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ORIGINAL ARTICLE

Early outcomes in patients undergoing off-pump coronary artery bypass grafting

Gautam Rampratap Agarwal[1] · Neethu Krishna[1] · Greeshma Raveendran[2] · Rajesh Jose[1] · Murukan Padmanabhan[1] · Aveek Jayant[3] · Praveen Kerala Varma[1]

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Abstract

Background In spite of general decline worldwide, off-pump coronary artery bypass grafting (CABG) surgery is performed in more than 60% of patients undergoing CABG in India; mainly because of shorter operative time and reduced procedure cost. However, paucity of data exists in literature about early outcomes following off-pump CABG from India.

Methodology We conducted a prospective observational study of 800 consecutive cases that underwent off-pump CABG (OPCAB) from August 2015 to October 2017. Primary end point of the study was the 30-day/in-hospital mortality from any cause.

Results On multivariate analysis, emergency surgery (OR 9.72; CI 1.96–48.21, *p* value 0.005), severe left ventricular dysfunction (OR 2.28; CI 1.25–4.76, *p* value 0.026), postoperative atrial fibrillation (OR 9.95; CI 3.12–32.01, *p* value 0.05), and dialysis-dependent renal failure (OR 29.7, CI 10.02–87.99, *p* value 0.006) were the factors associated with mortality. The observed mortality was 1.6%, and the expected mortality by EuroSCORE II was 2.6%. The median EuroSCORE II of expired patients was 3.03 and of entire cohort was 1.54 (*p* value 0.001). Stroke rate was 0.9%. Deep sternal wound infection occurred in 0.9%, and 3.8% patients were readmitted to the hospital after discharge.

Conclusion Early outcome of off-pump CABG was excellent in this study. Increased incidence of deep sternal wound infection remains a concern. Multicenter study with a larger sample size is required for a dependable evaluation of the efficacy of off-pump CABG in Indian population.

Keywords Off-pump CABG · Coronary artery bypass grafting · Outcomes

Introduction

CABG is the gold standard for revascularization in coronary artery disease. Patients with left main disease, multivessel disease, and left ventricular (LV) dysfunction benefit from CABG rather than percutaneous coronary intervention (PCI) or medical therapy [1]. CABG is commonly performed with the use of cardiopulmonary bypass (CPB) and cardioplegic arrest. With this approach, the composite outcome of perioperative mortality and major adverse cardiac and cerebral events is less than 10% [1]. The development of cardiac stabilizers in the late 1990s allowed widespread application of alternative technique of coronary revascularization that does not require CPB [2]. Many studies reported reduced operative morbidity with OPCAB relative to on-pump CABG. OPCAB patients had less transfusion requirement, less inotropic support, shorter ventilation time, lower stroke rate, lower incidence of acute kidney injury, and shorter intensive care unit stay [3]. Routine patients may achieve an excellent outcome irrespective of the type of procedure; however, it was thought that OPCAB gave substantial benefit to high-risk and elderly patients [4].

However, there is a decline of interest in OPCAB worldwide [5]. Only 13% of CABG were performed by OPCAB technique in the latest Society of Thoracic Surgeons (STS) database [6]. Besides being technically more demanding and concerns about the quality of anastomosis, many studies had

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✉ Praveen Kerala Varma
varmapk@gmail.com

[1] Division of Cardiothoracic Surgery, Amrita Institute of Medical Sciences and Research Center, Amrita University, Kochi, India

[2] Division of Biostatistics, Amrita Institute of Medical Sciences and Research Center, Amrita University, Kochi, India

[3] Division of Anesthesiology, Amrita Institute of Medical Sciences and Research Center, Amrita University, Kochi, India

shown a tendency to incomplete revascularization, lower graft patency, and increased need for repeat revascularization with reduced long-term survival in patients undergoing OPCAB technique [7, 8]. Moreover, OPCAB has not shown any substantial benefit in high-risk groups, e.g., patients with depressed LV function, patients with renal dysfunction, and elderly subjects [9, 10]. Even though a newer randomized trial showed similar results in both on-pump and off-pump in early and 5-year outcomes, need for repeat revascularization remained higher in the off-pump group [11]. These factors led to even an opinion to abandon off-pump revascularization altogether [12, 13]. Most of these data and studies were based on western patients. Hence, this data may not be applicable in Indian context.

