Title
Off-pump versus on: long-term outcomes after coronary artery bypass in a veteran population

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Off-pump versus on: Long-term outcomes after coronary artery bypass in a Veteran population

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ABSTRACT

Objective: We sought to investigate long-term outcomes after revascularization with and without use of cardiopulmonary bypass, and hypothesized off-pump would be comparable to on-pump. Our primary outcome of interest was survival, and secondary outcomes included need for reintervention with new coronary stent, or new diagnosis of myocardial infarction (MI) occurring any time after surgery during the 8-12 year follow up period.

Design: Retrospective cohort analysis Setting: Veterans Affairs Medical Center Participants: All patients undergoing primary isolated coronary bypass between January 1, 2004 and December 31, 2008 (n=555).

Interventions: Coronary artery bypass on-pump (n=238) or off-pump (n=317).

Measurements and Main Results: Demographic and clinical variables were documented, as well as information on mortality, new myocardial infarction, and need for reintervention in the 8-12-year period following surgery. The on- and off-pump groups were similar regarding all demographic and clinical variables ($p>0.05$) except for higher incidence of prior percutaneous coronary intervention in the off-pump group. There were more perioperative complications in the on-pump group ($p=0.007$), as well as a higher number of grafts utilized ($p=0.000$). Kaplan Meier survival analysis demonstrated no significant difference ($p>0.05$) in overall survival, reintervention free-survival, or postoperative MI-free survival between patients who underwent bypass grafting on- or off-pump over extended follow up averaging ten years.

Conclusions: Our data did not show differences in key long-term outcomes between patients who underwent revascularization with or without cardiopulmonary bypass, supporting the idea that both methods achieve similar late results with regards to overall survival, need for reintervention, and post-operative myocardial infarction.

INTRODUCTION

Conflicting literature exists regarding the long-term safety and efficacy of off-pump versus on-pump coronary artery bypass [1-4]. Shroyer and colleagues recently published 5-year outcomes from the ROOBY trial showing a higher incidence of death and major adverse cardiovascular events associated with off-pump surgery [5]. However, in another large randomized off-pump versus on-pump trial, Lamy and colleagues found no significant difference in composite outcome of death, stroke, myocardial infarction, renal failure, or repeat revascularization [6]. The 30-day and one-year outcomes frequently reported in the literature fail to address the long-term implications several years after surgery [7]. Our clinical experience with off pump surgery has demonstrated excellent short and long-term outcomes, and seemed contradictory to the well-publicized results of the ROOBY-FS group, prompting the development of this study. The Veterans Affairs (VA) patient population, made up of predominantly older males with various comorbidities including hypertension, hyperlipidemia, smoking, and diabetes, are highly susceptible to coronary artery disease and the eventual need for coronary artery bypass surgery. Some surgeons in our group adopted off pump techniques in 2000-2001. Other surgeons continued to perform bypass surgeries on pump with the heart arrested. Given that a considerable number of these procedures were performed at our institution using both on- and off-pump techniques, we aimed to compare key long-term outcomes after bypass surgery between these two populations.

METHODS

We conducted a retrospective chart review of patients who underwent primary isolated coronary artery bypass grafting from January 1, 2004 through December 31, 2008 with the primary outcome of interest being all-cause mortality. Secondary outcomes were revascularization via percutaneous stenting or reoperation, and readmission with diagnosis of myocardial infarction postoperatively at any point until chart review occurred in 2016.

The Institutional Review Board at the VA and University affiliate approved this retrospective chart review. Patients were identified through a query of all cardiothoracic surgical procedures performed at the VA between January 1, 2004 and December 31, 2008. Patients having reoperative bypass surgery or requiring any additional procedures beyond coronary artery bypass grafting were excluded. Of the 818 patients identified through the Cardiothoracic surgery database, 555 met eligibility criteria in that they underwent primary isolated coronary bypass surgery.

