STUDY DOCUMENT COVER PAGE

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The Role of Swan–Ganz Catheter in Hemodynamic Resuscitation for Patients with Cardiogenic Shock

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Principal Investigator (PI):
Thang Pham Xuan
Emergency Center, BachMai Hospital

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Statistical Analysis Plan

1. Introduction

This Statistical Analysis Plan (SAP) describes the statistical methods and analytical strategies to be applied to the study: “The Role of Swan–Ganz Catheter in Hemodynamic Resuscitation for Patients with Cardiogenic Shock Due to Acute Myocardial Infarction.” The SAP adheres to the finalized protocol and complies with ICH E9 statistical principles. It outlines all primary and secondary endpoints, statistical testing approaches, and subgroup and sensitivity analyses, ensuring transparency and reproducibility of results.

2. Study Objectives and Outcomes

Primary Outcomes:

1. Achievement of Hemodynamic Targets within 24 Hours:
   - Mean Arterial Pressure (MAP) ≥ 65 mmHg
   - Cardiac Index (CI) ≥ 2.2 L/min/m²
   - Pulmonary Capillary Wedge Pressure (PCWP): 12–15 mmHg
   - Central Venous Pressure (CVP): 8–12 mmHg
   - Mixed Venous Oxygen Saturation (SvO_2) ≥ 65%
   - Serum Lactate < 2 mmol/L
   - Acceptable Vasoactive–Inotropic Score (VIS)
2. 30-Day All-Cause Mortality.
3. In-Hospital Mortality.

Secondary Outcomes:

1. PAC-Related Complications: bleeding, hematoma, pneumothorax, catheter obstruction, infection, arrhythmia.
2. Technical Feasibility and Challenges: time to placement, number of attempts, wave detection.
3. Length of Stay in ICU and hospital.
4. Ventilator Days.
5. Requirement for Renal Replacement Therapy.

3. Study Design and Population

This is a single-arm clinical trial involving adult patients with cardiogenic shock secondary to acute myocardial infarction (AMI). Patients are enrolled consecutively at the Emergency Center of Bachmai Hospital. All participants undergo Swan–Ganz catheterization within the early shock phase and receive goal-directed hemodynamic resuscitation.

4. Populations for Analysis

Eligibility criteria for the study

Inclusion criteria

Participants will be eligible for enrollment if they meet all of the following criteria:

- Aged ≥18 years and voluntarily provide informed consent to participate in the study.
- Diagnosed with cardiogenic shock secondary to acute myocardial infarction (AMI), based on the IABP–SHOCK II criteria, including:
    - Systolic blood pressure (SBP) <90 mmHg for at least 30 minutes, or requiring vasopressor support to maintain SBP >90 mmHg.
    - Evidence of end-organ hypoperfusion, defined by at least one of the following: Altered mental status, Urine output <30 mL/hour, Cold extremities or mottled skin, Serum lactate >2 mmol/L.

Exclusion Criteria:

Patients meeting any of the following criteria will be excluded from the study:

- Active cervical cellulitis or history of neck irradiation, or inability to identify cervical vascular anatomy.
- Coagulopathy, defined as an international normalized ratio (INR) >1.5 and/or a platelet count <50 × 10^9/L.
- Terminal-stage chronic illnesses, including:
    - Advanced malignancy with palliative intent.
    - End-stage HIV infection.
    - Liver cirrhosis classified as Child–Pugh class C.
    - End-stage renal disease requiring maintenance hemodialysis.
    - Prolonged immobility (bedridden >3 months).
    - Pre-existing cardiac arrest or mechanical complications of myocardial infarction (e.g., ventricular free wall rupture) before Swan–Ganz catheter insertion.
    - Known intracardiac shunts or congenital heart defects that may affect hemodynamic measurements.
    - Refusal to participate or withdrawal of informed consent at any point during the study.

Analysis sets include:
- Full Analysis Set (FAS): All patients who received PAC and had ≥1 post-insertion hemodynamic measurement.
- Per-Protocol Set (PPS): Patients who achieved ≥80% protocol adherence.
- Safety Analysis Set: All patients who had any PAC-related complication documented.

5. Statistical Methods

Descriptive statistics will summarize baseline demographics and clinical variables. Mean ± SD or median (IQR) will be used for continuous variables based on normality (Shapiro–Wilk test). Categorical variables will be reported as frequencies and percentages.

For between-group comparisons (e.g., survivors vs non-survivors):
- Student’s t-test or Mann–Whitney U for continuous data.
- Chi-square or Fisher’s exact test for categorical variables.

For within-group comparisons over time:
- Paired t-test or Wilcoxon signed-rank test for repeated measurements.
- Repeated measures ANOVA or Friedman test for hemodynamic parameters (CI, CPO, SvO_2, PAOP, CVP, lactate).

Multivariate logistic regression will be used to identify predictors of 30-day mortality and failure to achieve hemodynamic targets. Variables significant in univariate analysis ($p < 0.2$) and those of clinical importance will be entered into the model.

Receiver Operating Characteristic (ROC) curves will evaluate predictive performance of parameters (e.g., CI, CPO, SvO_2) for mortality. AUC > 0.80 is considered good.

Statistical analyses will be performed using SPSS 16.0. Two-sided p-values < 0.05 will be considered statistically significant.

6. Amendments

Any revisions to this SAP will be dated and documented before the database lock. Deviations will be reported in the final study publication with justification.