CABG is difficult in Indian patients because of smaller caliber of coronary vessels, diffuse nature of disease, and tendency to early calcification of atheromatous plaque [14]. In India, currently OPCAB surgery is performed in more than 60% of patients undergoing CABG; mainly because of shorter operative time and reduced procedure cost. However, there is a paucity of published data on outcomes of OPCAB in Indian patients [15–17]. Hence, we designed a prospective study to evaluate the early outcomes of OPCAB patients in our institute.

Patients and methods

Study design and data collection

A prospective observational study of early outcomes in patients undergoing off-pump coronary artery bypass grafting was conducted at the Department of Cardiovascular and Thoracic Surgery. Eight hundred consecutive patients who underwent OPCAB from August 2015 to October 2017 were included in the study. Three consultant cardiothoracic surgeons performed all the procedures. Eight hundred twenty-three patients were planned for OPCAB procedure, of which 23 patients underwent elective conversion to on-pump CABG. Patients who required emergency intraoperative conversion were included in the analysis and were reported as an outcome. The variables collected are included in Table 1. Follow-up at 30 days was carried out by direct follow-up of patients in outpatient department.

Ethics committee approval

The study was approved by the hospital ethics committee. The need for informed consent was waived off. All personal identifying data was removed from the study database so that individuals could not be identified.

Table 1 Distribution of preoperative variables

Variables	*N* (%) 800 (%)
Female	144 (18)
Male	656 (82)
Mean age (years)	61.75 ± 8.78
Mean age (female)	62.09 ± 8.49
Mean age (male)	61.67 ± 8.85
Mean EuroSCORE II	2.30 ± 2.80
Elective	780 (97.5)
Emergency	20 (2.5)
Diabetes	531 (66.37)
Dyslipidemia	368 (46)
Hypertension	553 (69.12)
Peripheral vascular disease	124 (15.5)
Chronic kidney disease (GFR < 60)	129 (16.12)
Chronic obstructive airway disease	141 (17.62)
Normal sinus rhythm	790 (98.75)
Recent MI	488 (61)
Severe LV dysfunction (EF ≤ 35%)	37 (4.62)
Number of grafts	
1	3 (0.37)
2	63 (7.87)
3	272 (34)
4	365 (45.62)
5	88 (11)
6	8 (1)
7	1 (0.12)
Average number of grafts	4
LIMA grafts used	783 (97.9)

GFR glomerular filtration rate, *LIMA* left internal mammary artery, *LV* left ventricle, *MI* myocardial infarction

OPCAB technique

All patients underwent median sternotomy. Heparin was administered to achieve a target activated clotting time of more than 400 s. Left internal mammary artery (LIMA) was the preferred conduit to bypass left anterior descending artery (LAD). Ninety-five percent of patients received saphenous vein grafts to bypass the other systems. Proximal anastomoses were constructed in ascending aorta using partial occlusion clamp. Our strategy was to perform all proximal anastomoses separately whenever possible. Sequential grafts and vein to vein anastomosis were performed only if the vein length was inadequate. Heparin was fully reversed with protamine after the procedure. Patients were shifted to dedicated intensive care unit (ICU) for postoperative monitoring.

Perioperative care

Angiotensin-converting enzyme (ACE) inhibitors, β-blocker therapy, and aspirin were continued to the day of surgery. Clopidogrel was withdrawn 2 days prior to operation. Aspirin was started within 6 h after CABG. β-Blocker was started on postoperative day 1, if the patients were not on inotropes and vasopressor agents. All patients received atorvastatin 20 mg on the first postoperative day. Patients were monitored with continuous cardiac output with pulmonary artery flotation catheter (Edwards Lifesciences, USA) during perioperative period. Patients were treated with dual antiplatelet therapy (aspirin 150 mg + clopidogrel 75 mg) for 1 year post-CABG; thereafter, only aspirin was prescribed.

