

## Research

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# Beneficial Effects of Pre-Operative Intra Aortic Balloon Pump Support in High Risk Patients Undergoing Coronary Artery Bypass Graft Surgery

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## ABSTRACT

**Objective:** The purpose of this study was to evaluate the efficacy and the cost-benefit of pre-operative Intra-aortic Balloon Pump (IABP) treatment on peri- and post-operative cardiac performance, improved hemodynamic stability, reduced mortality and morbidity and the optimal timing in high-risk patients undergoing Coronary Artery Bypass Grafting (CABG), when compared to patients who did not receive IABP therapy.

**Methods:** Between January 2011 and June 2012, a total of 1149 patients underwent CABG at our institution of which IABP was inserted in 90 patients, out of which 30 patients satisfied the inclusion criteria. Out of 30 patients 10 had IABP insertion pre-operative, 10 had intra-operative, and 10 had post-operative period. Euro score additive and logistic were comparable in all the three groups to determine the benefit of using IABP prior to operation.

**Results:** Inotropic support in pre-IABP group is less as compared to intra- and post-IABP group ( $p < 0.02$ ). The mean duration of ICU stay was more in intra-operative and post-operative IABP group ( $p < 0.28$ ). No hospital mortality in pre-operative IABP group (0/10), 2 patient died in intra-operative IABP group (2/10), 3 died in post-operative IABP group (3/10).

**Conclusions:** This study demonstrated pre-operative IABP therapy is an efficient and safe supportive modality which significantly decreases the risk for hemodynamic instability in high-risk patients undergoing CABG, improved cardiac performance, reduced inotropic requirements, lower rate of hospital mortality and less post-operative morbidity, improve survival and shortens both ICU and hospital length of stay significantly and is therefore cost effective. Further studies with inclusion of more cases are required to verify our findings.

**KEYWORDS:** Intra-aortic balloon pump; Coronary artery bypass grafting; Coronary artery disease.

**ABBREVIATIONS:** CABG: Coronary Artery Bypass Grafting; IABP: Intra-aortic Balloon Pump; ICU: Intensive Care Unit; CAD: Coronary Artery Disease; LVEF: Left Ventricular Ejection Fraction.

## INTRODUCTION

Pre-operative intra-aortic balloon pump (IABP) therapy is an effective modality in protecting high-risk patients undergoing coronary artery bypass grafting (CABG) surgery.<sup>1-5</sup> Pre-operative IABP therapy improves cardiac performance and facilitates access to the target vessels while maintaining hemodynamic stability, even in high-risk patients.<sup>6,7</sup> In our institution, pre-operative IABP is used selectively as a modality to support CABG surgery in high-risk patients since provides better hemodynamic stability and coronary perfusion and minimizes low output syndrome and organ dysfunction.<sup>8</sup>

CABG, in low to moderate risk coronary patients, has demonstrated excellent immediate and long-term results,<sup>9</sup> allowing shorter stay in intensive care unit (ICU) and shortening of the total length of hospital stay, which has kept the total procedural cost on a steady level. In contrast to this stands, the CABG procedure performed in high-risk patients, which still is associated with high post-operative mortality and morbidity.<sup>10</sup> This results in a prolonged stay in the intensive unit as well as in the hospital. The purpose of this study was to evaluate the efficacy and the cost-benefit of pre-operative IABP treatment on peri- and post-operative cardiac performance, improved hemodynamic stability, reduced mortality and morbidity and the optimal timing in high-risk patients undergoing CABG, when compared to patients who did not receive IABP therapy.

## MATERIAL AND METHODS

### Patient Population and Study Design

Institution Ethical Committee (IEC) clearance was obtained for the study. This study was a prospective, cross-sectional study. Between January 2011 and June 2012, a total of 1149 patients underwent CABG at our academic institution of which IABP was inserted in 90 patients, out of which 30 patients met the inclusion criteria. Out of 30 patients 10 had IABP insertion pre-operative, 10 had intra-operative, and 10 had post-operatively.

The treatment was defined as insertion of IABP before surgery and control was represented by patients who did not receive IABP pre-operatively and those who received IABP intra-operatively, or post-operatively.

The definition of high-risk patients was based on the logistic European Risk Score System in Cardiac Operations (EuroSCORE)<sup>11</sup> and the cutoff of 5 points or higher was chosen on the basis of the available literature.<sup>11</sup> The logistic EuroSCORE was calculated using the current online version ([www.euroscore.org/calc.html](http://www.euroscore.org/calc.html)).

