The Effects of Intra Aortic Balloon Pump Prior to Revascularization on Mortality of Myocardial Infarction Patients Complicated With Shock

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Study Protocol

Title

The Effects of Intra Aortic Balloon Pump Prior to Revascularization on Mortality of Myocardial Infarction Patients Complicated With Shock

Principal Investigator

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Sponsor

Indonesia University

Aim

To observe the effects of intra aortoc balloon pump prior to revascularization on mortality of myocardial infarction patients complicated with shock

Study Design

Randomized clinical trial.

Anticipated Outcome

Intra aortic balloon pump insertion prior to revascularization will improve mortality rate of myocardial infarction patients complicated with shock.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Age over 18 years and less than 75 years
2. Myocardial infarction patients complicated with shock
3. Agree to participate in the study (signed consent)

Exclusion Criteria

1. Age over 80 years
2. Cardio pulmonary resuscitation for more than 30 minutes
3. Shock onset > 12 hours (if onset time is clearly known) and > 18 hours (if the exact time of shock onset is unknown or patient presented with shock on admission)
4. Mechanical complication of myocardial infarction
5. Moderate and severe aortic regurgitation
6. No revascularization treatment (PCI) is done
7. Patient dies prior to intra aortic balloon pump insertion

***Withdrawal or Discontinuation* Criteria**

1. Treatment termination requested by family

Procedures

1. Patients who meet the criteria and agree to participate on the study were taken as research subjects. Patients with myocardial infarction with shock complications who do not meet the criteria will continue to be recorded for registry.
2. Patients will be treated according to standard shock guideline, with peripheral oxygen saturation target > 92% and mean arterial pressure ≥65 mmHg. Inotropic administration is based on physicians discretion with dobutamine and norepinephrine

as the drug of choice.
3. Patients will be randomized into two groups, control and treatment group (group of subjects receiving IABP).
4. Anamnesis, physical examination (including vital signs) and electrocardiography, echocardiography, laboratory assessment will be performed.
5. Non-invasive hemodynamic examination with echocardiogram will be performed (Global Longitudinal Strain data will be recorded) and will also be repeated on the 3rd day of hospitalization.
6. Peripheral venous blood samples taken as many as 5 cc at the time of admission for basic laboratory profile such as routine blood assessments (hemoglobin, hematocrit, leucocytes, platelets), blood glucose, CKMB, hs-Troponin, SGOT, SPGT, urea, creatinine.
7. Peripheral venous blood samples of 3 cc were taken at the 0^{th} hour or the 1st day of admission, at 48^{th} hour (3^{rd} day) and 96^{th} hour (5^{th} day) for serum creatinine, NT - proBNP and sST2 assessment.
8. Peripheral arterial blood samples of 3 cc were taken at the 0th hour and the 12th hour of admission for lactate level assessment.
9. IABP insertion will be performed on IABP group, as early as possible either bedside or in the catheterization room before revascularization. IABP insertion is done through a communist femoral artery with or without a sheath, according to the operator's assessment. The timing of IABP initiation will be recorded.
10. Revascularization will be performed on all patients with the target time from randomization to coronary intervention is two hour.
11. After percutaneous revascularization is performed, the patient is transferred to the intensive care unit and the secondary prophylactic medication for coronary artery disease was administered to both groups according to the standard of medical care.
12. The patient will be continously monitored. Records were made on in hospital mortality and 30 days after the revascularization.

Analysis Method

Data will be analyzed using SPSS 16.0 software program with appropriate statistical test. A two-way p value <0.05 is considered as statistically significant. Categorical variables are reported as frequency and percentage. The data will be analyzed using Fisher test or $\chi 2$. After assessing the normality of the data distribution with the Kolmogorov-Smirnov normality test, continuous variables will be presented in the mean ± standard deviation (SD) or median, and analyzed according to the normality of the distribution by Student's t or Mann-Whitney U test.

Treatment Duration

During hospitalization

Primary Outcome

In-hospital mortality and 30-day-after-revascularization mortality.

SUBJECT INFORMATION AND CONSENT FORM

The study aim to observe the effect of Intra Aortic Ballon Pump (IABP) prior to revascularization in myocardial infarction patients complicated with shock in National Cardiovascular Center Harapan Kita Hospital. 92 individuals will be enrolled in the study.

A. Participation in the research

You are free to participate in this study without any coercion. Once you have decided to participate, you are also free to resign / change your mind at any time without any penalty or sanction. If you refuse to participate then the patient will still be treated according to hospital procedures.

B. Research Procedures

1. Patient personal data and history will be taken: name, age, history of disease, smoking and family history.
2. Physical examination will be performed to obtain vital signs and urine production. Electrocardiography will also be performed.
3. All patients will be receiving treatment according to guidelines.
4. On the day of admission, peripheral blood sampling will be done and echocardiography examination will also be performed to determine the patient's hemodynamic status.
5. If the patient is receiving IABP, the insertion will be done by an interventionalist prior to revascularization.
6. At 12 hours after the admission, arterial blood sampling will be done for as much as 3 ml.
7. On the 3rd day of hospitalisation, peripheral blood sampling will be done for as much as 6 ml and echocardiography examination will also be performed for the second time.
8. On the 5th day of hospitalisation, peripheral blood sampling will be done for as much as 3 ml.
9. The patient's condition and progress will be monitored during hospitalization**.**

C. Risks and Side Effects

Complications that may occur in the intra-aortic balloon pump insertion including blood vessel-related complications such as angio-ischemia, thrombocytopenia, infection, tearing of the aortic vessels, renal failure, neurological disorders, and bleeding. Studies show a complication of limb ischemia of less than 1%. Bleeding occurred in 0.8% of cases. If acute limb ischemia is occured, duplex evaluation and the removal of intra-aortic balloon pump will be done continued with fibrinolytic therapy or thrombus transcatheter aspiration.

D. Benefits

This study will prove the benefit of the intra-aortic balloon pump prior to revascularization in improving the prognosis of cardiogenic shock patients, therefore increase the life expectancy of myocardial infarction patients complicated with shock.

E. Confidentiality

All information relating to the study will be kept confidential and will be known only to researchers and research staff. The results of the study will be published without the identity of the study subjects.

F. Financing

All research related costs will be borne by researchers and National Cardiovascular Center Harapan Kita Hospital.

G. Additional Information

If at any time further explanations are needed, you can contact Dafsah A. Juzar, MD at ICVCU National Cardiovascular Center Harapan Kita Hospital.
You can also inquire the information about the research from the Research Ethics Committee of National Cardiovascular Center Harapan Kita Hospital, Phone +62-5681111, ext. 2837/2831 or email: irb.kometik_rsjpdhk@gmail.com.

SUBJECT INFORMATION AND CONSENT FORM

Name :
Age :
Gender :
Address :
ID number :

As myself / husband / wife / child / parent / sibling * of:

Name :
Date of birth :
Gender :
Address :

With this stated AGREE to participate in the study. The purpose, nature, benefits of this study, and the risks it may cause has been adequately explained by the physician / researcher and I have fully understood.
This consent I make with full consciousness and without coercion.

Signature : _____

Date : _____

*cross the unnecessary ones