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The relationship of lung recruitability assessment by recruitment to inflation ratio, electrical impedance tomography, and lung ultrasound: The research protocol

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ABSTRACT:

Background: Recently, the recruitment-to-inflation ratio (R/I ratio) from the single-breath technique has been proposed for identifying lung recruitability in acute respiratory distress syndrome (ARDS). This technique is based on measuring end-expiratory lung volume (EELV). Also, electrical impedance tomography (EIT) can estimate the EELV, providing the potential role of EIT in measuring the R/I ratio. In addition, the lung ultrasound was proved to identify lung recruitment. However, a study validating those techniques has not been conducted.

Methods: We plan to conduct a single-center prospective physiological study on moderate to severe ARDS patients. The R/I ratio by single-breath technique and EIT will be collected before the recruitment maneuver. If the patient has no airway opening pressure (AOP), PEEP of 8 cmH₂O will be set as PEEP_{low}. The PEEP_{high} defines as initially set at +10 cmH₂O from the PEEP_{low}. However, if the patients have AOP presence, AOP +10 cmH₂O will be set as PEEP_{high}. The lung ultrasound score (LUS) will be performed at PEEP_{high} and PEEP_{low} during the single-breath technique. Variables that will be used to analyze the relationship are recruited volume (V_{rec}), R/I ratio, and LUS.

Hypothesis: We hypothesize that there are associations between the R/I ratio by both techniques and lung ultrasound score (LUS).

Ethics: The study protocol has been approved by the ethics committee of the faculty of medicine, Ramathibodi Hospital, Mahidol University (COA.MURA2021/433).

Keywords: Acute respiratory distress syndrome, Recruitment-to-inflation ratio, Lung ultrasonography, Electrical impedance tomography, Recruitability assessment

INTRODUCTION

The recruitment maneuver (RM) is one of the life-saving procedures for moderate to severe acute respiratory distress syndrome (ARDS) [1]. Several methods have been applied to assess alveolar recruitment as the volume of gas reaeration from poorly aerated lungs, defined as the lung recruitability [2,3]. Unfortunately, no best method can accurately predict high recruiter patients in various features of ARDS lung.

The gold standard assessment method is the volumetric chest computed tomography (CT) to evaluate the gas volume and lung tissue changing during RM [3-5]. In current practice, imaging studies, namely lung ultrasound, electrical impedance tomography (EIT), and lung volume measurements, have become comfortable and well-established bedside tools for assessing lung recruitability. However, chest CT is impractical and potentially increases the risk of hemodynamic instability during transportation and radiation exposure.

Chiumello et al. found good correlations between end-expiratory lung volume (EELV) measurement by the nitrogen wash-out/wash-in technique and helium dilution and CT scan in patients ventilated with low levels of positive end-expiratory pressure (PEEP) [6]. Moreover, PEEP-induced change in lung volume is another method for determining lung recruitability by measuring the volume trapped by PEEP above functional residual capacity (FRC) by prolonged exhalation to the atmospheric pressure [7,8] at two levels of PEEP. Chen et al. have recently developed a simplified method using the same principle of PEEP-induced change in lung volume by single-breath reduction technique [9]. The single breath reduction technique provided the recruitment/inflation (R/I) ratio derived from the ratio of recruited lung compliance (C_{rec}), which is calculated from recruited volume (V_{rec}) over the respiratory system compliance at low PEEP (Crs at $PEEP_{low}$). The author reported that the V_{rec} was strongly correlated with the standard multiple pressure/volume (P/V) methods. The R/I ratio that discriminates recruiters from non-recruiters corresponds to the median value of 0.5 [9].

Lung ultrasound score (LUS) as a reaeration score is the most non-radiated simple imaging tool. Bouhemad et al. found that PEEP-induced lung recruitment greater than 600 ml related to detection on lung ultrasound reaeration score of more than 18 [10]. Nevertheless, lung ultrasonography is limited in detecting the overdistension zone. This problem can be solved with EIT, another bedside imaging method that may be similar to a CT scan. EIT can give real-time regional zone gas distribution and tidal impedance during PEEP titration [11]. Also, EIT can estimate the EELV, providing the potential role of EIT in measuring the R/I ratio. However, a study validating those techniques has not been conducted.

