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Original Research Article

A RETROSPECTIVE COMPARATIVE STUDY OF THE BENEFICIAL EFFECTS OF PREOPERATIVE IABP INSERTION VS NON-INSERTION IN PATIENTS UNDERGOING HIGH RISK CABG

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ABSTRACT

Background: The purpose of this study was to determine the efficacy of pre-operative Intra-Aortic Balloon Pump therapy on peri & post-operative cardiac performance, morbidity & in hospital mortality in high-risk stable patients undergoing CABG as compared to those who did not receive this therapy. Also, to ascertain the optimal timing of IABC insertion in these patients preoperatively.

Materials and Methods: It is a retrospective study conducted between July 2022 to June 2024 in which 50 consecutive high-risk coronary artery disease patients undergoing CABG work included. Patients were selected as per inclusion criteria. 21 patients (Group 1) received IABP preoperatively (12 to 24 hours prior to surgery) and 29 patients (Group 2) did not receive this therapy. Their demographic & clinical profiles were studied & intra & postoperative parameters & outcomes were compared & benefits evaluated.

Results: Conversion to on pump CABG was more in Group 2 (Non IABP) than Group 1 (IABP Group) (P=0.0401). There was also increased ionotropic requirement postoperatively in Group 2 (P=0.0093). Though there was no hospital mortality in either of the group, but there was prolonged ICU stay in Group 2 patients (P=0.0435). However, this did not translate into significant increase in hospital stay.

Conclusion: This study demonstrated that preoperative IABP therapy is an efficient and safe supportive modality which significantly reduces the risk for hemodynamic instability in high-risk patients undergoing CABG. Insertion of IABC, 12 to 24 hours prior to CABG in these patients enables smooth induction of anaesthesia & safe performance of off- pump CABG (OPCAB) & converts high-risk to medium or low risk surgery.

Keywords: Intra-aortic Balloon Pump, Coronary Artery Bypass Grafting, Coronary Artery Disease, Off Pump Coronary Artery Bypass.

INTRODUCTION

The use of intra-aortic balloon pumps (IABPs) as a temporary mechanical support for ventricular assistance in treating heart disease and left ventricular dysfunction is well established.[1] Ischemic heart disease is the primary cause of left ventricular dysfunction.[2] Despite advances & development within interventional cardiology, Coronary Artery Bypass Grafting (CABG) remains the guideline treatment of choice for patients with severe coronary artery disease due to excellent outcomes achieved.[3-4]I IABPs are used prophylactically and have been shown to augment myocardial oxygen supply,[5-6] decrease myocardial oxygen demand, and increase diastolic perfusion of coronary arteries.[7] The incidence of operative mortality is high in patients with poor LV function undergoing CABG than in patients with normal or moderately dysfunctional hearts.[8]

The American Heart Association recommends CABG as a class-1 indication for patients with symptomatic CAD and left ventricular (LV) dysfunction. The 2011 American College of

Cardiology/American Heart Association Guideline for Coronary Artery Bypass Graft surgery, which is based on results of several randomized control trials (RCTs), recommended use of IABP to reduce in-hospital mortality for high-risk patients, who have severe left main CAD, left ventricular EF<30% or recent MI.[9]

The use of IABP could provide critical temporary support for the functioning of left ventricle and help to prevent ischemic heart failure thus reducing peri-operative mortality associated with CABG.[10]

The results of perioperative use of IABP in patients with low EF and hemodynamic instability are well studied,[11] however there are limited studies about pre-operative use of IABP in stable patients with critical CAD undergoing high-risk CABG. Nevertheless, there is no recommendation on whether to use IABP in such patients, leading to experience-based application of IABP being implemented in many centres. More-over the effective timing for IABC insertion has also not been clearly established.[12]

This study aims to analyse the pre-operative insertion of IABP, timing and its efficacy in peri and post-operative performance in high-risk patients undergoing CABG when compared to patients who did not receive IABP therapy.

MATERIAL AND METHODS

This retrospective analytical study examined the data collected from Himalayan Institute of Medical Sciences, Dehradun (a tertiary care centre) between July 2022 and June 2024. The study was approved by the Institutional Scientific Committee and conducted in accordance with the Ethical Committee of the Institute.

Patient Selection

The study population comprised of all the patients considered as high-risk who were subjected to elective Coronary Artery Bypass Grafting (CABG) at Himalayan Institute of Medical Sciences between July 2022 and June 2024. Included patients were diagnosed as cases of coronary artery disease (CAD) by Coronary angiography. 2D echocardiography was used to determine their ejection fractions. Biplane Simpson method was used to assess LV regional wall motion abnormality and LV enlargement[13]. Patients were categorized into two groups: Group 1 (IABP group) received preoperative IABP therapy, while Group 2 (non-IABP group) did not. Those who received preoperative IABP therapy had IABC insertion 12-24 hours prior to CABG & constituted Group 1 of the study.