Definition of variables

Early mortality was defined as "death due to any cause within 30 days of surgery or during hospitalization." Emergency surgery was defined as patients requiring immediate surgery due to ongoing chest pain or cardiogenic shock. Recent myocardial infarction (MI) was defined as MI occurring within 30 days prior to surgical intervention. Chronic kidney disease (CKD) was defined as glomerular filtrate rate (GFR) < 60 ml/min/1.73 m^2. Cerebrovascular disease was defined to include those patients who had asymptomatic internal carotid artery stenosis with luminal narrowing of < 69%. Patients with symptomatic carotid occlusion or with > 70% luminal narrowing were excluded as they underwent concomitant carotid end arterectomy. Peripheral vascular disease was defined to include those patients who had asymptomatic luminal narrowing of lower limb arteries on Doppler analysis.

Statistical analysis

Based on the mortality rate among the patients undergoing OPCAB observed in the earlier publications, minimum sample size comes to 1200 patients. However, this study included a total of 800 cases, making it slightly underpowered. Statistical analysis was done using IBM SPSS 20.0 version (SPSS Inc., Chicago, USA). For all the continuous variables, the results are given in mean ± SD or median with interquartile range where appropriate and for categorical variables as percentage. To compare the mean difference of numerical variables between groups, independent two-sample "*t*" test was applied. To study the association of categorical variables with mortality, chi-square test was applied. *P* value < 0.05 was considered as statistically significant. Those variables with *p* value of less than 0.2 were used for multivariate logistic regression analysis for association with mortality.

Results

Early outcomes are reported in Table 2. Mean age of the study group was 61.75 ± 8.78 years. Eighteen percent were female patients; however, there was no difference in their mortality compared to male patients (*p* value 0.227). In univariate analysis, chronic kidney disease (*p* value 0.027), emergency surgery (*p* value < 0.001) development of postoperative atrial fibrillation (PoAF) (*p* value < 0.001), dialysis-dependent renal failure (*p* value < 0.001), and severe LV dysfunction (*p* value < 0.001) were associated with mortality. On multivariate analysis, emergency surgery (HR 9.72; CI 1.96–48.21, *p* value 0.005), severe LV dysfunction (HR 2.28; CI 1.25–4.76, *p* value 0.026), PoAF (HR 9.95; CI 3.12–32.01, *p* value 0.05), and dialysis-dependent renal failure (HR 29.7, CI 10.02–87.99, *p* value 0.006) were the factors associated with mortality (Tables 3 and 4). Nine patients (1.2%) required emergency conversion to on-pump due to hemodynamic instability. Seven (53.89%) patients died due to ventricular arrhythmia, two (15.3%) patients died from septic shock, and four (30.7%) died from low cardiac output and multiorgan dysfunction in the postoperative period. The observed mortality was 1.6% (13/800); the expected mortality by EuroSCORE II was 2.6% [18]. The median EuroSCORE II of expired patients was 3.03 and of entire cohort was 1.54 (*p* value 0.001). Stroke rate was 0.9%. Deep sternal wound infection occurred in 0.9%, and 4% patients were readmitted to the hospital after discharge. PoAF occurred in 18.7% patients.

Discussion

Our study showed that emergency surgery, severe LV dysfunction, POAF, and dialysis-dependent renal failure were

Table 2 Thirty-day/in-house outcomes

Variables	*N* (%) 800 (%)
Median ICU stay (days)	3 ± 2
Median ventilator hours	8.3 ± 8.2
Reexploration	8 (1)
PoAF	147 (18.37)
Post-op dialysis	8 (1)
Post-op stroke	7 (0.87)
Blood sepsis	18 (2.25)
Deep sternal infections	7 (0.88)
Readmissions	30 (3.75)
Expired	13 (1.62)
Emergency conversion	9 (1.12)