Using the VA comprehensive electronic medical record system (CPRS and VistaWeb), we were able to collect baseline demographic and clinical variables from all VA facility visits (Table 1). Clinical variables were collected preoperatively, always within 30 days of surgery. Operative data were collected as well (Table 2). Peri- and postoperative data were collected, including information regarding perioperative complications. These were categorized as major (graft failure, cardiac arrest, stroke or death) or other (Table 3). Medical record review specifically included all admissions and procedures during the follow up period until 2016 to document new diagnosis of myocardial infarction or additional cardiac catheterizations. Cardiology and primary care notes were also reviewed in order to screen for patients being diagnosed with new myocardial infarction at an outside facility during the review period. If deceased, date of death was documented. Any additional re-intervention procedures (percutaneous stenting or reoperative bypass surgery) were documented, as was whether each patient was diagnosed with MI at any time after surgery during the 10 years of follow up.

In order to conduct a power analysis, an expected mortality rate of 35% was estimated for a 65 year-old male veteran ten years after bypass surgery [8-10]. To test the hypothesis that off-pump procedures lead to increased mortality, we used an increased risk of 35% over the baseline resulting in a mortality of 47.25% in the off-pump group. (The well-publicized ROOBY trial used a risk increase of 40% [5].) Power analysis revealed that a minimum of 513 subjects would need to be studied to detect a 35% greater mortality at ten years as a result of off-pump surgery with power = 0.8 and α=0.05.

For continuous demographic, preoperative clinical, and perioperative variables (i.e. age, BMI) we used the independent sample T test for comparison of means between the on and off pump groups. For categorical variables, we used chi-square test or Fisher's exact (when N was small) for comparison between groups. For our competing risk analysis, we used 1-Kaplan Meier reintervention free survival to estimate cumulative incidence of reintervention where death was a competing risk. In addition, we performed Kaplan-Meier survival probability estimates and compared overall survival stratified by treatment group (on- versus off-pump) as well as reintervention-free survival stratified in the same manner. Finally, we used Cox proportional hazards regression to build a model for risk of death, controlling for significant covariates. All analysis was performed using SPSS (IBM SPSS Statistics for Macintosh, Version 22.0. Armonk, NY: IBM Corp).

RESULTS

Of the 555 patients in the study population, 238 underwent revascularization on pump, and 317 underwent off-pump bypass surgery. Follow up ranged from 7.6 to 12.6 years with mean follow up 10.1 years. Follow up data was available for 99.6% of patients. Table 1 shows baseline demographic information for the two groups of patients. Independent sample t-testing revealed no significant difference in age, preoperative ejection fraction (EF), or creatinine between the two groups. Chi-square and Fisher's exact tests showed no significant difference in race, ethnicity, marital status, the presence of cardiac risk factors (diabetes, hypertension, hyperlipidemia, tobacco use) or past medical history (cancer, PVD, CVA, COPD, CHF) between the two groups. It did reveal, however, a significant difference in rates of prior percutaneous coronary intervention ($p=0.004$), greater in the off-pump subset. When comparing perioperative and postoperative data between on- and off-pump patients (Table 2), a statistically significant increase in number of grafts ($p=0.000$) was used in the on-pump group (mean 3.39) compared with the off-pump group (mean 2.79). No significant differences were observed with postoperative myocardial infarction, LIMA graft use, or postoperative reintervention. No patients in either group went on to require reoperative bypass surgery; all reinterventions refer to percutaneous intervention with stenting. In terms of perioperative complications, there was no significant difference in major complications (graft failure, cardiac arrest, stroke, death) between the on- and off-pump groups. However, there was a higher incidence of other complications in the on-pump group compared to the off-pump group ($p=0.035$).

Kaplan-Meier survival analysis (Figure 1) revealed no significant difference in overall survival after surgery for patients who underwent procedures with or without cardiopulmonary bypass (p= 0.926). Kaplan-Meier time-to-event curves for revascularization (Figure 2) revealed no significant difference in revascularization after CABG surgery in patients who underwent the procedure on- or off-pump (p=0.775), nor was there a difference in incidence of postoperative myocardial infarction (Figure 3) (p=0.281). Using 1-KM as a surrogate estimate for cumulative incidence and adjusting for death as a competing risk, there was no significant difference in probability of needing reintervention with stenting after CABG between groups (p=0.85). The 5-year cumulative incidence probability of reintervention in the off-pump group was 0.076 compared to 0.058 in the on-pump group.