Inclusion and Exclusion Criteria,[14]

High-risk patients were defined as those with at least two or more of the following risk factors:

Inclusion Criteria

1. Poor left ventricular (LV) function (LVEF ≤ 35%).
2. Diffuse CAD requiring three or more distal anastomoses.
3. Left main stenosis > 70%.
4. Unstable angina despite optimal medical management.
5. NYHA class III or IV.
6. Recent myocardial infarction (MI of over 24 hours but < 4 weeks at the time of CABG).
7. Acute ongoing angina.

IABC was inserted approximately 12-24 hours prior to CABG in Group 1 patients.

The High-risk CABG patients who were not subjected to IABP therapy were the ones who had:

a. Severe Peripheral Vascular Disease.
b. Low moderate aortic regurgitation (AR).
c. Those who did not give consent for IABP.

They were in Group 2 of the study.

Patients having any one of the following criteria were excluded from the study.

Exclusion Criteria

1. Patients requiring emergency CABG.
2. Patients with hemodynamic instability.
3. Patients undergoing CABG with valve replacement.
4. Ischemic mitral regurgitation greater than Grade-2.
5. Patients with post-MI complications (like MR or post-MI VSD).

Definitions of Perioperative Events,[15]

1. Hospital mortality was considered as any death in postoperative period or within 30 days of surgery and was considered as primary end point or major adverse event.
2. Conversion to on-pump CABG (use of Cardio Pulmonary Bypass) was noted as an unfavorable event.

Peri-operative MI was defined as

a. new Q waves of > 0.04 milli-seconds in ECG
b. reduction in "R" waves of >25% in at least two leads.
c. new akinetic or dyskinetic segment on ECHO.
d. peak Troponin I level of at least 3.1 g/L at 12 hours of surgery.

4. Hospital morbidity was defined as any complication requiring specific treatment, causing a delay in discharge from ICU or hospital or complication occurring within 30 days of surgery.

5. ICU stay was defined as hours required for intensive care. Prolonged ICU stay was considered as 7 or more days in ICU.

6. Hospital stay was defined as days required for hospitalization from the day of surgery. Prolonged hospital stay was considered if patient was discharged on 12th or more POD (post op day).

7. Neurological complications were any new transient or permanent neurological deficit appearing after surgery & corroborated using Computed Tomography and Magnetic Resonance Imaging. Final diagnosis was done by neuro-surgeon. Transient ischemic attacks were not included.

8. Postoperative renal failure was defined as increase in serum creatinine value of > 2.5 mg/dl or patient requiring dialysis.
9. Pulmonary complications were defined as atelectasis or x-ray-verified pneumonia after surgery.
10. Prolonged ventilation was considered if patient needed ventilatory support for more than 12 hours.
11. High inotropic support was considered if:
a. three or more inotropes were required.
b. inotropes required on higher side of dose range.
c. inotropic support required for more than 48 hours.

This study examined 50 high-risk patients undergoing elective coronary artery bypass grafting (CABG) at our center. Patients were divided into two groups: Group 1 (IABP group, n=21) and Group 2 (non-IABP group, n=29). All Group 1 patients underwent preoperative IABC insertion 12-24 hours prior to surgery in the intensive care unit. Sheath less IABC insertion was performed using Seldinger's technique through the femoral artery. A 40 cc, 8 Fr balloon catheter was used for patients with heights between 5'4" and 6 feet, while a 36 cc, 7 Fr balloon catheter was used for patients with heights between 5' and 5'4". The balloon catheters were connected to a Data scope pump CS 300. Positioning was confirmed immediately with chest x-ray, and the tip of the balloon was ensured to be just distal to the arch of the aorta. All patients were anticoagulated with intravenous heparin to maintain APTT 1.5-2 times that of normal value.

Intra-aortic balloon pump assistance was set at a 1:1 ratio in all patients. The protocol for flushing of the IABP catheter every hour and hourly checks on peripheral pulses (Dorsalis Pedis & Posterior Tibial) of the limb with IABP was strictly followed. Patients returning from the operating room with IABP were anticoagulated with 1 mg/kg of heparin given eight hourly, started after six hours of return from the operating room and after watching mediastinal drain. Weaning of IABP was done after extubation and was dependent on hemodynamic stability of the patient post-surgery[15].

