

High OPCAB Surgical Volume Improves Midterm Event-Free Survival

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ABSTRACT

Background: The aim of this study was to evaluate the midterm results of the initial phase of off-pump coronary artery bypass (OPCAB) surgery adoption in a single surgical unit, assessing the impact of procedural volume.

Methods: Study participants were 312 patients who underwent OPCAB during the period between August 2000 and January 2005 at S. Croce Hospital. Of these patients, 126 patients with an indication selected for comorbidities or 1-vessel disease underwent OPCAB performed by 4 low-volume surgeons, and 186 unselected patients underwent OPCAB performed by a single high-volume surgeon.

Results: OPCAB performed by low-volume surgeons was associated with less complete revascularization and less arterial conduit use. Early result analysis showed a low rate of in-hospital or 30-day adverse events. The 5-year survival was 0.88 (0.02 SE). OPCAB performance by a high-volume surgeon and complete revascularization were shown have a protective effect for midterm major adverse cardiac events (respectively, hazard ratio = 0.28, 95% confidence interval 0.11-0.74 and hazard ratio = 0.33, 95% confidence interval 0.15-0.73).

Conclusion: Our study on the initial phase of OPCAB adoption suggests a benefit on midterm outcome from surgery performed by a high-volume surgeon.

INTRODUCTION

Despite the widespread use of off-pump coronary artery bypass (OPCAB) surgery, concerns still remain regarding its applicability. It has been shown that OPCAB surgery can be successfully taught to trainee surgeons, with no detrimental effects to patients [Murphy 2005; Asimakopulos 2006]. These established training programs are actually applied in only a few high-volume centers, where trainee performance can also be monitored also with control charts [Rogers 2004; Caputo 2004].

The learning curve in OPCAB surgery can be traversed by units during the initial adoption of this technique, with established surgeons fully experienced in conventional on-pump

coronary artery bypass grafting (CABG) operations but with no prior OPCAB surgery experience. In these cases, surgical teams generally adopt strategies deriving from training centers and apply them to their own operative reality. Nevertheless, the perception of higher technical difficulties and the fear of deleterious effects on patient health lead some surgeons to avoid OPCAB surgery or to perform it only on selected high-risk patients or patients requiring only single-vessel surgery. This strategy can lead to a low procedural volume experience, which may be associated with suboptimal surgical outcome. Hence the initial phase of adoption of OPCAB surgery is a crucial point in the experience of a surgical team. The goal of achieving improved clinical outcomes with OPCAB surgery, as indicated by multicenter observational and randomized trials [Angelini 2002; Al-Ruzzeh 2003 and 2006; Hannan 2007], must be obtained by acquiring proficiency in a procedure that is more technically demanding than on-pump CABG, with less training availability.

The aim of this study was therefore to analyze short-term and midterm outcomes in patients undergoing OPCAB surgery in a single center without a structured training program, where this procedure has been adopted by surgeons with 2 different indication criteria. Furthermore, we assessed the impact of surgical volume on the short-term and midterm outcomes after OPCAB surgery.

MATERIALS AND METHODS

Data for the study came from 5 sources: (a) an institutional database of preoperative characteristics, surgical information, and in-hospital outcomes, including complications and adverse events, collected prospectively on all OPCAB surgery patients treated in our unit; (b) death certificates from hospital databases; (c) information about cardiac-related events from a postal questionnaire or telephone calls to patients and to their family physicians; (d) clinical assessments in hospital outpatient clinics; and (e) the institutional Cardiac Catheter Laboratory database.

This study was approved by the Institutional Ethics Committee on May 22, 2007. Informed consent was obtained from each patient included in the study.

Patient Population, Indication Criteria, and Data Definitions

From June 2000 to February 2005, 1183 patients underwent isolated CABG surgery at the Cardiac Surgery Unit of

Received March 11, 2009; accepted April 24, 2009.

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Santa Croce Hospital, Cuneo, Italy. Of these patients, 312 (26%) were scheduled for OPCAB. For the surgeons, this group of operations was their initial experience in OPCAB surgery. All surgeons were fully experienced in on-pump CABG but did not have any prior OPCAB expertise.

Of the 1183 patients, 126 selected patients (40%) were scheduled for OPCAB performed by 4 surgeons adopting the same indication criteria, which were: (a) presence of comorbidities considered as high risk for cardiopulmonary bypass, and (b) 1-vessel coronary artery disease not suitable for percutaneous intervention (group A).

