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Hemodynamic assessment of different septic shock resuscitation strategies: a comparison of volume expansion versus norepinephrine administration, a prospective: Study protocol

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ABSTRACT:

Background: Fluid resuscitation and vasopressors are the mainstays of septic shock management. However, individual hemodynamic responses vary significantly based on baseline cardiac function and preload status. Bedside echocardiography is a valuable tool for assessing these parameters, monitoring fluid responsiveness, and predicting vasopressor efficacy, which can ultimately improve patient outcomes. While recent studies have explored echocardiographic responses to vasopressin, evidence comparing hemodynamic responses to available vasopressors (like norepinephrine) versus fluid therapy in early septic shock remains limited, particularly in Thailand, where vasopressin is unavailable. This bedside echocardiography will help identify hemodynamic responders and guide individualized, precise management.

Objective: To test the hypothesized assumption that hemodynamic response would differ between volume resuscitation and norepinephrine infusion resuscitation, in terms of cardiac index and stroke volume.

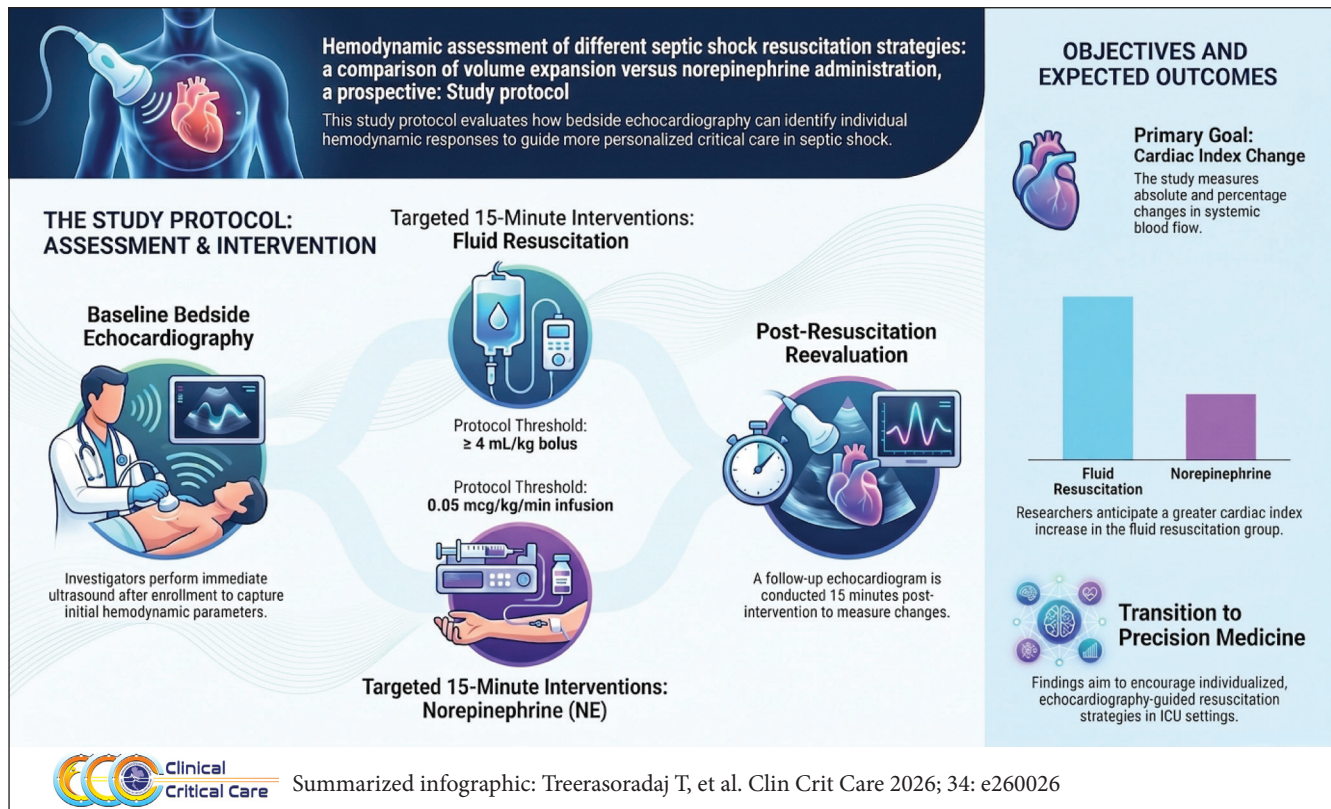
Methods: This is a prospective cohort study conducted in the medical and surgical intensive care units of a tertiary care hospital in Thailand. We perform pre- and post-resuscitation echocardiography on patients with septic shock. Resuscitation strategies follow the Surviving Sepsis Campaign 2021 guidelines and are entirely directed by the attending physicians without blinding or randomization. To standardize the assessment, post-resuscitation echocardiography is performed 15 minutes after one of two physician-selected interventions: either fluid resuscitation with an intravenous bolus of isotonic fluid (≥ 4 mL/kg ideal body weight) or vasopressor resuscitation by norepinephrine with an infusion reaching 0.05 mcg/kg/min. The primary outcome is the change in the echocardiographic cardiac index from baseline to post-resuscitation.

