

# Original articles

## Off-pump coronary surgery in a single center experience: from selective to systematic use

Giovanni Troise, Federico Brunelli, Marco Cirillo, Margherita Dalla Tomba, Giordano Tasca, Zen Mhagna, Gian Battista Danzi\*, Bruno Amari\*\*, Eugenio Quaini

Cardiac Surgery Unit, \*Catheterization Laboratory, \*\*Cardiac Anesthesia and Intensive Care Unit, Poliambulanza Hospital, Brescia, Italy

**Key words:**  
Cardiopulmonary bypass;  
Coronary artery surgery;  
Myocardial  
revascularization.

**Background.** The feasibility of the systematic use of the off-pump technique for myocardial revascularization was investigated.

**Methods.** From September 1997 to June 2001, 1221 isolated coronary artery bypass grafting operations were performed consecutively: 771 (group A) were completed with cardiopulmonary bypass, and 450 (group B) without. Since July 2000 all patients were considered as potential candidates for off-pump coronary artery bypass. In group B, a specific original instrumentation was used for coronary stabilization.

**Results.** The differences in the preoperative data were: a higher age, a higher incidence of chronic obstructive pulmonary disease and a left ventricular ejection fraction < 30% in group B; a higher incidence of critical left main stenosis in group A. More grafts per patient were completed in group A ( $3.0 \pm 1.4$  vs  $2.2 \pm 0.9$ ,  $p < 0.001$ ). The hospital mortality (group A 1.0%, group B 0.7%) and the incidence of perioperative myocardial infarction (group A 2.5%, group B 1.1%) and that of cerebrovascular accidents (group A 1.4%, group B 0.9%) were comparable. Bleeding ( $610 \pm 370$  vs  $496 \pm 215$  ml,  $p < 0.001$ ), the transfusion rate ( $36$  vs  $19.7\%$ ,  $p < 0.001$ ), the intubation time ( $13.4 \pm 3.5$  vs  $8.3 \pm 5$  hours,  $p < 0.001$ ), the intensive care unit stay ( $1.7 \pm 2.7$  vs  $1.2 \pm 2.1$  days,  $p < 0.001$ ) and the hospital stay ( $5.8 \pm 3$  vs  $5.1 \pm 3.2$  days,  $p < 0.001$ ) were lower in group B. At follow-up, the mortality (2.5 vs 1.1%), the rate of recurrence of angina (2.5 vs 2.0%), and those of re-angiography (4.1 vs 5.3%) and of new revascularization (1.6 vs 1.1%) were similar. The actuarial survival rates were 99.8, 98.6 and 96.3% in group A, and 98.8, 96.7 and 96.7% in group B at 1, 2 and 3 years of follow-up respectively (log rank  $p = 0.3387$ ).

**Conclusions.** The increase in the use of off-pump coronary artery bypass up to its systematic employment is feasible. The early and intermediate results are satisfactory.

(Ital Heart J 2002; 3 (8): 446-454)

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Received April 26, 2002;  
accepted July 4, 2002.

**Address:**

Dr. Giovanni Troise

U.O. di Cardiochirurgia  
Casa di Cura  
Poliambulanza  
Via Bissolati, 57  
25125 Brescia  
E-mail:  
cch-segreteria.poli@  
poliambulanza.it

### Introduction

Coronary surgery without cardiopulmonary bypass (CPB) was started and popularized by Kolessov<sup>1</sup> in the 1960s. Except for a few reported experiences<sup>2,3</sup>, in the last 30 years the CPB-supported operation has been generally considered as the gold standard in coronary surgery. The recent introduction of and continuous improvement in coronary mechanical stabilizers has stimulated a renewed interest in off-pump coronary artery bypass (OPCAB) surgery so that many surgeons have rehabilitated the technique for selected groups of patients<sup>4</sup>. Especially since it avoids total sternotomy in favor of small incisions, minimally invasive surgery rapidly attracted interest as a new technique<sup>5,6</sup>.

Although the OPCAB technique was shown to be a suitable alternative to conventional CPB operations in high-risk pa-

tients, only few surgeons have systematically taken the procedure into consideration for most of their patients<sup>7</sup>.

To qualify as an alternative approach to the conventional procedure, the OPCAB technique must respond to all anatomies, use similar vascular conduits and achieve equivalent results in terms of mortality and morbidity rates.

In our center the technique has been applied in more than 36% of patients, but there was a gradual increase in off-pump procedures so that this technique is now the first choice approach to coronary surgery. This change in policy has not compromised the basic principles of coronary surgery, namely the completeness of revascularization and the extensive use of arterial conduits.

In this report we describe our experience with this technique and compare it with conventional CPB operations.

