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Research Article

Prophylactic Application of an Intra-Aortic Balloon Pump in High-Risk Patients Undergoing Off-Pump Coronary Artery Bypass Grafting

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Abstract: The use of prophylactic intra-aortic balloon pump (IABP) in off pump coronary artery surgery (OPCAB) debated and not well established. The aim of this study is to evaluate whether prophylactic IABP improves the early outcome in hemodynamically stable, high-risk patients undergoing coronary artery bypass grafting (CABG). From January 2013 to March 2014, 80 high risk patients underwent CABG. Of these 45 received prophylactic IABP. The remaining 35 patients underwent operation without preoperative insertion of the device. Results of the study shows that patients in the IABP group had a significantly shorter duration of IABP support (18.9 ±5.9 vs. 46.7±8.9 hours, $p < 0.0001$), shorter duration of inotropic drug treatment (28.9 ± 8.6 vs. 68.6 ± 6.5 hours, $p < 0.0001$), shorter duration of mechanical ventilation (13.4 ± 6.4 vs. 29.8 ± 8.2 hours, $p < 0.0001$), shorter length of intensive care unit stay (41.5 ± 7.8 vs. 111.6 ± 15.9 hours, $p<0.0001$. This study shows that prophylactic IABP treatment for hemodynamically stable high-risk patients undergoing CABG may improve postoperative course.
Keywords: IABP, OPCAB, CABG.

INTRODUCTION

Intra-aortic balloon pump (IABP) is used to augment myocardial function by decreasing oxygen demand and increasing oxygen supply to the myocardium. It has been introduced in 1962, a device for mechanical circulatory support by Moulopoulos et al.; [1] Insertion of an IABP in the failing myocardium results in a more favorable myocardial supply: demand balance [2]. After load is reduced and diastolic pressure augmented [3, 4] resulting in an increased stroke volume and cardiac output. Previous studies have demonstrated that the augmented diastolic pressure results in a redistribution of coronary blood flow towards ischemic areas of the myocardium [5, 6]. IABP has evolved as a means of providing mechanical circulatory support in patients with coronary artery disease (CAD) that has progressed into cardiogenic shock. IABP is an established additional support to pharmacological treatment of the failing heart after myocardial infarction, unstable angina and cardiac surgery [7, 8, 9].

On off pump coronary artery bypass (OPCAB) grafting in patients with severe preoperative left ventricular dysfunction, because of inadequate myocardial protection, it could results in peri operative myocardial infarction, prolonged cardiopulmonary bypass (CPB) and intra operative ischemic times, technical difficulties with the conduct of the operation or incomplete revascularization.(10) In these clinical conditions, patients may benefit Preoperative IABP. Timing of IABP implantation has been shown to be closely related to mortality. Preoperative insertion is associated with a mortality of 18.8–19.6%; intra-operative insertion with 27.6–32.3%, and postoperative insertion with 39–40.5 % [11] Several studies demonstrated the efficacy of preoperative IABP in terms of postoperative mortality and morbidity [11, 12, 13, 14] IABP is an established tool in unstable patients undergoing urgent myocardial revascularization for an acute myocardial infarction. The aim of our study is to analyze the role of prophylactic IABP in high risk Patients Undergoing Off-Pump Coronary Artery Bypass Grafting.

MATERIAL AND METHODS

The study was conducted at L.P.S Institute of Cardiology, G.S.V.M Medical College, Kanpur. After obtaining Institutional Ethics Committee approval 80 patients were included in the study that was conducted from January 2013 to march 2014. The study is prospective randomized and double blinded.

High-risk Hemodynamically stable patients undergoing scheduled OPCABG were included in the study. High-risk patients were identified by the presence of more than two of the following risk criteria at preoperative evaluation:

(1) Left-ventricular ejection fraction <40%;
(2) Left-ventricular end-diastolic internal diameter >65 mm;
(3) Left main stenosis >70%;
(4) Refractory unstable angina despite intravenous administration of heparin sodium and nitroglycerine
(5) Diffuse coronary artery disease (defined as the requirement for four or more distal anastomoses to achieve complete revascularization).