Conclusions: This study aims to evaluate pre- and post-intervention echocardiographic profiles in septic shock patients receiving either fluid boluses or norepinephrine infusion resuscitation.

Ethics and dissemination: This study was approved by Siriraj institutional review board (IRB) on Certificate of approval (COA) no. Si 061/2025 Written informed consent was obtained from all participants or legally authorized representative (LAR) prior to inclusion in the study.

Trial registration: NCT07438301

Keywords: Sepsis; Septic Shock; Echocardiography



INTRODUCTION

Septic shock is a life-threatening condition. A bundle of care in septic shock patients has been published to improve the quality of treatment globally [1]. Fluid expansion and vasopressors have been the mainstay for shock resuscitation in septic shock. Novel studies such as use of methylene blue [2], dynamic fluid and vasopressor assessment [3,4], or echocardiography [5] have shown benefit in practice of septic shock management.

Echocardiographic profiles are able to assess cardiac functions in both the left and right sides of the heart [6]. The surrogates from echocardiogram could interpret various aspects of outcomes in septic shock patients, such as monitoring fluid responsiveness [7,8], and predicting the response of vasopressors in each patient [9]. Performing bedside echocardiography resulted in a better outcome and reduced mortality rate in critically ill settings [10].

There are limited studies that focus on echocardiographic response to vasopressor infusion in septic shock patients. A recent study about pre-vasopressin-infusion echocardiography has been the pioneer study in critically evaluating the association between echocardiographic response and patient outcomes. The study could guide the possibility of responders, who had prior higher LV systolic function, to adjunctive vasopressin infusion [11].

Hemodynamic responses to fluid resuscitation and norepinephrine administration vary widely. Fluid resuscitation typically increases stroke volume and cardiac output, especially in fluid-responsive patients, by augmenting preload and improving left ventricular filling. However, excessive fluid administration may lead to hemodynamic derangements without further improvement in cardiac output [12]. Studies have shown that patients with a low LVOT-VTI or collapsible inferior vena cava are more likely to benefit from fluid resuscitation, as these parameters reflect pre-

KEY MESSAGES:

- **Clinical Gap:** While fluid boluses and vasopressors are standard resuscitative strategies for septic shock, individual hemodynamic responses vary significantly, necessitating precise, individualized management.
- **Dynamic Assessment:** This prospective study utilizes bedside echocardiography to evaluate changes in the cardiac index and related parameters before and 15 minutes after targeted fluid or norepinephrine resuscitation.
- **Clinical Impact:** By identifying specific hemodynamic responder profiles, this study aims to guide tailored resuscitation strategies and personalized approaches.

load dependency and fluid responsiveness. Conversely, in non-fluid-responsive patients, the effect of fluid boluses on hemodynamic parameters is often negligible or transient, highlighting the need for precise volume management in septic shock [13].

