Off-Pump Coronary Artery Bypass Grafting Decreases Morbidity and Mortality in a Select Group of High-Risk patients

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ABSTRACT

Background: The ideal indication for off-pump coronary artery bypass grafting (OPCABG) has yet to be defined. "High-risk" surgical patients may benefit the most when cardiopulmonary bypass (CPB), aortic cross clamping, and cardioplegic arrest are avoided. The aim of this study was to determine whether off-pump coronary artery bypass grafting might decrease the operative morbidity and mortality in a select group of "high-risk" patients with multivessel coronary artery disease.

Methods: Utilizing a Parsonnet risk stratification model we analyzed two year prospectively collected coronary artery bypass data. "High-risk" patients were defined as those with a Parsonnet score of 9 or greater. OPCABG was used in 50 patients and comparisons were made to a group of 50 on-pump CABG patients of the same group of surgeons.

Results: The OPCABG patients had significantly higher Parsonnet scores (20.1±11.2 vs. 14.3±8.8), more Renal failure (20% vs. 6%), PVD (30% vs. 8%), and pre-op neurologic disorders (14% vs. 2%). An average of 2.6±1.0 grafts/patient (vs. 3.1±0.8) were performed and the posterior descending artery (PDA) and marginal branches of the circumflex artery (LCX) were grafted in 80% (vs. 94%) of the OPCABG patients. The conversion rate to on-pump CABG was 10% (n=5), while two patients in the OPCABG group were intra-opconversions from an anticipated on-pump CABG due to severe porcelain aorta. The morbidity and mortality rate were 6% (n=3) and 2% (n=1) in the OPCABG group vs. 8% (n=4) and 10% (n=5) in the on-pump group.

Conclusions: OPCABG can be performed with a reasonably low morbidity and mortality in this select group of "high-risk" patients. Despite its application to sicker patients there is a trend towards a reduced morbidity and mortality from that seen with on-pump CABG. OPCABG is a reasonable, and might even be preferable, operative strategy in this "high-risk" group of patients.

INTRODUCTION

In an effort to avoid the adverse effects of cardiopulmonary bypass, myocardial revascularization without cardiopulmonary bypass or off-pump coronary artery bypass grafting has been rediscovered. It has assumed an increasing role in many surgical practices. Over the last three years several groups reported its safety, effectiveness, and excellent short-term results in selected patients [Buffolo 1996, Subramanian 1997, Calafiore 1998]. The most critical issues in beating heart coronary artery bypass grafting are that of patient selection and benefit, long-term graft patency, and safety of beating heart coronary revascularization for multivessel coronary artery disease. The purpose of this study is to report the outcome and indication of coronary revascularization without cardiopulmonary bypass in a select population of "high-risk" surgical patients with coronary artery disease.

MATERIAL AND METHODS

Over a two-year period the surgical procedures and outcomes of 100 prospectively selected patients were reviewed. Fifty patients underwent coronary revascularization without cardiopulmonary bypass (OPCABG), while a second group of 50 patients were revascularized with the aide of cardiopulmonary bypass. The age of the patients ranged from 52-85 years in a predominantly male population (Table 1, Figure 2). The majority (67%) of patients underwent surgical revascularization within 24 hours of their hospital presentation. Eight patients were transferred directly from the heart catheterization laboratory to the operating room for emergency surgical coronary artery revascularization either due to failed percutaneous interventions, acute myocardial infarctions, or pathoanatomical complexity of the coronary artery lesions. Eighteen patients presented with decreased left ventricular function. Left ventricular function was assessed by ejection fraction (EF) on contrast ventriculograms or by transesophageal echocardiogram (TEE, four patients). The EF ranged from 25% to 60% (Table 1). The risk of the patients was assessed using a univariate model of risk stratification [Bernstein 2000] and "high-risk" patients were defined as those with a parsonnet score of 9 or greater. Operative mortality was defined as any death occurring within 30 days of surgery. The intention was to perform complete coronary revascularization with or without cardiopulmonary bypass as an urgent treatment option for single- or multivessel coronary artery disease. No consideration was given to perform minimally invasive coronary revascularization in order to select patients for earlier discharge, less blood product administration, or reducing hospital charges. On-pump coronary artery bypass was performed with moderate hypothermia (28°C) and cold blood cardioplegia, while proximal anastomosis were performed under a single aortic cross-clamp.

