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RESEARCH PROTOCOL

# Comparison of ultrasound assessment for diaphragmatic workload during spontaneous breathing trial between automatic tube compensation and pressure support ventilation: Study protocol

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## ABSTRACT:

**Background:** The process of weaning from mechanical ventilation is crucial. Less demanding spontaneous breathing trials (SBT) can be done by either automatic tube compensation (ATC) or pressure support ventilation (PSV) to decrease inspiratory effort by endotracheal tube resistance compensation. This study aimed to assess the patient's effort, by diaphragm ultrasonography with ATC compared to PSV during SBT.

**Methods:** Patients who have been on mechanical ventilation for more than 48 hours and meet the weaning requirements are given 30 minutes for ATC and 30 minutes for PSV in this randomized control experiment. The diaphragm workload difference, as assessed by diaphragm thickness fraction, was the primary outcome. The sensitivity and specificity of ultrasound-measured diaphragmatic muscle activity measures in predicting ventilator weaning and effective extubation were secondary outcomes.

**Hypothesis:** Intubated patients should be (1) weaning with lower effort SBT mode (2) predicted weaning success with more accurately parameters
Ethics and dissemination: Ramathibodi Human Research Ethics Committee has approved the trial. The findings plan to summitted in peer-reviewed publications and conferences in critical care medicine or anesthesiology.

**Trial registration number:** TCTR20210317004

**Keywords:** Automatic tube compensation, Pressure support ventilation, Ultrasound diaphragm, Diaphragm thickness fraction, TDI-derived maximal relaxation rate

## BACKGROUND

Although ventilators are helpful in saving lives, long-term use can produce complications for the patient [1]. As a result, once the reason for each patient's intubation or use of a ventilator has been determined. Intubation and mechanical ventilation should be stopped as soon as possible. It started with a test to see if weaning the ventilator was successful, and then weaning the ventilator with a spontaneous breathing trial (SBT) [2]. This is due to the reason that failure to extubate is associated with increased mortality [3]. Therefore, the ventilator weaning process is important [4,5].

Automatic tube compensation (ATC) and pressure support ventilation (PSV) are two modes for setting up a breathing device for SBT to compensate for endotracheal tube resistance. Overcompensation can lead to inaccurate ventilator assessments, while low-responsible SBT creates additional pressure on the patient, e.g., T-piece breathing is associated with a higher re-intubation rate [6]. ATC is a type of assisted breathing in which the patient controls the breathing rhythm. The ventilator will determine the optimum pressure for each patient based on flow rates calculated from the size and length of the endotracheal tube being used. This will enable the patient to obtain proper compensation and achieve a breathing pattern that is as natural as possible [7]. SBT with ATC had a reduced re-intubation rate than a T-piece [8], but no difference when compared to PSV [9–11]. When comparing the usage of force to perform SBT between ATC and PSV with pressure support 7 $cmH_2O$ and CPAP 4 $cmH_2O$, it was discovered that ATC needed higher effort [12]. When pressure support of 5 $cmH_2O$ is used instead of t-piece, inhalation work can be reduced by 31-38 percent as measured by the pressure-time product [13]. The SBT did not differ statistically between ATC and PSV with pressure support 5 $cmH_2O$ and CPAP 5 $cmH_2O$ [10]. Performing SBT with pressure support of 7 $cmH_2O$ may be excessive. PSV with pressure support of 5 $cmH_2O$ and CPAP with 5 $cmH_2O$ may be suitable and now used in SBT at Ramathibodi Hospital. The researchers hypothesized that using an ATC during SBT would result in lower inspiratory effort than using a PSV with the decease difference of diaphragmatic thickness fraction (DTF).

The effort and exertion required for breathing may be assessed by the diaphragm muscles. The use of ultrasonography to examine the function of the diaphragm muscles may be done quickly and non-invasively at the bedside. In addition to the parameters that can already be evaluated by the ventilator, ultrasound may be monitored in terms of efficiency and working force. The diaphragm thickness fraction and diaphragm excursion data acquired from ultrasonography were used to measure the breathing force during SBT in this study. In critically ill patients, DTF values can indicate moderate success in weaning from ventilators that were significantly higher specificity than diaphragmatic excursion [14]. However, another study discovered that the rate of re-intubation is unpredictable [15]. Successful and unsuccessful weaning patients had different values determined using diaphragmatic tissue doppler imaging [16]. In this study, the results obtained from the diaphragm muscle's tissue Doppler imaging (TDI) were utilized to determine the force of breathing as well as the likelihood of re-intubation.