## Methods

From September 1997 (date of introduction of the technique) to June 2001, 1234 consecutive isolated coronary artery bypass grafting operations were performed at our Institution. Thirteen patients with acute myocardial infarction (4 cases) or acute ischemia and pump failure (9 cases), for whom CPB was considered part of the myocardial protection strategy<sup>8</sup>, were excluded. The analysis was performed on the remaining 1221 patients: 771 (group A) were operated upon with the use of CPB, and 450 (group B), who constituted 36.9% of the overall population, were submitted to treatment without CPB. The preoperative, intraoperative and postoperative data were prospectively recorded. The two groups were retrospectively analyzed, comparing the early and intermediate results.

One surgeon was responsible for the progress of the "beating heart program". The operations were performed by three surgeons.

After an initial period in which the patients scheduled for OPCAB were selected according to recognized contraindications to CPB (unapproachable arterial cannulation site, malignancy, severe chronic obstructive pulmonary disease) or according to the presence of the typical risks for CPB (age > 75 years, organ failure, widespread arteriopathy), since July 2000 we have gradually extended the indications, considering all patients as potential candidates to off-pump surgery (Fig. 1).

In neither group was aspirin stopped before surgery. Patients in both groups received a single anesthetic protocol including general anesthesia (narcotics, benzodiazepines, pancuronium) and received postoperative care in a single "fast track" protocol. A continuous infusion of nicardipine (0.1-0.5  $\mu$ g/kg/min), starting after the completion of the anastomosis until the first postoperative day, was used to prevent spasm of the arterial conduits in both groups.

Postoperative aspirin therapy was routine for all patients: 320 mg i.v. 6 hours after the end of surgery, 320 mg i.v. on the first postoperative day, and chronic oral

administration (160 mg/day) in totally arterial revascularized patients and 325 mg/day in mixed arterial/saphenous vein revascularized patients.

**Off-pump surgical technique.** Most of the procedures (80.2%) were performed through a standard sternotomy. In 89 patients (19.8%) the approach was a reversed "L" shaped (83 patients) or a "T" shaped (6 patients) ministernotomy. No drug was given to reduce the heart rate. A mean arterial pressure > 80 mmHg was obtained by volume loading and, if necessary, by administering low doses of metaraminol (bolus). Electrocardiographic ST-segment modifications were dealt with by infusing nitroglycerin.

The protocol of heparin sodium administration has evolved and now consists of 1.5 mg/kg administered prior to sectioning of the internal mammary artery and of supplemental doses of 3000 U if the activated clotting time is  $\leq$  250 s. This is reversed with a calculated 1:1 dose of protamine sulfate after the last anastomosis is completed.

The proximal right coronary and the left anterior descending (LAD) arteries were directly accessed with very little heart manipulation. If necessary in order to gain access to the posterior descending and obtuse marginal arteries, the heart was positioned vertically by applying two or three traction sutures in the posterior pericardium spaced between the left inferior pulmonary vein and the inferior vena cava. Tilting the table head-down and turning it towards the surgeon, the exposure of posterior vessels was improved; finally, two strips of wet sponge encircling the inferior vena cava and the great arteries guided the apex of the heart towards the right or left shoulder of the patient, according to the position of the target vessel.

Coronary artery immobilization was achieved with a compressive stabilizer (Fig. 2A) which is characterized by some peculiar features: the instrument's feet, about 5 cm long, have a cylindrical section, a slight curvature with a superior concavity and are covered with rubber; the feet are connected by a small screw to a supporting

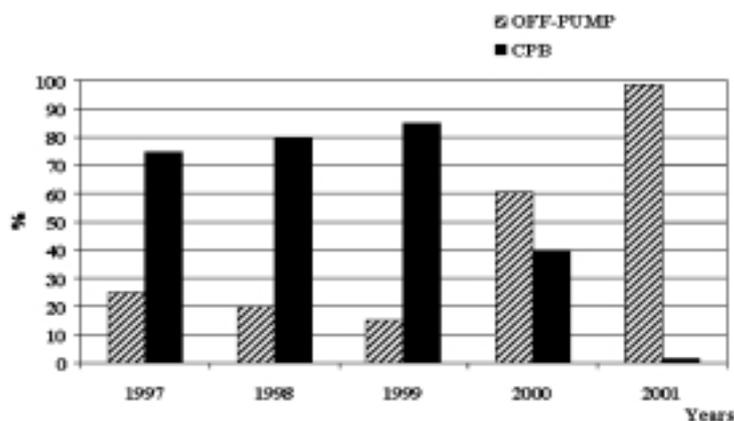


Figure 1. Frequency distribution of cardiopulmonary bypass (CPB) and of off-pump procedures.

arm with the possibility of moving to several different positions. The stabilizer is adaptable to the supports of the Cosgrove self-retaining mitral retractor (Kapp Surgical, Inc., Cleveland, OH, USA) in full sternotomy operations, and to a special retractor (Fig. 2B) in ministernotomy operations. This instrument is characterized by a sliding supporting bar which runs along two cylindrical lines mounted on the superior side of the retractor.

