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RESEARCH PROTOCOL

The incidence and risk factors of post-extubation dysphagia in critically ill surgical patients: protocol for prospective observational study

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ABSTRACT:

Background: Post-extubation dysphagia (PED) is commonly reported in critically ill patients. Although dysphagia is not a fatal disease, it is an important medical condition that required the appropriate treatment. Early detection of PED is essential to reduce complications. There is no well-established standard screening and treatment protocol for surgical intensive care unit. The aims of this study are to report the incidence and identify the risk factors of PED in critically ill surgical patients.

Methods: This study is a prospective observational study. Two hundred patients who are intubated and on mechanical ventilation for ≥ 24 hours and successfully extubated without exclusion are needed to be enrolled. The patients will be performed water swallowing test (WST) at bedside in surgical ICU within 3-6 hours after extubation. For those patients who failed the WST, swallowing specialists will perform bedside fiberoptic endoscopic evaluation of swallowing (FEES) in SICU within 24-48 hours to establish the diagnosis of dysphagia. The primary outcome is the incidence and risk factors of post-extubation dysphagia. The secondary outcomes include time to resume oral diet after extubation, Functional Oral Intake Scale at follow-up, and adverse outcomes related with PED.

Discussion: The early detection of PED could be accomplished by using an effective screening tool, the WST, and confirmed the diagnosis by FEES performed by swallowing specialists. The incidence and risk factors of PED reported in this study will be helpful in developing the protocol for screening and treatment for PED in critically ill surgical patients.

Trial registration: The Thai Clinical Trials Registry (TCTR20211023003) Registered on 23 October 2021

Keywords: Dysphagia, Post-extubation dysphagia (PED), Aspiration, Water swallowing test (WST), Fiberoptic endoscopic evaluation of swallowing (FEES)

BACKGROUND

Post-Extubation Dysphagia (PED) is a common condition in critically ill patients who admitted in the ICU [1]. The occurrence is about 41% with some studies reported vary widely from 3% to 83% [2,3]. It occurs frequently in patients who have high risks including elderly patients, preexisting dysphagia, prolong intubation with mechanical ventilation > 48 hours [4], stroke and neurological problems, renal failure, cervical spine or head & neck radiation/surgery and post tracheostomy patients[2,5,6].

Although dysphagia is not a fatal disease, it is an important medical condition that required the appropriate treatment since it associated with an increased risk of morbidities and mortalities in the ICU patients [7]. The common consequences of PED include pulmonary aspiration leading to aspiration pneumonia, an increase in reintubation rate, inadequate nutritional support, prolong duration of feeding tube with delayed reinstitution of oral feeding, a prolonged ICU and hospital stay, a decrease in the quality of life [1,3,8,9]. The possible mechanisms of developing the PED in ICU patients were multifactorial.

The PED screening is an important procedure to detect the probability of dysphagia. There are few recognitions about ICU bedside dysphagia screening test to identify the risk of PED, as a result ICU personnel are unable to detect patients at risk and lead to morbidities when start oral feeding in the ICU or after discharging form the ICU [10-12]. Accordingly, the early detection of PED could help the ICU team to choose the appropriate treatment leading to a reduction of complications related with dysphagia [4,5,8,13,14]. Water Swallowing Test (WST) is a cost-effective screening tools, performed by oral water ingestion to detect the swallowing-related aspiration. This technique is effective for aspiration screening with sensitivity 91% and specificity 53% [15]. Moreover, WST can easily be performed by different healthcare providers including ICU physicians and nurses [7,9,15].

To confirm the diagnosis of PED, the gold standards for diagnosis of oropharyngeal dysphagia are video fluoroscopic swallow study (VFSS) and/or fiberoptic endoscopic evaluation of swallowing (FEES). Both VFSS and FEES are mainly used when the diagnosis is uncertain after bedside swallow evaluation. FEES is able to perform at the bedside which is feasible and well-tolerated for ICU patients [5,7].