PoAF postoperative atrial fibrillation, *ICU* intensive care unit

Table 3 Association of preoperative variables with mortality

Variables	Univariate analysis			Multivariate analysis	
	Alive *n* (%) 787 (%)	Expired *n* (%) 13 (%)	*p* value	OR (95% CI)	*p* value
Age	61.69 ± 8.73	65.54 ± 10.84	0.210		
Female	140 (18)	4 (31)	0.227	0.487 (0.148–1.603)	0.227
COPD (Y)	138 (17)	3 (23)	0.603	0.709 (0.193–2.609)	0.603
PVD (Y)	120 (16)	4 (30)	0.233	0.674 (0.354–0.892)	0.233
CVD (Y)	30 (4)	3 (23)	0.312	0.986 (0.967–0.994)	0.312
DM (Y)	521(66)	10(77)	0.417	0.592 (0.164–2.134)	0.417
HTN (Y)	541 (69)	12 (92)	0.068	0.183 (0.024–1.417)	0.068
DLP (Y)	361 (46)	7 (54)	0.567	0.726 (0.242–2.181)	0.567
Recent MI (Y)	477 (61)	11 (85)	0.078	0.280 (0.062–1.271)	0.078
CKD (Y)	124 (16)	5 (38)	0.027*	3.251 (1.081–9.780)	0.027
HBa1C > 8	30(4)	3 (23)	0.435	0.98 (0.968–0.992)	0.278
Sinus rhythm (Y)	777 (99)	13 (100)	0.683	0.984 (0.975–0.992)	0.683
Median EuroSCORE II	1.51 ± 1.32	3.03 ± 6.35	0.001*		
Emergency	16 (2)	4 (31)	< 0.001**	9.72 (1.96–48.21)	0.005*
LVEF (≤ 35%)	32 (4)	5 (38)	< 0.001**	2.28 (1.25–4.76)	0.026*

COPD chronic obstructive pulmonary disease, *PVD* peripheral vascular disease, *CVD* cerebrovascular disease, *DM* type II diabetes mellitus, *HTN* systemic hypertension, *DLP* dyslipidemia, *MI* myocardial infarction, *CKD* chronic kidney disease, *LV* left ventricle, *OR* odds ratio, *CI* confidence interval

Significant *p* value < 0.05* and highly significant *p* value < 0.01**

the factors associated with early mortality. Emergency surgery, severe LV dysfunction, and dialysis-dependent renal failure are well-known risk factors for early mortality in cardiac surgery [19]. We also found that PoAF was significant risk factor for mortality. In the past, PoAF was considered as a self-limiting and benign arrhythmia [20]; however, multiple studies [21–23] have shown that PoAF increases the postoperative morbidity and mortality in short and long term. PoAF can lead to low cardiac output and hemodynamic instability and potentially increases the risk for early mortality in patients with diastolic and systolic dysfunction. It may also be a surrogate marker for a sicker patient [24].

EuroSCORE II is a robust risk model for predicting early mortality after cardiac surgery. Risk scoring systems are most

Table 4 Association of postoperative variables with mortality

Variables	Univariate analysis			Multivariate analysis	
	Alive *n* (%) 787 (%)	Expired *n* (%) 13 (%)	*p* value	OR (95% CI)	*p* value
Median ICU stay (days)	3 ± 2	5 ± 5.5	< 0.001**		
Median ventilation (h)	8.25 ± 7.96	28.4 ± 104.23	< 0.001**		
PoAF	138 (17)	9 (69)	< 0.001**	9.995 (3.12–32.01)	0.05*
Post-op dialysis-dependent renal failure	3 (0.3)	3 (23)	< 0.001**	29.7 (10.02–87.99)	0.006*
Post-op stroke	7 (0.9)	0 (0)	0.733	NA	
Post-op blood sepsis	18 (2.1)	0 (0)	0.563	NA	
Reexploration	7 (0.9)	1 (7)	0.641	0.917 (0.902–0.954)	0.641
Deep sternal wound infection	7 (0.9)	0 (0)	0.733	NA	
Readmission	30 (4)	0 (0)	0.316	NA	

PoAF postoperative atrial fibrillation, *ICU* intensive care unit, *OR* odds ratio, *CI* confidence interval

Significant *p* value < 0.05* and highly significant *p* value < 0.01**

reliable when the patient characteristics and quality of healthcare delivery are comparable with those on which the system originated [25]. Even though it is still not very well validated in Indian patients, it is important to measure risk-adjusted mortality to ensure the quality of the performance of the hospital, unit, or surgeon. In the absence of central registry, database, or public reporting of results in India, we relied on EuroSCORE II for measuring risk-adjusted mortality. Our observed mortality was less than the expected mortality by EuroSCORE II, which was reassuring. The median EUROSCORE II of expired patients was 3.03, meaning those patients had increased risk for cardiac surgery.