Norepinephrine, a primary vasopressor in septic shock management, exerts its effects by increasing vascular tone and subsequently improving cardiac output [14]. Studies have demonstrated that norepinephrine can also augment stroke volume in patients with vasodilatory shock by enhancing contractility via beta-adrenergic effects. However, the hemodynamic response to norepinephrine is influenced by baseline cardiac function, preload status, and the degree of vasodilation, underscoring the importance of individualized therapy and close monitoring through echocardiographic parameters [15].

Since the difference in pathophysiologic response between vasopressin and noradrenaline. Moreover, vasopressin is currently non-available in Thailand. The study of the aspect of hemodynamic response by echocardiography to available vasopressors versus fluid treatment, which both are mainstays during the early phase of septic shock, currently lacks concrete evidence.

We designed this study to evaluate pre-intervention and post-intervention echocardiographic profiles of those who receive either fluid bolus or vasopressor resuscitations.

OBJECTIVES

To test the hypothesized assumption that echocardiographic profile would be a greater increase of echocardiogenic cardiac index in volume resuscitation compared to vasopressor administration during the initial 15 minutes of resuscitation.

MATERIALS AND METHODS

Trial design

This is a prospective cohort study. The protocol was approved by the Ethics Committee of the Siriraj Institutional Review Board (Certificate of Approval No. Si 061/2025). This trial was already registered on ClinicalTrials.gov (NCT07438301). The manuscript adheres to STROBE protocol.

Study settings

The study was conducted in the medical and surgical intensive care units of Siriraj Hospital, Mahidol University, Bangkok, Thailand, from March 2025 onwards.

Participants

Inclusion criteria:

1. Adult patients aged 18 years old or older who will be admitted to the Intensive Care Unit
2. Diagnosis with sepsis with hypotension (Sepsis-3 definition of sepsis)
3. Hypotension, SBP < 90 mmHg, or mean arterial BP < 65 mmHg, who requires resuscitation, either fluid boluses or norepinephrine infusion resuscitation

Exclusion criteria:

1. Patients who receive two or more vasopressors.
2. Patients who receive inotropic medications.
3. Patients with insufficiently quality ultrasound images for determining echocardiography
4. Patients or their legally authorized representatives (LAR), who decline participation in the study or are unable to provide informed consent before enrollment

Study procedures

Enrollments

Patients with the diagnosis of sepsis or septic shock, who are admitted to intensive care units, will be evaluated for eligibility by the investigators daily.

Informed consent

Informed consent will be sought from each patient or their legally authorized representative (LAR) after identifying those who meet the inclusion criteria and do not have any exclusion criteria. This consent process will occur within 3 hrs. before enrollment in the study.

After enrollments

Upon admission to the ICU, patients receive standard evaluation and treatment in accordance with established guidelines. Following enrollment, they undergo a baseline bedside transthoracic echocardiography performed by the investigator to evaluate hemodynamic-related cardiac function parameters. Subsequently, the included patients receive resuscitation management according to the study protocol prior to a follow-up dynamic assessment via bedside echocardiography.

Resuscitation protocols

Resuscitation protocols follow the Surviving Sepsis Campaign 2021 guidelines, utilizing isotonic fluid boluses and vasopressors (norepinephrine or adrenaline). The single dose increment of fluid resuscitation using weight-guided fluid challenge with 4 mL/kg.[16] For norepinephrine, a single dose incrementing 0.05 mcg/kg/min has been proven to be practical in emergency critical settings [17]. The overall study diagram is illustrated as Figure 1. The study protocol guides attending physicians regarding the specific threshold of resuscitation patients must receive prior to the post-resuscitation echocardiographic assessment. The choice of resuscitation is not mandated, blinded, or randomized; attending physicians retain full clinical discretion to determine the most suitable strategy for each participant. The interventions required prior to the follow-up assessment are defined as follows:

- Fluid Resuscitation: An intravenous bolus of isotonic fluid (≥ 4 mL/kg of ideal body weight) administered over 15 minutes, followed by echocardiography.
- Vasopressor Resuscitation: A vasopressor infusion reaching a norepinephrine-equivalent dose (NEQ)[18] of 0.05 mcg/kg/min for 15 minutes, followed by echocardiography.