Different methods have been used to avoid bleeding from the anastomotic site: vessel proximal snaring with a 4/0 polypropylene suture (112 cases), the intracoronary occluder (12 cases) and a soft and flexible intracoronary shunt (from May 1999, 326 cases). A filtered blower/aerosolizer has been used to perform the anastomosis under perfect vision, avoiding any trauma to the arterial walls.

In redo surgery, adhesiolysis and revascularization were carried out progressively starting from the anterior branches; a similar sequential strategy of revascularization was used for patients with critical left main stem stenosis or a depressed left ventricular function, in which careful manipulation of the heart is necessary to reach the posterior vessels. In cases of unstable angina unresponsive to maximal intravenous therapy or in the presence of

severe left ventricular dysfunction (ejection fraction  $\leq 25\%$ ), the off-pump operation has been performed after prophylactic insertion of an intra-aortic balloon pump.

**On-pump surgical technique.** Myocardial revascularization with CPB was performed under conditions of moderate hypothermia ( $32-34^{\circ}\text{C}$ ) with a membrane oxygenator (Bentley, Baxter Inc., Irvine, CA, USA, or D708 Simplex, Dideco, Mirandola-MO, Italy) primed with crystalloid solution and equipped with an arterial air filter (Bentley AF-1040GOLD, Baxter Inc.).

The protocol of heparin sodium administration consists of 3 mg/kg and of supplemental doses of 5000 U if the activated clotting time is  $\leq 480$  s. This is reversed with a calculated 1:1 dose of protamine sulfate at the end of CPB.

Myocardial protection during aortic cross-clamping was obtained by means of antegrade and/or retrograde infusion of Buckberg cardioplegic blood solution<sup>8</sup>.

**Follow-up.** All patients were evaluated in our out-patient clinic 2 to 3 months after discharge and were periodically followed up by phone interview or by contacting the referring physician. Questions were aimed to assess the functional status and to identify the recurrence of angina and the need of further revascularization procedures. All patients had an echocardiogram and an ergometric test 3 to 6 months postoperatively, followed, in case of a positive/doubtful response, by a scintigraphic evaluation.

**Definitions.** All the definitions used are those deduced from the Society of Thoracic Surgeons National Cardiac Surgery Database (data collection form) 1998.

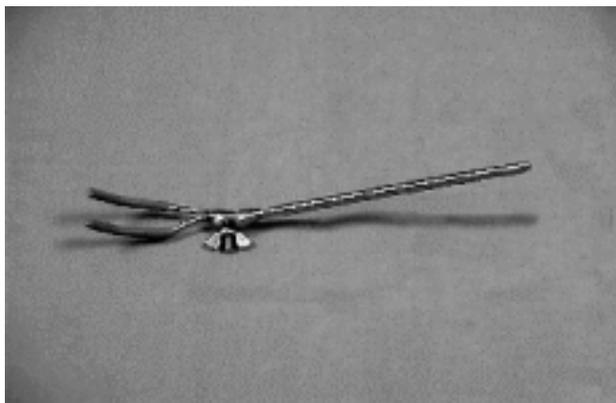
The postoperative hospital stay is defined as the interval of time between the day of operation and that of discharge. Discharge from the hospital is considered as the patient's transfer to a rehabilitation institute. The criteria for discharge were: the absence of complications, an adequate heart rate and blood oxygen saturation, permanently stable hemodynamic conditions, self-sufficiency in normal physical activity, and normal healing of the surgical scars.

**Statistical analysis.** Values of continuous variables are expressed as mean  $\pm$  SD. Comparisons between the two groups were established with the unpaired Student's t test (two-tailed) for continuous variables and with the  $\chi^2$  test for discrete variables.

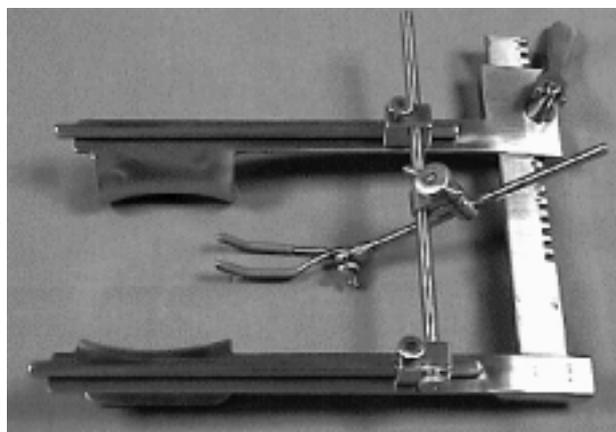
Time-related events were analyzed with the Kaplan-Meier method. Comparison between curves was performed using a log rank test.

