Clinical Critical Care

E-ISSN 2774-0048

VOLUME 31 NUMBER 1

JANUARY-DECEMBER 2023

Clinical Critical Care
eISSN 2774-0048

Clinical Critical Care
Volume 31, Article ID e0008, 7 pages
https://doi.org/10.54205/ccc.v31.260187

RESEARCH PROTOCOL

Dynamic arterial elastance for predicting mean arterial pressure responsiveness after fluid challenge in spontaneously breathing septic patients: A protocol for prospective observational study

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OPEN ACCESS

Citation:
Injampa S, Luetrakool P, Morakul S, Petnak T. Dynamic arterial elastance for predicting mean arterial pressure responsiveness after fluid challenge in spontaneously breathing septic patients: a protocol for prospective observational study. Clin Crit Care 2023; 31: e0008.

Received: November 28, 2022
Revised: February 13, 2023
Accepted: April 17, 2023

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Data Availability Statement:
The data and code were available upon reasonable request (Punchika Luetrakool, email address: punchika.lue@mahidol.ac.th)

Funding:
This research project is supported by the Faculty of Medicine Ramathibodi Hospital Mahidol University.

Competing interests:
No potential conflict of interest relevant to this article was reported.

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ABSTRACT:

Background: Fluid resuscitation is essential for patients with sepsis and septic shock; however, the response of blood pressure to fluids is still challenging. Dynamic arterial elastance (Ea_{dyn}), defined as the ratio between pulse pressure variation (PPV) and stroke volume variation (SVV), is one of the parameters that has been proposed to predict mean arterial pressure (MAP) response to fluid administration. PPV and SVV are obtained from the heart-lung interaction concepts, in which spontaneous breathing is an important limitation. In this study, we evaluate the accuracy (sensitivity and specificity) of Ea_{dyn} in predicting the MAP response after fluid administration in predicted fluid responsive, spontaneously breathing septic patients.

Methods: Spontaneously breathing patients with sepsis or septic shock and acute circulatory failure who were predicted to be fluid responders by the passive leg raising test or the mini-fluid challenge test were enrolled. PPV, SVV, Ea_{dyn} and the other hemodynamic parameters were measured by an arterial catheter connected to FloTrac™ sensor integrated with the HemoSphere™ platform before and after a fluid challenge. Patients were classified according to the increase in MAP after fluid administration into 2 groups: MAP-responders (MAP increase ≥ 10%) and MAP-nonresponders (MAP increase < 10%).

Hypothesis: In predicted fluid responders and spontaneously breathing septic patients, Ea_{dyn} should have predicted blood responsiveness.

Ethics and dissemination: The Ramathibodi Human Research Ethics Committee has approved the trial. The findings plan to be presented in peer-reviewed publications and conferences in critical care medicine.

Trial registration number: TCTR20220517001

Keywords: Arterial pressure, Cardiac output, Fluid therapy, Hemodynamics, Stroke volume.

BACKGROUND

Sepsis and sepsis shock are life-threatening organ dysfunctions caused by a dysregulated host response to infection, which kill between one- third and one-sixth of the patients affected.[1]

Fluid resuscitation is essential for stabilizing sepsis-induced hypotension or septic shock patients and improving organ perfusion. Other than fluid under-resuscitation being related to complications, fluid over-resuscitation is associated with prolonged ventilation, progression of acute kidney injury, and increased mortality.[1] Fluid administration alone does not ensure that arterial blood pressure will be increased because both fluid responsiveness and arterial load are important factors in the response to arterial blood pressure.[2]

Multiple static parameters were used to assess fluid status, such as central venous pressure, heart rate, and systolic blood pressure. But compared to dynamic parameters such as the passive leg raising test combined with cardiac output measurement or fluid challenges against stroke volume or pulse pressure, static parameters seem to have lower accuracy at predicting fluid responsiveness.[1]

In addition to volume status assessment, arterial load assessment is also important for gathering data to decide between fluid therapy and vasopressors for correcting vasoplegia. So, proper parameters to assess arterial load will help in receiving proper treatment and preventing excessive fluid.

