally distributed between the 2 types of surgical groups? For instance, did the senior surgeons or the more experienced surgeons perform the operations in the RA composite graft group and the less-trained surgeons perform the operations in the opposite group? The reason for raising these issues is that our own RA patency and clinical outcomes study, which we presented here last year, showed that there was little difference between saphenous vein and RA graft patency at 5 years.

A weakness in your study is the inclusion of angina in the composite end point of event-free survival. Events that you included were death, reintervention, myocardial infarction, and angina. Death and reintervention are very robust end points; however, angina is a very weak end point and when included in a composite end point carries the same weight as death during the analysis. Therefore, the conclusion should receive some skepticism. The last question I ask is if angina was removed as an end point, would the difference in outcome between the composite arterial and conventional groups be significant?

In summary, Mr Chairman, I believe this is a very important article. I think Dr Muneretto and colleagues' preliminary data are very impressive. I believe a longer follow-up will be necessary to provide convincing evidence of the benefits of these grafts compared with conventional grafting, to justify the title that this is "the treatment of choice," and to convince surgeons to alter their practice. Thank you very much, and I thank the association and the 2 chairmen, Dr Crawford and Dr David, for the invitation.

**Dr Muneretto.** Thank you very much, Dr Buxton, for your kind remarks.

Concerning your first question on whether the SVGs were treated with the same level of protection as the RA grafts, both SVGs and RA grafts were harvested by resident surgeons; however, staff surgeons always evaluated the quality of the grafts before their use.

SVGs were routinely stored in heparinized saline solution, whereas, to avoid any damage derived from storage, the RA (after intraluminal dilatation with papaverine solution) was maintained in situ until the composite graft anastomosis was performed.

We did not use any calcium channel blocker in patients receiving SVGs because there is no evidence of beneficial effects of those drugs on saphenous grafts.

The quality of SVGs obviously affected the patency of those conduits, but my feeling is that with the increasing age

of the patient population, the quality of SVGs is progressively worsening, and that this process became particularly evident in the last few years.

As far as the surgical skill is concerned, there were only 2 surgeons performing operations in this study, and they were equally active in the arterial conduit and SVG groups. Therefore, I can exclude that differences in surgeons' experience and technical skill could negatively affect results in the SVG group.

Your last question concerning the inclusion of angina in the composite end point of event-free survival is very interesting. I have to agree with you that angina may be a weak end point, but its weakness depends on the definition criteria used.

In our study, very strict criteria were applied, and post-operative angina was recorded only when patients had post-operative angina of class II or more (Canadian class) with a concomitant demonstration of ischemia at myocardial scintigraphy.

Actually, a new onset of myocardial infarction may be considered a weak point because the definition of myocardial infarction may be weak too.

However, in our study, a new onset of myocardial infarction was recorded only in case of significant release of specific cardiac enzymes, thus reducing the risk of statistical survey errors.

In addition, the reason why we decided to include angina as the primary end point of the study, even with some concern about its weakness, is the fact that angina is the most important symptom affecting the quality of life of patients who undergo coronary surgery. In addition, especially in elderly patients, relief of angina is the primary goal of coronary surgery; therefore, we believe that angina should always be considered in the composite end point of myocardial revascularization.

Finally, to answer your last question, if angina is removed from the composite end point of event-free survival, the differences in patients' outcomes between the composite arterial and the conventional groups still remain significant.

**Dr John W. Hammon Jr** (*Winston-Salem, NC*). I also congratulate the authors for this very nice study and particularly the zeal required to do a randomized prospective study. We also share your feelings about all arterial grafting techniques and that they provide superior patency rates and neurologic outcomes.

I have 2 questions. To achieve your low pump times and ischemia times, did you suture the radial grafts to the side of the internal thoracic artery before instituting bypass? Do you believe that this technique could lend itself to an off-pump-type regimen?

**Dr Muneretto.** Thank you Dr Hammon for your questions.

Actually, we performed the anastomosis of the composite graft before the institution of cardiopulmonary bypass to reduce pump time. When we have a composite graft with more than 1 side branch, the RA is sutured first to avoid any storage. Then, all the side branches (after intraluminal injection of papaverine) are distally occluded, and the proximal clamp is removed. Then, the RA and venous cannulation sites are prepared, and cardiopulmonary bypass is instituted.

Your second question deals with a relevant aspect of arterial revascularization with composite graft. We definitely believe that the composite graft technique allows surgeons to easily perform off-pump full arterial revascularization. Composite graft technique, enhancing the length of the grafts, allows an extensive mobilization of the heart, reduces the risk of technical pitfalls and, most important, avoids the need of any aortic manipulation.

Therefore, in our opinion, the composite graft technique makes off-pump surgery easy and safe when compared with the standard technique.

**Dr Alain F. Carpentier** (*Paris, France*). I rise to congratulate the authors and to answer the question raised by the discussant regarding the long-term result of the use of the RA. I introduced the use of the RA before this association in the early 1970s, and 3 years later I advised abandoning this technique because of the high incidence of spasm and occluded artery. However, 8 years later, I saw a patient who was supposed to have an occluded artery post-operatively, but the artery was fully patent. This is why we revived the use of the RA. This has been reported by my pupil Dr Acar.

Now, the reason I remind you of this story is because spasm is an important component of the operation. We know that the RA is very different than the anterior descending. So you did not answer the important question raised by the first discussant with regard to the use of a calcium antagonism that we advised in the second part of our experience. Did you use a calcium antagonist? If so, how long did you use it to explain your good results?

**Dr Muneretto.** It is a pleasure to discuss this aspect with you because you pioneered the use of the RA in cardiac surgery. When we started the extensive use of the RA in our department, we considered the calcium antagonist treatment as one of the key issues to achieve good clinical results.

Our protocol for prevention of RA spasm includes pre-operative treatment 1 week before the operation (diltiazem 120 mL/day orally). At the time of the operation and post-operatively during the first 48 hours, diltiazem is administered by intravenous infusion (0.5-2  $\gamma \cdot \text{kg} \cdot \text{min}$ ). Then, diltiazem is switched to oral administration, and therapy is continued for at least 6 months.