## Results

**Demographics and risk factors.** The gender distribution was similar in the two groups, but the patients' age was higher ( $63 \pm 9.6$  years group A vs  $66 \pm 9.8$  years



A



B

**Figure 2.** Coronary stabilizer (A) and retractor for ministernotomy (B).

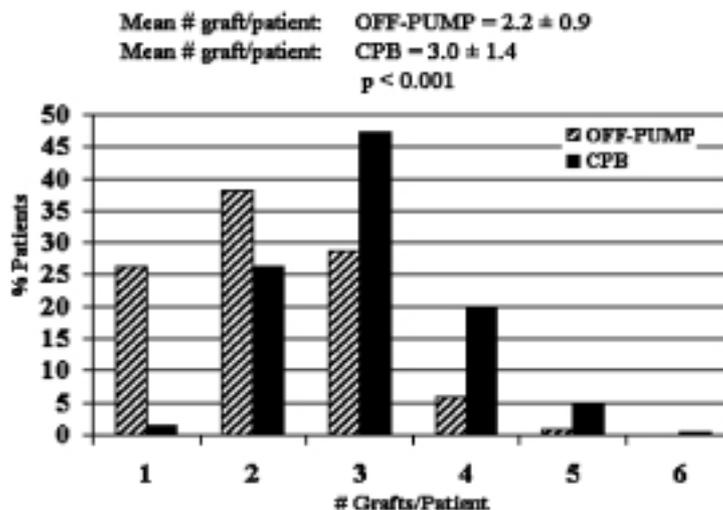
group B,  $p < 0.001$ ) in the off-pump group. There was a prevalence of patients with critical left main stem stenosis in the CPB group (21% group A vs 14.4% group B,  $p = 0.006$ ), whereas the incidence of chronic obstructive pulmonary disease and of left ventricular dysfunction, defined as a left ventricular ejection fraction  $< 30\%$ , was higher in the off-pump group. Significant differences in the frequency of diseased systems were recorded (Table I).

**Operative data.** The average number of grafts per patient was higher in the CPB group ( $3.0 \pm 1.4$  group A vs  $2.2 \pm 0.9$  group B,  $p < 0.001$ ). Figure 3 shows the frequency distribution of grafts per patient in the two groups. The use of both internal mammary arteries and the number of patients with totally arterial revascularization were significantly higher in the off-pump group. This prevalence was confirmed even when we excluded the patients who had a single arterial graft on the

**Table I.** Comparison of demographic, preoperative and operative data.

	Group A (n=771)	Group B (n=450)	p
Age (years)	$63 \pm 9.6$ (32-89)	$66 \pm 9.8$ (34-89)	$< 0.001$
Sex (M/F)	605/166	357/93	0.777
Diabetes	194 (25.2%)	98 (21.8%)	0.205
Hypertension	365 (47.3%)	220 (48.8%)	0.643
Renal failure	36 (4.7%)	24 (5.3%)	0.703
Chronic obstructive pulmonary disease	54 (7%)	49 (10.9%)	0.024
Left ventricular ejection fraction (%)	$60 \pm 11.5$ (20-82)	$59 \pm 14$ (18-80)	0.177
Left ventricular ejection fraction $< 30\%$	14 (1.8%)	19 (4.2%)	0.020
Previous cardiac operation	15 (1.9%)	16 (3.6%)	0.124
Unstable angina	166 (21.5%)	85 (18.9%)	0.304
No. diseased systems ( $> 50\%$ )			
1	21 (2.7%)	68 (15.1%)	$< 0.001$
2	276 (35.8%)	135 (30%)	0.045
3	474 (61.5%)	247 (54.9%)	0.028
Left main stem stenosis $> 50\%$	162 (21%)	65 (14.4%)	0.006
Preoperative intra-aortic balloon pump	4 (0.5%)	7 (1.5%)	0.125
Two internal mammary arteries (pts)	297 (38.5%)	207 (46%)	0.012
Totally arterial conduit (pts)	197 (25%)	299 (66.4%)	$< 0.001$
Totally arterial conduit (single bypass excluded) (pts)	187 (24.3%)	181 (40.2%)	$< 0.001$
Y or arterial sequential conduit (pts)	49 (6.4%)	149 (33.1%)	$< 0.001$
No. distal anastomosis			
LAD system	1054	538	
LCX system	738	270	
RCA system	533	169	
Grafts per patient	$3.0 \pm 1.4$	$2.2 \pm 0.9$	$< 0.001$

LAD = left anterior descending artery; LCX = left circumflex artery; pts = patients; RCA = right coronary artery.