### KEY MESSAGES:

- This study compares diaphragm effort of SBT with ATC made to PSV mode. We hypothesize that ATC mode should be less effort than another and TDI of the diaphragm may be as accurate as DTF in predicting success in weaning off a ventilator.

Therefore, this study compared the inspiratory force of 5 $cmH_2O$ support plus 5 $cmH_2O$ of CPAP versus ATC during SBT

## OBJECTIVES

### Primary objective

To assess the efficacy of lowering respiratory force between ATC and PSV of critical care unit patients in weaning the ventilator using ultrasound to measure the function of the diaphragm muscles.

### Secondary objectives

To assess the sensitivity and specificity of ultrasound-measured diaphragmatic muscle activity values in predicting ventilator weaning and successful extubation in critical care unit patients at.

## MATERIALS AND METHODS

### Study Design

Single-center, randomized, opened label, crossover study

### Study Setting

Patients are undergoing SBT to wean a ventilator in intensive care unit, Ramathibodi Hospital, Mahidol University.

### Eligibility criteria

### Inclusion criteria

1. Patients admitted to ICU Ramathibodi hospital
2. Age 18 years or older
3. Patients require invasive mechanically ventilation for more than 48 hours
4. Patients proceeded to perform spontaneous breathing trial (Table 1)

### Exclusion criteria

1. Patient contra-indicated for diaphragm ultrasound
2. Patient diagnosed diaphragm pathology or neuromuscular pathology e.g., myastinia gravis (MG), amyotrophic lateral sclerosis (ALS)
3. Patient couldn't communicate or co-operation
4. Pregnancy
5. Withdrawal of informed consent
6. The incomplete data collection form

### Withdrawal criteria

1. Patients desire to stop the study
2. Inability to participate until the end of the trial

**Table 1.** Assessing proceed to perform spontaneous breathing trial.

| | |
|---|---|
| Clinical assessment | Adequate cough<br>Absence of excessive tracheobronchial secretion<br>Resolution of disease acute phase for which the patient was intubated |
| Objective assessment | Clinical stability<br>- Stable cardiovascularstatus<br>- Stable metabolic status<br>Adequate oxygenation<br>- $SaO_2$ >90% on ≤ $FiO_2$ 0.4 (or $PaO_2$ ≥150 mmHg)<br>- PEEP ≤8 $cmH_2O$<br>Adequate pulmonary function<br>- RR ≤35 breaths/min<br>- MIP ≤-20 - -25 $cmH_2O$<br>- VT >5mL/kg<br>- VC >10mL/kg<br>- RR/VT <105 breaths/min/L<br>- No significant respiratory acidosis<br>Adequate mentation<br>- No sedation or adequate mentation on sedation |

Abbreviation: $SaO_2$, arterial oxygen saturation; $FiO_2$, fraction of inspired oxygen, $PaO_2$, partial pressure of arterial oxygen; PEEP positive end-expiratory pressure; RR, respiratory rate; MIP, maximal inspiratory pressure; RSBI (RR/VT), rapid shallow breathing index; VT, tidal volume; VC, vital capacity.

### Participant selection and recruitment

All intubated patients in the ICU (both medical and surgical ICU) are screened by the researcher. We provide information and informed consent to patients who are proceeded to perform to SBT and fulfill all inclusion criteria without exclusion criteria.

### Consent

Patients will be enrolled in the trial only when the study's investigators have completed the informed consent form. At any moment and for any reason, patients and their legal representatives can withdraw from the research. Patients' relatives have been told that the withdrawal would have no effect on the patients' care. Patients who refuse to participate in the trial will not be replaced by others.