Exclusion criteria included IABP implantation prior to coronary artery bypass grafting (CABG) for poorly controlled preoperative ventricular arrhythmias or mechanical complications due to acute myocardial infarction, emergent or urgent CABG surgery. Patients undergoing urgent switching from off-pump to on-pump CABG during surgery were also excluded.

Patients were randomly allocated according to a Computer-generated randomization into two groups. One group underwent preoperative insertion of an IABP before OPCAB and the other group underwent OPCAB without support of IABP. In the IABP group, an 8-F non-sheathed catheter with a 35 – 40-ml, Balloon was inserted percutaneously via the common femoral artery, under local anaesthesia, 12 hour prior to OPCAB surgery. The IABP console was set to be triggered by the ECG or arterial waveform and was programmed to produce counter pulsation at a frequency of 1: 2. All procedures were performed through a median sternotomy. The internal mammary arteries, the great saphenous veins and the radial arteries were obtained as conduit vessels. Heparin 100 IU/kg was administered to maintain an activated clotting time (ACT) > 300 seconds. After the anastomoses at the end of surgery, protamine was administered to neutralize the heparin. The IABP was removed when the patient was conscious, extubated and haemodynamic stability was restored, as demonstrated by a cardiac index > 2 l/min per m2 for ≥ 10 min on suspension of the IABP counter pulsation, with only minimal pharmacological inotropic support. In the control group, OPCAB was performed without the use of an IABP.

Definitions

Peri operative myocardial infarction was defined as elevation of creatinine kinase MB fraction and or troponin I with the development of new electrocardiographic Q-wave. Postoperative renal dysfunction (PDR) was defined as patients with postoperative creatinine level >2.3 mg/dl or patients requiring dialysis. Neurological complications were defined as transient or persistent postoperative hemi paresis or neurological dysfunction with morphological substrate confirmed by computer tomography or nuclear magnetic resonance imaging. Postoperative mortality was defined as death occurring within 30 days from surgery. The threshold for blood transfusion was hemoglobin values <8 mg/dl in a stable situation and <9 mg/dl in an unstable situation.

Statistical analysis

Continuous data with normal distribution are given as Mean±SD; Comparisons were performed with Student's test or Mann–Whitney tests or with x2-test or Fisher's exact test, when appropriate. Propensity score matching analysis was performed to select background-matched patients to the IABP group. Each postoperative variable was compared with preoperative ones or those for postoperative day 1 on Dennett's test when repeated analysis of variance was significant.

RESULTS

A total number of 80 high-risk patients undergoing OPCAB were included in our study. Out of 80, 45 patients underwent preoperative insertion of an IABP before OPCAB (IABP group), while the other 35 patients underwent OPCAB only (control group).

Patients characteristic are almost similar in both the groups. Demographic profile, clinical and laboratory profile variables in both the groups are statistically insignificant. (Table 1).

Peri operative variables during our study, of IABP group were compared with patients in the control group, patients in the IABP group had a significantly shorter duration of IABP support (18.9 ±5.9 vs. 46.7±8.9 hours, $p < 0.0001$), shorter duration of inotropic drug treatment (28.9 ± 8.6 vs. 68.6 ± 6.5 hours, $p < 0.0001$), shorter duration of mechanical ventilation (13.4 ± 6.4 vs. 29.8 ± 8.2 hours, $p < 0.0001$), shorter length of intensive care unit stay (41.5 ± 7.8 vs. 111.6 ± 15.9 hours, $p<0.0001$). There are also lower incidence of pacing requirement, respiratory failure, renal failure and stroke in the IABP group as compared to control group but not statistically significant. (Table 2)

Table-1: Demographic, Clinical and Laboratory Variables

Variable	IABP Group (Mean±SD)	Control (Mean±SD)
Age(years)	48±5	45±7
Male	28	25
Female	17	10
Heart failure	20	16
Unstable Angina	11	9
myocardial infarction	21	16
Co morbid Disease		
COPD	11	9
Diabetes Mellitus	16	18
Hypertension	17	19
Renal Dysfunction	7	5
Smoker	17	14
2D Echo		
Ejection Fraction (<40%)	35	28
LVEDD (>65mm)	19	14
LVESD (mm)	34±3.5	35±5.2
MR	11	9
Angiography		
LMCA (>70%)	14	8
DVD	23	21
TVD	17	13
Laboratory		
Hemoglobin(g/dl)	12.7±1.2	12.3±0.9
Serum Creatinine(mg/dl)	1.5±1.4	1.4±1.7
Serum Total Bilirubin(mg/dl)	1.7±1.2	1.9±1.4
Serum Albumin(mg/dl)	3.1±2.1	3.5±1.2