**Figure 3.** Frequency distribution of grafts per patient in the two study groups. CPB = cardiopulmonary bypass.

LAD from the analysis. Similarly, the use of an “Y” conduit with two arteries or sequential arterial graft, was higher in the off-pump series (Table I).

Figure 4 shows the frequency distribution per year of bilateral mammary arteries, of totally arterial and of “Y” conduits.

In an attempt to highlight the differences in the surgical approach related to the learning curve, the off-pump group was arbitrarily divided into two cohorts of patients: those operated upon before July 2000 and those operated upon afterwards. At the breakpoint, a substantial increase in the percentage of OPCAB vs CPB procedures occurred and a significantly more frequent use of bilateral mammary arteries (13.6 vs 69.8%,  $p < 0.001$ ), “Y” conduits (11.0 vs 36.7%,  $p < 0.001$ ) and an increased graft per patient ratio ( $1.6 \pm 0.6$  vs  $2.6 \pm 0.9$ ,  $p < 0.001$ ) were registered in the more recent era.

**Hospital mortality.** The hospital mortality rate was 1.0% (8 deaths) and 0.7% (3 deaths) in the CPB and off-pump groups respectively ( $p = 0.571$ ) (Table II).

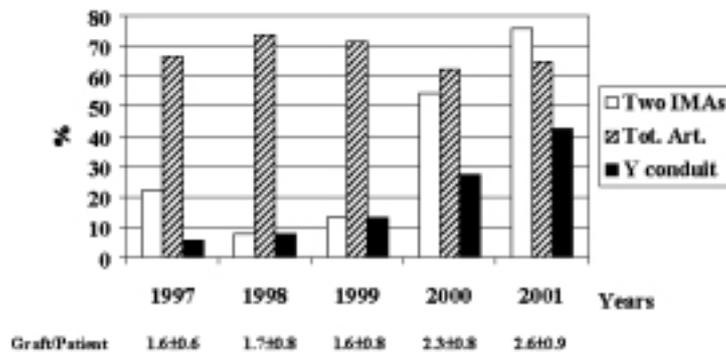
In group A the causes of death were: late bleeding on postoperative days 2 (2 cases); sudden cardiac arrest on postoperative days 2, 5 and 10 without previous evidence of myocardial ischemia (3 cases); untreatable

low cardiac output syndrome on postoperative days 7 and 35 due to perioperative myocardial infarction (2 cases); sepsis on postoperative days 5 (1 case).

In group B the causes of death were: sudden cardiac arrest occurring 8 hours after the procedure in one patient with a postinfarction chronic dilated cardiomyopathy and a left ventricular ejection fraction of 18% and without previous signs of ischemia; an acute leukemoid crisis (white blood cell count  $150\,000/\text{mm}^3$ ) on postoperative day 4 in one patient with myelodysplasia; an acute ischemic episode 8 hours after surgery (thrombotic occlusion of the grafts and of the native coronary arteries revealed by angiography) in one patient presenting with heparin-induced thrombocytopenia.

**Postoperative course.** Postoperative blood losses have been significantly lower in the group of patients operated on without CPB ( $610 \pm 370$  ml group A vs  $496 \pm 215$  ml group B,  $p < 0.001$ ). Furthermore, avoiding CPB allowed to significantly reduce the percentage of transfused patients (36% group A vs 19.7% group B,  $p < 0.001$ ).

Intubation time, intensive care unit stay and postoperative hospital stay were significantly shorter in group B. No statistically significant differences between the two groups were recorded regarding incidence of peri-



**Figure 4.** Frequency distribution of bilateral internal mammary arteries (IMAs), totally arterial revascularization, Y conduits and mean grafts/patient ratio per year in the off-pump group.

**Table II.** Comparison of early results.

	Group A (n=771)	Group B (n=450)	p
Hospital deaths	8 (1.0%)	3 (0.7%)	0.571
Bleeding (ml/24 hour)	610 ± 370	496 ± 215	< 0.001
Redo for bleeding (pts)	8 (1.0%)	3 (0.7%)	0.571
Transfused patients	278 (36%)	89 (19.7%)	< 0.001
Renal failure	38 (4.9%)	12 (2.7%)	0.076
Stroke and TCI	11 (1.4%)	4 (0.9%)	0.580
Perioperative AMI	19 (2.5%)	5 (1.1%)	0.153
Intubation time (hours)	13.4 ± 3.5	8.3 ± 5	< 0.001
Intensive care unit stay (days)	1.7 ± 2.7	1.2 ± 2.1	< 0.001
Postoperative hospital stay (days)	5.8 ± 3	5.1 ± 3.2	< 0.001

AMI = acute myocardial infarction; pts = patients; TCI = transient cerebral ischemia.

operative myocardial infarction and cerebrovascular accidents. A lower, but not statistically significant, incidence of postoperative renal failure occurred in group B (Table II).