Cox proportional hazard analysis for all-cause mortality demonstrated no significant difference between the on and off bypass groups after controlling for independently significant covariates including age, tobacco history, pre-surgical disease burden (using number of grafts), congestive heart failure history, cancer history, creatinine, peripheral vascular disease history, stroke history, and ejection fraction (HR 1.014, 95% CI: 0.759, 1.356, p=0.924) (Table 3). Furthermore, there were no significant differences between the on and off bypass groups when calculating the Cox hazard ratios for reintervention or postoperative MI (Table 3).

Overall, 124 of the 555 patients underwent at least one cardiac catheterization during the 8-12 years of follow up. Fifty-eight patients required intervention and stent placement and these were equally divided between the on and off pump groups (p=0.78). Thirty of these patients had their stent placement in the setting of a myocardial infarction that occurred after surgical revascularization. An additional 11 patients were diagnosed with MI at some point after surgery. Two of these patients died at the time of the admission for MI, eight underwent cardiac catheterization without stent placement, and one was managed medically. There was a trend toward more myocardial infarctions in the off-pump group during the extended follow up period (9% versus 6%) but this was not statistically significant (p=0.24).

DISCUSSION

Our study utilized a robust data set of patients belonging to a similar at-risk population with their bypass procedures performed by a small group of surgeons at the same institution. The number of surgeries performed on-pump and off during the period of study was comparable as some surgeons had adopted off-pump techniques and others in the group preferred to use cardiopulmonary bypass and arrest the heart. The surgeons who adopted off pump techniques did so in 2000-2001, so by 2004, there were two on-pump and two off-pump surgeons operating at the VA. These procedures were performed in a training institution, but attending surgeons choosing off-pump surgery had at least two years of experience with off-pump techniques prior to supervising trainees during the operations performed during the study period.

The electronic medical record for the VA hospital system is linked across the country, providing us with greater assurance at the accuracy of time-to-event survival analysis. Patient deaths are updated and reflected in the system with pooled input from Social Security Administration, Veterans Benefits Administration, and National Cemetery Administration, ensuring timely notification of patient death regardless of where the patient was living at the time of death. Admissions, notes, and procedures including cardiac catheterization and PCI are all documented in the electronic chart, legible and readily available to reviewers. Follow up data after surgery was available for 99.6% of patients until either time of death or end of the study period in 2016. In addition to admissions, discharge summaries, and procedures, cardiology clinic and primary care notes for all patients were reviewed through 2016 in order to capture outside hospital admissions and new diagnoses of myocardial infarction. If a Veteran needed emergency admission to a community facility for an MI and underwent PCI, that event would be documented by the primary care physician and/or cardiologist in the subsequent VA clinic notes and captured in our chart review.

However, there are several limitations to this analysis including that retrospective data was used and analyzed in 2016 with a sample that underwent coronary bypass surgery in a specific window of time (2004-2008). This specific window was intentionally selected to allow for the off-pump surgeons to have progressed through the learning curve prior to studying patients and to allow for longer term follow up extending to over twelve years. The patients were not randomized, and choice of technique was primarily driven by surgeon preference. We are postulating that the two populations are non-distinct given the lack of demonstrable differences between them in preoperative demographic and clinical variables, but there could be differences between the groups that we did not capture in the analysis. The only major difference of statistical significance was a higher incidence of prior PCI in the off-pump group. If anything, this would imply a higher risk profile for the off-pump group with an earlier presentation of significant coronary artery disease requiring intervention. In addition, we used a predicted increase in mortality of 35% associated with off-pump surgery, and our study would be underpowered to detect a smaller treatment effect.