### Randomization

Patients were given the option of starting with ATC or PSV at the beginning of the SBT by computer-generated randomization in a 1:1 ratio. After the washout period, they were crossover to another intervention. (Figure 1)

### Starting with ATC then PSV

Patient's parameters will be recorded before and after SBT with ATC (tube compensation 100%, CPAP 5 $cmH_2O$) for 30 minutes then parameters will be recorded again before and after PSV (pressure support 5 $cmH_2O$, CPAP 5 $cmH_2O$)

### Starting with PSV then ATC

Patient's parameters will be recorded before and after SBT with PSV (pressure support 5 $cmH_2O$, CPAP 5 $cmH_2O$) for 30 minutes then parameters will be recorded again before and after ATC (tube compensation 100%, CPAP 5 $cmH_2O$)

### Blinding

Because of the data collection procedure, which includes a ventilator setting protocol, the investigator cannot be blinded; nevertheless, the data is blinded from outcome assessors and statisticians.

### Intervention

When the physician determined that the patient was eligible for the spontaneous breathing trial (Table 1), the investigator recorded baseline patient ultrasound diaphragm parameters, then the patient received the first mode of SBT for 30 minutes (ACT in group 1 and PSV in group 2), and the investigator recorded patient ultrasound diaphragm parameters again after the first mode of SBT was completed.

During the washout period, the investigator set the ventilator to the baseline setting before SBT until the patient's $SpO_2$, RSBI, respiratory rate, and heart rate were the same as the baseline before SBT for 10 minutes but no longer than 1 hour (total intervention time not more than 2 hours) because it is recommended that SBT should at least 30 minutes but no longer than 120 minutes [17].

The investigator recorded another baseline patient ultrasound diaphragm parameters, then started the second mode of SBT for 30 minutes (PSV in group 1 and ACT in group 2) and recorded the last patient ultrasound diaphragm parameters after the second mode of SBT was completed.

Successful extubation, re-intubation rate, using non-invasive mechanical ventilation rate, and using high flow nasal oxygen rate was given for up to 7 days during the follow-up period.

### Outcome measurement

Before starting to collect data, the investigator was a critical care medicine fellowship who was trained in ultrasound of the diaphragm muscle with a specialist in Pulmonary Medicine and Pulmonary Critical Care and had inter-rater reliability of no more than 10% for 20 patients.

Each diaphragm parameters were measured three times and the mean or median was recorded when normal respiration.

### Primary outcome

Diaphragm workload differential between ATC and PSV for 30 minutes using DTF measurement.

### Secondary outcomes

Ultrasound-measured diaphragmatic muscle activity parameters' (diaphragm thickness fraction, diaphragm excursion, peak contraction velocity, peak relaxation velocity, velocity-time integral, TDI-derived maximal relaxation rate) sensitivity and specificity in predicting ventilator weaning and successful extubation.

### Exploratory outcomes -

### Timeline

Eligibility patients were enrolled in the trial. When the patients were ready to wean, they were allocated into two groups and given 30 minutes of the first mode of SBT,