Dynamic arterial elastance (Ea_{dyn}), the ratio between pulse pressure variation (PPV) and stroke volume variation (SVV), is one of the parameters assessing arterial load.[3] It represents the change in arterial pulse pressure for a given change in stroke volume during a respiratory cycle.[4] Many studies have found Ea_{dyn} can predict an increase in mean arterial pressure (MAP) after fluid expansion.[4-7] Most studies were conducted in patients with controlled ventilation, but theoretically, if the PPV and SVV values were high enough to determine the slope of the pressure-volume curve, the ratio of PPV to SVV remained stable even with spontaneous ventilation.[8]

In a previous study, PPV and SVV values were used to determine Ea_{dyn} in spontaneous patients and predict the increase in blood pressure after fluid administration. In that study, the Nexfin monitoring system (BMEYE, Amsterdam, The Netherlands), which provides non-invasive monitoring of the circulatory system, was used, and it was found that Ea_{dyn} values obtained from Nexfin could accurately predict changes in blood pressure after fluid administration.[9] But in our institute, an arterial catheter is preferred in patients with sepsis and septic shock to measure cardiac output (CO), stroke volume (SV), and SVV. Therefore, the research team is interested in studying the reliability of the Ea_{dyn} value calculated from PPV and SVV values obtained from minimally invasive hemodynamic monitoring that uses pulse contour analysis techniques to predict pressure responsiveness after fluid administration in sepsis or septic shock patients with spontaneous breathing.

KEY MESSAGE:

- This study assesses the effectiveness of Ea_{dyn} in predicting pressure responsiveness in sepsis and septic shock patients with predicted fluid-responsive, spontaneously breathing septic patients. We hypothesize that Ea_{dyn} could predict pressure responsiveness even though patients are spontaneously breathing; known as a limitation of other pulse contour analysis parameters.

OBJECTIVES

Primary objective

To determine the accuracy of Ea_{dyn} values obtained from The HemoSphere™ platform combined with the FloTrac™ sensor transducer in predicting the rise in blood pressure after fluid administration in sepsis or septic shock patients with spontaneous breathing.

Secondary objective

To determine a cut point for Ea_{dyn} based on PPV and SVV values measured using the HemoSphere™ platform combined with the FloTrac™ sensor transducer in predicting the rise in blood pressure after fluid administration in sepsis or septic shock patients with spontaneous breathing.

Hypothesis

In predicted fluid responder, spontaneous breathing septic patients, Ea_{dyn} should be predicted pressure responsiveness.

MATERIALS AND METHODS

Trial design

This prospective observational study was approved by the ethics committee of Ramathibodi Hospital, Mahidol University (COA. MURA2022/38) and registered in the Thai Clinical Trials Registry (TCTR20220517001). Informed consent was obtained from each patient and/or patient representative or relative.

Study setting

This study was conducted in the medical and surgical intensive care unit (ICU), Ramathibodi Hospital, Mahidol University, Bangkok, Thailand.

Participant selection and recruitment

All patients admitted to the ICU (both the medical and surgical ICU) are considered for participation. When the patient is identified by the attending physician as having circulatory failure (as defined below) with sepsis and/or septic shock and requires fluid administration, fluid responsiveness prediction will be done by a passive legs raising test or mini-fluid challenge test. If patients are flu-

id responders, they are included in the study. Only one fluid challenge per patient is included in the analysis.

There is no time limit in this study from the time a patient is diagnosed with circulatory failure to inclusion.