We aim to analyze the relationship between the R/I ratio by single breath reduction from exhaled tidal volume measurement, EIT-derived parameters, and LUS.

KEY MESSAGES:

- Lung recruitability assessment by recruitment-to-inflation ratio (by single breath reduction and electrical impedance tomography) and lung ultrasonography

OBJECTIVES

To analyze the relationship between the R/I ratio by the single breath method, the R/I ratio by EIT, and the lung ultrasound score (LUS).

MATERIALS AND METHODS

Study design

A prospective cohort study had been planned to conduct in moderate to severe ARDS patients in ICU Ramathibodi hospital between December 2020 and February 2023. Therefore, this study protocol was registered retrospectively. The ethics committee of the faculty of medicine, Ramathibodi Hospital, Mahidol University, approved this study with an approval number of COA.MURA2021/433. The written informed consent will be obtained from the patient's next of kin.

Study population

Patients over 18 years old undergoing mechanical ventilators will be evaluated. The patients will be recruited in the study if they meet the following inclusion criteria.

Inclusion criteria

- Diagnosed moderate to severe ARDS[1]
- Currently on mandatory mechanical ventilation, received sedative and neuromuscular blocking agents, and presence of arterial line and central line.

Exclusion criteria

- The patient who has a history of recent exacerbated obstructive airway disease within eight weeks according to the Global Initiative for Chronic Obstructive pulmonary disease criteria [12]
- The presence of pneumothorax or intercostal chest drainage catheter
- Pregnancy
- The patient who has the contraindications for insertion of the esophageal balloon catheter
- The patient who has the contraindications for RM (hemodynamic instability, received norepinephrine dosing $> 0.5 \text{ mcg/kg/min}$ or increased dosage of norepinephrine in the past 6 hours of $> 30\%$ of the previous baseline, uncorrected acute respiratory acidosis, has the PaCO_2 of $> 50 \text{ mmHg}$ with the pH change, and intracranial hypertension).

Baseline characteristics, including the severity of the medical comorbidities, causes, and types of ARDS; Acute Physiology and Chronic Health Evaluation II (APACHE II) score in the first 24 hours of admission, the pattern of ARDS by imaging, and baseline hemodynamic data will be collected.

Measurements

Every patient is ventilated supine with the ventilator, which can be performed with the pressure/volume tool (Hamilton G5 or S1). With the head of the bed raised to 30 degrees, an esophageal balloon catheter (global trade item no. GTIN: 07630002803755) will be inserted and positioned in the lower 1/3 of the esophagus at a 35-40 cm depth from incisor teeth and inflated with air volume between 1-2 ml. The esophageal balloon catheter is normally connected to an auxiliary ventilator port to measure the pressure. The proper position of the esophageal balloon will be tested by the end-expiratory pause technique [13].

The EIT belt from the PulmoVista 500 by Dräger® will apply to the patient. The respiratory mechanic, esophageal pressure, and EIT parameters are continuously recorded and exported from the ventilator for offline interpretation.

The protocol will be initiated with AOP measurement by the low flow pressure-volume (P/V) tool. The measuring measuring V_{rec} by single-breath method performs as Chen et al. reported [9]. All patients are passively ventilated without spontaneous effort in a volume control mode. If the patient has no AOP, PEEP of 8 cmH₂O will be set as PEEP_{low} in the lung-protective strategy. The PEEP_{high} is initially set at +10 cmH₂O from the PEEP_{low}. However, if the patients have AOP presence, AOP +10 cmH₂O will be set as PEEP_{high} but not exceed 12 cmH₂O of transpulmonary driving pressure [14].