Our study, like many others, demonstrated significantly fewer grafts in the off-pump patients. Part of this difference is explained by surgeon preference in that one of the surgeons in the group would use off-pump for one, two, or three vessel surgeries, but preferred on-pump arrested technique for four bypasses. Given that the patients are not randomized, number of grafts needed and target quality likely played a role in preoperative decision-making. Complete revascularization has many different definitions, but typically our group employs a concept of regional revascularization, considering the three walls (anterior, lateral, and inferior) and selecting the best target from each diseased territory for bypass [11]. The anterior wall is generally the only territory to warrant two bypasses, although exceptions will occur in certain anatomical circumstances. We hypothesize that since both on-pump and off-pump patients were treated with this philosophy in mind, the fewer number of grafts in the off-pump group does not necessarily translate to incomplete revascularization. The similar long-term outcomes in both groups would also support that appropriate revascularization was accomplished, regardless of on or off-pump technique.

Another guiding philosophy is that the patient should get the same operation, whether on-pump or off. Intraoperative conversion electively to address a particularly challenging target vessel is not associated with worse outcomes, and this is distinct from urgent or emergent conversions for hemodynamic instability [12]. We did not track conversion rate specifically in this study since the goal was to evaluate long term outcomes after either on-pump or off-pump surgery, but in a previous study evaluating short term outcomes we found an urgent/emergent conversion rate of 0.8% and an elective conversion rate of 7%.

Graft patency is another area of controversy in the on-pump versus off-pump debate. Hattler and colleagues from the ROOBY study group concluded that off-pump CABG resulted in lower patency for arterial and venous grafts and less effective revascularization [13]. However, it is important to note that this trial randomized patients to on-pump or off, and surgeons were only required to have experience with 20 off-pump procedures prior to participating. Puskas and colleagues also published a randomized trial comparing the two techniques with all surgeries performed by a very experienced off pump surgeon. The authors found no difference in arterial or venous graft patency between the groups, evaluated by angiogram at 30 days and again at one year [14]. We elected to study secondary outcomes of need for reintervention or new diagnosis of myocardial infarction to functionally have a measure of long term graft patency and did not find a significant difference between on-pump and off-pump groups for either of these measures.

The use of off-pump techniques for coronary artery bypass continues to be controversial with conflicting evidence in the literature, and this is a challenging area to study. It is difficult to assign measurable data points to subjective things like target vessel quality or runoff and those factors likely play a key role in long term outcomes. With our data examining the Veterans Affairs population from 2004-2008 and documenting follow up over 10 years, we did not find that on-pump or off-pump technique was one of those factors. We did not find any significant difference in overall survival, need for reintervention with PCI, or incidence of postoperative myocardial infarction between patients who underwent CABG either on or off cardiopulmonary bypass. Similarly, in multivariable analysis there was no demonstrable difference for the hazards of all-cause mortality, need for reintervention, or occurrence of postoperative MI between groups when controlled for significant covariates. Our data support the non-inferiority of off-pump CABG when performed by teams experienced in the technique and applying similar criteria for revascularization. Moreover, the statistically significant increase in perioperative complications in the on-pump group suggests that off-pump may be safer and less resource intensive in the short term. With fewer perioperative complications and similar excellent long-term outcomes, off-pump surgery offers a durable, effective option for coronary revascularization.

