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Low Ejection Fraction Is Not a Contraindication to Off-Pump Coronary Artery Surgery

Dr. Abraham

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INTRODUCTION

Patients with coronary artery disease (CAD) and severe left ventricular dysfunction (LVD) have a bleak prognosis despite recent advances in medical therapy, with an estimated two-year survival rate of only 30% [Isom 1975, Cosgrove 1984]. Although cardiac transplantation is an effective treatment for end stage cardiomyopathy, limited donor availability and high mortality among patients on the waiting list make transplantation an increasingly limited option.

Myocardial revascularization prevents further ischemic injury to functional myocardium, restores function to hibernating myocardium, and has been shown to improve survival in patients with moderate to severe LVD [Isom 1975, Faulkner 1977]. Three large control trials of coronary artery bypass grafting (CABG) versus medical management have shown that patients with three vessel CAD and mild to moderate LVD (35%-50%) have better survival with CABG [Faulkner 1977, Tyras 1984, CASS 1983]. Cohort studies [Bounous 1988] of patients with LVEF of < 35% have shown that it is exactly this population of patients who will benefit most from revascularization, particularly if they have symptoms of angina.

It is difficult to predict the actual operative mortality in patients with severe left ventricular dysfunction who undergo CABG. When only patients with LVEF, less than 35% are considered. Results of CABG are confusing because mortality rates range from 1.6% to almost 40% [Bounous 1988]. Christakis et al. at the University of Toronto identified contemporary risk factors for isolated CABG [Christakis 1998]. As expected, operative mortality rates varied with LVEF: patients with LVEF higher than 40% had a lower operative mortality rate (2.3%) than patients with LVEF between 20%-40% (4.8%) or patients with LVEF lower than 20% (9.8% $p < 0.001$). Traditional risk factors—urgency of surgery, female sex, reoperation, left main coronary artery stenosis, and age—predicted operative mortality in patients with LVEF higher than 40%. In patients with LVEF between 20%-40%, operative risk was predicted not only by these risk factors, but also by myocardial protection. However, the only multivariate predictor of operative mortality for patients with LVEF less than 20%, was urgency of operation [Christakis 1998].

A significant predictor of operative mortality in patients with LVEF between 20%-40% was myocardial protection, probably because these patients are more likely to have extensive areas of jeopardized myocardium [Guyton 1987]. Perioperative mortality rates in excellent centers appear to range from 3%-10% in carefully selected patients with severe LVD, provided that meticulous attention is given to preoperative myocardial protection [Elefteriades 1997].

Despite the success of CABG with CPB, the deleterious effects of CPB are well documented. Many centers, including ours, have shown that beating heart CABG can be performed safely with results similar to CABG with CPB [Buffalo 1996, Pfister 1992, Calafiore 1997, Subramaniam 1997]. Today advances in technology allow for a near bloodless operative field and near motionless target area to ease the technical difficulty of performing a beating heart anastamosis. The aim of the present study was to analyze the potential beneficial role that CABG without CPB (i.e., off CPB) may have in reducing morbidity and improving outcomes in patients with LVEF < 40%. This was accomplished by comparing the outcomes of

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matched patients in whom revascularization was performed with and without CPB.

METHODS

We performed a retrospective, non-randomized, non-blinded study on 903 patients between 1995-1999 with ejection fractions (EF) below 40%. Seven hundred two of these patients underwent conventional CPB CABG and the remaining 201 had off pump CABG's. In the time frame of this study, it is important to keep in mind some technical milestones that included the use of stabilizers as of 1997 and the left internal mammary artery (LIMA) stitch in January of 1999 [Bergsland 1999b]. Median sternotomy was the exposure of choice in most instances for complete myocardial revascularization in both groups. Revascularization of the marginal branches of the circumflex were not considered contraindications to "off pump" coronary grafting.

Technical considerations included use of the single suture ("LIMA" stitch) technique in the oblique sinus of the posterior pericardium used to obtain exposure [Bergsland 1999b], and mechanical stabilization with an epicardial foot-plate to reduce motion. Ischemic preconditioning especially of LAD vessels was routine for 3-5 minutes and this was the first vessel grafted during off pump cases. Intracoronary shunts were used to facilitate flow during anastamosis, the details of which have been previously described [Rivetti 1998]. The CO_2 blower/saline aerosolizer [Bergsland 1998a] was used to maintain a bloodless field of vision. All off pump grafts were interrogated by use of the transit time flow meter.