Echocardiographic assessment

To validate the ultrasound assessment technique, all examinations are performed by a critical care fellow trained in point-of-care ultrasound (POCUS) and transthoracic echocardiography. These assessments are closely supervised by an expert sonographer to ensure consistency and accuracy during data collection. To minimize potential bias, all bedside echocardiographic examinations are conducted by the same operator. To ensure data reliability, the sonographic results will be independently reviewed and validated by an institutional critical care cardiologist. Patients with missing or insufficient-quality ultrasound images are excluded from the analysis.

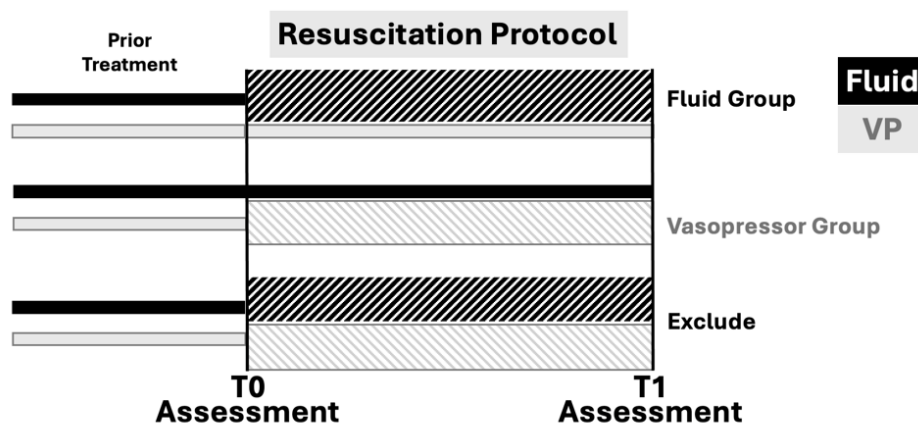


Figure 1. Overall study diagram and resuscitation protocol. T0 indicates the time of baseline echocardiographic assessment, and T1 indicates the follow-up echocardiographic assessment to evaluate hemodynamic changes. Solid black and solid grey lines represent intravenous (IV) fluid and vasopressor (VP) therapy administered prior to T0, respectively. Thick striped black lines denote the IV fluid intervention, while thick striped grey lines denote the intervention of increasing the vasopressor dose. The Fluid Group consists of patients receiving increased IV fluid alone, with any pre-existing vasopressor maintained at the baseline rate. The Vasopressor Group consists of patients receiving an increased vasopressor dose alone, with any pre-existing IV fluid maintained at the baseline rate. Patients receiving simultaneous increases in both IV fluid and vasopressors are excluded from the study.