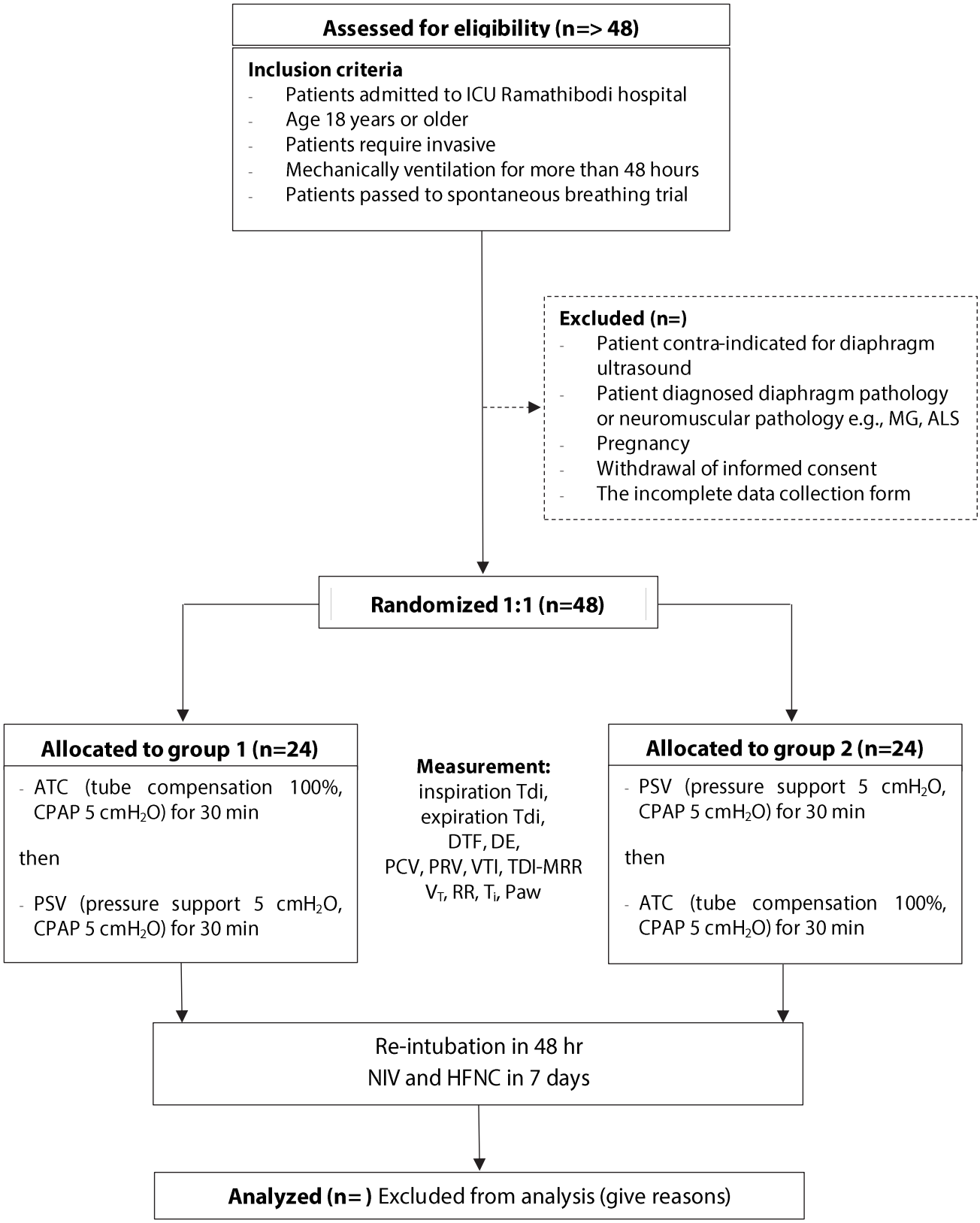


**Figure 1.** Study diagram.
Abbreviation: SBT, spontaneous breathing trial; ATC, automatic tube compensation; PSV, pressure support ventilation; CPAP, continuous positive airway pressure; NIV, non-invasive ventilation; HFNC, high-flow nasal cannula; Tdi, diaphragm thickness; DTF, diaphragm thickness fraction; DE, diaphragm excursion; PCV, peak contraction velocity; PRV, peak relaxation velocity; VTI, Velocity-time integral; TDI-MRR, tissue Doppler imaging-derived maximal relaxation rate; VT, tidal volume; RR, respiratory rate; Ti, inspiratory time; Paw, airway pressure.

followed by a washout period before crossover to another mode of SBT. If patients could tolerate along with the trial were extubated, then observation of the patient for 7 days to determine successful extubation, re-intubation rate, use of high flow nasal canular rate, and non-invasive ventilation. (Figure 2)

## DATA ANALYSIS PLAN

### Sample size calculation

We used the datas from diaphragm ultrasound as indicators of respiratory effort in critically ill patients undergoing assisted mechanical ventilation: a pilot clinical study by Michele U. et al.[18]. found the DTF of SBT using PSV was 28.2 mm, with a standard variation of 9.9 mm. The mean difference in DTF of ATC was considered to be 15% lower. The sample size calculation was performed as the following formula.

$$n = \frac{(Z_{1-\frac{\alpha}{2}} + Z_{1-\beta})^2 \sigma^2}{\triangle^2}$$

A sample size of 42 patients would be required with a two-sided type I error of 0.05 and an 80% power. To protect research power from withdrawal patients, the sample size should be raised by 10%. As a result, a total sample size of 48 patients will be required.