All relevant information which included demographic data, preoperative risk factors and comorbid conditions, angiographic data with severity and distribution of significant coronary artery disease, morbidity and mortality rates were recorded. The severity of angina was categorized according to the Canadian Cardiovascular Society (CCS) classification. The LVEF was determined in all cases by left ventriculography during coronary angiography. The type of operative priority was defined as emergent when severity and distribution of coronary pathology in combination with hemodynamic instability mandated immediate intervention. The management of some of these patients had included vasopressors, intra-aortic balloon counterpulsation, and cardiopulmonary resuscitation. Patients in whom surgical intervention was promptly undertaken in the face of ongoing ischemia, failed angioplasty, or as a result of unfavorable anatomy (i.e., left main disease), were referred to as urgent.

The data collected from both study groups was statistically analyzed and compared. Statistical analysis was conducted using Epi Info, version 6. Continuous variables were contrasted using the Student's t test. The Fisher exact test was used when the expected value of a cell was less than 5. Differences between variables were considered significant when the p value was less than 0.05.

RESULTS

The risk adjusted mortality for the off- pump CABG group was not statistically significant (1.5 % vs. 2.2 %, p = NS). A higher proportion of the off CPB group were "re-do" cases compared to the CPB group (34.3% vs. 9.7%, $p < 0.005$) and the incidence of calcified aorta was higher in the off pump group (8.0% vs. 3.6%, $p = 0.016$). Postoperative complications (stroke, transmural MI, deep sternal wound infection, bleeding, renal and respiratory failure) were identical in both groups. The overall lack of complications was 88.6% vs. 81.8% ($p = 0.024$) for the off CPB and CPB groups respectively. There were no differences in age, sex, or elective/urgent status. Preoperative risk factors (stroke, hypertension, previous MI, diabetes, and CHF) were identical in both groups.

COMMENT

Revascularization of ischemic myocardium in patients with severely impaired left ventricular (LV) function remains a surgical challenge. In the past, perioperative mortality after CABG in patients with poor LV function has been reported to be between 10%-37% [Kaul 1996] but more recent reports indicate a much lower mortality (2.3%-5%) attributed to advances in myocardial management and surgical technique.

In the New York State Cardiac Surgery Reporting System, the risk of perioperative myocardial infarction was 1.5%, the risk of stroke was 1.6% and the risk of all major nonfatal complications was 9.2%. These data suggest that CABG can be safely performed in patients with severe LVD with low operative mortality and minimal morbidity [CASS 1983, Mochtar 1985, Milano 1993].

As noted in the results, there was a significantly higher percentage of patients in the off pump group who were re-do's with a higher percentage having calcified aortas. Other preop risk factors that were higher in the off pump group included a higher pre-op stroke and renal failure incidence. When followed and calculated, the risk adjusted mortality rate was 1.5% in the off pump group as compared to the 2.2 % in the CPB group but was not of statistical significance. While not statistically significant, the stroke rates (new neurological deficit) in the off pump group was 2.5% and 2.7% in the CPB group. There was also a statistically significant higher freedom from overall complications (88.6% off pump and 81.8% CPB). There was no significant difference in the grafts per patient, distribution of diseased vessels, male-female ratios, length of stay, or specific post operative complications (stroke, GI bleeding, sepsis, wound infection, cardiac and respiratory compromise).

The concept of chronic myocardial ischemia has broadened to include the metabolic responses of stunned and hibernating myocardium, both of which have been identified as independent predictors of cardiovascular complications or death [Jones 1978, Pryor 1987]. Hibernation, defined as cessation of contraction without loss of viability, is caused by sustained or repetitive hypoperfusion and can be metabolically expressed by an increased uptake of 18fluorodeoxyglucose (FDG+) in myocardial segments with reduced blood flow (flow-metabolism mismatch) on positron emission tomography (PET). The most widely available and accepted physiologic test for determining the presence of ischemic myocardium is myocardial perfusion scintigraphy, such as Thallium 201 imaging with poststress, redistribution, and rest injection imaging. The absence of angina in patients with advanced symptoms of heart failure does not exclude the presence of extensive areas of myocardial viability [Pryor 1987]. Despite improvements in surgical technique and perioperative care, LVEF remains an important predictor of operative mortality [Hung 1980]. However it has been shown that patients at highest risk are also the ones who derive the greatest benefit from CABG. The reported benefits of beating heart or off-pump CABG include: shorter post operative hospital stays, shorter time with ventilatory support, less blood loss and need for transfusions, less likelihood of low output syndrome, reduced systemic inflammatory response, fewer postoperative arrhythmia and neurologic complications, and potential cost savings [Moshkovitz 1997, Bergsland 1998a].