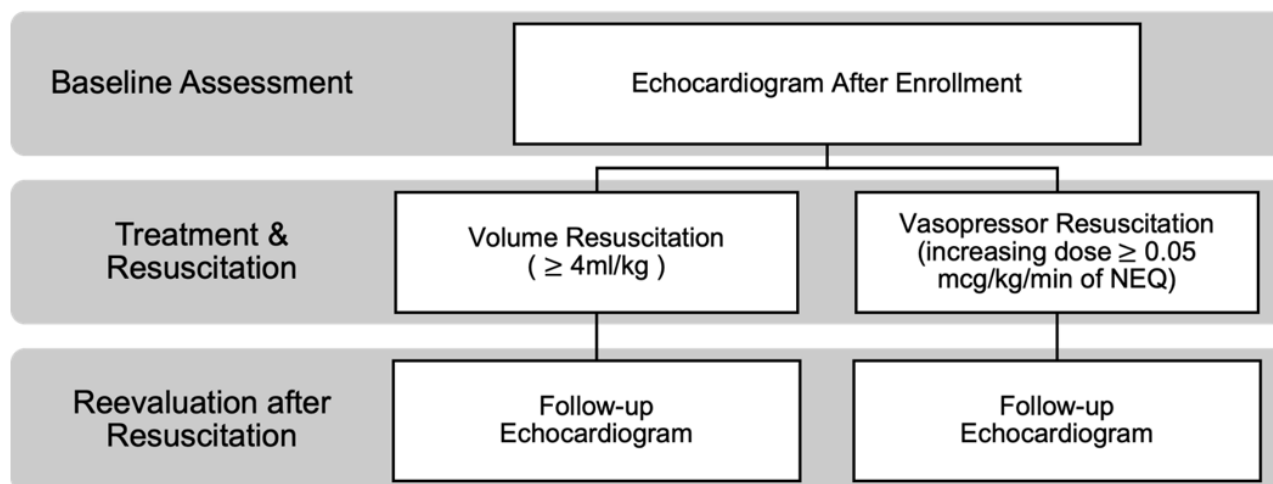


Figure 2. Flowchart of the resuscitation interventions and echocardiographic assessment timeline. Following a baseline echocardiogram at enrollment, patients are subjected to either volume resuscitation (receiving $\geq 4 \text{ ml/kg}$ of intravenous fluid) or vasopressor resuscitation (defined as an increased dose of $\geq 0.05 \text{ mcg/kg/min}$ of norepinephrine equivalent [NEQ]). A follow-up echocardiogram is performed exactly 15 minutes after the initiation of the respective resuscitation protocol to reevaluate hemodynamic changes.

Echocardiography is conducted at two primary time points, as in Figure 2: initially at baseline, immediately following patient enrollment, and subsequently post-resuscitation, following the completion of either the fluid or vasopressor protocol, which is 15 minutes after initiating resuscitation. These sequential assessments allow for the detection of dynamic echocardiographic responsiveness according to the duration to detect fluid challenges [16]. Because the echocardiographic examination occurs concurrently with active resuscitation, blinding the operator is not feasible in this study. Furthermore, the treating physicians cannot be blinded to the echocardiographic findings, as these results may determine and guide subsequent clinical management plans.

Investigators perform bedside echocardiography in the intensive care unit using a commercially available ultrasound system equipped with a cardiac transducer with a frequency range of 3.5 to 11.5 MHz. Color Doppler imaging and pulsed-wave (PW) Doppler are utilized to quantify the study parameters listed below. The approximate time required for patient and machine preparation is 5 minutes, while the echocardiographic examination itself takes 5 to 10 minutes to complete.

Echocardiographic parameter assessment

Investigators perform bedside echocardiography in the ICU to systematically evaluate the following parameters [6]:

- **Inferior Vena Cava (IVC) Variation:** The IVC diameter is measured in its intrahepatic portion, approximately 2 cm from the junction with the hepatic veins, using a longitudinal subxiphoid view. If the subxiphoid window is suboptimal, the probe is moved laterally to the right side of the body (transhepatic view) until an adequate window is achieved. Both maximal and minimal diameters during the respiratory cycle are recorded to assess respiratory variation.
- **Left Ventricular (LV) Function:** A comprehensive transthoracic echocardiogram is obtained to systematically measure systolic and diastolic parameters.
 - o **LV Systolic Function (LVEF):** Assessed using the Teichholz method in the parasternal long-axis (PLAX) view.
 - **Definitions:** LV systolic dysfunction is defined as $LVEF < 50\%$. LV hyperkinesia is defined as $LVEF > 70\%$.
 - o **LV Diastolic Function:** Assessed in the apical 4-chamber (A4C) view utilizing pulsed-wave (PW) Doppler and tissue Doppler imaging (TDI) techniques as appropriate.
 - **E:** Peak early diastolic velocity of mitral LV inflow.
 - **A:** Peak late diastolic velocity during atrial systole.
 - **E':** Peak early diastolic velocity of the septal mitral annulus.
 - **Definition:** LV diastolic dysfunction is defined as an $E/E' \text{ ratio} > 13$.
- **Stroke Volume (SV) and Cardiac Output (CO):** SV is determined using left ventricular outflow tract (LVOT) parameters. Consequently, CO is calculated by multiplying the LVOT velocity-time integral (VTI) with LVOT area and the concurrent heart rate. The cardiac index is calculated by CO divided by body surface area.
 - o **LVOT Diameter:** Measured in the PLAX view.
 - o **LVOT VTI:** Measured in the apical 5-chamber (A5C) view using the PW Doppler technique.
 - o **To minimize the variability of the measurement,** LVOT VTI will be measured with the average value of each LVOT VTI within 1 respiratory cycle, approximately 3-5 beats.