Eligibility criteria

Inclusion criteria

- Patients are admitted to the medical and surgical intensive care unit, Ramathibodi hospital, Mahidol University
- Patients diagnose sepsis or septic shock according to diagnostic criteria in Sepsis-3[10].
- Patients have spontaneous breathing, including those with no oxygen support, on conventional oxygen therapy, high-flow oxygen nasal cannulas, non-invasive ventilation, and mechanical ventilation that is triggered by the patients.
- Patients are monitored CO by the invasive hemodynamic monitoring connected to an arterial catheter (not limited to a radial artery catheter).
- Patients have acute circulatory failure (1 or more).
  - o MAP < 65mmHg or systolic blood pressure (SBP) < 90mmHg or decrease in SBP > 40mmHg from baseline
  - o Urine output < 0.5 ml/kg/hour consecutively for 2 hours
  - o Serum arterial lactate > 2 mmol/l
- Patients and/or patient representatives or relatives willing to participate in the research project must sign a consent letter to participate in the research project.
- Patients who have positive results from the passive leg raising test or the mini-fluid challenge test
  - o Passive leg raising test: CO increases by 10% or more after leg raising.
  - o Mini fluid challenge test: CO increases by 10% or more after an infusion of 100 mL of intravenous fluid over one minute.

Exclusion criteria

- Patients have arrhythmias including premature ventricular complex, premature atrial complex, atrial fibrillation, ventricular tachycardia, and sinus arrhythmia.
- Patients have right heart failure, defined here as evidence of abnormal RV structure or function with clinical signs of right heart failure, including edema in both legs, hepatomegaly, etc.
- Patients have intra-abdominal pressure > 12 mmHg.
- Patients have a ratio between heart rate and respiratory rate of less than 3.6.
- Patients are using neuromuscular blocking agents.
- Patients receiving a vasoactive agent other than norepinephrine.
- Patients, patient representatives, or relatives may decline to participate in the research project and sign a consent letter to participate in the research project.

HEMODYNAMIC MEASUREMENT

CO, systolic blood pressure (SBP), diastolic blood pressure (DBP), MAP, and heart rate (HR) are continuously monitored using the HemoSphere™ platform combined with a FloTrac™ sensor transducer (Edwards Lifesciences, Irvine, CA, USA) connected to an arterial catheter. HemoSphereTM monitoring calculates PPV, SVV, and SV every 20 seconds. Ea_{dyn} is calculated from the PPV over SVV ratio. During the study period, ventilator settings, dosage of sedation, and dosage of vasopressors remain unchanged.

The arterial pressure transducer is zeroed to atmospheric pressure, and optimal damping of the arterial waveform is carefully checked by fast flushing the line before recording parameters.

TIMELINE

Eligible patients will be enrolled in the study (Fig. 1). When an attending physician decides to give an intravenous fluid bolus, hemodynamic data measured by the HemoSphere™ platform combined with the FloTrac™ sensor transducer is recorded 1 minute before 300 ml of Acetar® is administered over 15 minutes. After fluid administration is done, hemodynamic parameters are recorded at 20, 40, and 60 seconds by the researcher, who is not involved in the treatment process. Then we use the mean of the after-fluid-administration parameters to be analyzed.

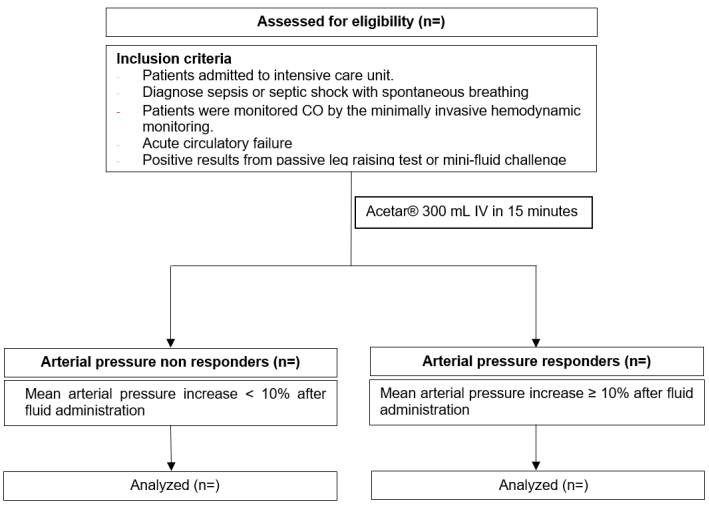

Figure 1. Study flow chart.

