

Use and Outcomes of Intra-Aortic Balloon Pump in Conventional Vs Off Pump Coronary Artery Graft Surgery: A Comparative Study

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ABSTRACT

Objective: To compare the usage and outcomes of IABP undergoing conventional on-pump coronary artery bypass grafting (CABG) and off-pump coronary artery bypass grafting (OPCAB) patients.

Study Design: Comparative Cross-sectional study.

Place and Duration of Study: Adult Cardiac Surgery Unit, Tertiary Care Cardiac Center, Rawalpindi Pakistan, from Nov 2022 to Feb 2023.

Methodology: The study population comprised patients experiencing isolated coronary artery bypass grafting surgery irrespective of age and gender through non-probability consecutive sampling. CABG procedures with another concomitant procedure and conversion from OPCAB to on-pump CABG were excluded. Data entered and analyzed in SPSS v-24. Descriptive statistics were calculated and comparison between variables was made by chi-square test and independent sample t-test.

Results: 328 patients were recruited during the study duration. Out of 328, 207(63.1%) had on-pump CABG while 121(36.9%) had off-pump CABG (OPCAB). Most of the study population were males 276(84.1%), whilst 52(15.9%) were females. 202(61.6%) of the patients were hypertensive, 159(48.5%) were diabetics, 38(11.6%) were smokers and 32(9.7%) patients had intra-aortic balloon pump (IABP) insertion. Comparison between IABP usage and outcome variables was significant with CPB time ($p=0.031$), ICU stay ($p<0.001$), hospital stay ($p=0.004$), priority status of the surgery ($p<0.001$), ejection fraction ($p=0.008$) and mortality ($p<0.001$).

Conclusion: Overall, IABP remains a valuable support tool in managing high risk CABG patients.

Keywords: Coronary Artery Bypass Graft, Intra-Aortic Balloon Pump, Off Pump CABG, On Pump CABG, Outcome.

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INTRODUCTION

Globally, coronary artery disease (CAD) ranks as one of the most prevalent factors contributing to mortality. For a substantial subset of patients with CAD, coronary artery grafting surgery (first performed in 1952) is the gold standard and despite modern perioperative care and techniques the morbidity and mortality remains high.¹ The gold standard treatment for many patients with severe coronary artery disease is coronary artery bypass grafting (CABG). The traditional method of performing CABG surgery is with the help of cardiopulmonary bypass (CPB), however this is accompanied with complications such as an increased risk of stroke, a triggered inflammatory response, acute kidney injury and respiratory complications. CABG on a beating heart was introduced in the mid-1980s in attempt to avoid the complications of CPB.

Since then, there has been ongoing discussion about the ideal method and despite multiple meta-analyses' it is not yet conclusive. The fact that 95% of CABG surgery in India is performed off-pump, compared to 20% in the United Kingdom, is an excellent example of this contradiction.^{2,3}

The intra-aortic balloon pump (IABP), introduced for the first time in 1962, is one of the commonly used mechanical assistance devices in cardiac surgery.⁴ An IABP is usually inserted via the femoral artery into the descending aorta just distal to the left subclavian artery and increases coronary perfusion whilst reducing afterload on the heart.^{5,6} It is frequently used in conditions such as low cardiac output, cardiogenic shock, myocardial infarction, ventricular arrhythmias and unstable angina. It is also used to help in weaning off from CPB in the struggling heart and in optimizing hemodynamics and decreasing inotropic requirements.^{6,7} The IABP device has certain complications which include limb ischemia, hemorrhage, femoral

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pseudo-aneurysm formation, hematoma formation, acute kidney injury and mesenteric ischemia.⁹

There is a paucity of data comparing the use of IABP between conventional CABG and off pump CABG (OPCAB), despite the similarity of their early postoperative outcomes.⁸ The rationale of this study was to determine the occurrence of IABP and its associated outcomes in patients undergoing conventional and off-pump CABG surgery. Our aim was to ascertain the incidence of IABP among patients undergoing off-pump and conventional CABG, its associated factors, and its effect on short term (in-hospital) mortality.

METHODOLOGY

This Comparative Cross-sectional study was conducted during November 2022 to February 2023 at Adult Cardiac Surgery Department, Tertiary Care Unit, Rawalpindi. Approval was obtained from Institutional Ethical Review Board (IERB approval letter no. 9/2/R&D/2022/214) before the initiation of study. Data was collected through non-probability consecutive sampling technique.