Based on current studies, early detection of PED is beneficial in choosing the appropriate treatment to improve the swallowing function leading to a reduction of complication rates. However, there is no well-established standard screening and treatment protocol for surgical intensive care unit.

OBJECTIVES

This study is designed to establish the screening and diagnosis for PED. The aims are to evaluate the incidence and identify the risk factors of PED in critically ill surgical patients.

Trial Design

This is a prospective observational study (Intervention in a single center); the protocol was approved by the Ethics Committee of the Siriraj Institutional Review Board (Certificate of Approval No. Si 591/2021) and was registered in The Thai Clinical Trials Registry (TCTR20211023003).

KEY MESSAGES:

- Post-extubation dysphagia (PED): the difficulty or inability to transfer food and liquid effectively and safely from the mouth to the stomach after extubation
- Water Swallowing Test (WST) is a cost-effective screening tools, performed by oral water ingestion to detect the swallowing-related aspiration
- Fiberoptic endoscopic evaluation of swallowing (FEES): the gold standard for evaluation of oropharyngeal dysphagia, which allows real-time imaging of all stages during swallowing and be able to perform at the bedside which is feasible and well-tolerated for ICU patients.

MATERIALS AND METHODS

Study setting

- The study was conducted in surgical intensive care unit Siriraj Hospital, Mahidol University, Bangkok, Thailand from June 2021 to February 2022

Participant

- The patients who have planned for surgery and are at risk of postoperative surgical ICU admission with the use of invasive mechanical ventilation and the patients who admitted in surgical ICU with plan for extubation will be enrolled by critical care teams. Written informed consent will be obtained from the participant and/or participants' family members.

Eligibility criteria

1. Surgical ICU patients who were intubated and on mechanical ventilation for ≥ 24 hours after intubation [2]
2. Successful extubation
3. Stable hemodynamics (MAP ≥ 65 mmHg) without vasopressors use at the time of enrollment
4. Patient is awake, alert, and able to follow commands [9]

Exclusion criteria

1. Surgical procedure involving head and neck, cervical, cranial trauma, cardiothoracic surgery, neurosurgery [4,8]
2. Surgical procedure involving GI tract that need to NPO [1]
3. Tracheostomy [10]
4. Profound deafness [4,8]
5. Pre-existing dysphagia before underwent surgical procedure from other diseases e.g., neurological conditions: previous stroke [10], Parkinson disease, head& neck cancer, underwent head and neck surgery [9]

Withdrawal criteria

Patients who have rapid progression in their acute illness that preclude to participate in the study

Intervention

All the extubated patients who are eligible with the inclusion criteria will be enrolled and informed consent will be obtained from the participants and/or legal adopted relatives before undergoing protocol. For PED screening, physicians or trained ICU nurses will perform WST at bedside in surgical ICU within 3-6 hours after extubation [1,6,16,17].

From literature reviews, the person who was intubated at least 24-48 hours may take approximately 24-48 hours to return normal swallow function. Leder et al, 2019 [16] was the first study to investigate the use of swallowing test at 3 predetermined timepoints for detecting aspiration risk in post-extubation ICU patients. The data supported performing swallowing test as early as 1-hour post-extubation due to the high (82.2%) pass rate. An even higher, 91.6%, pass rate was found after repeated protocol administrations up to 24 hours post-extubation. That is, the clinician can determine the most appropriate time between 1 hour and 24 hours post-extubation to repeat the protocol. Systematic standardized bedside dysphagia screening was performed within 3 hours of extubation.

In this study, performing the WST at 3-6 hours after extubation is the optimal period because the patients must be ensured to be stable enough for the test and that the test does not delay the feeding and the discharge from the ICU. When failed WST, patients may be retested at 24-48 hours, if still failed WST, then a fiberoptic endoscopic evaluation of swallowing (FEES) will be performed at bedside to confirm the diagnosis of dysphagia.