### Statistical analysis

For baseline characteristics (gender, mean age, BMI, APACHE-II, intubation duration, intubation tube size, and cause of acute respiratory failure) and weaning parameters (respiratory, hemodynamic, and arterial blood gas) were analyzed as frequency, percentage, mean, standard deviation, median, and interquartile ranges.

## OUTCOME ANALYSIS PLAN

### Statistical analysis

The primary objective is to compare the diaphragm workload between ATC and PSV for 30 minutes by' regression for correlated measures (adjusted for period, treatment, and sequence effect).

To perform a sensitivity and specificity for the secondary outcome of ventilator weaning and successful extubation based on ultrasound-measured diaphragmatic muscle activity parameters' (DTF, diaphragm excursion, peak contraction velocity, peak relaxation velocity, velocity-time integral, TDI-derived maximal relaxation rate)

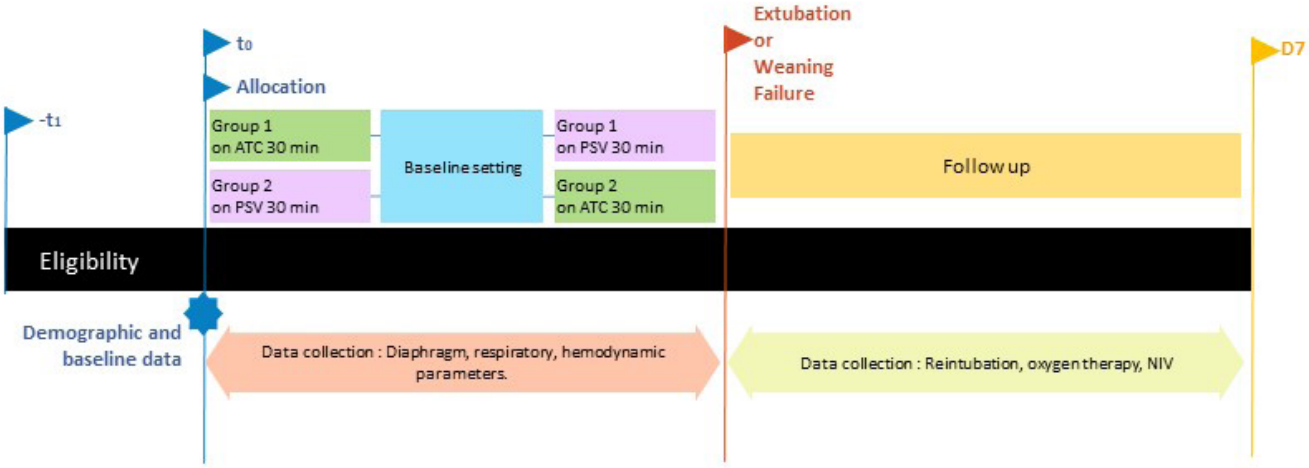


**Figure 2.** Study timeline.
Abbreviation: NIV, non-invasive ventilation.

## DATA MANAGEMENT AND DATA MONITORING

### Input data and monitoring method

Physical and clinical baseline characteristics of the patients (Table 2)

Diaphragm, respiratory and hemodynamic parameters in SBT (Table 3)

Reintubation, high flow nasal canular and NIV in 7 days after extubation (Table 4)

Primary outcome (Table 5)

Secondary outcomes (Table 6)

### Definition of variables

- Successful extubation was defined as no re-intubation in 48 hours.
- Patient contra-indicated for diaphragm ultrasound was define as patients who have a surgical wound, an infected wound, a skin infection, or wound dressing, and etc. at the evaluated sites.
- The incomplete data collection form was defined as missing some data that included in data collection form such as baseline characteristic, weaning parameter, or a patient's death before completion of 7-day follow-up period.
- Inability to participate until the end of the trial was defined as the patient can't be tolerated SBT until the trial is completed.

### Research instruments

Diaphragm thickness fraction is measuring the diaphragm muscle in three layers with a high-frequency linear transducer ultrasound placed in the intercostal space at the 8th or 9th intercostal space in the anterior or mid-axillary line (Figure 4A).