Of these 4 surgeons, 1 performed 17 off-pump procedures and then switched to an unselected OPCAB indication and under these conditions performed surgery on 186 consecutive patients (60%) in a 28-month period (group B).

Contraindications to OPCAB were unfavorable anatomy (intramyocardial vessels or vessels with distal calcification) and electrical and/or mechanical instability.

Surgeon OPCAB performance volume was expressed as percentage OPCAB ($\text{OPCAB}/\text{total CABG} \times 100$).

The definition of complete revascularization (CR) was adopted from the BARI Trial [Vander Salm 2002], in which CR was defined as a procedure in which all diseased arterial systems (left anterior descending coronary artery, left circumflex artery, right coronary artery, and ramus) receive at least 1 graft insertion.

An analysis based on the initial treatment intent was performed on the 312-patient cohort.

Early Outcomes

Operative mortality included any death occurring during the same hospital admission for surgery or within 30 days of surgery.

Operative cardiac mortality included any death from cardiac causes. Postoperative Q-wave acute myocardial infarction (AMI) included peak level of creatine kinase MB greater than 10% of total creatine kinase associated with new Q-wave or new left bundle block.

Postoperative non-Q-wave AMI was defined as greater than or equal to a 5-fold increase of creatine kinase MB in the first postoperative week. Any AMI included postoperative Q-wave and non-Q-wave infarction. Perioperative low-output syndrome (LOS) included all conditions with a cardiac index <1.8 L/min requiring inotropes.

The diagnosis of stroke was established according to neurological medical records and included any new postoperative central neurological deficit persisting more than 24 hours and confirmed by computed tomographic scans.

Postoperative acute renal failure (ARF) was defined as abnormal values of creatinine (>1.2 mmol/L) in patients with normal preoperative values and at least a 50% increase in preoperative serum creatinine concentration in patients with preoperative chronic renal failure or mild renal dysfunction.

Follow-up Outcomes

Mortality included death from any cause. Major adverse cardiac events (MACE) were defined as the composite end

point of cardiac death, unstable angina, AMI, and hospitalization for cardiac heart failure and repeat revascularization, with patients included only once.

Anesthetic and Surgical Techniques and Postoperative Management

The surgical and anesthetic techniques adopted have been previously described [Sergeant 2001; Myles 2003]. Briefly, cardiovascular monitoring was performed with a Swan-Ganz pulmonary artery catheter (when the ejection fraction was $<30\%$ a fiberoptic pulmonary artery catheter for continuous monitoring was used) and transesophageal echocardiography. Target artery stabilization was achieved with disposable suction devices (Octopus; Medtronic, Minneapolis, MN, USA). Traction sutures were always placed in the posterior pericardium to obtain heart verticalization. From January 2003 apical suction devices (Medtronic Starfish) were routinely used to optimize heart displacement. When an atheromatous ascending aorta wall was detected with transesophageal echocardiography, the procedure was performed in such a way as to avoid any aortic manipulation (no-touch technique). Silicon intracoronary shunts have been routinely used in performing distal anastomosis. After surgery, patients were transferred to the intensive therapy unit and managed according to a "fast-track" protocol [Myles 2003].

Follow-up

Cross-sectional follow-up data were collected through telephone interviews and clinical check-ups in our outpatient clinic 3 months after surgery and thereafter at yearly intervals. Patients who underwent a telephone interview were asked to transmit their clinical reports, including results of all postoperative invasive and noninvasive diagnostic tests and revascularization procedures, to the investigators. Cardiology laboratories provided descriptions of provocative tests, angiographic studies, and revascularization procedures. A total of 132 patients (42.3%) underwent a postoperative exercise stress test, 18 patients (6%) underwent myocardial perfusion scintigraphy, 14 patients (4.5%) underwent stress echocardiography, and 33 patients (10.5%) underwent coronary angiography. Five patients (1.6%) were lost to follow-up.