Off-pump Operative Technique

All patients underwent standard median sternotomy. EKG and ST segments were monitored continuously to detect myocardial ischemia. Hemodynamic monitoring and continuous cardiac output and SVO_2-analysis were performed with pulmonary artery catheters. Norepinephrine and nitroglycerine boluses and/or infusions were administered generously in combination with body position changes and gravity support (Trendelenburg, right and left table rotations) to stabilize hemodynamics and to maintain mean arterial pressures of greater than 70 mm Hg in the off-pump patients. No attempt was made to achieve regional myocardial tolerance to ischemia by preconditioning and/or target artery test occlusion before bypass grafting.

The following revascularization strategy was practiced. The culprit lesion was revascularized first. The distal anastomosis was completed before the proximal anastomosis. Sequential grafting was not performed. Single aortic side clamping was performed to minimize risk of aortic trauma in the case of multiple proximal anastomoses. Lesions of the left anterior descending artery (LAD) were bypassed with a left internal thoracic artery (LITA) pedicle graft Routine intra-coronary shunting of the target artery was not performed. An initial dose of Heparin 10,000 U was given intravenously and the ACT measured. Additional doses of Heparin were administered to maintain ACTs greater than 250 seconds. Protamin reversal was performed at the end of the operations for ACTs greater than 300 seconds.

Target artery immobilization and regional myocardial motion control were achieved through a commercially available mechanical stabilization system (Cohn Stabilizer, Genzyme Surgical Products, Fall River, MA) mounted on a special retractor (Genzyme Surgical Products, Fall River, MA), which in combination with silastic bands, allowed gentle and controlled vessel occlusion. A CO_2-blower/ NaCl mister device was used in situations where a bloodless field was not achieved with proximal target vessel occlusion. CO_2-flow was set at 2-3 L/min with the saline solution pressurized at 150 mm Hg. The tip of the device was held at least 5 cm from the target area. Coronary stabilizer changeovers and reconfiguration of the stabilizer were required during multivessel surgery.

Three deep 2-0 monofilament pericardial retraction sutures were placed in order to rotate the heart in the pericardial well. The first suture is placed 1 cm anterior to the left superior pulmonary vein. The second suture was placed close to the left inferior pulmonary vein. The third suture was placed in the pit of the pericardial sac between the second suture and the inferior vena cava, which also fixes the end of a gauze sling over a tourniquet [Spooner 1998]. A second gauze sling was passed through the transverse sinus of the heart. Traction on sutures #1 and #2 brought the LAD and diagonal branches into midline. Traction on retractor suture #3 in combination with slight traction on the gauze slings rotated the apex of the heart toward the right pericardium and elevated it leading to exposure of the posterior-lateral coronary circulation (circumflex marginal branches, posterior descending artery). This rotation and exposure can be facilitated with a right-sided pericardial incision, especially if bypass grafting is performed on dilated and enlarged hearts. The surgical table, rotated rightwards and set in Trendelenburg position, assisted in exposing the posterior coronary territory and maintaining right ventricular preload. If a right-sided pleuropericardial split and incision were made suture closure was done at the end of the operation.

Quality Control of the Anastomosis

Just prior to the completion of the distal anastomosis a fine vascular microdilator (sizes 1.0 and 1.5 mm) was used and the patency of the anastomosis probed. After antegrade flow was established (completion of the proximal anastomosis) or positioning of the LITA pedicle, flow was assessed qualitatively with an Ultrasonic Doppler Flow Detector (model 812, Parks Medical Electronics, Inc.).