Measurements

All patients in both groups were equipped with central venous catheters, urinary catheters, and multi-lead ECGs. Periodically, arterial blood gas analysis was done along with continuous ECG, arterial BP, CVP, and SPO2 monitoring. Pre- and post-operative samples were analyzed for hematocrit, platelet counts, serum creatinine, CPK-MB, and Trop I, along with 12-hourly ECG recordings. Hourly urine output and bleeding from mediastinal drains were recorded. Neurological status was checked once patients were awake.

Surgical Procedure

Standard induction of anesthesia and surgical techniques were used. CABG was performed in all patients with median sternotomy and conventional techniques were used for complete myocardial revascularization. In Group 2 patients, purse strings for aortic cannulation were taken in advance, in case of requirement of cardiopulmonary bypass. The left internal mammary artery (LIMA) was used as a pedicled graft to revascularize the most critical vessel in almost all patients, the left anterior descending coronary artery (LAD). This was done to provide backup for the less critical vessels and areas. Other conduits were mainly reverse saphenous vein grafts. LIMA was used to bypass LAD in all patients of both groups as a pedicled graft. The anastomosis was done using 8-0 polypropylene continuous suture. 7-0 polypropylene suture was used for all distal anastomoses for reverse saphenous vein grafts. Proximal anastomoses were done after distal anastomoses, and all were made on the ascending aorta using a single partial clamp with 6-0 polypropylene continuous sutures. The dose of heparin for OPCAB was 1.5 mg/kg to maintain ACT greater than 300 seconds. On conversion to on-pump CABG, the dose of heparin was doubled to 3 mg/kg to achieve target ACT greater than 480 seconds.

Normothermia was maintained, and this was aided by a warm circulating water blanket. In patients undergoing OPCAB, three deep pericardial stay sutures of number 1 silk were used at standard positions to help lifting and positioning the heart. Multiple wet gauze rolls were used along. Positioning of the heart was enabled by changing body position through Trendelenburg, right and left rotation of the table being carried out during surgery. Further exposure of coronary arteries was aided by suction, mechanical stabilizer, the Octopus 3 (Medtronic). Intra-coronary shunts (Medtronic Inc.) were used to maintain distal perfusion during coronary anastomosis. A CO2 Mist blower device provided a bloodless operative field for perfect anastomosis.

Conversion to on-pump (use of CPB) was considered if there was any hemodynamic instability like ventricular arrhythmia, hypotension (systolic BP $\leq$ 80 mmHg), or cardiac arrest during OPCAB surgery.

On-pump CABG was performed using the same techniques, primarily while the heart was beating, except in cases of cardiac arrest, where cardioplegia was used to arrest the heart. Grafting was performed in a standardized sequence, commencing with the left internal mammary artery to the left anterior descending coronary artery, followed by the right coronary artery, and finally, the left circumflex coronary artery branches.

The primary endpoint was postoperative 30-day mortality, defined as death occurring within 30 days of surgery. Conversion to on-pump CABG was considered as an adverse event. Secondary endpoints included major postoperative complications, such as:

1. Low cardiac output syndrome requiring high inotropic support
2. Myocardial infarction
3. Postoperative atrial fibrillation
4. Bleeding requiring re-exploration
5. Stroke
6. Major adverse cardiac and cerebrovascular events (MACCE)

These endpoints were carefully monitored and recorded to assess the safety and efficacy of the IABP therapy in high-risk patients undergoing CABG.

Statistical Analysis

Statistical analysis was conducted using SPSS version 20.0 and GraphPad Prism 8. The Mann-Whitney U test was employed for comparisons between the two groups. The association of comorbidities was assessed using the Chi-Square test. Statistical analysis is depicted in Table-3.

Their demography & preoperative clinical data are listed in (Table – 1) & (Table – 2).

Table 1: Patient Demography

Characteristic		Total (n=50)	Group 1: Prophylactic IABP (n=21)	Group 2: Non IABP (n=29)
Age, years	Mean		60.1429	57.6207
	Std. Deviation (SD)		9.46195	11.70291
	Median (IQR)		60.00	61.00
Gender	Male (%)		16 (76.2%)	25 (86.2%)
	Female (%)		5 (23.8%)	4 (13.8%)
	Total (%)		21 (100%)	29 (100%)
Height, cm	Mean		161.286	161.776
	Std. Deviation (SD)		9.5715	6.8915
	Median (IQR)		160.00	163.00
Weight, kg	Mean		61.81	66.24
	Std. Deviation (SD)		10.966	10.155
	Median (IQR)		63.00	65.00
BSA, m^2	Mean		1.647143	1.720345
	Std. Deviation (SD)		0.1808354	0.1512208
	Median (IQR)		1.60	1.70