**Follow-up.** Follow-up data were collected between June and September 2001 and were 98.8% (754 subjects among 763 discharged patients) and 99.1% complete (443 subjects among 447 discharged patients) in group A and group B respectively. The mean follow-up was  $28.8 \pm 9.6$  months (range 3-43 months) for the CPB group, and  $14.4 \pm 13.2$  months (range 2-44 months) for the off-pump group.

There was no statistically significant difference between the two groups concerning mortality, recurrence of angina, incidence of re-angiography, and need of new revascularization (Table III).

Nineteen late deaths (2.5%) were recorded in group A and 5 (1.1%) in group B. The causes of late death were cardiac in 7 and 2 patients and non-cardiac in 12 and 3 patients in group A and group B respectively.

The actuarial survival rate, excluding the hospital mortality, was 99.8, 98.6 and 96.3% in group A and 98.8, 96.7 and 96.7% in group B at 1, 2 and 3 years postoperatively; the log rank test for the equality of survival distributions for the two groups showed no statistically significant difference ( $p = 0.3387$ ) (Fig. 5).

The indications for re-angiography in the 31 patients of group A were: angina (5 cases) and induced silent ischemia (26 cases). Angiographic evaluation

showed: graft patency in 15 cases, graft stenosis in 8 cases, graft occlusion in 1 case, and progression of coronary disease in 7 cases. A new revascularization (coronary angioplasty) was performed in 12 cases (6 on a graft and 6 on a native vessel).

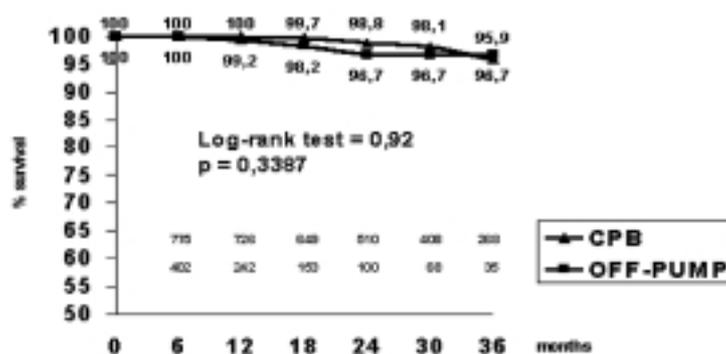
The indications for re-angiography in the 24 patients of group B were: elective control in a subgroup of patients treated with ministernotomy at the beginning of the experience (13 cases), angina (4 cases) and induced silent ischemia (7 cases). Angiographic evaluation showed: graft patency in 18 cases, graft stenosis in 3 cases, graft occlusion in 1 case, and progression of coronary disease in 2 cases. A new revascularization (coronary angioplasty) was performed in 5 cases (4 on a graft and 1 on a native vessel).

## Discussion

The advent of minimally invasive surgery in the 1990s has awakened interest in off-pump procedures, particularly since the diffusion of minimally invasive direct coronary artery bypass grafting, which is the direct off-pump anastomosis between the internal mammary artery and the LAD through small access sites<sup>9-11</sup>. Whereas the advantages of limited surgical incisions are still controversial, the avoidance of CPB is largely considered as a major breakthrough which has rendered coronary artery bypass grafting less invasive.

**Table III.** Comparison of mid-term results.

	Group A (n=763)	Group B (n=447)	p
Mean follow-up (months)	$28.8 \pm 9.6$ (3-43)	$14.4 \pm 13.2$ (2-44)	< 0.001
Completeness	98.8%	99.1%	0.861
Late deaths	19 (2.5%)	5 (1.1%)	0.150
Recurrence of angina	19 (2.5%)	9 (2.0%)	0.738
Re-angiography	31 (4.1%)	24 (5.3%)	0.363
Re-revascularization	12 (1.6%)	5 (1.1%)	0.693



**Figure 5.** Kaplan-Meier survival curve. CPB = cardiopulmonary bypass.

Many authors have demonstrated the reduced release of inflammatory response markers as a consequence of the avoidance of CPB<sup>12-14</sup>. The influence of the positive effect of the reduced inflammatory response is confirmed by a decrease in the postoperative morbidity rate after off-pump procedures reported by some authors<sup>15,16</sup>, particularly in patients with some absolute or relative contraindications to CPB such as renal, respiratory and neurological impairment.