In terms of the technical aspects of bypass, Winkel et al. [Winkel 1997] state that the operation should be expedient, avoiding prolonged aortic cross clamping. The demographics and presentation of more patients today include the fact that patients are older, are more frequently re-do operations, have more associated co-morbidities and lower LVEF's. The margin or threshold for viability and myocardial tolerance to any further insult is likely to be smaller. Off pump complete myocardial revascularization may prove to be that improvement in surgical technique necessary to overcome the problems plagued by the impaired, dysfunctional ventricle [Bergsland 1998a, Moshkovitz 1997].

While off-pump CABG surgery is proving, at the very least, as effective as CPB CABG in hemodynamically stable patients with EF greater than 40%, we have shown here its safe and efficacious use in patients with ejection fractions below 40%. The question of "how low is too low" in the evaluation of ejection fraction as a risk factor [Bolling 1999] may soon be made irrelevant in the decision to offer revascularization via off-pump CABG to patients.

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REVIEW AND COMMENTARY

1. Editorial Board Member MB134 writes:

The authors state that the complications are the same in both studied groups, but does not elaborate. What were the complication rates? There should at least be a table of data showing the complication rates in both groups with their corresponding p-values.

There was no comment on whether conversion to CPB was more common with low EF than normal EF. I would like to know this.

It would be helpful if the authors can examine their database to find if the usage of the IABP was more or less common with OPCAB compared with on CPB. This would support the claim for lessened disturbance of the remaining, viable myocardium by OPCAB as compared with standard CPB and cardioplegia.

Authors' Response by Reginald Abraham, MD:

The reviewer raised the question as to what the complications were (that were compared in the study), and suggested a table of data showing the complications (stroke, transmural MI, bleeding, renal and respiratory failure) and rates in both groups and their corresponding p-values. I have included such a table as an appendix below.

The table also addresses this reviewer's other query regarding IABP use: 6.9% CPB and 1.7% off pump ($p=0.045$). IABP use is 18% in the off pump group postoperatively.

Regarding conversion to CPB in low EF vs. normal EF, in the overall Buffalo experience, there was no greater rate of conversion based on EF. As can be expected, an increased CPB conversion rate was noted in the early off pump experiences in many institutional series.

2. Editorial Board Member NC124 writes:

The authors explained that in some cases, hemodynamic support was needed either with drugs or IABP. My question is if they considered or utilized "elective" pre-op IABP or off-pump cases as part of the management of these low EF-high risk patients?

Authors' Response by Reginald Abraham, MD:

Use of IABP was not considered "routine" in all low EF patients. Despite strong evidence in the efficacy of IABP use pre-op in this setting, the judgment of the individual surgeon mandated its use in each low EF case (numbers shown in table below).

3. Editorial Board Member GX21 writes:

The last sentence of the Introduction says that this was a comparison of "matched patients", but the Materials and Methods section does not mention the matching nor how it was done.

The Results section mentions "risk adjusted mortality" in the first sentence. It is not stated how this risk adjustment was done.

Authors' Response by Reginald Abraham, MD:

The matching of these 381 retrospective patients was done on the basis of number of grafts, gender distribution, EF operative status and pre-op risk factors as outlined in the table below.

Regarding the risk adjusted mortality, it was calculated by NYS Database standards.