Statistical Analysis

Results were expressed as mean value and range unless otherwise indicated. All data were analyzed with the SAS System 9.1.3 statistical package (SAS, Cary, NC, USA). A statistical analysis comparing 2 groups was performed with unpaired 2-tailed t testing for the means or χ^2 test (or Fisher exact test) for categorical variables. Survival curves were obtained according to the Kaplan-Meier method. The association between clinical prognostic factors and the survival function was assessed by use of the log-rank test. To check for potential confounders, a multivariate analysis based on the Cox proportional hazards regression model [Cox 1982] was performed. The variables analyzed included all the factors that were found to be significant in the

Table 1. Preoperative Patient Characteristics*

Preoperative data	Total patients (N = 312)	Group A (n = 126)	Group B (n = 186)	P
Mean age, y	68.7 (41-87)**	70.7 (44-87)**	67.3 (41-81)**	.0014†
Female sex	82 (26.3)	33 (26.2)	49 (26.3)	.092‡
One-vessel	28 (9.0)	24 (19.0)	4 (2.2)	
Two-vessel	84 (26.9)	47 (37.3)	37 (19.9)	< .0001‡
Three-vessel	200 (64.1)	55 (43.7)	145 (78.0)	
EF < 30%	23 (7.4)	11 (8.7)	12 (6.5)	.593‡*
Extracardiac arteriopathy	94 (30.1)	48 (38.1)	46 (24.7)	.016‡
Chronic obstructive pulmonary disease	57 (18.3)	33 (26.2)	24 (12.9)	.005‡*
Chronic renal failure	35 (11.2)	23 (18.3)	12 (6.5)	.002‡
Insulin-treated diabetes mellitus	38 (12.2)	17 (13.5)	21 (11.3)	.684‡*
Obesity	35 (11.2)	16 (12.7)	19 (10.2)	.618‡
Neurological dysfunction	18 (5.8)	11 (8.7)	7 (3.8)	.110‡
Mean EuroSCORE (range)	5.2 (0-15)	6.1 (0-13)	4.5 (0-15)	< .0001†
Unstable angina	191 (61.2)	76 (60.3)	115 (61.8)	.881‡

*Data are presented as n (%). EF indicates ejection fraction.

**Data are presented as n (range).

†t test.

‡ χ^2 test.

univariate analysis. For each variable, the proportional hazards assumption was tested graphically. The exponentiation of the coefficients estimated from the regression model can be assumed as the hazard ratio of disease progression in the exposed category of each variable, compared with the reference category, after allowing for the other factors entered in the model. Several Cox regression models were fitted. The goodness-of-fit of each model was assessed with the D statistic = -2 the likelihood ratio, and the comparison between 2 models, when feasible, was tested by calculating the likelihood ratio test. The limit of significance for all analyses was defined as a *P* value of .05. All statistical tests were 2 sided. Variables used for statistical analysis were the following: age, sex, extracardiac arteriopathy [Cooper 2006], carotid artery disease, obesity, chronic obstructive pulmonary disease [Nashef 1999], chronic renal failure [Nashef 1999], mild renal dysfunction, extrarenal depuration, any renal dysfunction, treated diabetes, IT diabetes, OT diabetes, treated malignancy, active malignancy, neurological dysfunction [Nashef 1999], chronic heart failure, preoperative critical state [Nashef 1999], recent myocardial infarction [Nashef 1999], unstable angina EuroSCORE, unstable angina [Braunwald 2000], number of stenotic vessels, left main stem stenosis, ejection fraction, left ventricular dysfunction [Nashef 1999], additive EuroSCORE, number of anastomoses, no-touch procedure, associated carotid endarterectomy, CR, no mammary artery usage, surgeon, surgeon high OPCAB procedure volume, surgeon low OPCAB volume, postoperative ARF, postoperative LOS, postoperative Q-wave AMI, postoperative non-Q-wave AMI, any postoperative AMI, and postoperative stroke.

RESULTS

Operative Data

The preoperative characteristics of the 312 patients scheduled for OPCAB are reported in Table 1. Group A patients showed a worse preoperative risk profile and less extensive coronary disease than group B patients.

The overall on-pump conversion rate was 3.8% (12 of 312), 4.7% (6 of 126) in group A and 3.2% (6 of 186) in group B. Causes of on-pump conversion were: (a) electrical and/or mechanical instability (7 patients), (b) unsatisfactory quality of anastomosis (2 patients), (c) ischemia following anastomosis (1 patient), (d) asymmetric sternotomy with impossibility of adequate lateral wall exposition (1 patient), and (e) unfavorable anatomy (1 patient). The operative data are reported in Table 2.