Data collection

The following data are collected during the study period:

- **Baseline Characteristics and Demographics:** Age, sex, weight, height, body mass index (BMI), body surface area (BSA), comorbidities, hospital and ICU admission dates and times, source of ICU admission, severity scores at ICU admission (APACHE II scores), ICU and hospital discharge dates and times, and discharge status.
- **Clinical Hemodynamic Parameters:** Systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), heart rate (HR), pulse pressure variation (PPV), and central venous pressure (CVP).
- **Baseline Laboratory Data:** Serum lactate, arterial pH, sodium, potassium, chloride, and bicarbonate.

- **Echocardiographic Parameters:** Left ventricular ejection fraction (LVEF), E/A ratio, E/E' ratio, left ventricular outflow tract velocity-time integral (LVOT VTI), and inferior vena cava (IVC) diameter variation.

- **Echocardiography-Derived Hemodynamics:** Cardiac index (CI).

- **Resuscitation Data:** Cumulative fluid volume administered prior to enrollment and baseline vasopressor dose (calculated as a norepinephrine-equivalent dose [NEQ]).

- **Mechanical Ventilation Parameters:** Fraction of inspired oxygen (FiO_2), positive end-expiratory pressure (PEEP), tidal volume (mL/kg), and minute ventilation.

- **Pre-Intervention Medications:** Vasopressors and corticosteroids (e.g., hydrocortisone).

- **Duration of Organ Support** (censored at day 28 post-enrollment): Dates and times of intubation and extubation, dates and times of vasopressor initiation and cessation, and total duration of the ICU stay.

- **Clinical Outcomes:** 28-day mortality, ICU mortality, hospital mortality, and time to shock reversal (defined as the time to the successful cessation of vasopressor support).

Outcome measurement

The primary objective of this study is to evaluate the change in the cardiac index from baseline to post-resuscitation, specifically comparing the percentage change and absolute differences between the fluid resuscitation and vasopressor resuscitation groups. We hypothesize that the cardiac index will increase by approximately 15% in the fluid resuscitation group, an increment expected to be greater than that observed in the vasopressor group.

The secondary objectives are to establish the correlation between these hemodynamic responses by echocardiogram within each intervention group and key clinical outcomes, including 28-day mortality, intensive care unit length of stay, mechanical ventilation-free days, and the requirement for renal replacement therapy.

Missing data will be handled using a complete-case analysis approach; patients with incomplete echocardiographic, laboratory, or follow-up data will be excluded from the final analysis.

DATA ANALYSIS PLAN

Sample size estimation

The primary objective of this study is to evaluate the change in the Cardiac Index (CI) from baseline to post-intervention among critically ill patients with septic shock at Siriraj Hospital. Specifically, the study compares the CI changes between patients receiving isotonic fluid resuscitation and those receiving vasopressor resuscitation as their initial therapy.

Based on a literature review, a previous study demonstrated that the mean percentage change in CI from baseline to post-fluid resuscitation was $24\% \pm 25\%$ ($n=228$), whereas the change following vasopressor resuscitation was $14\% \pm 18\%$ ($n=145$) [9].

The sample size was calculated based on the comparison of two independent means. Assuming a two-sided significance level (alpha) of 0.05 and a statistical power of 80%, a minimum of 81 patients per group is required to detect a significant difference between the two treatment arms. To account for an estimated 10% rate of missing data or drop-outs, the sample size is expanded to 90 patients per arm, resulting in a total required sample size of 180 patients (N = 180). The detail of the formula was based on the assumption of percentage change difference in cardiac index between each group using nQuery Advisor and is shown in the formula below.