We plan to perform LUS with a Sonosite M-turbo, portable ultrasound system, and 10-15 MHz probe. The LUS protocol involves the examination of eight lung regions, the upper and lower parts of the anterior and posterior aspects of the left and right chest walls demarcated by the 4th intercostal space of midclavicular and anterior axillary lines. A well-trained pulmonologist (K.G.) will perform transthoracic ultrasonography. According to the R/I ratio measurement method, we have to set 2 levels of PEEP (PEEP_{high} and PEEP_{low} as previously described). The lung ultrasound images will be recorded after 5-10 minutes of PEEP change during the R/I ratio measurement (LUS at PEEP_{high} and PEEP_{low} after PEEP reduction). All photos will be saved as video records and renamed in codes set by the operator. A total of video files will be sent to two independent observers in two separate file sets for scoring. If two observers' numbers of the score are discordant, the consensus score will be used.

After finishing the single-breath method, the RM and decremental PEEP titration will finally be performed. The RM will conduct in pressure-controlled mode with an inspiratory plateau pressure of 25 cm of water, a PEEP of 20 cm of water, a respiratory rate of 10 / per minute, and a 1:1 ratio of inspiration to expiration for two minutes. Then, the pressure control ventilation mode will be set with

a fixed inspiratory pressure of 15 cmH₂O. The decremental PEEP trial performs from PEEP of 20 cmH₂O to 8 cmH₂O with a decrease in 2 cmH₂O each step every 1 minute [15-18].

The hemodynamic parameters are simultaneously monitored via arterial line placement and pulse contour analysis equipment (EV 1000® or Vigellio®, Edward® life science). If the patients have signs and symptoms of clinical deterioration, for instance, inability to maintain blood pressure, need the titration of vasopressor greater than 0.5 mcg/kg/min or >30% of the previous baseline, presence of pneumothorax, or progressive respiratory failure acidosis (PaCO₂ >50 mmHg) with the pH change. The patient will be excluded from the study.

Variables defined definition

Lung ultrasound score

Four ultrasound aeration patterns define according to the worst observed ultrasound pattern: normal aeration, A-lines or a few separated B-lines = 0, three or more well-spaced B-lines = 1, coalescent B-lines = 2, subpleural consolidation and consolidation = 3 [18]. The LUS score is the summation of the aeration score of each area of interest. Then, calculating the total LUS difference of two PEEP levels interprets between regions into Δ LUS (LUS of PEEP_{high} - LUS PEEP_{low}).

Recruited volume and recruitment to inflation ratio

Recruited volume (V_{rec}) is the mathematical proportion of volume distributed into the recruited lung from the baby lung when PEEP is changed [9]. The baby lung volume terminology is a small, aerated lung tissue at PEEP_{low} or FRC. The R/I ratio by single-breath technique refers to the compliance of recruited lung (C_{rec}) over the baby lung compliance (compliance at PEEP_{low}) as presented by this equation.

$$\frac{R}{I} \text{ ratio} = \frac{C_{rec}}{\text{Respiratory system compliance } (C_{RS}) \text{ at PEEP}_{low} \text{ or above AOP}}$$

$$\text{Where } C_{rec} = \frac{V_{rec}}{PEEP_{high} - PEEP_{low} \text{ or } PEEP \text{ at AOP}}$$

The V_{rec} is the difference between the measured Δ EELV and the predicted Δ EELV (i.e., the compliance at low PEEP multiplied by the change of PEEP).

The measured Δ EELV is the exhaled tidal volume (VT) after single-breath reduction minus tidal volume at PEEP_{high}, as follows;

$$V_{rec} = VT \text{ at PEEP}_{high} \text{ to PEEP}_{low} \text{ (or PEEP at AOP)} - Exhale VT \text{ at PEEP}_{high} - \\ (C_{RS} \text{ at PEEP}_{low} \text{ or at AOP} \times \Delta P_{PEEP_{high} \text{ to PEEP}_{low} \text{ (or PEEP at AOP)}})$$

Regarding the R/I ratio by EIT, EELV is calculated from the end-expiratory lung impedance (EELI) and tidal impedance formula as below [19].