RESULTS

OPCABG was performed in “high-risk” patients with an average Parsonnet score of 20.1±11.2; which was statistically higher then the on-pump subset of patients (Average Parsonnet 14.3±8.8). The comparisons between the two groups of patients are summarized in Table 1 and Figures 1 and 2. The morbidity and mortality were 6% and 2% for the OPCABG group vs. 8% and 10% for on-pump CABG group; however, these differences failed to meet statistical significance. The morbidity in the OPCABG group included one infarction, one CVA, and one take-back for anterior wall ischemia and revision of the LIMA to LAD anastomosis. The morbidity in the on-pump CABG group included two take-backs for bleeding, acute lower extremity ischemia, and two CVAs. The on-pump CABG patients had significantly more obesity (28% vs. 8%), diabetes (30% vs. 14%), and pre-op IABP usage (8% vs. 0%). The OPCABG patients had significantly more renal failure (20% vs. 6%), PVD (30% vs. 8%), and pre-op neurologic disorders (14% vs. 2%). The conversion rate to on-pump CABG was 10% (n=5), while two patients in the OPCABG group were intra-op conversion from an anticipated on-pump CABG due to severe porcelain aorta. The OPCABG patients who where converted to an on-pump procedure where included in the OPCABG group for analysis. The number of grafts per patient was not statistically different between the two groups; however, there was a trend towards more grafts in the on-pump CABG group (3.1± 0.8 vs. 2.6±1.0), with a statistically significant increase in the number of grafts to the circumflex region for the on-pump group (Table 1).

Arrhythmias occurred most frequently during OPCABG RCA revascularization leading to urgent intraluminal shunt insertion in four cases. All distal anastomoses were evaluated by means of inserting a fine vascular dilator and confirmed with an ultrasound Doppler probe in the OPCABG patients. Routine cardiac enzyme analysis and EKG evaluations after the operations were negative for myocardial infarction. Follow-up coronary angiography was performed in ten OPCABG patients two to four weeks post-operatively, which revealed graft patency in all cases. One patient had a 50% proximal anastomotic vein graft stenosis. All patients where free of angina or reintervention at their follow-up clinic visit (4-6weeks post-operatively).

DISCUSSION

The refinements in off-pump technology and new mechanical stabilizers have led to the widespread application of coronary revascularization without CPB. Recent studies describe the success of complete revascularization in beating heart surgery [Baumgartner 1997, Cartier 1999a, Cartier 1999b, Iaco 1999]. However, the precise role of beating heart technology and the indications for OPCABG remain to be defined. Until the results of prospective randomized trials are released it is still too early to state that off-pump coronary surgery is more cost-effective, less morbid, accelerates post-operative recovery, and shortens the time to return to work compared to the conventional approach.

We do not consider the off-pump technology in competition with CPB, because both have their place in the strategy of myocardial revascularization. For us, coronary artery surgery without CPB seems to be a promising new alternative in patients where the adverse effects of extracorporal circulation and cardioplegic arrest may aggravate pre-existing complications and disorders. CPB and cardioplegic arrest can cause myocardial dysfunction, negative central nervous system effects, neuropsychiatric phenomena, severe systemic inflammatory response and coagulopathy associated with end-organ injury [Cremer 1996, Roach 1996, McKhann 1997a, McKhann 1997b]. A number of studies have demonstrated that advanced age, urgent operation, impaired left ventricular function, cerebrovascular disease, female sex, NYHA class III or IV status, and left main coronary artery stenosis were independent predictors of operative risk [Gabrielle 1997, Bernstein 2000] leading to high scores in risk stratification and assessment programs for cardiac surgery. Patients with these described comorbid conditions are the subject of this report. The cumulative risk score reached an average of 18 points using Parsonnet's operative predicted risk stratification method. For example, the operative risk score for a 70-year-old male patient with diabetes mellitus and hypertension with normal left ventricular function and three-vessel coronary artery disease is about 13.