DATA ANALYSIS PLAN

Sample size calculation

Cecconi et al. reported that preinfusion Ea_{dyn} can predict a positive MAP response to fluid administration with an area under the receiver operating characteristic curve (ROC-AUC) of 0.92 (95% confidence interval 0.78-0.99; P<0.0001) while SVR had a ROC-AUC of 0.52 (95% confidence interval 0.34-0.7; P-0.012)[9]. In that study, the incidence of MAP responders (defined as MAP increased by 10% or more) was 50% in preload-dependent patients. Based on these findings, thirty-eight fluid administrations were recruited in the present study with a type I error of 0.1 and an acceptable error of 20% (Medcalc version 20.118: MedCalc Software bvba, Ostend, Belgium). To protect research power from dropout patients, the sample size should be increased by 10%. As a result, a total sample size of forty fluid administrations will be required.

OUTCOME ANALYSIS PLAN

Statistical analysis

Baseline characteristics (gender, mean age, body mass index (BMI), the second version of the Acute Physiological and Chronic Health Evaluation (APACHE-II), the sequential organ failure assessment score (SOFA), the Glasgow coma scale score, arterial lactate level, vasoactive dose, sedative dose, mechanical respiratory support, and cause of acute circulatory failure) were analyzed as frequency, percentage, mean, standard deviation, median, and interquartile ranges. The Kolmogorov-Smirnov test will be used to test the normality of the data distribution. Normally distributed continuous variable data will be expressed as mean ± standard deviation. Non-normally distributed continuous data will be shown as the median. Categorical variable data will be shown as a percent. The Wilcoxon signed rank test will be used to compare continuous dependent variables in non-normally distributed data. The correlation between Ea_{dyn} and the change in MAP after fluid administration will be examined using a linear regression analysis. The area under the receiver-operating characteristic (ROC-AUC) curves and the 95% CI will be calculated and compared for sensitivity and specificity. Optimal cutoff values will be calculated by maximizing the Youden index. A grey zone for Ea_{dyn} cutoff will be created using the resampling method [11]. In summary, we will calculate the Youden index for each bootstrapped sample from 1,000 replications of the original study population, and then the median value and the 95% CI of these 1,000 optimal cut-offs will be obtained. This bootstrapped 95%CI defines a gray zone around the optimum criterion in which prediction of MAP responsiveness after fluid administration remains inconclusive. A p-value of less than 0.05 will be considered statistically significant. All statistical analyses will be performed using statistical software (StataCorp. 2021. Stata Statistical Software: Release 17. College Station, TX: StataCorp LLC.)4

DATA MANAGEMENT AND DATA MONITORING

Input data and monitoring method

- Patients' characteristic (Table 1)
- Effects of fluid administration on hemodynamic variables according to mean arterial pressure increase (Table 2)

Table 1. Patients' characteristic.

Characteristics	Collection method
Age (years)	Chart review
Gender (n of male: female)	Chart review
Weight (kg)	Chart review
Height (cm)	Chart review
Body mass index (kg/m^2)	Chart review
Vital sign	Chart review
Respiratory rate	Chart review
Body temperature	Chart review
Oxygen saturation	Chart review
Glasgow Coma Scale score	Chart review
APACHE II[a] score	Chart review
SOFA[b] score	Chart review
Arterial lactate level (mmol/L); median (range)	Chart review
Norepinephrine; n (%)	Chart review
Norepinephrine dosage (mcg/kg/min)	Chart review
Cause of acute circulatory failure; n (%)	Chart review
Hypotension	Chart review
Oliguria	Chart review
Hyperlactatemia	Chart review

Characteristics	Collection method
Sedative agents	Chart review
Dexmedetomidine; n, median (range[1])	Chart review
Fentanyl; n, median (range[2])	Chart review
Propofol; n, median (range[3])	Chart review
Mechanical respiratory support	Chart review
Pressure-controlled ventilator	Chart review
Pressure support ventilator	Chart review
None	Chart review
P 0.1[c]; mean (range)	Chart review