The data reveal significant difference from the population undergoing CABG in developed countries. The incidence of DM was 66% in our study which is much higher than 49% reported in STS database [7]. The study group seemed to have lower incidence of PoAF than reported in Western literature [26, 27]. Younger age group, racial differences, and lower body mass index are the likely reasons for this phenomenon. Continuous ECG monitoring of patients occurred only during ICU stay. More systematic ECG monitoring could result in a better identification and a higher detected incidence of PoAF. The very low incidence of intraoperative conversion to on-pump, reexploration for bleeding, new requirement of dialysis, and blood stream infection are noteworthy.

Stroke is a devastating complication after cardiac surgery. It increases the morbidity, affects the quality of life, and increases the period of hospital stay and hospital expenses. The stroke rate in this study group was 0.9% which is slightly lower than most reported series [28]. Younger age at the time of CABG and OPCAB technique could explain the lower stroke rate reported in this study compared to studies published from Western patients. Even though debatable [12, 28], OPCAB has been suggested to decrease the risk of stroke [29].

Patients requiring conversion to on-pump on emergency basis have increased morbidity and worse composite outcomes [30, 31]. Our conversion rates are lower than reported in most literature [1, 32]. The mean numbers of grafts placed were high, and LIMA usage was close to 98%. Very low usage of second arterial graft (< 5%), increased ventilator hours, and readmission rates remain a major concern and are potential areas for quality improvement.

There are several limitations in our study. India is a vast country with significant regional differences in the racial profile, socioeconomic factors, literacy rates, and healthcare delivery. Hence, outcome reported from single center may not be applicable to the entire population. Our study was also underpowered; hence, the results should be interpreted with caution. Perioperative myocardial infarction rates were not captured in the data collection. Hence, 30-day composite outcome could not be reported. We were also not able to show any data on completeness of revascularization since we did not collect information on the observed versus expected number of grafts in any patient. Outcomes of CABG have historically been measured in terms of mortality and morbidity; however, outcomes after CABG are a multidimensional phenomenon. They include long-term event-free survival, quality of life, cognitive function, and physical activity. We do not have any data on these important outcome variables.

Conclusions

Early outcome of off-pump CABG was excellent in this study. Very low usage of second arterial graft, increased ventilator hours, and readmission rates remain a major concern and are potential areas for quality improvement. Multicenter study with a larger sample size is required for a precise and dependable evaluation of the efficacy of off-pump CABG in Indian population.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Source of funding The author(s) received no financial support for the research, authorship, and/or publication of this article.

Ethical approval The study was approved by the hospital ethics committee. The need for informed consent was waived off. All personal identifying data was removed from the study database so that individuals could not be identified. “All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.”

Informed consent For this type of study, formal consent is not required.

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Discussant

Dr. Pradeep Narayan,
Consultant Cardiac Surgeon,
Rabindranath Tagore International Institute of Cardiac Sciences,
Kolkata, India.

The authors have carried out a very relevant prospective observational study assessing early outcomes of off pump coronary artery bypass [OPCAB] as a strategy for coronary revascularization in the Indian population. The study is especially important because post-CABG outcome data in Indian population is relatively sparse in the literature. However, few aspects of the study mostly related to design and statistical tests perhaps need further discussion.

Discussion

Q1. With regard to the sample size, by their own admission, the authors have reported data only on 800 (66.6%) patients of the 1200 required by the sample size calculation. A drop in sample size of this magnitude is quite significant and can the authors therefore reliably dismiss the presence of a type Ii error in their findings?