Before performing the WST, the patient must be evaluated for readiness by an indirect swallowing test including [18].

- Awake, alert, cooperative, able to follow command
- Vital signs are stable
- Able to maintain at least 75-degree in upright position
- The patient can cough effectively
- The patient can stick out tongue and move to the left and right
- The patient's mouth is clean
- The patient can breathe comfortably

Water swallowing test

The combined technique for water swallowing test; a single sip and consecutive sip technique is used because of concerning for safety and avoid the silent aspiration.

The patient will be asked to drink each 5 ml of water (1 teaspoon) 3 times respectively. If the patient shows any abnormal signs, the test will be discontinued. If all steps are passed, then the patient will continue to drink the entire 90 ml of water from a cup or with a straw in sequential slowly and steadily swallowing without stopping (cup or straw can be held by clinician or patient), (Fig.1).

The results of the test will be observed as "Fail and Pass" (Table 1).

Table 1. Water swallowing test result

WST Fail	WST Pass
Inability to drink 5 ml of water (1 teaspoon) at any time or Inability to drink the entire 90 ml (a glass of water) in sequential swallows due to stopping/starting or patient exhibits overt signs of aspiration either during or immediate after completion	Complete and uninterrupted drinking of all 5 ml (1 teaspoon) of water for 3 times respectively and all 90 ml (a glass of water) of water without overt signs of aspiration, no symptoms after drinking water
One of these symptoms • Cough • Choking up to 1 min after test • Drooling • Wet voice • Gurgly voice • Hoarse voice • Inability to drink entire amount continuously • Desaturation >2%	

Abbreviations: WST, water swallowing test; min, minute; ml, milliliter

If patients pass the test, collaborate with ICU physician or critical care team to order appropriate oral diet.

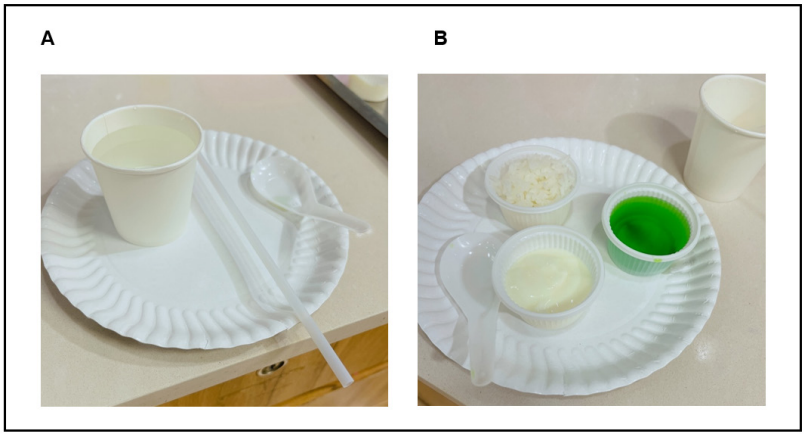

Figure 1. Materials for interventions. A, A glass of water for water swallowing test (WST). B, Various types of food during fiberoptic endoscopic evaluation of swallowing (FEES); pureed consistency as yogurt, liquid consistency as clear water with food coloring agents, and solid consistency as cooked rice

Fiberoptic endoscopic evaluation of swallowing

For those patients who failed the WST, critical care team will consult specialists from the Department of Physical Medicine and Rehabilitation to perform bedside FEES in SICU within 24-48 hours to establish the diagnosis of dysphagia.

Fiberoptic Endoscopic Evaluation of Swallowing (FEES) must be performed by rehabilitation physician who is the swallowing specialist with 5-year experiences and has performed FEES at least 50 patients. The appropriate time to perform FEES should be within 24-48 hours after failed WST. At 5-10 minutes before insertion of the scope, physician will apply 0.05% oxymetazoline hydrochloride (Iliadin) nasal drop for nasal decongestion and/or 4% xylocaine nasal packing for topical nasal anesthesia respectively. The topical anesthesia for oral cavity and oropharynx should not be used because it may interfere with the sensorium involved in the swallowing.