The results of this study demonstrated that complete coronary revascularization was achieved in all patients with a reasonable operative morbidity and mortality in both cohorts of patients. What is most interesting is the very low morbidity and mortality seen in the OPCABG group. These results were not statistically different from the On-pump cohort; however, there is a trend towards a reduction in operative complications and mortality. The morbidity and mortality observed in the OPCABG group of patients (mean Parsonnet of 20) is significantly better then that predicted by the Parsonnet risk stratification model, which would predict a 15-20% mortality in this subset of patients [Bernstein 2000]. The one mortality in the OPCABG group was in a patient who we converted to on-pump when she became hemodynamicly unstable. During RCA revascularization, the remainder of the conversions to on-pump were for arrythmias, primarly severe bradycardia. These patients suffered no morbidity or mortality.

The results of this report are comparable with the findings of a high-risk group of 15 patients with an average Parsonnet Acuity Score of 22 operated on by Rizzo et al. [Del Rizzo 1998] using the off-pump MIDCABG technique. The mortality rate was 0%. However these patients presented primarily with LAD disease and the number of grafts per patient was only 1.6. Moshkovitz et al. and Mohr et al. used the off-pump technique in patients with acute myocardial infarction and in patients with impaired left ventricular function. The mean number of grafts was 1.8 and only 23% of the patients received a graft to marginal branch of the left circumflex artery. The mortality rate was 3.8% and a peri-operative myocardial infarction rate 2.7% and improved compared to an equivalent patient population operated on with CPB [Moshkovitz 1997, Mohr 1999].

The youngest patient of the series presented with a large acute anterior wall myocardial infarction and developed a devastating cerebrovascular accident on the first post-operative day after successful off-pump LAD and PDA bypass grafting. Presumably the stroke was caused by embolization from a post-myocardial infarction left ventricular cavity thrombus. Even though, the predicted rate of adverse neurologic outcomes was high in ten OPCABG patients with a history of previous stroke and/or severely occluded bilateral internal carotid arteries [Dashe 1997], no new neurologic events were observed. With beating heart surgery, avoidance of the embolic potential associated with aortic cannulation and decannulation, and of the generation of microgaseous and microparticulate emboli from the pump circuit, would be expected to decrease cerebral embolic load and improve outcomes. It has been demonstrated that there is a correlation between aortic atherosclerotic load and the amount of cerebral embolization as a result of the "jet" of perfusate through the aortic cannula scouring the atherosclerotic aortic lumen. Maintenance of more normal aortic flow patterns during beating heart surgery would be expected to decrease the incidence of cerebral and systemic atheroemboli [Murkin 1998]. However, this study as well as others has failed to demonstrate a significant reduction in peri-operative nerologic events. The incidence of stroke from intracardiac sources, as demonstrated in our patient, may be higher from beating heart manipulations without a cross clamp. This alone provides a sound rationale for the investigation of alternative surgical approaches and identification of the optimal off-pump technology and patient.

The OPCABG patients who present with either acute myocardial infarction and/or severely impaired left ventricular function tolerated proximal target artery occlusion, heart manipulation, and adverse anatomical position very well. In these patients the LIMA was mobilized with a very long pedicle. The LAD was grafted first before branches of the left circumflex or posterior descending artery were bypassed. These patients made a rapid recovery tolerated the weaning and discontinuation of inotropic support. There was no evidence for new myocardial infarction or myocardial ischemia.

Efficiency with smooth flow of the operation and adequate target stabilization remained primary challenges and goals for successful beating heart surgery, particularly for multiple-graft operations. Our rapid progression to off-pump multivessel revascularizations in high-risk patients was inspired from the refinement of cardiac stabilizers permitting unhindered surgical access to all coronary territories, the improvement of a surgical off-pump technique enabling hemodynamically stable heart manipulations and circumflex exposure, and encouraging initial angiographies revealing excellent graft patency. The use of deep pericardial sutures, in particular, is of significant value. The pericardial-based sling is a simple and gentle traction and rotation tool in order to expose and stabilize the posterior-lateral coronary branches.