Response-

We were only able to operate on and include 800 cases during the time period of our study hence the study is stated to be underpowered and unfortunately we cannot reliably dismiss these errors.

Q2. It is well known that emergency conversions during OPCAB tend to be associated with higher adverse outcomes. Why did the authors therefore choose to include this group in the study population which brings lot of heterogeneity in the data? To identify how these patients influenced outcomes can the authors provide mortality data on the patients who underwent emergency conversion?

Response-

We have included emergency on-pump conversions as these patients had been initially included in the study preoperatively and planned for off-pump CABG. Since emergency conversion is associated with increased morbidity and mortality, we believe that this is an important variable to include in any analysis of off-pump procedures. Otherwise, it will reflect on the outcome of on-pump cases and unduly favors off-pump procedure if any comparative studies were to be undertaken.

Among the patients who underwent emergency conversions, 1 case (1/9, 11.1%) expired as compared to 8 cases that survived.

Q3. The authors have carried out a case-control study by creating two groups based on mortality. However, the two groups created are grossly unequal in numbers (787 vs. 13). Unequal sample sizes affect statistical power and type I error rates. Moreover, the chances of confounding also increase. Do the authors feel that findings of their comparison in Tables 3 and 4 are reliable or should the two groups have been created using propensity matching?

Response-

Seeing the number of cases of the two groups that are being compared it is improbable to subject these groups to propensity matching due to the stark difference in the number of cases in each group. Our statisticians have not been able to conduct propensity matching in these groups of patients; hence, difference in statistical power, type 1 error rates, and chance of confounding are present.

Q4. The incidence of HbA1c levels > 8.0 was seen in 30 (4%) in survivors and 3 (23%) in non-survivors. Quite strangely, the difference does not appear to be statistically significant. More importantly, the mortality in patients with HbA1c levels > 8.0 was nearly 9% (3 out of 33). This is an interesting finding because the mortality in this group is more than five times the mortality seen in the entire study population and in keeping with other studies which have shown that mortality quadruples at HbA1c > 8.0. [1] Did the authors include this variable in the multivariate model?

Response-

This variable has been included in the multivariate model and found to be statistically insignificant. This insignificance is probably a reflection of the different socioeconomic profile and patient population.

Q5. Cerebrovascular disease has been reported in 30 (4%) of survivors and 3 (23%) of non-survivors. Do the authors mean that these patients had previous neurological event? As patients with previous neurological event are more prone to developing adverse postoperative neurological outcomes are the authors able to comment on how many of the strokes ($n = 7$) seen in their study population occurred in patients with history of cerebrovascular disease.

Response-

Cerebrovascular disease which was reported in this study includes those patients who on Doppler analysis showed an asymptomatic non-flow limiting < 69% stenosis in unilateral internal carotid artery. None of the patients had preoperative history of any neurological event. Symptomatic carotid stenosis patients or those patients having flow limiting lesions requiring concurrent carotid endarterectomy were not included in the study. Postoperative stroke occurred only in seven cases (0.87%) in the survival group and three of them had documented cerebrovascular disease.

Q6. The study population has an extremely high number of patients with recent MI (61%). Data from the Danish, Tokyo, COAPT, SNAPSHOT, and many other registries worldwide have consistently shown CABG rates to be around 10% in patients with acute coronary syndrome. [2] Can the authors clarify whether this difference is related to the definition of recent MI used in their study or is it a reflection of a patient population with different socioeconomic profile and a different healthcare delivery strategy in India?

Response-

Recent myocardial infarction was defined as MI occurring within 30 days prior to surgical intervention. It does not mean that we had performed emergency or urgent surgery for acute coronary syndrome. Patients with documented recent myocardial infarction were seen in 61% of patients; this figure is higher than most series in CABG. This difference is probably a reflection of the different socioeconomic profile, patient population, and healthcare delivery as you rightly pointed out.

Despite some of the questions raised, the authors have to be congratulated for achieving excellent early results following OPCAB with a very low conversion rate. The report will certainly reiterate the belief that OPCAB in the Indian population is an effective strategy for coronary artery revascularization.

References

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