Sample size of $n=58$ was calculated using WHO sample size calculator by taking prevalence of IABP use in CABG patients as 3.9%.¹⁰ at 95% Confidence level and 5% margin of error. However, 328 patients were selected to increase the power of study.

Inclusion Criteria: Patients undergoing isolated CABG surgery irrespective of age and gender.

Exclusion Criteria: CABG procedures with another concomitant procedure, conversion from OPCAB to on-pump CABG.

Patients who had IABP pre, per and post operatively were observed. Pre-operative IABP was used in patients who had difficult and diffuse coronary anatomy as judged by operating surgeon, in patients with on-going ischemia refractory to medical treatment and in patients with hemodynamic instability. Per-operative IABP was used in patients who had difficulty separating from cardiopulmonary bypass and patients who developed hemodynamic instability and electrocardiographic changes consistent with ischemia immediately after separating from bypass. IABP was inserted post-operatively in patients who developed post-cardiotomy low cardiac output refractory to inotropic support and medical optimization. The primary and secondary outcomes were noted and comparison of off pump and

conventional CABG patients was made. Patients were followed till the day of discharge. A written informed consent from the patients was obtained.

Statistical Package for Social Sciences version 24:00 (SPSS-24.0) was used to analyze the data and descriptive statistics were employed to calculate percentages, frequencies and mean \pm SD. Comparison between variables was made by chi-square test for categorical and t-test for continuous variables. p -value of <0.05 was considered significant.

RESULTS

328 patients were recruited in this study, out of which 207(63.1%) had conventional CABG while 121(36.9%) had OPCAB. Most of the study population were males 276(84.1%), whilst 52(15.9%) were females. 202(61.6%) of patients were hypertensive, 159(48.5%) were diabetics, 38(11.6%) were smokers and 32(9.7%) patients had intra-aortic balloon pump (IABP). Mean CPB time was 136.49 ± 61.35 minutes, mean intensive care stay was 67.92 ± 80.21 hours and average hospital stay was 6.84 ± 4.42 days. Mortality included 15(4.6%) patients (Table-I).

Table-II shows, out of 328 patients; only 32(9.7%) patients had IABP insertion, while 296(90.3%) patients did not require IABP. Most of the study participants required IABP during the surgery 23(7.0%), 7(2.1%) patients required IABP post-operatively and only 2(0.6%) patients had pre-operative IABP insertion. When it was compared with short term in-hospital mortality, 5(21.7%) patients had per-op IABP insertion, 2(28.6%) patients had post-operative insertion while none had pre-operatively and these findings were significant ($p<0.001$).

Comparison of IABP usage in CABG patients with demographics, clinical findings and outcome variables was calculated by Pearson's chi square test and independent sample T-test. Comparison between IABP usage and independent variables was significant in CPB time ($p=0.031$), ICU stay ($p<0.001$), hospital stay ($p=0.004$), priority status of the surgery ($p<0.001$), ejection fraction ($p=0.008$) and mortality ($p<0.001$). (Table-II). There was no statistical significance when comparing IABP use amongst those undergoing conventional CABG and OPCAB ($p=0.34$).

No association was found between patients who had IABP with type of surgery (on pump vs OPCAB) as shown in Table-III.

Table-I: Descriptive Statistics of the Study Population ($n=328$)

