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STUDY PROTOCOL

"The Role of Swan-Ganz catheter in hemodynamic resuscitation for patients with cardiogenic shock"

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Abstract

Background: Cardiogenic shock (CS) is a life-threatening condition characterized by inadequate tissue perfusion due to severe impairment of myocardial contractility, most frequently resulting from acute myocardial infarction (AMI) with left ventricular dysfunction. Although contemporary therapies have improved, CS continues to carry a high in-hospital mortality rate. Timely and targeted hemodynamic resuscitation remains a cornerstone of management but poses significant challenges, particularly in advanced shock states.

Objective: This study aims to evaluate the role of invasive hemodynamic monitoring using a pulmonary artery catheter (PAC) in guiding goal-directed therapy and improving outcomes in patients with cardiogenic shock (CS) secondary to acute myocardial infarction.

Methods: A prospective observational study was conducted at Bachmai Hospital (2025–2027). Adult patients with AMI-induced CS were enrolled and underwent early PAC-guided hemodynamic assessment. Hemodynamic targets within the first 24 hours included: cardiac index (CI) \geq 2.2 L/min/m², cardiac power output (CPO) \geq 0.6 W, pulmonary artery occlusion pressure (PAOP) between 15–18 mmHg, right atrial pressure (RAP) between 8–12 mmHg, mixed venous oxygen saturation (SvO₂) \geq 60%, and lactate clearance. Vasoactive agents and fluid management were titrated accordingly.

Outcomes: Primary outcomes were in-hospital mortality and 30-day mortality. Secondary outcomes included length of stay in ICU, length of stay in hospital, duration of vasopressor use, and PAC-related complications.

Conclusion: Continuous hemodynamic monitoring via Swan–Ganz catheter enables precise characterization of cardiogenic shock phenotype and facilitates real-time, targeted interventions. This study is expected to provide critical data on the effectiveness of PAC-guided resuscitation in improving survival and hemodynamic stabilization in patients with AMI-related CS in a Vietnamese tertiary care setting.

Introduction

Cardiogenic shock (CS) is an acute circulatory failure state marked by critically low cardiac output, leading to tissue hypoperfusion and life-threatening oxygen debt. Acute myocardial infarction (AMI) remains the leading etiology, accounting for over 80% of CS cases with left ventricular dysfunction [1],[2],[3]. Despite advances in revascularization and mechanical support, in-hospital mortality remains high, ranging from 27% to 51% [4], [5], [6]. AMI with extensive left ventricular dysfunction accounts for approximately 81% of CS cases. Early recognition and targeted hemodynamic resuscitation are crucial for improving clinical outcomes. However, the clinical diagnosis and management of CS remain complex due to the heterogeneous nature of its presentation and the dynamic progression of hemodynamic instability.

The IABP-SHOCK II criteria provide a standardized clinical definition of CS, encompassing both hypotension (systolic blood pressure < 90 mmHg for ≥30 minutes or need for vasopressors to maintain SBP > 90 mmHg) and evidence of end-organ hypoperfusion manifested as altered mental status, oliquria (<30 mL/hour), cold

extremities or mottled skin, and elevated serum lactate (>2 mmol/L) [2]. Invasive hemodynamic monitoring plays a pivotal role in resuscitating cardiogenic shock, particularly when clinical markers such as blood pressure, urine output, or serum lactate levels become insufficient to guide complex therapeutic decisions. Advanced parameters, including cardiac index (CI), cardiac power output (CPO), pulmonary artery occlusion pressure (PAOP), right atrial pressure (RAP), and mixed venous oxygen saturation (SvO₂), offer a quantitative assessment of preload, afterload, contractility, and systemic oxygen delivery. The pulmonary artery catheter (PAC) enables real-time measurement of these variables and supports individualized titration of fluids, vasopressors, and inotropes. Recent data suggest PAC-guided management may improve short-term outcomes in CS.

In Vietnam, clinical data on the application of PAC in CS remain limited. This study aims to evaluate the role of Swan–Ganz catheterization in hemodynamic resuscitation among patients with cardiogenic shock due to acute myocardial inarction at Bachmai Hospital, focusing on achieving early hemodynamic goals (CI, CPO, PAOP, RAP, SvO₂, lactate) within 24 hours and their association with in-hospital and 30-day mortality.