The utilization of a Parsonnet score of greater then 9 was chosen as a means to objectively determine which patients where truly “high-risk”. The cutoff of >9 was chosen since this was the group of patients with the highest predicted mortality in the Parsonnet risk stratification system [Bernstein 2000]. We used the most recent version of the Parsonnet pre-operative risk stratification model, the “bedside estimation”, since it is simple and the patients were stratified into separate risk groups based on this score pre-operatively. Patients where divided into four groups based on there pre-operative bedside estimated risk score (<3, 3-6, 6-9, >9). In order to conclude that a patient is truly “high-risk” we felt they should meet the criteria of the highest risk group (>9). These patients had an expected mortality of approximately 15%, with an observed mortality of 20% [Bernstein 2000]. We used this pre-operative risk model to determine which patients should be included for evaluation, both for the OPCABG and on-pump groups.

A limitation of this study is that the two groups are non-randomization. We understand this limitation, and are not making direct comparisons between the two groups, but rather are trying to identify trends in our decision making process for patient selection. The goal of this study was to determine which patients would be best treated by an OPCABG procedure, and to see if we could do this with a reasonable morbidity and mortality. A limitation with using a database to stratify patient’s pre-operative risk is that there may be significant institutional variations in observed mortality. We felt that we should include our on pump patients, collected consecutively over the same time period, so that we could asses what our institutional mortality was for this select group of “high-risk” patients. Even though the Parsonnet risk stratification model predicted a 15-20% mortality in patients with a score of >9, we observed only a 10% mortality in our “small” group of patients done on pump.

We initially attempted to look at the individual risk factors, which prompted our decision to perform an OPCAB or On-pump CAB; however this data turned out to be very misleading. We had some patients with renal failure who were low risk (Parsonnet 4), while others had significant co-morbidities to make there pre-operative risk high (Parsonnet >9). In other words, there are low risk patients with renal failure and "high-risk" patients with renal failure. We feel it was more important to objectively determine which patients are truly "high-risk". We provided a breakdown of the individual risk factors in each group to help determine which individual pre-operative risk factors may have influenced the choice of the operative procedure. With the limited size of this sample set, it was impossible to determine how each individual factor contributed to the selection of one procedure over the other. We have identified a number of trends, which are of interest. For example, all patients with a pre-operative IABP were done on bypass. We had no mortality in this group of patients, and all the IABP were placed for unstable angina. We believe this represents our own selection bias towards an on-pump procedure when a patient presented with a pre-operative IABP. The trend toward an OPCABG in patients of PVD, Renal failure, and previous stroke also represents our bias, and belief that these are indications for an OPCABG procedure. Interestingly, eventhough there was not a statistically significant difference in the number of grafts performed in each group, there was a statistically significant difference in the number of circumflex grafts performed. We believe that this indicates that certain very proximal circumflex lesions are not amenable to an OPCABG approach. We had no specific pre-operative criteria for why a specific patient should be done on or off-pump, we where just interested in looking at a group of "high-Risk" patients treated with an OPCABG approach.

CONCLUSION

In conclusion, our results indicate that complete coronary artery revascularization is feasible on the beating heart in very high-risk patients with low morbidity and mortality and excellent early results. The ideal patient selected for OPCABG is actually the one who is elderly with other comorbid conditions (severe cardiac dysfunction and low ejection fraction, evolving myocardial ischemia, pulmonary or renal failure, sever peripheral vascular disease, and prior stroke). Future investigation should be directed to better delineate the source of neurologic events in the beating heart patient population. Identification of patients with intracavitary thrombus may represent a contraindication to off-pump techniques with a possible overall reduction in neurologic events associated with OPCABG.