**Table 2.** Physical and clinical baseline characteristics of the patients.

| Characteristics | Collection method |
|---|---|
| Age (years) | Chart review |
| Gender (n of male : female) | Chart review |
| Body mass index (kg/m$^2$) | Chart review |
| APACHE II score | Chart review |
| Mechanical ventilation duration (days) | Chart review |
| Endotracheal tube size (mm) | Chart review |
| Cause of ARF : | Chart review |
| Medical : Surgical (n:n) | |
| Pneumonia (n, %) | |
| Sepsis with ARDS (n, %) | |
| COPD exacerbation (n, %) | |
| Heart failure (n, %) | |
| Post-operation (n, %) | |
| Multi-trauma (n, %) | |
| Other (n, %) | |
| Physical data before weaning trial | |
| Respiratory parameters | Chart review |
| Respiratory rate (breaths/min) | |
| Maximal inspiratory pressure (cmH2O) | |
| Tidal volume (mL) | |
| Vital capacity (mL) | |
| RSBI (breaths/min/L) | |
| Hemodynamic parameters | Chart review |
| Heart rate (beats/min) | |
| Systolic blood pressure (mmHg) | |
| Diastolic blood pressure (mmHg) | |
| Arterial blood gas | Chart review |
| pH | |
| Oxygen tension (mmHg) | |
| Carbon dioxide tension (mmHg) | |
| Bicarbonate (mEq/L) | |

Abbreviation: APACHE II, Acute Physiology and Chronic Health Evaluation II; ARDS, acute respiratory distress syndrome; COPD, chronic obstructive pulmonary disease; RSBI, rapid shallow breathing index.

**Table 3.** Diaphragm, respiratory and hemodynamic parameters in SBT.

| Variability | Collection method | Timing |
|---|---|---|
| Diaphragm parameters | Bedside ultrasound | At start SBT and 30 minutes after SBT both ATC and PSV |
| Diaphragm thickness fraction (%) | | |
| Diaphragm Excursion (cm) | | |
| Peak contraction velocity (cm/s) | | |
| Peak relaxation velocity (cm/s) | | |
| Velocity-time integral (cm) | | |
| TDI-derived maximal relaxation rate (cm/s$^2$) | | |

**Table 3. (Continued)** Diaphragm, respiratory and hemodynamic parameters in SBT.

| Variability | Collection method | Timing |
|---|---|---|
| Respiratory parameters | Bedside monitoring | At start SBT and 30 minutes after SBT both ATC and PSV |
| Tidal volume (mL) | | |
| Respiratory rate (breaths/min) | | |
| Inspiratory time (sec) | | |
| Peak inspiratory pressure ($cmH_2O$) | | |
| Minute ventilation (L/min) | | |
| Oxygen saturation (%) | | |
| Hemodynamic parameters | Bedside monitoring | At start SBT and 30 minutes after SBT both ATC and PSV |
| Heart rate (beats/min) | | |
| Systolic blood pressure (mmHg) | | |
| Diastolic blood pressure (mmHg) | | |

Abbreviation: TDI, tissue Doppler imaging; SBT, spontaneous breathing trial; ATC, automatic tube compensation; PSV, pressure support ventilation.

**Table 4.** Reintubation, high flow nasal canular and NIV in 7 days after extubation.

| Characteristics | Monitoring method | Timing |
|---|---|---|
| Reintubation (n, %) | Chart review | 7 days after extubation |
| High flow nasal canular (n, %) | Chart review | 7 days after extubation |
| Noninvasive ventilation (n, %) | Chart review | 7 days after extubation |

**Table 5.** Primary outcome.

| | Monitoring method | Timing |
|---|---|---|
| **Primary outcome** | | |
| Difference of diaphragm thickness fraction (%) | Bedside ultrasound | At start SBT and 30 minutes after SBT both ATC and PSV |

Abbreviation: SBT, spontaneous breathing trial; ATC, automatic tube compensation; PSV, pressure support ventilation.