Complete revascularization and arterial graft usage were significantly higher in group B than in group A. In the 2- or 3-vessel disease patients, group B showed more total arterial revascularization (108 [58.1%] versus 49 [38.8%], *P* < .01).

In the group of 300 patients who actually underwent OPCAB, CRs were achieved in 81.3% of the patients. No-touch procedures were performed in 109 (39.9%) of the 273 patients affected by 2- or 3-vessel disease. Within this subgroup, group B patients showed more no-touch procedures than group A patients (45.5% versus 29.9%, *P* < .05).

The common indication criteria on selected patients led group A surgeons to perform a low OPCAB volume (OPCAB range 9%-15%, *P* = .42) with similar completeness of revascularization (CR range 36%-50%, *P* = 1.0). The group B surgeon performed a high OPCAB volume (91% OPCAB).

Table 2. Operative Data

Operative variables	Total patients (N = 312)	Group A (n = 126)	Group B (n = 186)	P
On-pump conversion	12 (3.8)	6 (4.8)	6 (3.2)	.695†
Grafts per patient	2.7 (1-5)	2.0 (1-5)	3.1 (1-5)	< .0001‡
2 Internal mammary arteries	98 (31.4)	12 (9.5)	86 (46.2)	< .0001†
Radial artery usage	124 (39.7)	23 (18.3)	101 (54.3)	< .0001†
Sequential grafts	78 (25.0)	9 (7.1)	69 (37.1)	< .0001†
Composite grafts	91 (29.2)	20 (15.9)	71 (38.2)	< .0001†
Carotid endarterectomy	21 (6.7)	10 (7.9)	11 (5.9)	.639†
Complete revascularization	253 (81.1)	78 (61.9)	175 (94.1)	< .0001†

*Data are presented as n (%).

†t test.

‡ χ^2 test.

Early Results

Four patients (1.3%) died during hospitalization or within 30 days. Two patients died of massive pulmonary embolism, 1 of sepsis, and 1 of mesenteric ischemia following perioperative LOS. The incidence of AMI, stroke, LOS, and ARF was 4.5%, 0.6%, 5.1%, and 15.1%, respectively.

The low number of observed events led us to perform only a simple descriptive analysis in the total group of patients, pointing out the differences between group A and group B through a univariate analysis (Table 3). Group A patients had significantly higher postoperative AMI and LOS rates than group B patients.

Midterm Results

Follow-up ranged from 8.9 to 72.3 months (mean 42 months) and was complete in 98% of patients. The cumulative patient survival, taking into account operative mortality, at 5 years was 0.88 (0.02 SE) (27 events).

Five-year freedom from MACE was 0.86 (0.03 SE) (30 events).

Five-year survival was influenced by postoperative ARF, extracardiac arteriopathy, chronic obstructive pulmonary disease, insulin-treated diabetes mellitus, and preoperative chronic renal failure. High OPCAB volume (Figure) and CR were shown to have protective effects for MACE. Predictors of analyzed mid-term end-points are summarized in Table 4.

CONCLUSIONS

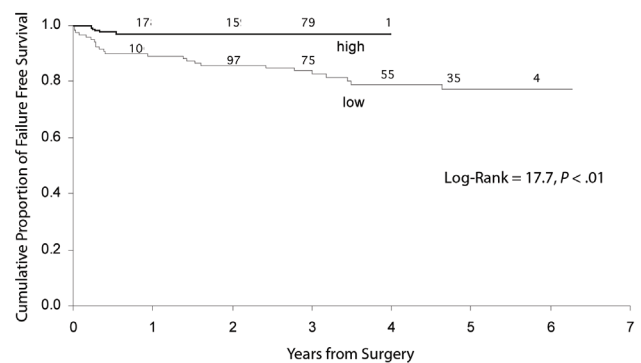
The analysis of the strategy of identifying indications for OPCAB in this initial experience revealed several issues. Performing OPCAB on selected patients resulted in treating patients with a worse preoperative risk profile and less extensive coronary artery disease. This strategy of indication was associated with a low procedural volume and low completeness of revascularization. It is worth noting that low-volume surgeons achieved similar revascularization completeness rates, which appeared to be comparable with those

obtained with percutaneous coronary intervention in multi-vessel disease [BARI 1996; Serruys 2001]. This result could be explained either by the strategy of “target vessel revascularization” [Kilo 2001], chosen to minimize the impact of surgery on high-risk patients, or by a common strategy of “intended incomplete revascularization” aimed at achieving the best feasible revascularization, avoiding cardiac manipulations perceived as “dangerous.”