Methods

Study design

The study design is a clinical trial without a control group, single-center (the Emergency Center, Bachmai Hospital). Eligible patients will be consecutively enrolled between January 2025 and December 2027 based on predefined inclusion and exclusion criteria (Table 1). A study flow chart is shown in Fig. 1.

Fig 1. Bold the figure title. Figure caption text here, please use this space for the figure panel descriptions instead of using subfigure commands. A: Lorem ipsum dolor sit amet. B: Consectetur adipiscing elit.

Ethical approval

All research documents were approved by the Ethics Committee of Bach Mai Hospital according to decision No. 33/BM-HDDD. All patients and family members agree to participate in the study and have signed an informed consent. All consent data are obtained in both verbal and written formats.

Sample size calculation

We applied the formula for estimating a proportion with a specified absolute precision to calculate the required sample size:

$$n = \frac{\left(Z_{\left\{1-\frac{\alpha}{2}\right\}}\right)^2 \cdot P(1-P)}{d^2}$$

Where: n is the required sample size, P is the estimated in-hospital mortality among patients with cardiogenic shock managed using pulmonary artery catheter (PAC); based on the study by Hernandez et al., P = 35% [46], d is the absolute margin of error (set at 9%), Z is the standard normal deviate corresponding to a confidence level of 95% (Z = 1.96), α is the significance level (set at 0.05). Substituting the values into the formula, we obtain a required sample size of n = 108.

At Bach Mai Hospital, approximately two patients are diagnosed with cardiogenic shock and admitted daily across four specialized units: the Cardiology Department (C1), the Coronary Care Unit (Q1), the Emergency Center, and the Intensive Care Center. This corresponds to an estimated 730 admissions for cardiogenic shock annually. Assuming a 20% attrition rate due to incomplete data collection or exclusion criteria, we anticipate approximately 584 eligible patients per year. Therefore, the target sample size is considered feasible within the proposed study period.

- Patient screening and enrollment Diagnosis: Cardiogenic shock (CS) due to acute myocardial infarction (AMI), based on IABP-SHOCK II criteria. Percutaneous coronary intervention (PCI) ± angioplasty, and stent insertion Inclusion and exclusion criteria were applied (Table 1) Proceed with placement of Swan–Ganz pulmonary artery catheter (PAC) Targeted hemodynamic monitoring within Catheter insertion details 24h (every 3 hours): documented: $CI > 2.2 L/min/m^2$. Site of access, CPO ≥ 0.6 (W) Catheter length, CVP: 8 - 12 mmHa. Waveform confirmation. PAOP: 15 - 18 mmHq. Any procedural complications. SvO2: 60-80%. Lactat < 2 mmol/L. Primary outcome: Achievement of 24-hour hemodynamic goals 30-day mortality. Secondary outcome:
 - PAC-related complications
 - Feasibility and challenges of catheter placement

Fig 1. Flow chart of the study design. PAC is Pulmonary Artery Catheter; CPO is Cardiac Power Output; CVP is Central Vein Pressure; PAOP is Pulmonary Artery Occlusion Pressure.

Table 1. 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

- 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°/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.	

Statistical analysis:

Statistical analyses will be conducted using SPSS software, version 16.0 (IBM Corp., Armonk, NY, USA). Continuous variables will be assessed for normality using the Shapiro–Wilk test. Data with normal distribution will be reported as mean ± standard deviation (SD), whereas non-normally distributed variables will be presented as median and interquartile range (IQR). Categorical variables will be summarized as absolute counts and proportions.

Comparisons of continuous variables between two independent groups (e.g., survivors vs. non-survivors) will be performed using the independent t-test for normally distributed data or the Mann–Whitney U test for skewed distributions. The Chi-square test or Fisher's exact test will be applied for between-group comparisons of categorical variables.

Paired t-test or Wilcoxon signed-rank test will be used to evaluate within-group changes in hemodynamic parameters over time. Where applicable, one-way ANOVA will be used to compare mean values across more than two subgroups.

Pearson or Spearman correlation analysis will be employed to explore associations between continuous variables such as cardiac index (CI), pulmonary artery occlusion pressure (PAOP), and serum lactate levels.

Receiver operating characteristic (ROC) curve analysis will be performed to evaluate the discriminatory performance of selected hemodynamic indices in predicting 30-day mortality. Area under the curve (AUC) values will be interpreted using standard benchmarks, with values >0.8 indicating good predictive accuracy.