**Table 6.** Secondary outcomes.

| | Monitoring method | Timing |
|---|---|---|
| **Secondary outcome** | Chart review | 48 hours after extubation |
| Diaphragm thickness fraction (%) | Bedside ultrasound | At 30 minutes after SBT both ATC and PSV |
| Diaphragm Excursion (cm) | Bedside ultrasound | At 30 minutes after SBT both ATC and PSV |
| Peak contraction velocity (cm/s) | Bedside ultrasound | At 30 minutes after SBT both ATC and PSV |
| Peak relaxation velocity (cm/s) | Bedside ultrasound | At 30 minutes after SBT both ATC and PSV |
| Velocity-time integral (cm) | Bedside ultrasound | At 30 minutes after SBT both ATC and PSV |
| TDI-derived maximal relaxation rate ($cm/s^2$) | Bedside ultrasound | At 30 minutes after SBT both ATC and PSV |

Abbreviation: TDI, tissue Doppler imaging; SBT, spontaneous breathing trial; ATC, automatic tube compensation; PSV, pressure support ventilation.

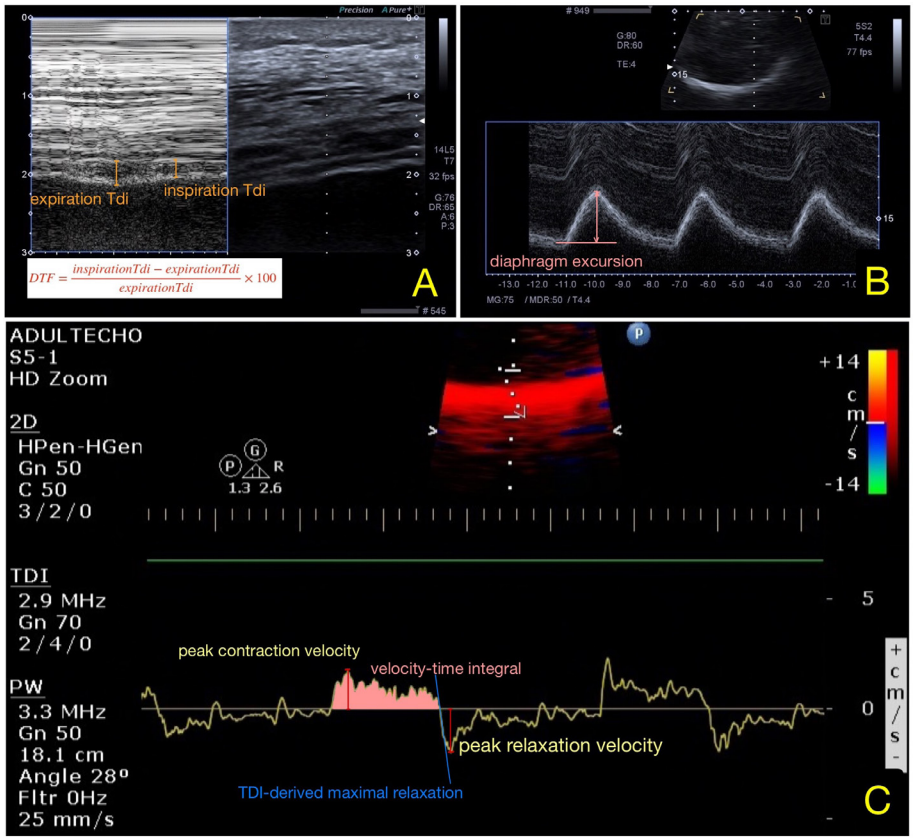


**Figure 4.** Diaphragm ultrasound.

Diaphragm excursion is measuring the slope of the diaphragmatic echoic line or the maximum distance in diaphragmatic movement during inhalation using a phased array transducer ultrasound with M-mode placed under the costal margin between the mid-clavicular and mid-axillary lines and measuring the slope of the diaphragmatic echoic line or the maximum distance in diaphragmatic movement during inhalation (Figure 4B).

Tissue doppler imaging of diaphragm are the peak contraction velocity, peak relaxation velocity, velocity–time integral, and TDI-derived maximal relaxation rate were measured with a phased array transducer ultrasound paired with a pulsed wave (PW) doppler placed under the right costal margin between the mid-clavicular line (Figure 4C).

## DISCUSSION

In a previous trial, the SBT was investigated utilizing the T-piece, PSV, and ATC. It was varied intubation periods and reintubation rates were discovered. There was a lengthier intubation time when employing a T-piece in SBT and had a greater risk of reintubation, although it was not statistically significant [8]. When comparing SBT between PSV and ATC, the pressure support utilized for comparison is important. In most studies, there was no difference in intubation times or rates of reintubation [9,10].