At the beginning of our activity (September 1997) in a private no-profit hospital with a volume load of about 500 cases per year (isolated coronary surgery constituting 68.7%), the project of less invasive surgery was particularly aimed at off-pump coronary revascularization.

Moreover, it was considered equally important to introduce, *pari passu*, those techniques highlighted as being optimal in coronary surgery. The completeness of revascularization, totally arterial whenever possible, and the extensive use of both internal mammary arteries have been demonstrated to ensure the best long-term outcome in patients with coronary artery disease<sup>17,18</sup>. Another issue regards the attempt to reduce neurological complications due to side clamping of the ascending aorta<sup>19,20</sup>, by means of the extensive use of *in situ*, sequential and "Y" conduits. Therefore, before extending the indication to all patients requiring surgical myocardial revascularization, the possibility that these goals could be achieved by performing off-pump procedures, was constantly explored.

In the light of these theoretical assumptions, the evolution of the approach to OPCAB surgery in our center practically moved through different sequential steps:

- availability of a versatile, effective and low-cost system of coronary stabilization (Fig. 2);
- revascularization of the LAD and of the proximal right coronary systems through a full or partial sternotomy;
- assessment of the patency of anastomosis by means of sporadic elective angiographic control;
- selective indication in those groups of patients for whom CPB was considered as an increased-risk procedure;
- acquisition of the heart verticalization technique to expose the postero-lateral vessels;
- improvement in the technical maneuvers required to perform distal anastomosis: from the coronary "snare" technique to the intracoronary occluder and lastly the intracoronary shunt;
- training of the staff surgeons and residents;
- continuous analysis of the results using a prospective computerized data collection system;
- extension of the indication to all types of coronary anatomy and clinical presentations but acute myocardial infarction or acute ischemia with pump failure;
- identification of strategies which permit an adequate approach to peculiar situations such as redo surgery,

critical left main stem stenosis, left ventricular dysfunction and unstable angina.

Figure 1 shows an incidence of OPCAB procedures of about 20% in the period 1997-1999, with a slight variability due to the selection criteria adopted at the time. The trend towards an increasing rate of OPCAB procedures up to about 98%, after the abolition of the selection criteria, and the results obtained in this series confirm the effectiveness of the approach.

With regard to the population of patients needing a single graft on the LAD, i.e. those cases with single vessel disease not suitable for coronary angioplasty or with multivessel disease with the LAD as the only accessible coronary artery, the ministernotomy approach has been adopted as an alternative to left anterior thoracotomy. The reasons for our choice are:

- 1) the possibility of a more extensive dissection of the left internal mammary artery;
- 2) the exposure of the entire LAD which allowed us to choose the best site for the anastomosis;
- 3) the possibility of approaching even a diagonal branch, the proximal right coronary artery (by transforming the reversed "L" to a "T" shaped sternotomy), and the ascending aorta (for proximal anastomosis or aortic cannulation);
- 4) the possibility of conversion to total sternotomy at any time during the procedure.

An immobile and bloodless surgical field seems to provide the best conditions to perform a technically perfect coronary anastomosis. The above described techniques for the exposure, stabilization and visibility of the target vessel, while the heart is still beating, match those "best conditions" just as well as in the cardioplegic arrested heart.

The use of the intracoronary shunt, minimizing the amount of ischemia and allowing to test the patency of the anastomosis constitutes one of the major improvements in the surgical method. Owing to the continuous improvement in surgical methods, the OPCAB technique becomes reproducible and accepted by staff and resident surgeons who can reach proficiency, as has occurred in our team, sometimes with no need of previous training in conventional CPB procedures.

Significant differences in terms of age, chronic obstructive pulmonary disease, left ventricular ejection fraction < 30% and left main stem stenosis were present in the two groups (Table I). In particular, the higher incidence of left main stem stenosis in group A can be explained by the fact that at the beginning of our experience this condition was considered as a relative contraindication to the off-pump approach, due to the risk of hemodynamic complications during the maneuvers made to expose and stabilize the target vessels, principally the posterior ones. Recently however, some authors<sup>21,22</sup> have demonstrated that myocardial revascularization in patients with left main stem stenosis can be safely and effectively performed without CPB. After the introduction of the above-mentioned strategy safeguards, the pres-

ence of critical left main stem stenosis has not been considered as a contraindication to off-pump procedures. In fact, after July 2000 51 out of 65 patients in group B with a left main stem critical lesion were operated upon.

A relatively low incidence of a left ventricular ejection fraction < 30% in the entire series of patients is reported.

