Study Protocol and Statistical Analysis Plan:

Evidence of the Advantages of Preoperative Intra-aortic Balloon Pump in Surgical Revascularization of Acute Myocardial Infarction

Brief Title: Use of Intra-aortic Balloon Pump Before Surgery for Acute Myocardial Infarction

NCT number: NCT06468982

Document date: May 1, 2021

Evidence of the Advantages of Preoperative Intra-aortic Balloon Pump in Surgical Revascularization of Acute Myocardial Infarction

Patients hospitalized due to acute myocardial infarction (AMI) and scheduled for coronary artery bypass grafting (CABG) surgery based on the decision of the Cardiology and Cardiovascular Surgery council will be included in this prospective observational cohort study. Based on their clinical conditions, the patients will be categorized into two groups: Group A, comprising those receiving intra-aortic balloon pump (IABP) support, and Group B, comprising those not receiving IABP support.

The patients' anamnesis, medical history, physical examination findings, laboratory results, and EuroScore-II scores will be meticulously recorded. Details of the assessments are as follows:

Assessment of Chest Pain (Angina): Chest pain severity will be evaluated on the first day of admission using a scoring system based on the Wong-Baker FACES® pain scale (0–10; Wong-Baker FACES Foundation; https://wongbakerfaces.org). For patients in the IABP group, pain severity will also be recorded immediately before IABP placement and at 12 and 24 hours post-implantation.

Laboratory Studies: The following parameters will be analyzed: hemoglobin (g/dL), hematocrit (%), platelet count, troponin (ng/mL), CK-MB (U/L), LDL (mg/dL), C-reactive protein (CRP, mg/L), glycated hemoglobin (HbA1c, %), and creatinine (mg/dL). High-sensitivity cardiac troponin I (hsCTI) levels will be measured, with the reference range of 0–0.04 ng/mL for both genders, as per our hospital's laboratory standards. hsCTI levels will be checked at admission and subsequently every 24 hours for both groups until the patient undergoes surgery.

Echocardiography (ECHO): On the first day, ECHO will be performed to assess ventricular function, ejection fraction (EF%), valve pathologies, and any ventricular abnormalities such as aneurysm or ventricular septal rupture. Follow-up ECHO will be conducted during the early postoperative period and at the first-month follow-up after discharge to reassess EF% and identify any pericardial effusion.

Patients who demonstrate a decline in hsCTI levels or experience recurrent chest pain attacks will undergo coronary artery bypass grafting (CABG). All surgical procedures will be performed by the same surgical team using a standardized approach. Surgical Approach: The surgeries will be conducted via a median sternotomy under cardiopulmonary bypass (CPB). Complete revascularization will be achieved with the application of an aortic cross-clamp (ACC), guided by the vascular anatomy identified during angiography. Assessment of Graft

Flow: Following the removal of the ACC and the termination of CPB, transit-time flow measurement (TTFM) will be employed to evaluate the graft flow rates, ensuring optimal surgical outcomes.

In the postoperative period, the following parameters will be recorded: Mechanical Ventilation Duration (MV): Measured in hours from the patient's admission to the intensive care unit (ICU) until the cessation of mechanical ventilation. Bleeding Volume: The total amount of bleeding in milliliters during the first 24 hours postoperatively. Length of Stay in the Intensive Care Unit (ICU): The duration (in days) from the postoperative phase until the patient is transferred to the general ward. Total Length of Hospital Stay (HS): The number of days from hospital admission to discharge. Low Cardiac Output Syndrome (LCOS): LCOS will be defined as the presence of the following criteria: Requirement for high-dose positive inotropic agents (e.g., adrenaline, dobutamine, or noradrenaline) administered via continuous infusion, lactic acidosis (lactate levels >4 mmol/L), persistent hypotension and decreased or absent urine output. In-Hospital Mortality: Any death occurring within 30 days postoperatively will be classified as in-hospital mortality.

Exclusion criteria

To ensure a homogeneous distribution of risk factors between the groups and to accurately evaluate the effect of IABP on troponin levels, the following patients will be excluded from the study:

- Patients requiring emergency surgery due to iatrogenic cardiac or coronary injuries caused by angiography.
- Patients with mechanical complications of acute myocardial infarction, such as chordae rupture or ventricular septal rupture.
- Patients undergoing surgery using the off-pump or pumped beating heart method.
- Patients with peripheral arterial disease.
- Patients with renal failure.
- Patients with a history of cerebrovascular accidents.
- Patients presenting with acute cardiogenic shock or cardiac arrest

Preoperative IABP Application and Indications:

The primary indications for intra-aortic balloon pump (IABP) application in patients include elevated troponin levels and recurrent or persistent chest pain at rest.

Other common indications are:

- Hemodynamic instability.
- Multivessel coronary artery disease.
- Left main coronary artery disease.
- Narrow and/or tortuous coronary artery anatomy where percutaneous coronary intervention (PCI) has failed or is not feasible.

Procedure:
The IABP catheter is typically inserted into the femoral artery by cardiovascular surgeons under local anesthesia. The placement of the catheter is confirmed either in a hybrid operating room or using a portable imaging scope.

Statistical Analysis

The research will be conducted utilizing IBM SPSS 24 (IBM, Armonk, NY, USA) software and R-project version 4.2.3 for statistical analysis. The statistics will be provided in terms of mean, standard deviation, median, minimum, maximum, percentage, and count. After testing for normality, baseline characteristics of the two groups will be compared using Student's t-test or the Mann–Whitney U-test for continuous variables and chi-square or Fisher's exact tests for categorical variables. Differences between the IABP group and the control group regarding repeatedly measured outcomes will be analyzed using mixed ANOVA. The prognostic value of risk factors for in-hospital mortality will be evaluated by multivariate logistic regression analysis. The propensity score will be computed using a logistic regression model, incorporating the following covariates: age, gender, creatinine, CK-MB, hs-CTI levels, preoperative LVEF, and EuroScore II. The statistical significance level will be set at $p<0.05$.