$$\text{Estimated } \Delta \text{EELV} = \frac{\Delta \text{EELI} \times \text{Tidal volume}}{\text{Tidal impedance}}$$

$$\frac{R}{I} \text{ ratio by EIT} = \frac{C_{rec} \text{ by EIT}}{C_{rec} \text{ at } PEEP_{low}}$$

And the reason for the equal pressure difference in the ratio.

$$\frac{R}{I} \text{ ratio by EIT} = \frac{V_{rec} \text{ by EIT}}{\text{baby inflated volume at } PEEP_{low}}$$

Lung recruitability by EIT

The EIT image is demonstrated in four quadrants axial view with the dynamic aeration reaching a region of interest (ROI), in which ROI 1-2 are the ventral part and ROI 3-4 are the dorsal part of the lungs. During the recruitment maneuver, If the lungs respond to RM, the percentage of gas distributive change in dependent lung regions will be demonstrated as the portion of gas distribution in the ROI 3 and 4 manifested by EIT may interestingly change. We plan to analyze the correlation between the R/I ratio produced by both EIT-derived and the single-breath technique and the average percentage change of gas distribution of ROI 3,4.

Adverse events

Due to the usual standard of protective open-lung concept ARDS treatment strategy and the using esophageal pressure-guided treatment, unexpected adverse events such as pneumothorax, progressive severity of ARDS, and

hemodynamic instability might occur as regular events during data collection. However, if an adverse event appears, the investigator will respond and notify the attending physician team immediately.

Outcome measurement

The primary outcome is the correlation between the R/I ratio using the single-breath method and the EIT technique, together with the correlation of LUS.

Timeline

(Figure1) the flowchart of data collection

DATA ANALYSIS PLAN

Sample size calculations

We aim to perform a physiologic pilot study. Therefore we do not calculate the sample size. We have estimated a sample size of 20.

OUTCOME ANALYSIS PLAN

Statistical analyses

Baseline characteristics will be presented as mean (\pm Standard Deviation, SD) or median (interquartile range, IQR) depending on the data distribution. The correlation coefficients between LUS, the R/I ratio by single breath reduction, and the R/I ratio by EIT will be determined by Pearson's or Spearman according to the characteristics of the data. Statistical analysis will be conducted with the IBM® SPSS® program version 22.0 software (IBM SPSS Statistics, IBM Corporation, New York, USA). A P-value of less than 0.05 determined statistical significance.