$$S_p^2 = \text{pool variance} = \frac{(n_1-1)s_1^2 + (n_2-1)s_2^2}{n_1+n_2-2} = \frac{(228-1)(25)^2 + (145-1)(18)^2}{228+145-2} = 508.19$$

$$s_p = \sqrt{508.19} = 22.543$$

$$n / \text{group} = \frac{2\sigma^2(Z_{\alpha/2} + Z_{\beta})^2}{(\mu_1 - \mu_2)^2}$$

$$\frac{n}{\text{group}} = \frac{2(22.543)^2(1.96 + 0.84)^2}{((24) - (14))^2}$$

Outcome analysis plan

Descriptive statistics are utilized to summarize the baseline characteristics of the study population. Categorical data, such as gender and comorbidities, are presented as frequencies and percentages. Continuous variables are reported as means and standard deviations if normally distributed, or as medians with minimum and maximum values (or interquartile ranges) if non-normally distributed. For inferential statistics, comparisons of continuous data between the fluid and vasopressor resuscitation groups—including the primary outcome of changes in the echocardiographic cardiac index and baseline laboratory values—are analyzed using an independent t-test, paired t-test, or Mann-Whitney U test, as appropriate. Categorical variables, including baseline clinical factors, in-hospital mortality, and the requirement for renal replacement therapy, are compared using a chi-square test or Fisher's exact test. Correlations are analyzed with Pearson correlation analysis. Given the non-randomized study design, comparisons of the primary and secondary outcomes between the treatment groups will be adjusted for baseline characteristics to mitigate potential confounding by indication. For secondary clinical outcomes, both univariable and multivariable analyses will be performed to adjust for relevant clinical covariates. All statistical analyses are two-tailed, and a p-value of < 0.05 is considered to indicate statistical significance.

DISCUSSION

The optimal initial resuscitation strategy for septic shock remains a critical challenge in intensive care. While the Surviving Sepsis Campaign guidelines advocate for initial fluid resuscitation [1] and a recent randomized controlled study demonstrates the benefits of early vasopressor administration [17], individual hemodynamic responses vary significantly. By evaluating changes in hemodynamic parameters, such as the cardiac index, this study will provide valuable insights into the relationships between

characteristic patient phenotypes and their responses to specific resuscitative strategies. Echocardiography is a useful bedside tool in the intensive care unit for evaluating hemodynamic responses during resuscitation scenarios. Cardiac index is selected as the primary endpoint because it provides the most comprehensive, real-time measure of systemic blood flow adjusted for patient size and directly captures the immediate forward flow response within the 15-minute assessment window. Ultimately, demonstrating these dynamic changes could encourage a shift toward more individualized, echocardiography-guided resuscitation strategies.

Strengths

The design reflects actual clinical practice in the ICU, making the findings highly applicable to real-world critical care settings. To ensure high data reliability, all assessments are performed by a single, trained critical care physician. The study utilizes a systematic protocol to capture the immediate, dynamic physiological responses to specific resuscitation strategies. Furthermore, the study specifically evaluates the hemodynamic response to norepinephrine, the first-line vasopressor used in septic shock resuscitation in Thailand. Therefore, the findings could also apply to resource-limited settings as well.

Limitations

As this is a study without randomization, the choice of intervention is dictated by the attending physician. Due to the nature of the interventions and the protocol, neither the operator nor the treating physicians can be blinded. To reliably detect differences in hemodynamic responses using echocardiography, the magnitude of change in the cardiac index must exceed 10% [19]. However, there is limited evidence regarding the least significant change required to detect differences in other echocardiographic parameters. Furthermore, being conducted in a single center may limit the generalizability of the findings. We acknowledged the limitation of the Teicholz technique to detect LV systolic function in accuracy compared to other methods such as the 2D Simpson's biplane technique. Despite the limitation, since its reproducibility in critical phases of patient conditions and operators who are not cardiologists, we decided to use the Teicholz technique. Lastly, the 15-minute post-resuscitation assessment window captures the immediate hemodynamic effects but may not account for delayed responses.

CONCLUSION

This study aims to evaluate pre- and post-intervention hemodynamic responses by echocardiography in septic shock patients receiving either fluid boluses or norepinephrine infusion.

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CRedit Author Contributions: Study conception and design: T.T., S.T.; Methodology: T.T., S.T.; Data Collection: T.T., S.T.; Data Analysis and Interpretation: T.T., S.T.

Institutional Review Board Statement: This study was approved by Siriraj institutional review board (IRB) on Certificate of approval (COA) no. Si 061/2025.

Informed Consent Statement: Written informed consent was obtained from all participants or legally authorized representative (LAR) prior to inclusion in the study.

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