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Preoperative use of intra-aortic balloon pump in multi vessels coronary artery disease patient's undergoing coronary artery bypass graft

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Abstract
Cardiovascular disease is considered a major problem in our society. Affected 110 million people and resulted in 8.9 million deaths. Use of pre-operative intra-aortic balloon pump (IABP) therapy is an effective modality in protecting high-risk patients undergoing coronary artery bypass grafting (CABG) surgery. The intra-aortic balloon pump (IABP) is a mechanical device that increases myocardial oxygen perfusion and simultaneously increases cardiac output. Increase cardiac output enhances coronary blood flow and therefore myocardial oxygen delivery. We observed that all were high risk cases and preoperative insertion of an intra-aortic balloon pump would benefit them. There were no cases of IABP-related mortality. No severe bleeding at the IABP insertion site, or balloon failure in any of the patients.

Keywords: use of intra-aortic balloon pump, in low ejection fraction & left main disease, with multi vessels coronary artery disease undergoing coronary artery bypass graft

Introduction
Cardiovascular disease is considered a major problem in our society, and is one of the major causes of death among humankind [1, 2]. In 2015 Coronary Artery Disease (CAD) affected 110 million people and resulted in 8.9 million deaths. It makes up 15.9% of all deaths making it the most common cause of death globally [3]. To prevent further sequela cardiac surgery has taken huge strides in the past 5 decades, ever since the first open heart surgery was performed by John Gibbon in 1952 using cardiopulmonary bypass [4]. CABG is a surgical procedure performed to relieve angina and reduce the risk of death from coronary artery disease.
Use of pre-operative intra-aortic balloon pump (IABP) therapy is an effective modality in protecting high-risk patients undergoing coronary artery bypass grafting (CABG) surgery [5, 6]. Pre-operative IABP therapy improves cardiac performance by providing better coronary perfusion, and facilitates access to the target vessels while maintaining hemodynamic stability [7, 8]. It enhances clinical outcomes and decreases the mortality rate in high-risk patients undergoing coronary revascularization.

IABP
The intra-aortic balloon pump (IABP) is a mechanical device that increases myocardial oxygen perfusion and simultaneously increases cardiac output. Increase cardiac output enhances coronary blood flow and therefore myocardial oxygen delivery. The balloon of IABP gets inflated at the onset of diastole thereby increasing diastolic pressure and deflates in early systole thus reducing left ventricle afterload. Inflation causes major volume displacement of blood within the aorta, both proximally and distally, leads to potential increase in coronary blood flow and potential improvements in systemic perfusion by augmentation. IABP improves the ventricular performance of the failing heart by facilitating an increase in myocardial oxygen supply and a decrease in myocardial oxygen demand [9, 10]. These effects predominately associated with enhancement of Left Ventricle performance simultaneously enhanced right ventricular function by complex mechanisms including accentuation of Right Ventricle myocardial blood flow, unloading the left ventricle causing reduction in left atrial and pulmonary vascular pressures and Right Ventricle afterload.

The magnitude of these effects depends upon
Balloon volume: The amount of blood displaced is proportional to the volume of the balloon.

Heart rate*:* Left Ventricle and aortic diastolic filling times are inversely proportional to heart rate, shorter diastolic time produces lesser balloon augmentation per unit time.

Aortic compliance: Aortic compliance increases (or SVR decreases), the magnitude of diastolic augmentation decreases. IABP balloon size is selected according to the height of the patients. The IABP balloon was connected to a Datascope or Arrow pump. IABP insertion is undertaken through the best femoral artery possible in all cases according to the results of an ultrasound examination of bilateral lower extremities.

Duration of study
Two months (March 2018 to April 2018)

Aims & objective
The efficacy of intra-aortic balloon pump to reduce mortality in patients with low ejection fraction and/or left main disease, having multi vessels coronary artery disease undergoing coronary artery bypass graft

Material method
The present study is a small observational cohort study conducted at MGM Hospital, Navi Mumbai.
A total of 5 patients enrolled in the study.
Patient detail:

1st Patient: 65/M 66 kg,
- 2D Echo - LVEF 30, Basal, mid & Distal ant wall Hypokinesis, Trileaflet aortic valve normal.
- Angiography = LAD 90% stenosed LCx Non dominant Artery 100 % stenosed RCA 90 % stenosed.