### Definition of High Risks

Any coronary artery disease (CAD) patient presenting with a minimum of two of the following pre-operative criteria and planned for revascularization was enrolled in this study:

- Left ventricular dysfunction;
- Left ventricular ejection fraction (LVEF) equal or less than 0.40;
- Pre-operative unstable angina despite optimal medical treatment (including nitroglycerin and heparin therapy);
- Left coronary main stem stenosis greater than 70%;
- Chronic occlusion of the three main coronary trunks (left anterior descending, right, and circumflex coronary arteries);
- Tight stenosis (>99%) of the proximal left anterior descending coronary artery (before the first septal or diagonal branch), proximal tight stenosis (>99%) of a dominant right coronary artery with remote branches for the posterior wall

of the left ventricle;

- Acute ongoing angina;
- Recent myocardial infarction less than 4 weeks prior to surgery.

### Inclusion Criteria

Adult patients with CAD were admitted for elective or urgent myocardial revascularization and classified as high-risk patients according to the definition given above.

### Exclusion Criteria

- Post-infarction ventricular septal repair;
- Pre-operative cardiogenic shock;
- Patient planned for additional cardiac surgical procedures.

Patients fulfilling the inclusion criteria were randomly allocated to either of two treatments paths: Group A-therapy Group-pre-operative IABP therapy, started prior to induction of anesthesia, followed by continuous IABP during the entire procedure as well as post-operatively.

Group B-control Group-no pre-operative IABP therapy. CABG was performed on beating heart with or without the use of CPB. Post-operative IABP treatment was initiated if fulfilling definitions stated above.

The amount of pharmacological inotropic support pre-operative and post-operatively (during the first 12 h) required to maintain an acceptable cardiac index (<2.0 L/min/m<sup>2</sup>) was monitored. Post-operative mortality and morbidity as well as required stay in the intensive care unit was registered for each of the groups.

### Indications for Post-operative IABP

When cardiac index cannot be maintained at a level greater than 2.0 L/min/m<sup>2</sup>, despite pharmacological support with adrenaline equal or more than 0.05 µg/kg/min, dobutamine equal or more than 10 µg/kg/min and dopamine equal or more than 10 µg/kg/min, an IABP treatment is indicated.

### IABP Support and Timing of Insertion

The Intra aortic balloon (Datascope Sensation 7F, 40 mL; Datascope Corp., Fairfield, NJ, USA) was inserted percutaneously with sheathless technique and was connected to a Datascope CS300 console (Datascope Corp.). Insertion through the best femoral artery was possible in all cases, pre-operatively, in the intensive care unit, on average 24 h prior to the start of surgery and the correct placement was assessed by chest roentgenography. Peri- or post-operative IABP catheter insertion and start was initiated when criteria described above were met. Exact time of insertion and start of IABC as well as termination of IABP was registered, as well as any complications (minor or major) related to the IABP therapy.

Intraaortic balloon pump assistance was set at a 1:1 ratio in all patients. Patients undergoing pre-operative insertion were therapeutically anticoagulated with heparin after IABP placement. Patients returning from the operating room with an IABP in place were anticoagulated with 1 mg/Kg of heparin once mediastinal drainage subsided (usually within 24 h).

We inserted IABP intra-operatively if the patient experienced hemodynamic instability during OPCAB. We inserted IABP intra-operatively when hemodynamic instability occurred such as a significant decrease of systemic systolic pressure to less than 80 mmHg, elevation of pulmonary diastolic pressure to more than 25 mmHg, or intractable ventricular arrhythmia, in spite of adequate anesthesia management.

#### Termination of IABC Therapy/Treatment

The IABP support was terminated when hemodynamic stability was restored (maintaining a cardiac index  $>2.0$  L/min/m<sup>2</sup> with minimal pharmacologic support). The same definition was used for termination of post-operative IABP.

#### Measurements

All patients were equipped with Swan-Ganz catheter, arterial catheter, and multi lead ECG.

Repeated blood gas analysis was performed to evaluate oxygen uptake and oxygen debt. Repeated cardiac output measurements were performed and CI calculated (cardiac performance).

Systemic arterial blood pressure (BP), heart rate (HR), means pulmonary artery pressure (MPAP), central venous pressure (CVP), and pulmonary capillary wedge pressure (PCWP) was registered. Repeated pre-operative and post-operative blood samples for analysis of hematocrit (Hct), platelet count (Plt), CK-MB (creatinine kinase MD fractions), CK (creatinine kinase phosphate).

#### Surgical Procedure

Surgery was performed in all cases through a median sternotomy. All conduits were harvested as for traditional CABG. Extensive arterial grafting and complete myocardial revascularization were preferred whenever possible. The most critical vessel in almost all the patients, the left anterior descending coronary artery, was revascularized first to provide a backup to the less critical area. The distal anastomosis was constructed using a continuous technique with 8-0 polypropylene sutures for arterial grafts or 7-0 polypropylene suture for a saphenous vein graft. All proximal anastomoses on the ascending aorta were constructed after distal anastomoses, using a single partial clamping of the aorta and 6-0 polypropylene continuous sutures.