Outcomes of IABP usage in CABG

Variables		(Mean±SD)/n(%)
Age (years)		58.35±9.49
Weight (kg)		74.56±13.91
Height (cm)		166.44±9.25
Gender	Male	276(84.1%)
	Female	52(15.9%)
Hypertension	Controlled on medication	200(61.0%)
	No HTN	126(38.4%)
	Uncontrolled HTN	2(0.6%)
Diabetes	No	169(51.5%)
	Insulin dependent	8(2.4%)
	Diet controlled	4(1.2%)
	Oral Therapy	147(44.8%)
Smoking	Ex-Smoker > 8 Weeks	71(21.6%)
	No Smoking	219(66.8%)
	Current Smoker (< 8 Weeks)	38(11.6%)
Pre-op Creatinine		1.64±7.23
Procedure	Conventional CABG	207(63.1%)
	OPCAB	121(36.9%)
Priority status	Elective	315(96.0%)
	Emergency	9(2.7%)
	Salvage	3(0.9%)
	Urgent	1(0.3%)
IABP usage	Not used	296(90.2%)
	Pre-op	2(0.6%)
	Per-op	23(7.0%)
	Post-op	7(2.1%)
Ejection Fraction (%)	Severe Dysfunction (<30)	4(1.22%)
	Moderate Dysfunction (30-39)	25(7.6%)
	Mild Dysfunction (40-49)	104(31.80%)
	Normal (50-70)	195(59.63%)
CPB time (min)		136.49±61.35
Cross clamp (CX) time (min)		80.14±37.33
ICU Stay (hours)		67.92±80.21
Hospital stay (days)		6.84±4.42
Mortality		15(4.6%)

*OPCAB: off pump CABG, CPB: cardiopulmonary bypass, ICU: intensive care unit

DISCUSSION

The goal of the present study was to identify the use and outcomes of IABP in our setup, with a special focus on how IABP is related with the type of CABG (conventional vs off-pump).

Several studies have compared the use of intra-aortic balloon pump (IABP) with pre-operative risk factors. A study in Pakistan conducted by Ahmad *et al.*, reported frequency of IABP insertion to be 3.9% and they noted that hypertensives, diabetics and patients with reduced ejection fraction were more prone to require IABP.³ In contrast another study found that IABP was more common in non-hypertensives.¹⁰ Our study, however, showed that ejection fraction was the only significant parameter, with patients having severely and moderately reduced ejection fraction requiring IABP more frequently. This is likely due to the fact that reduced left ventricular ejection fraction accompanies with it increased mortality and morbidity, hence requiring more frequent insertion of IABP.

Table-II: Comparison of Demographics, Peri-Operative Parameters and Mortality between Patients With and Without IABP Usage (n=328)

Variables		*IABP usage		p-value
		Yes (n=32)	No (n=296)	
Age (years)		59.43±8.68	58.20±9.60	0.49
Gender	Male	29(90.6%)	247(83.4%)	0.42*
	Female	03(9.4%)	49(16.6%)	
Hypertension	Controlled on medication	21(65.6%)	179(60.5%)	0.78
	No HTN	11(34.4%)	115(38.9%)	
	Uncontrolled HTN	--	2(0.7%)	
Diabetes	Diet controlled	--	4(1.4%)	0.91
	Insulin dependent	1(3.1%)	7(2.4%)	
	No Diabetes	17(53.1%)	152(51.4%)	
	Oral Therapy	14(43.8%)	133(44.9%)	
Smoking	Ex-Smoker (>8 Weeks)	6(18.8%)	65(22.0%)	0.80
	No Smoking	23(71.9%)	196(66.2%)	
	Still Smoking (<8 Weeks)	3(9.4%)	35(11.8%)	
Priority status	Elective	26(81.3%)	289(97.6%)	<0.001
	Emergency	5(15.6%)	4(1.4%)	
	Salvage	--	3(1.0%)	
	Urgent	1(3.1%)	0	
Ejection Fraction (%)	Severe Dysfunction (<30)	2(6.3%)	2(0.68%)	0.008
	Moderate Dysfunction (30-39)	6(18.8%)	19(6.4%)	
	Mild Dysfunction (40-49)	9(28.1%)	95(32.1%)	
	Normal (50-70)	15(46.9%)	180(60.8%)	
Pre-Op Creatinine		1.09±0.30	1.70±7.60	0.65
*CPB time (min)		171.08±79.2	132.12±57.5	0.03
*CX time (min)		92.66±49.4	78.7±35.6	0.10
*ICU stay (hrs)		157.62±119.5	58.15±68.2	<0.001
In-hospital stay (days)		11.68±8.4	6.28±3.3	0.004
Mortality		7(21.9%)	8(2.7%)	<0.001

* IABP: intra-aortic balloon pump, CPB: cardiopulmonary bypass, CX: cross clamp, ICU: intensive care unit

Table-III: Comparison of Demographics and clinical variables between Conventional versus Off-Pump CABG (n=328)