Table 2. Preoperative Clinical Data

Characteristic		Total (n=50)	Group 1: Prophylactic IABP (n=21)	Group 2: Non IABP (n=29)
Hypertension	Frequency		12	12
	Percentage		57.14	41.37
Diabetes mellitus	Frequency		7	12
	Percentage		33.33	41.3
Smoking	Frequency		10	15
	Percentage		47.6	51.7
Post PTCA	Frequency		3	6
	Percentage		14.28	20.6
Recent MI	Frequency		9	18
	Percentage		42.8	62
NYHA III & IV	Frequency		16	25
	Percentage		76.2	86.2
LVEF	Mean		46.1	46.1
	Median		45	45
Coronary Angiography	LM Disease		15	14
	TVD		6	15
Peripheral Artery Disease	Frequency		1	5
	Percentage		4.7	17.24
Serum Creatinine (mg/dl)	Mean		0.927143	0.87777
	Std. Deviation (SD)		0.1489679	0.1376678
	Median (IQR)		0.90	0.87
Serum Albumin (g/dl)	Mean		4.00	4.007931
	Std. Deviation (SD)		0.3856627	0.4669305
	Median (IQR)		4.00	4.00

RESULTS

This study included 50 consecutive high-risk patients undergoing CABG, divided into two groups: Group 1 (Pre-op IABP, n=21, 42%) and Group 2 (Non-IABP, n=29, 58%). Demographic data (Table 1) and pre-operative clinical data (Table 2) showed no significant differences between the two groups in terms of age, gender, body surface area (BSA), and clinical profile.

Intraoperative findings

- Induction of anesthesia was eventful in 4/29 patients in Group 2 compared to 1/21 patients in Group 1 (p=0.06).
- Conversion to on-pump surgery was significantly higher in Group 2 (8/29, p=0.04) compared to Group 1 (1/21).
- High inotropic support was required in 8/29 patients in Group 2 (p=0.009), which was statistically significant.

Postoperative outcomes:

- There was no hospital mortality in either group.
- ICU stay was prolonged in Group 2 (p=0.043), but hospital stay was not significantly different between the two groups. 10/29 patients in Group 2 required prolonged ICU stay where as only 2 patient of Group 1 required prolonged ICU stay.
- 12 patients in Group 2 required prolonged hospital stay compared to 5 patients in Group 1. This was of clinical significance but did not meet statistical significance (p=0.2).
- No patients had renal insufficiency or required re-exploration due to excessive bleeding.
- Adverse cardiac events were minimal, with 2 patients in each group experiencing atrial fibrillation, managed with intravenous amiodarone infusion.
- One patient in Group 2 had left hemiparesis, which recovered with conservative management within 24 hours. CT scan brain showed no changes, despite supra-aortic trunk disease (SAT) diagnosed preoperatively.

Postoperative follow-up

- 1 patient in Group 1 developed pseudoaneurysm of the right external iliac artery (side of IABC insertion) on the 22nd postoperative day and underwent exploration and repair.
- 2 patients in Group 2 had delayed wound healing due to poor sugar control, but no surgical wound infections occurred.

Table 3:

S. No.	Parameters	Group 1 with IABP	%	Group 2 Non – IABP	%	P Valve	95% Confidence Interval CI	Chi-Square
	No. of Cases	**21**	**42%**	**29**	**58%**			
1.	On Pump Heart lung machine used	1	4.76%	8	27.59%	**0.0401**	**0.7673% to 41.3789%**	**4.215**
2.	Eventful Induction of anaesthesia	0	0.00%	4	13.79%	0.079	3.7579% to 30.5533%	3.085
3.	High Inotropes Required	0	0.00%	8	27.59%	**0.0093**	**7.4593% to 45.7210%**	**6.76**
4.	Neurologic Complicated	0	0.00%	1	3.45%	0.3947	12.2722% to 17.1780%	0.725
5.	Vascular Complications	1	4.76%	0	0.00%	0.24	7.5748% to 22.6667%	1.38
6.	Paralytic Ileus	0	0.00%	2	6.95%	0.2239	9.3480% to 21.9692%	1.479
7.	Prolonged ICU Stay	2	9.52%	10	34.48%	**0.0435**	**0.7236% to 44.3874%**	**4.077**
8.	Prolonged Hospital Stay	5	23.81%	12	41.38%	0.2	8.9752% to 39.7860%	1.642
9.	Smoking	10	47.62%	15	51.72%	0.7769	22.3478% to 29.7284%	0.08
10.	Male Gender	16	76.19%	25	86.21%	0.3675	11.3068% to 32.8609%	0.812
11.	Diabetes	7	33.33%	12	41.38%	0.5667	18.5046% to 32.1377%	0.328
12.	No. of grafts > 3	9	42.86%	16	55.17	0.395	14.7974% to 36.9586%	0.724