APPENDIX

	Ejection Fraction >0 & <40				
	With Pump		Without Pump		
	n	%	n	%	p value
Total Patients	262	100.0	119	100.0	
Total Grafts	920		214		N.S.
Grafts per Patient	3.51		1.80		N.S.
Mortality Rate - Crude	12	4.6	7	5.9	N.S.
Mortality Rate - Expected		3.9		6.5	N.S.
Mortality Rate – Risk adj.		2.9		2.2	N.S.
Male	200	76.32	87	73.1	N.S.
Female	62	23.7	32	26.9	N.S.
Age - Average	65.3		68.0		N.S.
Age - Minimum	36.0		45.0		N.S.
Age - Maximum	85.0		84.0		
EF - Average	30.9		30.8		N.S.
EF - Minimum	10.0		13.0		N.S.
EF – Maximum	39.0		39.0		N.S.
Elective	128	48.9	61	51.3	N.S.
Urgent	113	43.1	55	46.2	N.S.
Emergency	21	8.0	3	2.5	N.S.
Length of Stay – Avg (adm-dis)	12.7		15.9		N.S.
Length of Stay – Avg (sur-dis)	8.4		10.0		N.S.
CCS Class I	9	3.4	3	2.5	N.S.
CCS Class II	9	3.4	4	3.4	N.S.
CCS Class III	37	14.1	32	26.9	0.004
CCS Class IV	207	79.0	79	66.4	0.011
Complications					
None	218	83.2	103	86.6	N.S.
Stroke (new neuro deficit)	8	3.1	4	3.4	N.S.
Transmural MI	1	0.4	2	1.7	N.S.
Deep sternal Wound Infection	1	0.4	1	0.8	N.S.
Bleeding requiring reoperation	11	4.2	2	1.7	N.S.
Sepsis or Endocarditis	5	1.9	2	1.7	N.S.
G-I Bleeding, Perf., or Infarction	4	1.5	0	0.0	N.S.
Renal Failure, dialysis	5	1.9	6	5.0	N.S.
Respiratory failure	9	3.4	6	5.0	N.S.
Preop Risk Factors	23	8.8	36	30.3	<0.005
Previous open heart	224	85.5	99	83.2	N.S.
Previous MI 1 or more days	118	45.0	38	31.9	0.018
Transmural MI	24	9.2	19	16.0	N.S.
Stroke	57	21.8	32	26.9	N.S.
Carotid/Cerebrovascular	16	6.1	8	6.7	N.S.
Aortoiliac	40	15.3	18	15.1	N.S.
Femoral/Popliteal	15	5.7	2	1.7	N.S.
Unstable	2	0.8	1	0.8	N.S.
Shock	66	25.2	39	32.8	N.S.
More than one previous MI	189	72.1	88	73.9	N.S.
Hypertension History	47	17.9	24	20.2	N.S.
IV NTG within 24 hours preop	30	11.5	19	16.0	0.007
ECG Evidence of LVH	49	18.7	36	30.3	N.S.
CHF, the admission	58	22.1	22	18.5	N.S.
CHF, before this admission	16	6.1	6	5.0	N.S.
Malignant ventricular arrhythmia	98	37.4	43	36.1	N.S.

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APPENDIX (CONTINUED)

	Ejection Fraction >0 & <40				
	With Pump		Without Pump		
	n	%	n	%	p value
COPD	0	0.0	0	0.0	N.S.
Myocardial rupture	10	3.8	11	9.2	0.05
Ext calcified ascending aorta	67	25.6	30	25.2	N.S.
Diabetes requiring medication	0	0.0	0	0.0	N.S.
Hepatic Failure	3	101	8	6.7	N.S.
Renal Failure, creainine>2.5	4	1.5	3	2.5	N.S.
Renal Failure, dialysis	3	1.1	3	2.5	N.S.
Immune system deficiency	18	6.9	2	1.7	0.045
IABP preop	6	2.3	1	0.8	N.S.
Emer xfer to OR after DX Cath	1	0.4	0	0.0	N.S.
Emer xfer to OR after PTCA	1	0.4	0	0.0	N.S.
Previous PTCA, this adm	22	8.4	15	12.6	N.S.
PTCA before this admission	11	4.2	4	3.4	N.S.
Thrombolytic therapy within 7 days	64	24.4	21	17.6	N.S.
Smoking history, in past 2 weeks	17	6.5	7	5.9	N.S.
Smoking history, in past year					N.S.
Vessels Diseased	23	8.8	5	4.2	N.S.
LMT: 50 – 69%	11	4.2	6	5.0	N.S.
LMT: 70 – 89%	16	6.1	5	4.2	N.S.
LMT: 90 – 100%	24	9.2	9	7.6	N.S.
Prox LAD: 50 – 69%	190	72.5	80	67.2	N.S.
Prox LAD: 70 – 100%	15	5.7	5	4.2	N.S.
Mid/Dist LAD : 50 – 69%	98	37.4	40	33.6	N.S.
Mid/Dist LAD : 70 – 100%	16	6.1	4	3.4	N.S.
RCA: 50 – 69%	208	79.4	97	81.5	N.S.
RCA: 70 – 100%	21	8.0	9	7.6	N.S.
LCX: 50 – 69%	195	74.4	78	65.5	N.S.
LCX: 70 – 100%					

Of the patients in the study group, there was a significantly higher percentage of patients with NYHA Class III and IV symptoms and with LVH in the off pump group and also a higher percentage of this off pump group were re-do's with a higher percentage having calcified aortas. When followed and calculated, the risk adjusted mortality rate was 2.2 as compared to the 2.9 in the CPB group—this represents a difference that is not significant. There was no significant difference in the grafts per patient, distribution of diseased vessels, male-female ratios, postoperative complications (stroke, GI bleeding, sepsis, wound infection, cardiac and respiratory compromise).