2nd Patient: 62/f 64 kg
- 2D Echo - LVEF 30, Global LV Hypokinesis, Trileaflet aortic valve appears thickened & Sclerosed & reduced LV function.
- Angiography = LAD 94% stenosed LCx Non dominant Artery 90 % stenosed RCA 100 % stenosed

3rd Patient: 65y/m 72 kg
2D Echo - LVEF 30, LV Hypokinesis, Trileaflet aortic valve appears thickened with reduced LV function.
Angiography = LM 70 stenosed. Lad Type 3 shows 70 stenosed ostial segment 80% mid & distal segment. Lcx 70 % stenosis in ostial segment, 80% stenosed mid & distal segment, RCA 80% in-stent re-stenosed in mid segment. Suggestive of Multiple vessels disease with Left Main Disease

4th Patient: 46y/m 65kg
2D Echo - LVEF 30, Trileaflet aortic valve appears normal with reduced LV function. grade 2 disatolic dysfunction.
Angiography = LM 70 stenosed. Lad proximal mid LAD 99 stenosed ostial segment 90%. LCx 90% mid segment stenosis, RCA 90 mid segment. Suggestive of multiple vessels disease with Left Main Disease

5th Patient: 74y/F 48kg
2D Echo - LVEF 30, Trileaflet aortic valve appears normal with reduced LV function.
Angiography = LM appears normal. Lad Type 3 proximal 100 stenosed Lcx 90% proximal segment stenosis with 90 mid segment, RCA 100 stenosed. Suggestive of multiple vessels disease with Left Main Disease.

Inclusion criteria
1. Patients of ASA Grade II and III undergoing CABG.
2. Patients between age 30 & 80 years.
3. Patients weighing between 30 & 90 kg.
4. Patients with left main stem disease and /or low ejection fraction (less than 45%)

Exclusion criteria
1. Patients belonging to ASA Grade I and IV.
2. Pre-operative cardiogenic shock
3. Patient refusal
4. LVEF 50 TO 60 %

Randomization of patient was done after preoperative assessment & investigation. The left ventricular ejection fraction (LVEF) of all patients was calculated from an echocardiography assessment performed before surgery.
Informed consent of the patient was taken. A day prior to surgery, preoperative evaluation done. All patients received Tab alprazolam 0.5mg and Tab ranitidine 150 mg on prior night of the surgery. Patients were kept nil by mouth from midnight. On the day of surgery, after checking preoperative orders, nil by mouth status, informed consent, equipment and anaesthesia machine the patient shifted to the operation theatre and monitors were attached for continuous monitoring of pulse oximetry, noninvasive blood pressure, electrocardiography, and capnography. An intravenous access was secured with a 16 G cannula and with right sided intrajugular central venous catheterisation triple lumen size 7Fr.Normal saline infusion was started. Arterial access was secured with 20g arterial catheter. And invasive blood pressure monitored continuously.
Patients pre-oxygenated for 3 min & pre-medicated with Inj. Fentanyl 2mcg/kg, Inj. Midazolam 0.03mg/kg and then Etomidate was given for induction of anaesthesia in a dose of 0.3 to 0.6mg/kg. Neuromuscular blockade was achieved with inj. Rocuronium 0.6 mg/kg. After 3 mins of assisted ventilation, the patient was given the 'morning sniffing' position. Videolarygoscopy done after visualisation of vocal cords following which endotracheal intubation was done with an appropriate-sized endotracheal tube. General anaesthesia was maintained with oxygen and Sevoflurane with controlled ventilation through closed circuit. IABP inserted via suitable femoral artery and appropriate-sized IABP balloon was selected according to the height of the patients. The IABP was set on automatic mode with variables settled at a 1:1 balloon inflation synchronized with the electrocardiogram or aortic blood pressure tracing. Heparin was systematically used for anticoagulation. At end of surgery, Patients shifted to CVTS ICU and maintained on CMV. IABP support was gradually weaned as per hemodynamic response of the patient and eventually terminated on achieving hemodynamic stability around second post operative day.

Result and discussion
Coronary arterial bypass graft was performed on all 5 patients out of whom three had left main stem disease with low ejection fraction while the other two had low ejection fraction of 30% on echocardiography.
All were urgent referrals from the cardiologists after being admitted 3 weeks ago with unstable angina, but has been stable since admission. We observed that all were high risk cases and preoperative insertion of an intra-aortic balloon pump would benefit them.
There were no cases of IABP-related mortality. No severe bleeding at the IABP insertion site, or balloon failure in any of

the patients. From the perspective of pathophysiology, the positive effect of IABP insertion is believed to increase coronary blood flow while simultaneously decreasing myocardial oxygen demand.