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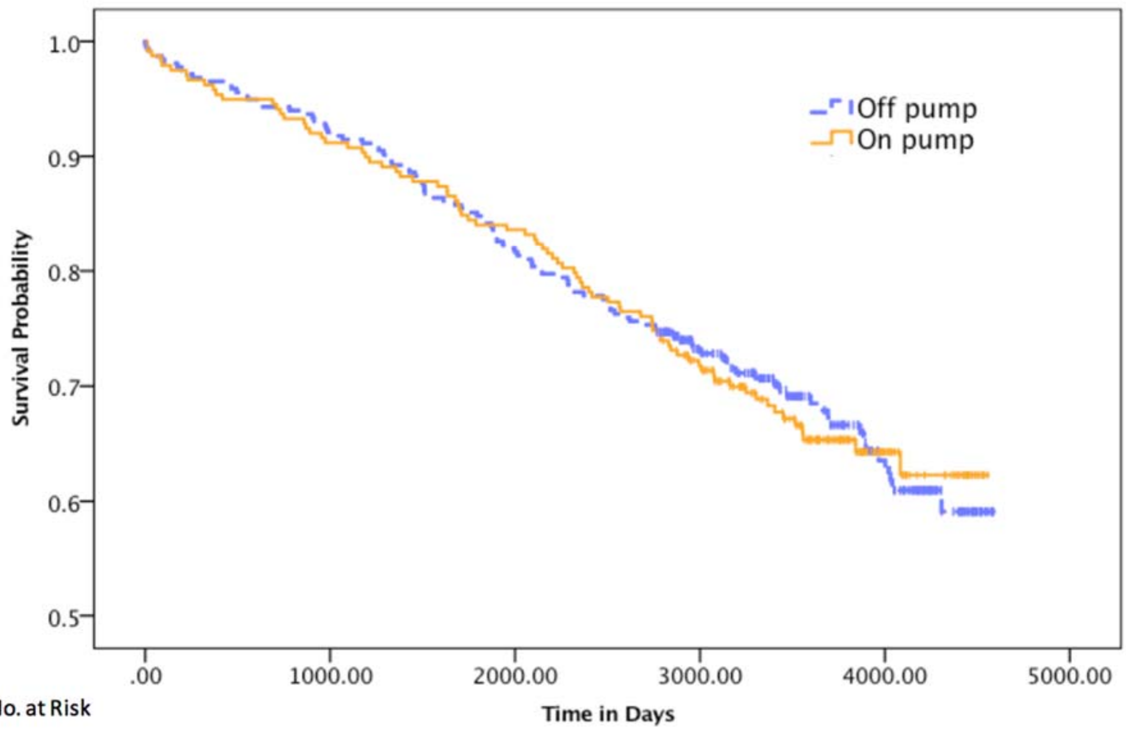
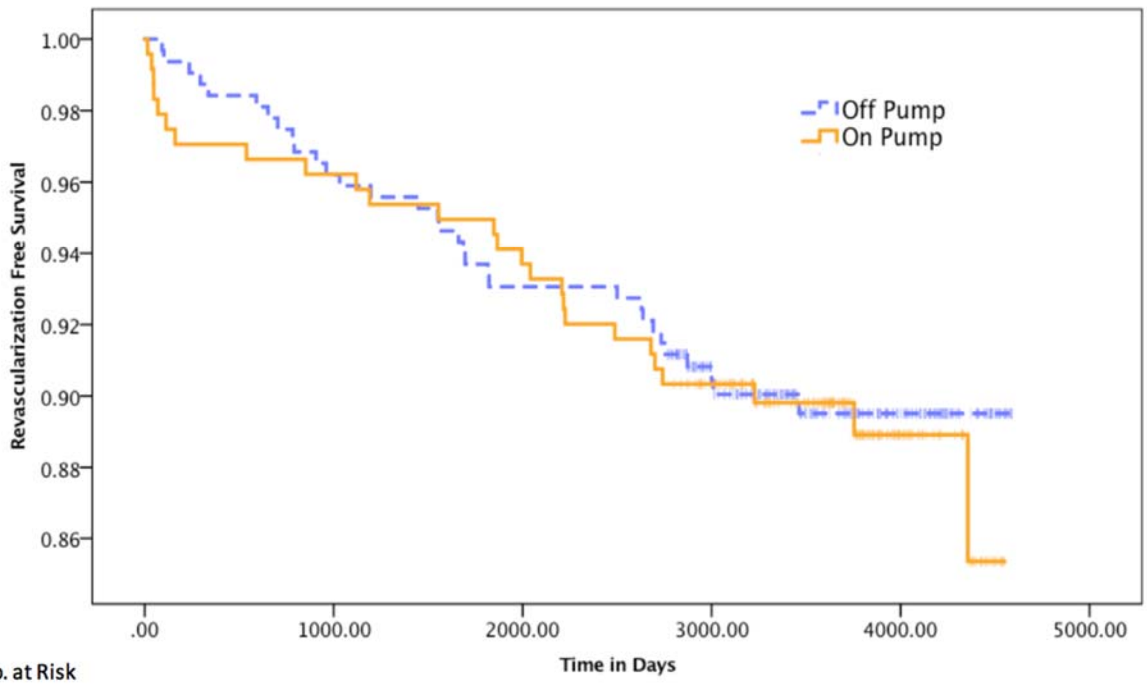
FIGURES