The procedure is performed by passing a small nasopharyngoscope (Glide scope®) with 3.8 mm in diameter through one nostril into oropharynx and visualize the entire glottis (Fig.2). The duration of the procedure is about 20-30 minutes. If the findings show saliva aspiration or large amount of secretion, specialist will stop the procedure. Without exclusion, specialist will go on FEES by various types of food, each 5 ml, step by step; starting with pureed consistency such as yogurt for 2 teaspoons, then liquid consistency such as clear water for 2 teaspoons, and solid diet as cooked rice for 2 teaspoons (Fig.1). Findings from FEES when testing by types of food can be diagnosed dysphagia by measurement using Penetration-Aspiration Scale (PAS) [19].

The penetration-aspiration scale (PAS) is an 8-point scale used to characterize both the location of airway invasion events and a patient's response during swallowing studies (Table 2). It is a multidimensional scale, meaning that more than one type of event is judged. The scale was designed to capture three constructs: depth of airway invasion, material remaining after the swallow, and a patient's response to aspiration. The scale ranks depth of airway invasion as superordinate to other parameters [19,20].

Table 2. PAS scale

Score	Description
1	Material does not enter the airway
2	Material enters the airway, remains above the level of the vocal folds, and is ejected from the airway
3	Material enters the airway, remains above the level of the vocal folds, and is not ejected from the airway
4	Material enters the airway, contacts the vocal folds, and is ejected from the airway
5	Material enters the airway, contacts the vocal folds, and is not ejected from the airway
6	Material enters the airway, passes below the level of the vocal folds, and is ejected into the larynx or out of the airway
7	Material enters the airway, passes below the level of the vocal folds, and is not ejected out of the trachea despite effort
8	Material enters the airway, passes below the level of the vocal folds, and no effort is made to eject

Abbreviations: PAS, penetration-aspiration scale

The PAS score 1-2 is normal. The score value from 3 or more considered as positive result for diagnosis of dysphagia [20].