Preoperative prophylactic IABP assistance provides better hemodynamic stability in crucial times of higher oxygen demand when the heart is displaced in OPCAB procedures [11]. However, many contemporary studies have challenged the effectiveness of preoperative IABP in high-risk patients undergoing CABG [12].

Our study was found relevant with studies undertaken by Christenson [13, 14, 15] *et al*. which also provide evidence for the placement of an IABP in patients with two of the following: LVEF, 30 or 40%, left main stem disease, unstable angina or redo-operation.

Although their individual papers are on the margins of significance, if all patients recruited in these three papers are different then taken together there is a significant mortality reduction. The IABP mortality in the three studies was 3.4%.

Table 1

Author date and country Key results	Patient group	Study type, (level of evidence)	Outcomes	Key results	Comments
Christenson *et al*. (1999) Ann Thorac Surg, Switzerland [13]	60 consecutive high risk patients undergoing CABG. 30 patients had a 9.5F IABP placed at 2, 12 or 24 h preoperatively. 30 controls who did not have preoperative IAPB. Definition of high risk: the presence of two or more of the following, LVEF of, 30%, Left main stem disease. 70%, unstable angina, reoperation	RCT single blinded study	In hospital mortality CPB time Complications	IABP group, one death. Control group, six deaths. Two-sided Fisher's test P ¼ 0.1028 IABP group 83.6 ^ 21.7 min, control 127.3 ^ 45.6 min P ¼ 0.001 Five patients (5/53 ¼ 9.4%), two removals of IABP, one thrombectomy, one thrombectomy and fasciotomy and one interposition graft	Study sponsored by Datascope. The significance test for mortality was not reported by this paper. Therefore we calculated this P-value, 53/60 patients were male (88%). 23/30 control patients ended up having an IABP postoperatively due to poor CI. Mortality of controls is high (20%). No sample size estimates
Christenson *et al*. (1997) Eur J Cardiothorac Surg, Switzerland [14] Fasseas *et al*. (2001) J Invasive Cardiol, USA [15] Christenson *et al*. (1997) Ann Thorac Surg, Switzerland [4]	52 High risk patients undergoing CABG (different cohort to 1999 patients). 13 patients had 9F IABP 24 h prior to surgery 19 had IABP 1–2 h pre-op, 20 controls. Definition of high risk: two or more of left ventricular ejection fraction, 40%, left main stem stenosis. 70%, redo-CABG, unstable angina. 29 patients were redo-CABG 457 stable patients with severe left main stem disease. 170 patients had prophylactic IABP. Definition of patients: left main stem disease. 50%, and multivessel coronary disease, but no angina or haemodynamic compromise, heart failure, shock or previous CABG 24 high risk redo-CABG patients received 9F St. Jude IABP 2 h pre-op. 24 high risk redo-CABG patients randomised as controls. Definition of high risk: any two of; LVEF, 40%, unstable angina or left main stem disease >70%	RCT single blinded study (level 2b) Retrospective cohort study RCT single blinded study	Mortality ICU stay IABP versus control CI 30 min post CPB Complications Mortality Hospital stay Mortality CPB time Complications	IABP 24 h, one death, IABP 2 h, one death, controls, five deaths (25%), P, 0.05 2.39 ^ 0.9 versus 3.59 ^ 1.1 days, P, 0.004 4.17 ^ 0.64 versus 2.01 ^ 0.61 P, 0.001 No IABP related mortality or complications IABP group, six deaths, control group, two deaths, P ¼ 0.02. This became P ¼ 0.1 after multivariate analysis allowed for confounding variables No difference in hospital stay or bypass time IABP group, no deaths, control group, four deaths P ¼ 0.049 IABP group, 88 min, control group, 110 min, P ¼ 0.006 Two patients had leg ischaemia, one required thrombectomy	Our calculation of IABP mortality versus control gives Fishers two sided P value of 0.0925, in contrast to their figures. 45/52 were men (87%) only nine patients had LIMA used. No sample size estimates Higher PVD, ejection fraction and less diabetes in non-IABP group. No sample size estimate Five women in this study in total. No sample size estimates. Supported by Grant from St. Jude. Our calculation of their Fishers two sided test is that the P-value is 0.1092 for mortality

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