Figure 1: Overall survival. Kaplan-Meier survival estimates, stratified by use of cardiopulmonary bypass (on pump versus off pump), p=0.926



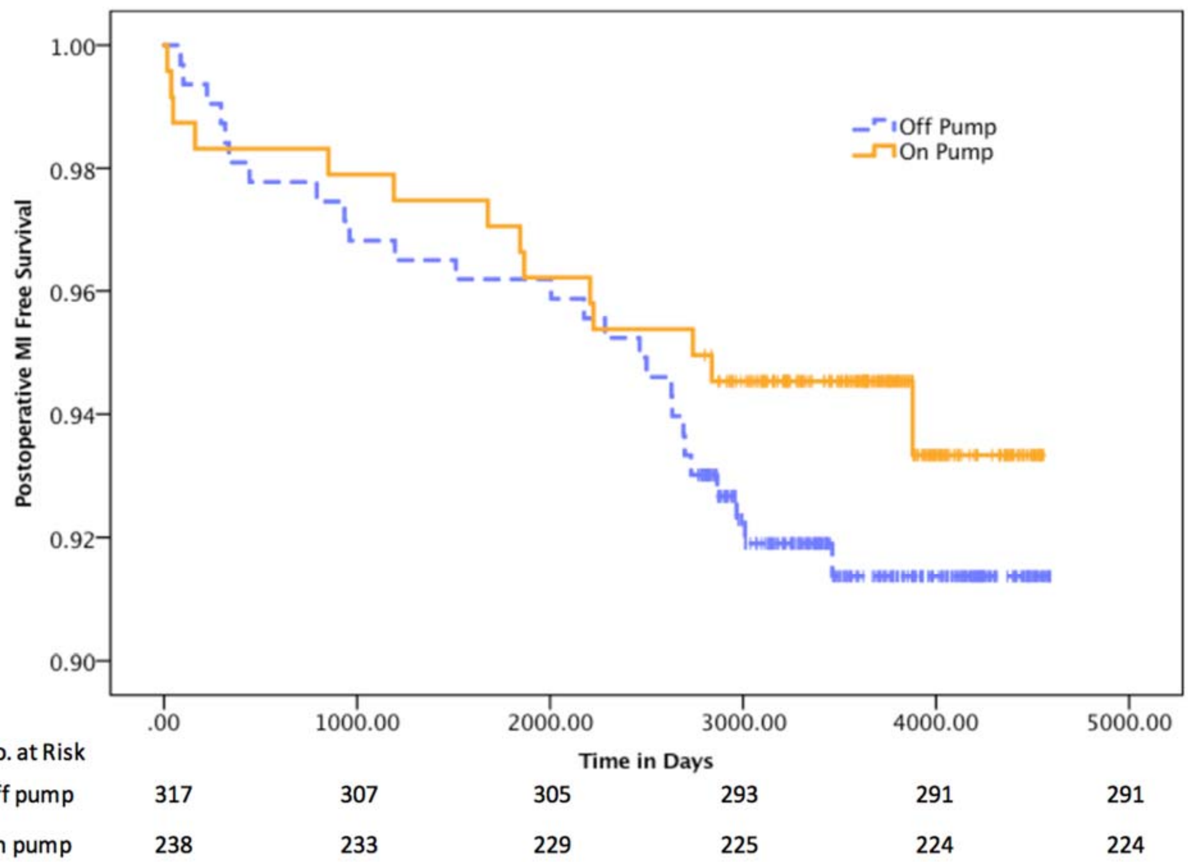
No. at Risk						
Off pump	317	292	259	233	216	212
On pump	238	217	199	170	158	157

Figure 2: Revascularization-free survival. Kaplan-Meier estimate for revascularization, stratified by use of cardiopulmonary bypass (on pump versus off pump), p=0.775



No. at Risk						
Off pump	317	305	295	287	285	285
On pump	238	229	223	215	213	212

Figure 3: MI- free survival. Kaplan-Meier survival estimate for postoperative myocardial infarction, stratified by use of cardiopulmonary bypass (on pump versus off pump), p=0.281



TABLES

Table 1. Baseline demographic of patient cohort (N = 555).