Multivariable logistic regression will be used to identify independent predictors of unfavorable 30-day outcomes. Variables included in the model will be selected based on clinical plausibility and significance in univariate analysis. Adjusted odds ratios (ORs) and 95% confidence intervals (CIs) will be reported to quantify associations.

All statistical tests will be two-sided, and a p-value of less than 0.05 will be considered statistically significant. All data inputs from the patients are recorded and reported in **Table 2**.

Primary outcome:

The primary outcome is the rate of achieving hemodynamic targets within the first 24 hours following Swan–Ganz catheter.

Hemodynamic targets are defined as:

- MAP ≥ 65 mmHg.
- Cardiac Index (CI) ≥ 2.2 L/min/m².
- Pulmonary Capillary Wedge Pressure (PCWP) between 12–15 mmHg.
- Central Venous Pressure (CVP) between 8–12 mmHg.
- Mixed venous oxygen saturation (SvO₂) ≥ 65%.
- Lactat < 2 mmol/L.
- VIS (Vasoactive Inotropic Score)

Additionally, **30-day all-cause mortality and in-hospital mortality** will be assessed as clinical endpoints related to early hemodynamic stabilization.

Secondary outcomes:

- Advantages and disadvantages of the PAC placement procedure.
- Complications related to PAC.
- Length of stay in ICU.
- Length of stay in hospital.
- Ventilator days.
- Renal replacement therapy requirement.

Table 2. Clinical and subclinical characteristics of patients.

Variable	Unit / Classification
Patient Characteristics	
Age	Years (mean ± SD)
Sex	Male / Female (n, %)
Body mass index (BMI)	kg/m² (mean ± SD)
Medical history	
Hypertension	Yes / No (n, %)
Diabetes mellitus	Yes / No (n, %)
Dyslipidemia	Yes / No (n, %)
Clinical Scores	
SCAI stage	A, B, C, D, E (n, %)
APACHE II score	Mean ± SD
SOFA score	Mean ± SD
Clinical Presentation	
Time from symptom onset to admission	Hours (mean ± SD)
Type of AMI	I, II, III, IV, V
Infarct location	Anterior / Inferior / Lateral / etc.
Reperfusion strategy	PCI / Fibrinolysis / None
Mechanical ventilation	Yes / No (n, %)
Renal replacement therapy	Yes / No (n, %)
Laboratory Values	
Lactate	mmol/L
NT-proBNP / BNP	pg/mL
Troponin I/T	ng/mL
Serum creatinine, AST, ALT, and BIL	µmol/L
eGFR	mL/min/1.73 m ²
Hemodynamic (PAC)	
Mean arterial pressure (MAP)	mmHg
Central venous pressure (CVP)	mmHg
Pulmonary artery pressure (systolic/diastolic/mean)	mmHg
	mmHg
Cardiac index (CI)	L/min/m²
Systemic vascular resistance (SVR)	dyn·s·cm⁻⁵
Mixed venous oxygen saturation (SvO ₂)	%
Cardiac power output (CPO)	Watts (W)
Pulmonary artery pulsatility index (PAPi)	(PASP - PADP) / RAP
Vasopressor-Inotropic Score (VIS)	Unitless

Table 3. Technical Challenges:

Category	Details (from research case record form)
PAC-Related Complications	
Bleeding at the insertion	Yes / No
Pneumothorax	Yes / No
Hematoma	Yes / No
Pericardial effusion	Yes / No
PAC obstruction	Yes / No
PAC-related thrombosis	Yes / No
Local site complications.	Bleeding, dislodgement, redness, skin breakdown, suture loss.
Technical Challenges	
Time factors	Time to prepare, sheath insertion, wave detection (RA, RV, PA, PAOP) all documented.
Number of attempts	PAC successfully placed on 1st / 2nd / 3rd
PAC position	Pulmonary Artery (Right/Left)
Infection risk	Cultures of PAC tip, blood (CVC, PAC, peripheral).