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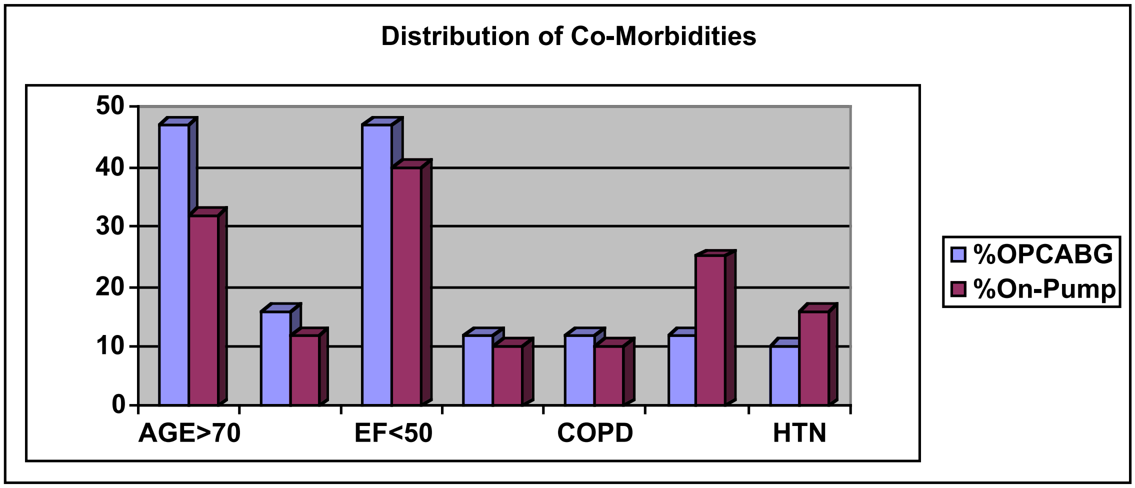
Table 1. Patient Comparisons

	OPCABG	On-Pump CABG
AGE	69.8 ± 10.2*	63.1 ± 9.7
EF	47.3 ± 11.1	49.2 ±12.2
LMD>90%	14% (n=7)	10% (n=5)
Circ/PDA graft	80% (n=40)	94% (n=47)*
Grafts/patient	2.6 ± 1.0	3.1 ± 0.8
Parsonnet Score	20.1 ± 11.2*	14.3 ± 8.8
Morbidity	6% (n=3)	8% (n=4)
Mortality	2% (n=1)	10% (n=5)

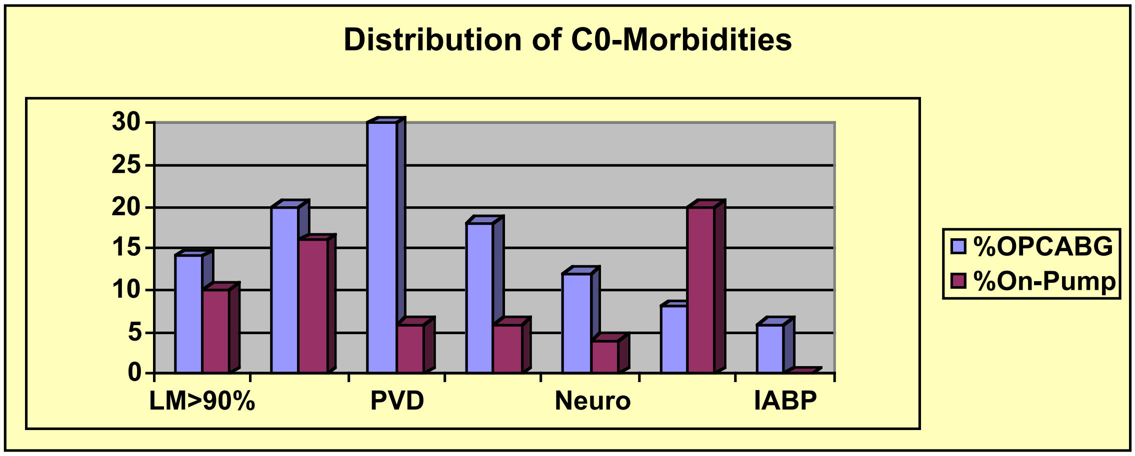
Ef=Ejection Fraction, LMD=Left Main disease, Circ=Circumflex artery, PDA=Posterior descending artery, *p<.05 unpaired student's t-test

Figure 1.



EF=Ejection Fraction, CHF=Congestive Heart Failure, COPD=Chronic obstructive lung disease, DM=Diabetes Mellitus, HTN=Hypertension

Figure 2.



LM=Left Main, PVD=Peripheral vascular disease, RF=Renal failure, acute or chronic, Neuro= Severe neurologic disorder, OB=obesity, IABP=pre-operative intra-aortic balloon pump