Moreover, low OPCAB volume was associated with a different quality of surgery, with less arterial graft usage and more aortic manipulation.

Unfortunately our analysis was limited by the small sample size and the low early event number. These characteristics did not allow performance of a multivariate analysis to assess early outcome predictors. A larger surgical population might better clarify influences of these variables on early results.

Within the limits of our analysis, in-hospital mortality appears similar in low and high OPCAB volume surgery,



Kaplan-Meier estimates of major adverse cardiac event-free survival distribution function by level of off-pump coronary artery bypass (OPCAB) volume (312 patients). Residual numbers of patients at risk are reported for each year of follow-up. Low indicates low OPCAB volume; High, high OPCAB volume.

Table 3. Hospital and 30-Day Results*

	Group A		Group B		P
	OPC (n = 6)	Total Group (n = 126)	OPC (n = 6)	Total Group (n = 186)	
Death	0	2 (1.6)	0	2 (1.1)	.35†
Cardiac death	0	1 (0.8)	0	1 (0.5)	.48†
Q AMI	0	2 (1.6)	0	1 (0.5)	.29†
Non-Q AMI	2	8 (6.3)	1 (16.6)	3 (1.6)	.02†
AMI	2 (33.3)	10 (7.9)	1 (16.6)	4 (2.1)	.02†
Stroke	0	1 (0.8)	0	1 (0.5)	.48†
LOS	1 (16.6)	13 (10.3)	0	3 (1.6)	< .01†
ARF	2 (33.3)	20 (15.9)	2 (33.3)	27 (14.5)	.74‡

*Data are presented n (%). OPC indicates on-pump conversion; Q AMI, Q-wave acute myocardial infarction; Non-Q AMI, non-Q-wave AMI; AMI, any acute myocardial infarction; LOS, postoperative low-output syndrome; ARF, postoperative acute renal failure.

†Fisher exact test.

‡ χ^2 test.

according to the findings of a recent large retrospective cohort study [Glance 2005].

Our midterm analysis showed 3 main findings,

- Survival was predicted by determinants widely reported in literature [Leavitt 2004; Kubal 2005; Brevetti 2006; Cooper 2006; Hillis 2006; Leavitt 2006].
- Completeness of revascularization was a protective factor for event-free survival.
- Low surgical volume was shown to be an independent risk factor for MACE.

The association between OPCAB surgical volume and midterm outcome had not been reported previously [Plomondon 2006; Hannan 2007], but it appears intuitive and consistent with the principle “the more you do, the better you are,”

encouraging surgeons to perform OPCAB, if ever, on a systematic rather than on an occasional basis. The possible influence of variability in personal technical skill on surgical results must be addressed as a possible limit of our analysis. It is hard to assess precisely this technical factor, because it is largely subjective. To verify the issue, in this study, operators were individually included as variables in the multivariate analysis. The high-volume surgeon was included twice, also as a low-volume surgeon, in relation to cases performed in a different period of his OPCAB experience, when he worked at low volume. None of the operators were found to be a variable independently associated with outcome.

In conclusion, our data show that the impact of the procedural volume on OPCAB surgical outcome can be underestimated by an evaluation focused only on early outcome. The disadvantages of a low surgical exposure, which might favor a higher rate of incomplete revascularization and a lesser quality of anastomosis, could be better evaluated through a longer-term outcome analysis.

Our study suggests the superiority of high surgical volume versus a low surgical volume in the initial phase of OPCAB adoption.

Table 4. Results of Cox Analysis*

Variables	Mortality		MACE	
	HR	(95% CI)	HR	(95% CI)
Chronic obstructive pulmonary disease	3.7	(1.6-8.8)		
Insulin treated diabetes	3.4	(1.3-8.9)		
Postoperative acute renal failure	4.0	(1.8-8.9)		
Extracardiac arteriopathy	3.7	(1.4-9.9)		
Preoperative chronic renal failure	2.4	(1.1-5.5)		
Complete revascularization			0.33	(0.15-0.73)
High off-pump coronary artery bypass volume			0.28	(0.11-0.74)

*MACE indicates major adverse cardiac events; HR, hazard ratio; CI, confidence interval.

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