Table-2: Peri operative Variables

Variables	IABP Group	Control Group
Times of IABP (hour)	18.9±5.9	46.7±8.9
Inotropic Support	28.9±8.6	68.6±6.5
CPB Support	4	7
Pacing	7	12
Re-Exploration(bleeding)	6	9
Mechanical Ventilation	13.4±6.4	29.8±8.2
Respiratory Failure	3	5
Renal Failure	3	6
Stroke	2	3
Media stinitis	3	3
ICU Stay	41.5±7.8	111.6±15.9
Mortality	2	4

DISCUSSION

IABP is common temporary mechanical circulatory assistance device used in clinical practice for weaning from CPB and management of low cardiac output during CABG [15]. The IABP is a volume displacement device designed to provide partial assistance to the left ventricle by inflation and deflation of IAB catheter synchronized to the patient's cardiac cycle. By deflating the balloon just prior to the ventricular systole, inertial resistance to blood flow is reduced and left ventricular after load falls, this result in increased stroke volume and cardiac output (10-40%), decrease in heart rate and pulmonary artery wedge pressures [16, 17].

Inflation of the balloon at the commencement of the diastole results in increased aortic diastolic pressure (up to 70%). Since diastolic blood flow is responsible for 70% of cardiac perfusion, coronary and cardiac flow should theoretically increase [18]. It also improves the sub endocardial perfusion and promotes the redistribution of coronary blood flow to the ischemic myocardium [19]. There is a fall in peak systolic arterial pressure of 5%-15%, with no change in mean arterial pressures [20]. Previously IABP used as a rescue therapy in case of failure of inotropic support to improve low cardiac output following CABG but there are evidences for preoperative IABP use during CABG in patients with low ejection fraction, re-operation, and NYHA class III–IV symptoms [21, 22]. In addition,

IABP helps to improve the hemodynamic stability and reduce the myocardial oxygen consumption when the heart is displaced to expose and graft the target coronary artery during OPCABG, especially in high-risk patients who were previously considered to be inoperable [23].

The ultimate aim of prophylactic IABP is to increase myocardial oxygen supply and decrease myocardial oxygen demand, increases the safety of surgery, avoiding the anaesthesic or surgical crises, which may be associated with later insertion.

Christenson *et al.;* showed reduction in morbidity, mortality and hospital stay [5, 6] similar result shown by gutfinger et al.; with population of older patients in his study [17]. Oberhofffer *et al.;* study concludes similar results and also shown marked reduction in inflammatory marker (serum lactate and interleukin-6) in IABP group [24]. One study also shows zero rate of conversion to CPB with use of prophylactic IABP during OPCAB. several randomized controlled studies (RCT) and 2 meta-analyses [5,6,7,8.25,26] have also shown favorable outcomes with prophylactic use of IABP preoperatively.

Basket *et al.* shows no effectiveness of prophylactic IABP and there is increase mortality shown in his study, the patients population in the study has high proportion of urgent operation [20]. Holman *et al*. study also shows shorter length of hospital stay with no survival advantage [19]. Our study demonstrated that with the use of preoperative IABP placement, we can ensure the patient safety during OPCAB surgery and help in improvement in the prognosis for patients with high risk CAD, there is reduced IABP support time, inotropic support, mechanical support and ICU stay and also there are fewer peri operative complications with the use of preoperative IABP. Although there is much change seen in mortality rate with IABP that may be due to short duration of the study, and enrollment of relatively sicker populations, which may inherently be predisposed to instability. These findings of our study confirm the results of previous clinical trials investigating preoperative insertion of IABP by showing advantage in terms of outcomes compared to intra- or postoperative insertion in high-risk patients.

CONCLUSION

Prophylactic application of IABP during high-risk OPCAB surgery, lowers the duration of IABP support, reduces the risk of hemodynamic instability, and shortens both ICU and hospital length of stay significantly.

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