The utilization of inhalation force during SBT, in which diaphragmatic muscle activity measures could indicate the force put on breathing, was compared in this study. Diaphragm ultrasonography is a simple approach to perform at the bedside. DTF values were able to predict effectiveness in weaning critically ill patients off ventilators using diaphragm ultrasonography to predict diaphragmatic muscle activities. When comparing the use of force in SBT to ATC and PSV [14]. Nowadays, the values of diaphragmatic muscle TDI differ between successful and failed weaning individuals [16]. As a result, this study compared the inhaling force of PSV on pressure support 5 $cmH_2O$ with CPAP 5 $cmH_2O$ and ACT 100% with CPAP 5 $cmH_2O$ in SBT by DTF, as well as other measurements such as TDI diaphragm muscle to determine extubation success.

Weaning with high effort produces poor outcomes, whereas ATC is less forceful and more likely to succeed in weaning from a ventilator. DTF, which measures diaphragmatic muscle activity, is the most accurate way to predict success in weaning a ventilator today. DTF demands high precision, DE is easier but less detailed, and TDI of the diaphragm is more informative and may be as accurate as DTF in predicting success in weaning off a ventilator.

Study strength: because this is a crossover study, there is no change in baseline characteristics. This is one of the first trials using DTF usage in diaphragm effort prediction. In an ultrasound method that is operator dependent, only one investigator is measured.

Limitations: Because this is a single-center study, this may not be applicable to a wide range of people. Due to the open label trial, there is some bias. From a crossover trial, the period treatment and sequence effect should be concern. For secondary outcomes, the experiment may be underpowered.

## ETHICS

There is no financial support for this research. The trial has been approved by the Ramathibodi Human Research Ethics Committee (COA. MURA2021/168) and enrolment has commenced

## CONFIDENTIALITY

Informed consent is obtained at bedside isolated room in ICU. Instead of personal information such as name-surname, hospital number, admission number, and identification number, an ID code is utilized and recorded. The data for this study is only kept in collected data form and is password secured on the computers of the researchers. When the research is concluded, all physical data will be destroyed, and all digital data will be deleted from all computers.

## DISSEMINATION POLICY

The results of a study will be submitted in peer-reviewed journals and presented at conferences in critical care medicine and anesthesiology.

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## AUTHORS' CONTRIBUTIONS

(I) Conceptualization: Nutarpa Kulkanokwan; (II) Data curation: Nutarpa Kulkanokwan; (III) Formal analysis: Nutarpa Kulkanokwan, Sunthiti Morakul, Chawika Pisitsak; (IV) Funding acquisition: Nutarpa Kulkanokwan; (V) Methodology: Nutarpa Kulkanokwan, Chawika Pisitsak, Sunthiti Morakul, Pongdhep Theerawit; (VI) Project administration: Nutarpa Kulkanokwan; (VII) Visualization: Nutarpa Kulkanokwan; (VIII) Writing – original draft: Nutarpa Kulkanokwan, Chawika Pisitsak, Sunthiti Morakul; (IX) Writing – review & editing: Nutarpa Kulkanokwan, Chawika Pisitsak, Sunthiti Morakul.

## SUPPLEMENTARY MATERIALS

none

## ABBREVIATIONS

APACHE, Acute physiology and chronic health evaluation; ARDS, Acute respiratory distress syndrome; ARF, Acute respiratory failure; ATC, Automatic tube compensation; BMI, Body mass index; CPAP, Continuous positive airway pressure; COPD, Chronic obstructive pulmonary disease; DE, Diaphragm excursion; DTF, Diaphragm thickness fraction; HFNC, High-flow nasal cannula; ICU, Intensive care unit; NIV, Noninvasive ventilation; Paw, Airway pressure; PCV, Peak contraction velocity; PRV, Peak relaxation velocity; PSV, Pressure support ventilation; RR, Respiratory rate; RSBI, Rapid shallow breathing index; SBT, Spontaneous breathing trial; Tdi, Diaphragm thickness; TDI, Tissue doppler imaging; TDI-MRR, Tissue doppler imaging - derived maximal relaxation rate; Ti, Inspiratory time; VT, Tidal volume; VTI, Velocity time integral.

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