The left internal mammary artery was used to the left

anterior descending coronary artery in all patients. Saphenous veins were usually preferred for diagonal artery, obtuse marginal coronary artery and right coronary artery revascularization as an aortocoronary graft. The initial heparin dose for OPCAB was 1.5 mg/Kg, with a target ACT greater than 300 seconds. If conversion to CPB was required the heparin dose was 3 mg/Kg to achieve a target activated clotting time of greater than 480 seconds. Temperature was maintained at normothermia using adequate room temperature, warm circulating water blankets, and warm infusion solutions.

For patients undergoing off-pump CABG exposure We used the suction-type (Octopus® 3; Medtronic Inc., Minneapolis, USA) mechanical stabilizers, to immobilize the target coronary artery and Starfish (Medtronic Inc., Minneapolis, USA) was used to expose the posterior and inferior surfaces of the heart. A shunt (Medtronic Inc., Minneapolis, USA) was inserted in the coronary artery during all anastomoses to avoid ischemic damage and peri-operative rhythm disturbances. A blower/mister was systematically used to obtain a bloodless operative field and perfect the visualization of the coronary artery.

#### Definitions of Perioperative Events

Hospital mortality was defined as death occurring during hospitalization. Conversion to cardiopulmonary bypass was recorded as an unfavorable event. Peri-operative myocardial infarction was defined as new Q waves of greater than 0.04 milliseconds, reduction in R waves of greater than 25% in at least two leads, or both; new akinetic or dyskinetic segment on echocardiography; and a peak troponin I level of at least 3.1 g/L at 12 hours.<sup>12</sup> Post-operative renal failure was defined as an increase in serum creatinine value of greater than 2.5 mg/dL.

Low-output syndrome (LOS) was diagnosed when CI decreased to less than 2.0 L/min/m<sup>2</sup>, pulmonary capillary wedge pressure exceeded 15 mmHg, left ventricular stroke work index (LVSWI) decreased to less than 22 g/m/m<sup>2</sup> and results of mixed systemic venous oximetry were less than 60% for at least 30 minutes after correction of all electrolyte or blood gas abnormalities and after pre-load optimization. High dose inotropic support was defined when greater than 7 µg/Kg/min of dopamine or dobutamine was given or any dose of adrenaline was added.

Hospital morbidity was defined as any complication requiring specific therapy or causing a delay in hospital or intensive care unit discharge. Intensive care unit stay was defined as the time (hours) required for intensive care; hospital stay, as the time (days) required for hospitalization starting from the day of the surgery.

#### Clinical Outcomes

- Hospital mortality;
- Neurological complications (any new transient or permanent deficit appearing after surgery) ;

- Duration of intubation;
- Required stay in ICU;
- Length of total hospital stay;
- Incidence of renal insufficiency (serum-urea greater than 9 mM and serum creatinine greater than 125  $\mu$ m patients with normal pre-operative values);
- Gastro-intestinal complications (any diagnosed gastro-intestinal complication not present prior to surgery) and;
- Pulmonary complications (X-ray verified pneumonia or atelectasis).

### Statistical Analysis

Statistical analysis was performed with the Statistical Analysis System Software Package (SASSP) (version 6.12; SAS Institute, Cary, NC, USA). The significance of differences between the group of patients with IABP and without IABP was assessed by unpaired Student's *t*-test, X-square test, or likelihood ratio test. All results are expressed as mean  $\pm$  standard deviations, and a value of  $p < 0.05$  is considered statistically significant.

### RESULTS

EuroSCORE additive and logistic were compared in all of the three groups with significant difference noted in the group with use of pre-IABP ( $p < 0.05$ ). Inotropic support in pre-IABP group is less as compared to intra- and post-IABP group as the ( $p < 0.02$ ).

The mean duration of ICU stay was longer in the post-operative IABP group than that in the intra-operative ( $p = 0.28$ ), although this did not reach statistical significance. The post-operative acute kidney injury on day 1 and day 2 was compared in all the three groups with no statistical significant, conversion of off pump to on pump rate was high in intra-operative IABP

group, and ventricular fibrillation was more in both intra-operative (2/10) and post-operative IABP (3/10) groups.

No hospital mortality occurred in the pre-operative IABP group (0/10), however, mortality was seen in the two groups with 2 patient died in the intra-operative IABP group (2/10), 3 died in the post-operative IABP group (3/10). Table 1 shows key findings among these three groups.