	On CPB (n=238)	Off CPB (n= 317)	Significance
Age- mean in years (SD)	64.18 (7.9)	63.8 (8.4)	p= 0.620
Gender– n (%) Male Female	 233 (98) 5 (2)	 314 (99) 3 (1)	p= 0.298

Race – n (%)			p= 0.5
White	191 (80)	247 (78)	
Black	13 (5)	20 (6)	
Asian	8 (3)	15 (5)	
American Indian or Alaska	4 (2)	2 (1)	
Native	3 (1)	3 (1)	
Native Hawaiian or Pacific	2 (1)	19 (6)	
Islander			
Other or Decline to Answer			
Ethnicity – n (%)			p= 0.286
Not Hispanic	203 (85)	277 (87)	
Hispanic	26 (11)	26 (8)	
Decline to Answer	9 (4)	14 (4)	
Marital status – n (%)			p= 0.711
Married	109 (46)	151 (48)	
Divorced	83 (35)	94 (30)	
Separated	7 (3)	10 (3)	
Single	22 (1)	37 (12)	
Widowed	17 (1)	25 (8)	
Cardiac Risk factors – n (%)			
Diabetes	104 (44)	134 (42)	p= 0.972
Insulin Dependent	30 (13)	38 (12)	
Hypertension	207 (87)	276 (87)	p= 0.975
Hyperlipidemia	212 (89)	284 (90)	p= 0.846
Tobacco history	184 (77)	223 (70)	p= 0.066
Tobacco current	57	80	p= 0.728
Past Medical History – n (%)			
Prior PCI	31 (13)	72 (23)	p= 0.004*
Cancer	36 (15)	59 (19)	p= 0.281
PVD	32 (13)	47 (15)	p= 0.645
CVA	26 (11)	32 (11)	p= 0.752
COPD	27 (11)	31 (10)	p= 0.551
CHF	22 (9)	27 (9)	p= 0.765
Preoperative EF – mean (SD)	55.7 (13.3)	57.2 (12.7)	p= 0.189
BMI- mean (SD)	29.23 (5.29)	29.02 (5.72)	p= 0.661
Creatinine- mean (95% CI)	1.21 (1.12 – 1.30)	1.18 (1.12 – 1.24)	p=0.587

CPB: Cardiopulmonary bypass, SD: Standard deviation, PCI: percutaneous coronary intervention, PVD: peripheral vascular disease, CVA: cerebrovascular accident, COPD: chronic obstructive pulmonary disease, CHF: congestive heart failure, EF: ejection fraction, BMI: body mass index, CI: confidence interval

Table 2. Perioperative and postoperative data (N=555)

	On CPB (n=238)	Off CPB (n= 317)	Significance
CPB Time- mean mins (CI)	137 (131.8 – 142.1)	--	
Cross Clamp Time- mean mins	83.3	--	
Number of grafts – mean (SD)	3.39 (.756)	2.79 (.830)	p= 0.000*
Used LIMA Graft- n (%)	229 (96)	313 (99)	p= 0.052
Major Perioperative Complication- n (%)	6 (2.5)	5 (1.6)	p= 0.43
Other Perioperative Complication- n (%)	82 (34)	83 (26)	p= 0.035*
Postoperative MI- n (%)	14 (6)	27 (9)	p= 0.240
Postoperative Reintervention (Cath/PCI)- n(%)	32 (13)	26 (8)	p= 0.780

CPB: cardiopulmonary bypass, CI: confidence interval, SD: standard deviation, LIMA: left internal mammary artery, MI: myocardial infarction, Cath/PCI: cardiac catheterization/percutaneous coronary intervention

Table 3. Univariate and Multivariate Cox Regression Hazard analysis for death, reintervention, and postoperative myocardial infarction.