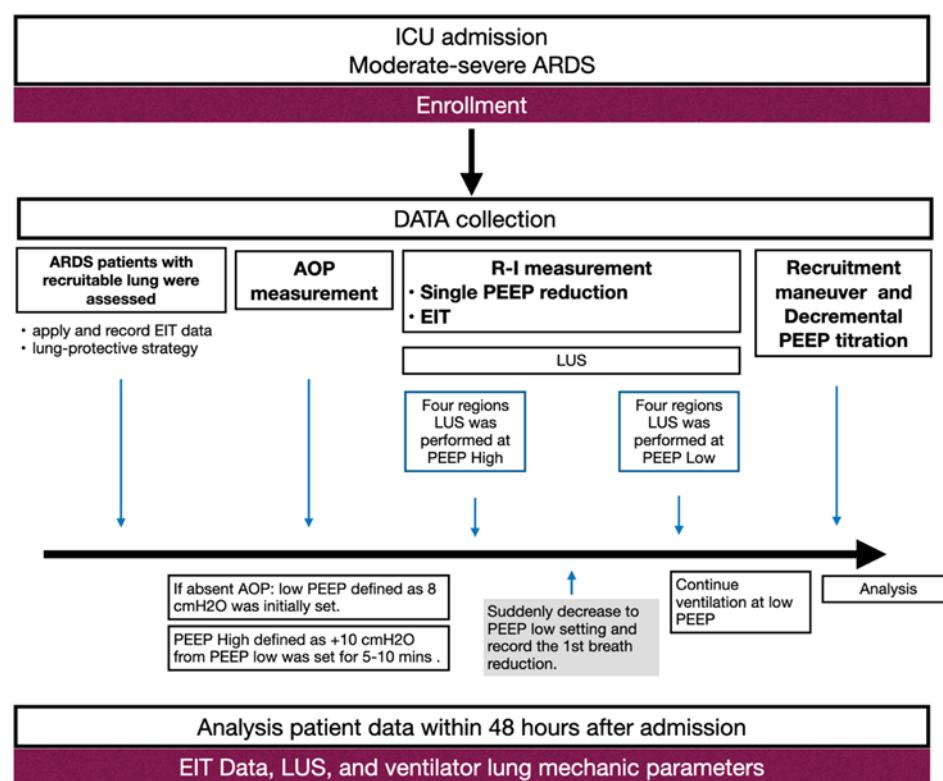


Figure 1. The flowchart of data collection.

DATA MANAGEMENT AND DATA MONITORING

Input data and monitoring method

Table 1. Clinical characteristics with baseline hemodynamic data in ARDS patients

Characteristics	Collection method
Sex, female, n (%)	Chart review
Age, years	Chart review
BMI, kg/m ²	Chart review, manual calculation
Comorbidities, n (%)	
• Immunocompromised	Chart review
• Hematologic malignancy	Chart review
• HT	Chart review
• DM type 2	Chart review
• non-RRT CKD	Chart review
• Currently on immunosuppressant	Chart review
APACHE II at 1 st 24hr admission	Chart review
Type of ARDS, n (%)	
• Intrapulmonary cause	Chart review
• Homogenous pattern on chest CT	Chart review
Berlin definition of ARDS severity, n (%)	
• Moderate	Chart review
• Severe	Chart review
PaO ₂ / FiO ₂ ratio at inclusion	Chart review
Baseline Hemodynamic data	
• SBP, mmHg	Chart review
• DBP, mmHg	Chart review
• MAP, mmHg	Chart review
• Vasopressor during inclusion, n (%)	Chart review
• Dose of norepinephrine, mcg/kg/min	Chart review
• Arterial lactate, mmol/l	Chart review
• PPV, %	Chart review
• SSV, %	Chart review
• CO, liters/min	Chart review

Definition of abbreviations: ARDS=acute respiratory distress syndrome; APACHE=Acute Physiology and Chronic Health Evaluation; BMI=body mass index; CO=cardiac output; DBP=diastolic blood pressure; PPV=pulse pressure variation; RRT=renal replacement therapy; SBP=systolic blood pressure; MAP=mean arterial pressure; SVV=stroke volume variation.

Dichotomous or nominal categorical variables are described as numbers (percentage); continuous variables are expressed as mean + SD or median (interquartile range 25-75), as appropriate.

Table 2. Respiratory mechanic and gas exchange parameter at the time of inclusion.

Respiratory mechanic and gas exchange parameters	Collection method
Baseline lung mechanic profiles, n (%)	
• VCV mode	Chart review
• SetVTi/PBW	Chart review
• RR, times/min	Chart review
• AOP> 5 cmH ₂ O, n (%)	Chart review
• Mean AOP, cmH ₂ O	Chart review
• SpO ₂ , %	Chart review
• PaO ₂ / FiO ₂ ratio at inclusion	Chart review

Respiratory mechanic and gas exchange parameters	Collection method
• P peak, cmH_2O	Chart review
• Plateau pressure, cmH_2O	Chart review
• C_{RS} , $\text{ml}/\text{cmH}_2\text{O}$	Chart review
• Elastance _{RS} , $\text{cmH}_2\text{O}/\text{ml}$	Chart review
• P_{es} end inspiratory, cmH_2O	Chart review
• P_{es} end expiratory, cmH_2O	Chart review
• TP end inspiratory, cmH_2O	Chart review
• TP end expiratory, cmH_2O	Chart review
• TP end inspiratory elastance ratio, cmH_2O	Chart review

Definition of abbreviations: AOP= Airway opening pressure; C_{RS} = respiratory system compliance; Elastance_{RS} =respiratory system elastance; P peak= Peak airway pressure; PBW=predicted body weight; P_{es} end inspiratory= end-inspiratory esophageal pressure; P_{es} end expiratory= end-expiratory esophageal pressure; RR=respiratory rate; TP=transpulmonary pressure; VCV= Volume controlled mandatory ventilation; VTi=Inspiratory volume.