This population represents only 50% of the left ventricular dysfunction patients. At our center we have adopted several techniques of volume reduction surgery, associated with myocardial revascularization when necessary, for patients with ischemic cardiomyopathy identified as left ventricular ejection fraction < 35%, left ventricular systolic volume index > 50 ml and congestive heart failure as the predominant symptom. Thus, in case of depressed left ventricular function, isolated coronary surgery is indicated in those patients with angina, inducible ischemia, and/or myocardial viability. The significant difference in the number of patients with this condition in the two groups is due to the policy of treating these cases with the off-pump method.

The possibility of following the modern and well-explained principles of coronary revascularization, in terms of the completeness of the technique and of the extensive use of both internal mammary arteries, is confirmed in our experience in which the increase in the number of off-pump procedures paralleled an increased use of arterial conduits (*in situ*, composite "Y" graft, sequential arterial anastomosis) and an increase in the graft/patient ratio.

The overall significantly lower number of grafts performed in group B is partly explained by the low incidence of single bypass procedures in group A (Fig. 3). Moreover, in the early phases of our experience, we favored the off-pump technique in patients needing revascularization only on the anterior left ventricular wall.

The hospital mortality and perioperative myocardial infarction rates did not significantly differ between groups, suggesting that, as confirmed by previous reports<sup>7</sup>, the early results are not related to the technique.

As many authors have already described<sup>2,7,23</sup>, the postoperative course in off-pump procedures is principally characterized by a shorter intubation time, a shorter intensive care unit and in-hospital stay, a reduction in blood losses and related transfusions and a more rapid recovery of respiratory function. In our experience, despite the higher number of elderly and chronic obstructive pulmonary disease patients in group B, some of the advantages of this technique compared with CPB revascularization (Table II) were still felt. The reduction in intubation time, intensive care unit stay and in-hospital stay were not part of an "intention-to-treat" policy. Fast track protocols are adopted in every patient operated upon, whatever the type of disease and surgical treatment.

The clinical outcomes during a mean of 28.8 and 14.4 months in groups A and B respectively were comparable (Table III) and similarly maintained over time

(Fig. 5). Moreover, they are comparable with those of other series with or without CPB<sup>15,24-26</sup>.

In contrast to other previous reports<sup>15,27,28</sup> no negative trend in the recurrence of angina and in the need of new revascularization occurred in our OPCAB series.

In the definition "recurrence of angina" we have included the new onset of any kind of chest pain, but only patients with typical symptoms (5 in group A and 4 in group B) and those with induced silent ischemia (26 in group A and 7 in group B) had a re-angiography. We have not performed any systematic angiographic control of the patency of the anastomosis, except in a selected group of patients treated with a ministernotomy access at the beginning of our experience, in view of the fact that a high patency rate in OPCAB surgery comparable to that observed in conventional surgery has already been clearly demonstrated by other authors<sup>23,24</sup>. In our experience, no difference between the OPCAB and CPB groups was noted in terms of the indications to re-angiography on the basis of these clinical criteria.

The results regarding graft stenosis and graft occlusion were similar in the two groups. In particular, only one graft occlusion among 40 grafts in 24 patients controlled in the off-pump group occurred. No statistically significant difference in the need of graft coronary angioplasty was recorded in the two groups even though the incidence of graft coronary angioplasty was higher in the off-pump group (4 out of 5 off-pump patients vs 6 out of 12 CPB patients).

These follow-up observations are sensitive enough to consider the intermediate-term results of the OPCAB operations as satisfying. In addition, differently from other authors' statements<sup>15,27,28</sup>, in our series the low mortality (1.1%), recurrence of angina (2.0%) and need of new revascularization (1.1%) rates at 1-year follow-up are good indicators of a complete myocardial revascularization.

The limitations of the present study are:

- the results show only the feasibility of a progressive increase in OPCAB procedures to reach a high percentage of patients treated with this method;
- the two groups were neither randomized nor matched, even though all the procedures were consecutively and equally performed by three surgeons during the same period;
- the two groups differed in terms of the periods of time during which the two procedures were performed. Consequently, the length of follow-up was significantly different;
- the two groups differed in terms of the surgical techniques employed (arterial conduits).

In conclusion, with currently available instruments, off-pump revascularization through a median sternotomy can be performed for lesions in virtually any coronary artery. The patient's safety and the surgeon's comfort are not jeopardized.

The off-pump approach allows for better results in terms of an early postoperative course. Only a large

prospective, longitudinal comparison of the long-term clinical outcomes and graft patency after coronary artery bypass grafting procedures performed with and without the use of CPB can ultimately validate the superiority of this technique.

The spreading up to the systematic use of OPCAB depends on a progressive learning curve and on a better understanding by all staff members (surgeons and anesthesiologists) of the methods required to obtain hemodynamic stability.

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