Cox Regression Hazard Ratios for Death				
	Univariate HR (95% Confidence Interval)	p value	Multivariate HR (95% Confidence Interval)	p value
Age at CABG	1.057 (1.039-1.076)	0.000	1.052 (1.032-1.072)	0.000
BMI	0.969 (0.944-0.996)	0.023	0.994 (0.965-1.024)	0.710
Diabetes	1.289 (0.967-1.718)	0.084		
Hypertension	1.525 (0.937-2.480)	0.089		
Hyperlipidemia	0.874 (0.559-1.362)	0.555		
Prior PCI	1.289 (0.911-1.823)	0.152		
Current Tobacco Use	1.169 (0.845-1.617)	0.345		
Any Tobacco Usage	1.2010 (0.863-1.697)	0.270		
Hx Cancer	1.553 (1.098-2.198)	0.013	1.210 (0.840-1.742)	0.305
Hx PVD	2.413 (1.719-3.387)	0.000	1.521 (1.057-2.191)	0.024
Hx CVA	1.765 (1.180-2.639)	0.006	1.359 (0.895-2.063)	0.150
Hx COPD	2.137 (1.459-3.132)	0.000	1.924 (1.304-2.840)	0.001
Ejection Fraction	0.985 (0.974-0.995)	0.004	0.980 (0.969-0.990)	0.000

Number of Grafts	0.899 (0.760-1.063)	0.213		
Creatinine	1.590(1.387-1.822)	0.000	1.506 (1.305 - 1.739)	0.000
CPB	1.014 (0.759-1.356)	0.924		

Cox Regression Hazard Ratios for Reintervention				
	Univariate HR (95% Confidence Interval)	p value	Multivariate HR (95% Confidence Interval)	p value
Age at CABG	0.952 (0.920-0.985)	0.005	0.957 (0.924-0.990)	0.012
BMI	1.048 (1.002-1.095)	0.042	1.034 (0.988-1.082)	0.149
Diabetes	1.287 (0.769- 2.153)	0.337		
Hypertension	2.879 (0.901-9.205)	0.075		
Hyperlipidemia	0.639 (0.314- 1.301)	0.217		
prior PCI	1.288 (0.695-2.388)	0.421		
Current Tobacco Use	1.524 (0.881-2.638)	0.132		
Any Tobacco Usage	1.151 (0.631-2.101)	0.647		
Hx Cancer	0.456 (0.182-1.142)	0.094		
Hx PVD	0.967 (0.459-2.040)	0.930		
Hx CVA	1.245 (0.565-2.744)	0.587		
Hx COPD	0.995 (0.427- 2.316)	0.990		
Ejection Fraction	1.007 (0.987-1.028)	0.506		
Number of Grafts	1.254 (0.926-1.699)	0.144		
Creatinine	0.992 (0.647-1.521)	0.971		
CPB	1.079 (0.643- 1.810)	0.775		

Cox Regression Hazard Ratios for Postoperative Myocardial Infarction				
	Univariate HR (95% Confidence Interval)	p value	Multivariate HR (95% Confidence Interval)	p value
Age at CABG	0.975 (0.937-1.014)	0.201		
BMI	1.012 (0.957-1.071)	0.666		
Diabetes	1.150 (0.618-2.140)	0.658		
Hypertension	1.383 (0.492-3.885)	0.539		
Hyperlipidemia	0.675 (0.283-1.609)	0.375		
Prior PCI	1.517 (0.741-3.103)	0.254		
Current Tobacco Use	0.955 (0.477-1.911)	0.896		
Tobacco Current	1.311 (0.667-2.579)	0.432		
Hx Cancer	0.542 (0.193-1.524)	0.246		

Hx PVD	0.493 (0.152-1.598)	0.238		
Hx CVA	1.286 (0.504-3.284)	0.598		
Hx COPD	1.255 (0.492-3.203)	0.635		
Ejection Fraction	0.999 (0.975- 1.023)	0.933		
Number of Grafts	1.047 (0.726 -1.510)	0.806		
Creatinine	1.104 (0.722-1.689)	0.647		
CPB	0.701 (0.366-1.342)	0.283		

CABG: coronary artery bypass grafting, BMI: body mass index, PCI: percutaneous coronary intervention, PVD: peripheral vascular disease, CVA: cerebrovascular accident, COPD: chronic obstructive pulmonary disease, CPB: cardiopulmonary bypass