Variables		Type of surgery		p-value
		On pump CABG (n=24)	Off pump CABG (n=08)	
Age (years)		58.96±8.7	60.8±8.9	0.59
Gender	Male	23(95.8%)	6(75.0%)	0.08
	Female	1(4.2%)	2(25.0%)	
*IABP	Pre- Op	2(8.3%)	--	0.48
	Per- Op	16(66.7%)	7(87.5%)	
	Post- Op	6(5.0%)	1(12.5%)	
*ICU stay (hours)		143.90±52.60	198.60±227.20	0.27
In-hospital stay (days)		10.50±5.30	14.70±13.60	0.26
Mortality		4(16.7%)	3(37.5%)	0.21

*IABP: intra-aortic balloon pump, ICU: intensive care unit

A systematic review evaluated 35 randomized controlled trials of IABP use in CABG surgery and found that the usage of IABP was related with a reduced occurrence of perioperative complications.¹¹ A study published in 2017 by Wang *et al.*, also found that IABP use was linked with a decreased likelihood of in-hospital mortality and post-operative morbidity

in patients undergoing on-pump CABG surgery, however it did not have a substantial consequence on outcomes in patients who had off-pump CABG surgery.¹² Another study published in 2021 found that the use of IABP was related with a decreased rate of postoperative complications in high-risk patients undergoing CABG surgery, regardless of whether the surgery was performed on-pump or off-pump.¹³ In contrast, complication rate and mortality was higher in patients of IABP group in a study conducted in Iceland.¹⁴ and the findings of this study were similar to ours (i.e. 21.9% mortality rate of IABP group). A reason for this mortality could be that IABP is usually indicated in patients who are already at high risk for complication and mortality during and after surgery. Two more recent trials, one of which was an RCT, found no differences in the clinical endpoints among patients but showed that the IABP group had a longer ICU stay and increased requirement of inotropes.^{15,16} Likewise other studies have also showed the increased risk of in-hospital morbidity associated with IABP.^{12,17} Data from our study reaffirms these findings and showed that use of IABP was related with longer ICU stay ($p<0.001$), hospital stay ($p=0.004$) and an increased mortality rate of 21.9% ($p<0.001$).

Meta-analysis by Poirier *et al.*, showed the use of preoperative IABP was related with a substantial decrease in mortality (OR 0.43; 95% CI 0.25-0.76; $p=0.003$), length of intensive care unit and hospital stay. They discovered a 3% incidence of IABP-related problems.¹⁸ Similar benefits of preoperative IABP use were shown by Deppe *et al.*, including a substantial decrease in hospital mortality (OR 0.44; 95% CI 0.24-0.77; $p=0.003$), and other complications.¹⁹ Rampersad *et al.*, cited many studies in their meta-analysis, that showed preoperative IABP use was linked to reduced mortality (OR 0.48; 95% CI 0.30-0.76; $p=0.002$) and post-operative outcome.²⁰ Our data also showed similar findings as no mortality was seen in patients who had a pre-operative IABP inserted, but in our sample only 2(0.6%) patients had pre-operative IABP usage ($p<0.001$). Additionally, there is some data that contradicts these assertions. For instance, Baskett *et al.*, demonstrated in a multicenter observational study that using IABP before surgery had no benefit and increased mortality in the IABP group.²¹ Slottosch *et al.*, concluded that the use of an intra-aortic balloon pump does not yield any additional advantage in patients undergoing CABG for acute coronary syndrome.¹⁶

It must be noted that the outcomes of these studies can differ depending on the patient population, surgical technique, institutional preferences and other factors. However, it seems that IABP use may benefit certain patients undergoing CABG surgery, particularly those at high risk for adverse events.

LIMITATIONS OF STUDY

This study has some limitations such as it was conducted in just one center and it was cross-sectional. One of the main limitations is that this study doesn't have equal comparable groups, which might have curtailed its significance.

CONCLUSION

IABP usage varied between ONCAB and OPCAB patients. Its use was more frequent in patients who underwent conventional CABG surgery. Overall, IABP remains a valuable support tool in managing high risk CABG patients.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript:

DAK & MIA: Concept, study design, drafting the manuscript, approval of the final version to be published.

SS & VIP: Concept, data acquisition, critical review, approval of the final version to be published.

MUA & AA: Data acquisition, data analysis, data interpretation, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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