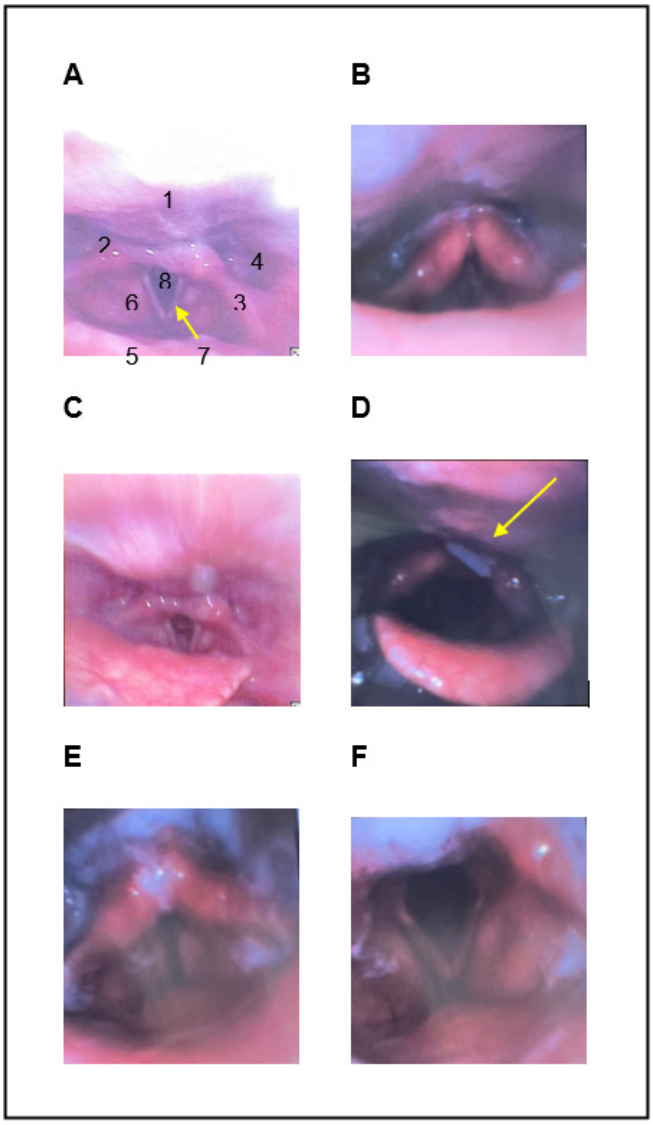

Figure 2. The entire glottis as visualized endoscopically during fiberoptic endoscopic evaluation of swallowing. **A**, No food enters the airway as PAS 1 (*1, posterior pharyngeal wall; 2, arytenoid; 3, aryepiglottic fold; 4, pyriform sinus; 5, epiglottis; 6, false vocal fold; 7, true vocal cord; 8, trachea*). **B**, Yogurt enters the airway, remains above the level of the vocal folds (PAS 2). **C**, Some cooked rice enters the airway and remains above the level of the vocal folds (PAS 3). **D-E**, Cooked rice and yogurt enter the airway and contacts the vocal folds (PAS 4-5). **F**, Saliva and clear water enter the airway and passes below the level of the vocal folds (PAS 6-8).

Functional Oral Intake Scale

For following the clinical of patients, the swallowing specialists will evaluate the severities of swallowing function by using Functional Oral Intake Scale (FOIS) which scale varies from 1 to 7 (Table 3). The FOIS has been internationally validated. It is a multidimensional tool, organized to determine the type of diet that the patients are able to ingest and the need for supervision that should be used in each case [21,22].

Table 3. Functional Oral Intake Scale (FOIS) categorized swallowing outcome into 7 levels (score 1-7) [21,23,24]

Level	Oral function
	Tube dependent (levels 1-3)
1	No oral intake
2	Tube dependent with minimal/inconsistent oral intake
3	Tube supplements with consistent oral intake
	Total oral intake (levels 4-7)
4	Total oral intake of a single consistency
5	Total oral intake of multiple consistencies requiring special preparation
6	Total oral intake with no special preparation, but must avoid specific foods or liquid items
7	Total oral intake with no restrictions

The Swallowing rehabilitation composes of sensory stimulation, oromotor exercise, compensation technique, food modification, swallowing maneuver and perhaps use technology for example electrical stimulation. The way we providing a treatment as mentioned above depends on the pathology and severity of disease [23,25]. The occupational therapists (OT) can make the decision for treatment program. The swallowing treatment will be scheduled about 30-60 minutes/session, 3 sessions/week.

The OT will re-evaluation FOIS again after treatment process and compare the levels of swallowing function by FOIS at initial swallowing assessment and at day 7, 14, or achieve pre-surgery diet status after swallowing therapy in dysphagia subjects.

Finally, all the studied patients will be followed-up at 28 days post-extubation to collect the dysphagia-related adverse outcomes (by telephone; if discharged/ follow-up at ward; still admitted). Flow chart in Figure 3 represents the screening algorithm, specialist examination and follow up.

Outcome measurement

Primary outcome

1. Incidence of post-extubation dysphagia

(Authors need to specify the incidence of PED in Thai population in only surgical ICU setting. Those patients who failed the WST and were diagnosed dysphagia from FEES will be evaluated as incidence of PED.)

2. Risk factors of post-extubation dysphagia

According to various mechanisms of post-extubation dysphagia, PED may be affected from different factors e.g., duration of intubation, endotracheal tube size, attempts of intubation, re-intubation; may be associated with trauma and inflammation of mucosa or muscle related swallowing function. Age and co-morbidities may represent to ability to recovery and strength of swallowing muscles. Intraoperative data such as anesthetic agents use, surgery type, may be associated with decrease in sensation, motor function, and/or ICU-acquired weakness. We assume the predefined risk factors from the reported risk factors of the previous studies.