[a] APACHE II: Acute Physiology and Chronic Health Evaluation II; [b] SOFA: Sequential Organ Failure Assessment; [c] P 0.1: Airway Occlusion Pressure at 0.1 second; [1] Dose range in mcg/kg/hour; [2] Dose range in mcg/kg/hour; [3] Dose range in mg/kg/min

Table 2. Effects of fluid administration on hemodynamic variables according to mean arterial pressure increase.[a]

Variability	Before fluid administration	After fluid administration	P value [b]
SBP			
Responders			
Non-responders			
DBP			
Responders			
Non-responders			
MAP			
Responders			
Non-responders			
PP			
Responders			
Non-responders			
CO			
Responders			
Non-responders			
PPV			
Responders			
Non-responders			
SVV			
Responders			
Non-responders			
SVR			
Responders			
Non-responders			
Ea_{eff}			
Responders			
Non-responders			
Ea_{dyn}			
Responders			
Non-responders			

CO=cardiac output; DBP=diastolic blood pressure; Ea_{dyn}=dynamic arterial elastance; Ea_{eff}=effective arterial elastance; MAP=mean arterial pressure; PP=-pulse pressure; PPV=pulse pressure variation; SBP=systolic blood pressure; SVR=systemic vascular resistance; SVV=stroke volume variation.
[a] Responders are defined by a mean arterial pressure (MAP) increase ≥ 10%. Data are shown as mean ± SD. [b] P-values refer to group (responder vs non-responder) and time (pre-infusion vs post-infusion) interaction using analysis of variance for repeated measurements. [c] P<0.05 versus before fluid challenge. [d] P<0.05 versus nonresponder patients.

DISCUSSION

In previous trials, the parameters derived from pulse contour analysis, such as PPV, SVV, CO, etc., were mostly studied in controlled ventilation patients, and it was found that the parameters were reliable for predicting fluid responsiveness in controlled ventilation patients [12-14]. But in spontaneous ventilation patients, the results are a dilemma [15,16].

Several studies have looked at PPV and SVV in spontaneously breathing patients. The findings were quite varied, with D. M. Hong et al. showing that PPV values could be used to predict fluid responsiveness in patients with spontaneous breathing during forced inspiration (area under the curve 0.910, $p < 0.0001$)[16]. On the other hand, Cecconi et al. found that PPV and SVV were unable to predict fluid responsiveness, whereas Ea_{dyn}, mean arterial pressure, and net arterial compliance could.[9].

Ea_{dyn} is also studied for predicted fluid responsiveness and pressure responsiveness. Recent studies have investigated the use of Ea_{dyn} in a variety of patients, such as patients with low blood pressure in the operating room, patients with low blood pressure in the intensive care unit, patients with distributive shock, and patients with hypovolemic shock. Ea_{dyn} can be used to predict rises in blood pressure after fluid administration, despite the studies' widely variable findings.

The vascular tone of patients with sepsis or septic shock differs from that of the other patient population. Research conducted on patients with sepsis and sepsis shock has revealed that the effects are also variable. A study determined that Ea_{dyn} could not be utilized to predict a rise in blood pressure following fluid administration[17], although a subsequent study by Guarracino et al. found that PPV, SVV, and Ea_{dyn} could be used to predict an increase in blood pressure following fluid administration[18]. The use of the Ea_{dyn} parameter in patients with sepsis or septic shock should be researched further.

Vasoactive agents may be one of the factors that affect PPV, SVV, and Ea_{dyn} parameters because they alter vascular tone, but the effects of these agents were variable in the study. In post-operative cardiac surgery, Hadian et al. discovered that vasodilator therapy increased PPV and SVV, whereas increasing inotropes or vasoconstrictors had no effect on PPV, SVV, or Ea_{dyn}[19]. In patients with sepsis and septic shock, each agent has a different effect. Norepinephrine decreased PPV and SVV but increased Ea_{dyn}, whereas dobutamine had no effect on PPV and SVV[18].