Discussion

The Swan-Ganz pulmonary artery catheter (PAC) remains the most comprehensive bedside tool for real-time, invasive hemodynamic assessment, offering continuous data on cardiac output (CO), cardiac index (CI), pulmonary capillary wedge pressure (PCWP), systemic vascular resistance (SVR), and mixed venous oxygen saturation (SvO₂). These parameters enable accurate classification of shock phenotypes (e.g., left-dominant, right-dominant, mixed), optimization of fluid resuscitation, and titration of vasopressors, inotropes, or mechanical circulatory support (MCS) devices [7], [8], [9], [10], [11]. In a pivotal 2021 study published in the Canadian Journal of Cardiology, Réa et al. reported that among 1,043 CS patients, PAC use (47%) was associated with a significantly lower in-hospital mortality (29.3%) compared to those not monitored invasively (36.2%; P=0.02), particularly in patients classified as SCAI stages D and E. Furthermore, the PAC group had significantly higher rates of MCS device utilization (Impella, LVAD, RVAD), suggesting that invasive hemodynamic data guided more aggressive and timely interventions [12]. This survival benefit was further corroborated in a large-scale meta-analysis by Chow et al., involving over 2.7 million patients with CS. The use of PAC was associated with improved survival to hospital discharge (RR=0.72, 95% CI: 0.60-0.87) [9]. Similarly, Bertaina et al. (2022) analyzed pooled data from six studies totaling 1.16 million CS cases and found lower short-term mortality in the PAC group (36% vs. 47%, OR=0.71, 95% CI: 0.59-0.87, P<0.01), along with increased MCS use (59% vs. 48%, OR=1.6, 95% CI: 1.27-2.02, P<0.01) [7]. Further reinforcing these findings, Ta Kyung et al. conducted a 21-year retrospective analysis of 950,530 CS cases and found that PAC placement was significantly associated with reduced mortality (OR=0.63, 95% CI: 0.41-0.97) [13]. In another multicenter study across 34 cardiac intensive care units, Kadosh et al. found lower mortality in PACmonitored patients (28.4%) compared to those without PAC (35%, OR=0.79, 95% CI: 0.66-0.96, P=0.017) [14].

Our study seeks to further contribute to this evidence base by evaluating whether early PAC-guided resuscitation can improve achievement of hemodynamic targets (CI \geq 2.2 L/min/m², CPO \geq 0,6W, PCWP beetween 12 and 18 mmHg, SvO₂ from 60% to 80%, lactat <2 mmol/L) and reduce 30-day mortality and in-hospital mortality. Mixed Venous Oxygen Saturation (SvO₂) and Oxygen Extraction Ratio (O₂ER): Provide dynamic insight into balance between oxygen delivery and consumption; SvO₂ <60% or O₂ER >30% may signal insufficient perfusion [15]. Cardiac Power Output (CPO) and Cardiac Power Index (CPI): Strongly predictive of survival in CS; CPO <0.6 W and CPI <0.3

W/m² are associated with poor prognosis [16], [17], [18], [19]. Beyond static hemodynamic thresholds, continuous trend analysis of dynamic parameters as implemented through serial measurements every 3 hours during the first 24 hours is used to evaluate therapeutic efficacy and identify early signs of hemodynamic deterioration. For example, a rising cardiac index (CI) trajectory coupled with a declining lactate and improving SvO₂ trend reflects restored oxygen delivery relative to demand, indicating resuscitation success. In contrast, plateauing or declining CI despite escalating inotropic support, or a persistently low SvO₂ <60% despite normalized mean arterial pressure (MAP), may suggest underlying myocardial reserve exhaustion or maladaptive vasodilation. Likewise, trends in pulmonary capillary wedge pressure (PCWP) can indicate evolving left ventricular compliance or fluid overload, while progressively rising right atrial pressure (RAP) or decreasing PAPi values can herald right ventricular failure or volume mismanagement. Hemodynamic phenotyping is critical in guiding device-specific mechanical circulatory support (MCS) strategies. For example, a low PAPi (<1.0) with elevated RAP and preserved PCWP may indicate isolated RV-failure, suggesting the need for targeted right ventricular assist devices (RVAD) or temporary RV support (e.g., Protek Duo). In contrast, a low CPO (<0.6 W) with high PCWP and low CI suggests severe left ventricular failure, potentially responsive to Impella or tandem LV support. When profound biventricular failure or mixed shock exists, especially with systemic hypoxemia or lactic acidosis, veno-arterial extracorporeal membrane oxygenation (VA-ECMO) may be the most appropriate strategy [20]. Additionally, we aim to assess the frequency of PAC-related complications to better define its safety profile.

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