DISCUSSION

The use of intra-aortic balloon pump (IABP) for temporary mechanical support to assist a failing heart has been established for a long time [1]. However, the consensus on the benefits of prophylactic IABP use is not yet widespread. Several studies have shown that prophylactic IABP insertion in high-risk patients undergoing bypass surgery reduces postoperative mortality.[3,11] For instance, Dyub et al. reported a mortality benefit with an odds ratio (OR) of 0.41 (95% CI 0.21-0.82; p=0.01) for patients who received prophylactic IABP preoperatively.[17]

Despite multiple studies reporting the benefits of prophylactic IABP[1,2,3,] it has not been established as the gold standard for high-risk CABG due to concerns about complications. Patients receiving IABP are considered at higher risk of bleeding, prolonged ventilation, limb ischemia, and prolonged ICU stay.[18,19] However, if patients are evaluated preoperatively for possible contraindications to IABP (such as peripheral vascular disease) and strict postoperative surveillance is maintained, the complications of IABP can be minimized.

The purpose of this study was to evaluate the benefits of preoperative use of IABP in stable patients with critical CAD undergoing high-risk CABG and to determine the optimal timing of IABC insertion and its effect on perioperative performance in these patients compared to those who did not receive IABP therapy.

Recent studies have suggested that preoperative prophylactic use of IABP has proven efficacy in significantly decreasing morbidity and hospital mortality in high-risk patients undergoing CABG.[20] The beneficial effects of preoperative IABP insertion in high-risk CABG patients are due to improved myocardial oxygen supply and demand ratio, reduced

ventricular wall stress, and improved coronary perfusion and redistribution of blood flow to ischemic myocardium.[5,12]

Preoperative IABC insertion results in reduction of myocardial ischemia avoiding progressive cardiac dysfunction and minimizes low flow episodes with subsequent end organ dysfunction.[14]

Timing of IABC insertion is important. Crucial times for higher oxygen demand include induction of anesthesia and the time when conduits are being harvested. Any transient hypotension during these phases may induce critical ischemia leading to acute myocardial damage or even myocardial infarction.[15]

Preoperative IABP institution not only reduces mortality in high risk patients[20] but also stabilizes patient for safe induction of anaesthesia[11] and allowing off pump CABG (OPCAB) thus avoiding all side effects of cardio-pulmonary bypass.[15,21]

The Benchmark Registry showed that prophylactic use of IABP was associated with reduced mortality in high-risk patients.[21]

Intra-aortic balloon catheter insertion can occasionally be cumbersome or risky due to severe and diffuse atherosclerosis of peripheral arteries & descending aorta or even contraindicated because of abdominal aortic aneurysms and aortic regurgitations. Major disadvantages related to IABP use thus far were, complications associated with its placement, which include aortic dissection, balloon rupture, balloon entrapment, bleeding, limb ischemia & vascular injury.

Limitations

This study has several limitations. The primary limitation is the small sample size, which may not be representative of the entire population. To address this, future research should aim to recruit a larger number of participants, preferably in a multi-centric study, to increase the generalizability of the findings. Additionally, the study's follow-up period was limited to in-hospital morbidity and mortality, as well as short-term follow-up. To fully validate the results, longer-term follow-up is necessary to assess the extended effects of preoperative IABP insertion on patient outcomes.

Future studies should also consider addressing other limitations, such as

- Potential biases in patient selection and allocation
- Limited generalizability to other patient populations or settings
- Inability to control for all confounding variables
- Limited assessment of long-term outcomes and quality of life

By acknowledging and addressing these limitations, future research can build upon the findings of this study and provide more comprehensive and generalizable insights into the benefits and risks of preoperative IABP insertion in high-risk CABG patients.

CONCLUSION

Our study demonstrates that preoperative IABP therapy is a safe and effective supportive modality that significantly reduces the risk of hemodynamic instability in high-risk patients undergoing CABG. It improves cardiac performance and should be used liberally. Optimal timing of IABP insertion is 12 to 24 hours prior to surgery, allowing for smooth induction of anesthesia and safe performance of off-pump coronary artery bypass (OPCAB).

Conflict of Interest: The authors declare that they have no conflicts of interest.

Consent: This study was performed in accordance with the institutional ethics committee's guidelines and regulations.

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