Additionally, spontaneous ventilation may influence the Ea_{dyn} parameter. Heenen et al. reasoned that heart-lung interactions, particularly PPV, in spontaneous breathing patients may not be reliable, as respiratory changes in alveolar and pleural pressure are lower during spontaneous breaths than during mechanically assisted breaths, active expiratory movements can alter the cyclic changes in alveolar pressure, the respiratory rate may be higher in patients with spontaneous respiratory movements so that the number of cardiac beats per respiratory cycle may be reduced, and patients under less sedation may also experience variations in cardiac output independently of their preload status[15]. Theoretically, Ea_{dyn} can be used even in spontaneous ventilation patients if PPV and SVV values are high enough to determine the slope of the pressure-volume curve[8].

There was one study that found Ea_{dyn} in spontaneous breathing patients derived from non-invasive hemodynamic monitoring could predict pressure responsiveness[9]. But in our team institute, using minimally invasive monitoring such as an arterial catheter connected to a transducer is mandated.

This study has several strengths, including the use of equipment that is used in actual practice in our institute, so obtaining the results of the study can confirm the reliability of popular devices at our institution, and the HemoSphere™ monitoring system is a minimally invasive monitoring platform capable of interpreting PPV and SVV simultaneously on a single device, so the reliability of using this device to calculate Ea_{dyn} should be increased.

This study has some limitations. First, the calculation of the area under the arterial line waveform by the HemoSphere™ platform may be inaccurate in septic shock with a wide range of vascular tones, although the manufacturer claims that the parameters representing vascular tone can be modified as appropriate. Therefore, the use of non-calibrated pulse contour analysis in SIRS or sepsis cases may require additional reliability considerations.

Second, since PPV and SVV are from the same device This is both an advantage and a contradiction in itself since both parameters depend on pressure-based devices, so the values may be inverse, unlike the Ea_{dyn} value that the SVV obtained from the flow-based device. Future studies may need to investigate the sensitivity and specificity of Ea_{dyn} from the Flotrac™ sensor in patients without vascular tone variation problems, such as perioperative blood loss cases.

CONFIDENTIALITY

The researchers only obtained informed consent in a separate, private space within the ICU. Code is used and recorded instead of the patient's name, hospital number, and admission number. Date of birth, initials of name-surname, or other personal information are not collected. This study's data is recorded only in research record form and password protected in investigators' personal computers. After the trial, all information will be permanently deleted from all computers and physical documents.

ACKNOWLEDGEMENT

I would like to express gratitude to all critical care nurses for helping make this research happen. This research project is supported by the Faculty of Medicine Ramathibodi Hospital Mahidol University.

AUTHORS' CONTRIBUTIONS

(I) Conceptualization: Subundit Injampa, Punchika Luetrakool; (II) Data curation: Subundit Injampa, Punchika Luetrakool; (III) Formal analysis: Subundit Injampa, Punchika Luetrakool, Sunthiti Morakul; (IV) Funding acquisition: Subundit Injampa, Sunthiti Morakul; (V) Methodology: Subundit Injampa, Punchika Luetrakool, Sunthiti Morakul, Tananchai Petnak; (VI) Project administration: Subundit Injampa; (VII) Visualization: Subundit Injampa; (VIII) Writing – original draft: Subundit Injampa, Punchika Luetrakool, Sunthiti Morakul;

SUPPLEMENTARY MATERIALS

None

ABBREVIATIONS

APACHE, Acute physiology and chronic health evaluation; AUC, Area under the curve; CO, Cardiac output; DBP, Diastolic blood pressure; Ea_{dyn}, Dynamic arterial elastance; Ea_{eff}, Effective arterial elastance; HR, Heart rate; ICU, Intensive care unit; MAP, Mean arterial pressure; P 0.1, Airway Occlusion Pressure at 0.1 second; PP, Pulse pressure; PPV, Pulse pressure variation; ROC, Receiver operating characteristic; SBP, Systolic blood pressure; SOFA, Sequential organ failure assessment; SV, Stroke volume; SVR, Systemic vascular resistance; SVV, Stroke volume variation

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