### DISCUSSION

The IABP method has long been established as a valuable mechanical support for temporary ventricular assistance in the treatment of the failing heart.<sup>13</sup> Several clinical studies have reported worse outcome and high rates of complications in patients who required placement of emergency IABP support during intra-operative or post-operative critical hemodynamic decompensation.<sup>14</sup>

The purpose of this study was to evaluate if the use of pre-operative intra-aortic balloon pump treatment could improve the outcome after surgical myocardial revascularization, the optimal timing of IABP insertion and if efficient, to evaluate whether this additional treatment is cost beneficial or not.

Pre-operative prophylactic IABP support has recently been suggested to have proven efficacy in significantly lowering hospital mortality and morbidity in high-risk coronary patients undergoing CABG.<sup>15</sup>

The positive effect of pre-operative insertion of IABP in high-risk patients is thought to be due to an improved myocardial oxygen supply/demand ratio and reduced ventricular wall stress before the operation in addition to diastolic augmentation and decreased afterload resulting in the redistribution of coro-

Table 1: Comparison of Results among the Three Comparable Groups.				
Variable	Pre-op IABP	Intra-op IABP	Post-op IABP	<i>p</i> -Value
EuroSCORE additive (mean $\pm$ SD)	7.8 $\pm$ 1.54	7.9 $\pm$ 1.37	7.1 $\pm$ 1.96	<0.05
EuroSCORE logistic (mean $\pm$ SD)	8.9 $\pm$ 3.6	9.2 $\pm$ 3.6	7.6 $\pm$ 4.9	<0.05
Aki post-operative day 1 (n)	1/10	2/10	2/10	ns
Aki post-operative day 2 (n)	0/10	1/10	2/10	ns
Inotrope hours post-operative (hrs)	40.3 $\pm$ 13.7	59.9 $\pm$ 24	78 $\pm$ 44.8	<0.02
Off-pump to on pump conversion intraoperative (N)	1/10	2/10	2/10	ns
Ventricular fibrillation (n)	0/10	2/10	3/10	ns
LVEF at discharge (%)	43 $\pm$ 3	52 $\pm$ 5	42 $\pm$ 8	<0.05
ICU stay (hrs)	65 $\pm$ 20	64 $\pm$ 28	91 $\pm$ 45	0.28
30 day mortality (n)	0/10	2/10	3/10	ns

IABP = Intraaortic Balloon Pump; LVEF=Left Ventricular Ejection Fraction; ns=not significant.

nary blood flow toward the ischemic areas of the myocardium enhancement of sub-endocardial perfusion, and in the recovered energy depletion of myocardial cells.<sup>16</sup>

Pre-operative IABP therapy could lead to pre-operative reduction of myocardial ischemia, avoidance of progressive cardiac dysfunction, and minimization of low-flow episodes with subsequent end organ dysfunction, and may thereby permit safer induction of general anesthesia and improve surgical outcome in high-risk coronary patients.<sup>1,17</sup>

Crucial times for higher oxygen demand include when anesthesia is induced and conduits are harvested; thus, any transitory hypotension during these phases may induce critical ischemia leading to acute myocardial damage or even infarction.<sup>18,19</sup>

Intra-operative and post-operative IABP insertion has been disappointing because of the associated high mortality rate, as well as complication rate.<sup>4,5</sup> In patients who had an IABP inserted post-operatively, the treatment was required for a substantially longer time, which not only increases the total procedural cost (by prolonged stay in the intensive care unit and massive pharmacologic support) but also could increase the risk of IABP-related complications.

The Benchmark Registry showed that prophylactic IABP use was associated with reduced mortality in high-risk patients.<sup>20</sup> These data are confirmed by The Society of Thoracic Surgeons National Database, which also clearly showed a survival benefit with pre-operative IABP assistance.<sup>21</sup>

Intraaortic balloon pump insertion can occasionally be cumbersome or risky because of severe and diffuse atherosclerosis of the descending aorta and peripheral arteries, or even contraindicated because of abdominal aortic aneurysms. The major disadvantages related to IABP use thus far were complications associated with its placement, aortic dissection, balloon rupture, balloon entrapment, bleeding, vascular injury, and limb ischemia.<sup>22</sup>

#### STUDY LIMITATIONS

Firstly, small sample size is one of the main limitations. Further research is needed to include more cases. Preferably in a multi-centre study. Secondly, no follow-up was performed as this study only assessed the hospital mortality and hospital study including duration at ICU.

#### CONCLUSION

In conclusion, this study demonstrated pre-operative IABP therapy is an efficient and safe supportive modality which significantly decreases the risk for hemodynamic instability in high-risk patients undergoing CABG, improved cardiac performance, reduced inotropic requirements, lower rate of hospital mortality and less post-operative morbidity, improve survival and shortens

both ICU and hospital length of stay significantly and is therefore cost-effective.

#### CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

#### CONSENT

Informed consent were obtained from the study patients along with the ethical clearance from the Institutional Ethics Committee (IEC).

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