Table 3. The correlation between Lung Ultrasound Score and R/I ratio by both techniques.

Lung ultrasound score	V_{rec} by single breath	V_{rec} by EIT	R/I by single breath	R/I by EIT
ΔLUS at upper anterior axillary chest	Correlation Coefficient P-value N			
ΔLUS at upper anterior chest	Correlation Coefficient P-value N			
ΔLUS at lower anterior axillary chest	Correlation Coefficient P-value N			
ΔLUS at lower anterior chest	Correlation Coefficient P-value N			
ΔLUS total 4 regions	Correlation Coefficient P-value N			

Definition of abbreviations: EIT=electrical impedance tomography; LUS=lung ultrasound score (summation of each area aeration score); N=number of participants; R/I ratio=recruitment to inflation ratio; ΔLUS= LUS difference between the two PEEP level (LUS_{PEEPhigh} - LUS_{PEEPlow}). The Aeration score of LUS [19] is defined as scoring 3=consolidated tissue; 2=multiple (≥ 3) coalescent B-lines; 1= three or more well-demarcated B-lines; 0= A-lines or few separated B-lines; V_{rec} =recruited volume.

DISCUSSION

The R/I ratio by the single-breath technique is recently used in many ICU settings with different validation methods. We are conducting a trial investigating the association of the R/I ratio by the EIT method and the single breath. Mauri et al. studied the comparison between lung volume measurement by helium dilution technique and EIT and found a strong correlation [21]. In the experimental study by Yang et al., in pig model-induced ARDS, the author reported that EIT-derived V_{rec} was significantly correlated with flow-derived V_{rec} [22]. EIT yield benefits over helium dilution technique and EELV measurements in continuously tracking inflation, strain, and recruitment at varying PEEP levels, either regional or global ventilation, while avoiding airway disconnection.

Bouhemad et al. compare the P/V curve method with LUS for assessing PEEP-induced lung recruitment in forty patients with ARDS. They found that PEEP-induced lung recruitment measured by P/V curves and ultrasound re-aeration scores were significant (10). Therefore, LUS may be another method to validate the R/I ratio by single breath method and recruited lung.

Strengths:

- (1) We will conduct the first EIT-derived R/I ratio study to investigate the correlation of lung volume parameters with the R/I ratio from the single-breath technique.
- (2) Our study uses feasible bedside ultrasonography for the accessibility of lung recruitment.
- (3) Our study promotes a safe recruitability assessment procedure by EIT and lung ultrasound, which can discriminate recruiters from non-recruiters.

Limitations:

- (1) Small sample size over a short period of data collection.
- (2) Lung ultrasound may not be a precise tool to detect an overdistended part of the lung.
- (3) We did not perform a quantitative volumetric CT scan, the gold standard for assessing recruitability.

CONFIDENTIALITY

Informed consent is obtained within the isolated private room in the ICU by the researchers only. Patients' data are encrypted with the hospital-based healthcare personnel passcode-locking system in the database. After the trial, all data will be eliminated from all computers or physical documents.

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AUTHORS' CONTRIBUTIONS

(I)Conceptualization: Kridsanai Gulapa; (II) Data curation: Kridsanai Gulapa; (III) Formal analysis: Kridsanai Gulapa, Yuda Sutherasan, Detajin Junhasavasdikul, Pongdhep Theerawit ; (IV)Funding acquisition: Kridsanai Gulapa; (V) Methodology: Kridsanai Gulapa, Yuda Sutherasan, Detajin Junhasavasdikul, Pongdhep Theerawit; (VI) Project administration: Kridsanai Gulapa; (VII) Visualization: Kridsanai Gulapa; (VIII) Writing-original draft: Kridsanai Gulapa; (IX) Writing – review & editing: Kridsanai Gulapa, Yuda Sutherasan, Pongdhep Theerawit.

SUPPLEMENTARY MATERIALS

None

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