Secondary outcomes

1. Time to resume oral diet after extubation
2. Functional Oral Intake Scale at follow-up
3. Adverse outcomes related from PED: aspiration pneumonia, re-intubation, in hospital death, 28-day mortality

Exploratory outcomes -

Timeline

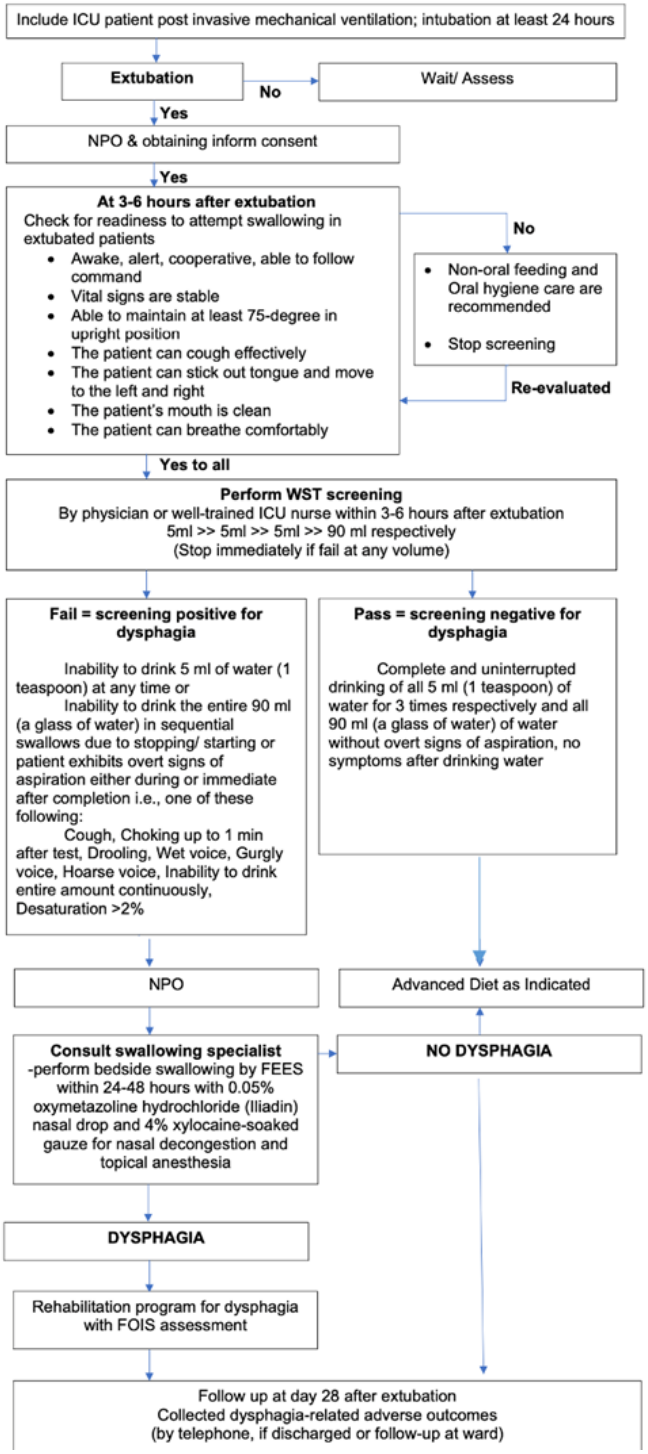

Figure 3. Flow chart of screening algorithm, specialist examination and follow up

DATA ANALYSIS PLAN

Sample size estimation

From the objectives to evaluate incidence and risk factors of post-extubation dysphagia, M. Mcintyre et al. 2020 [3] reported weight incidence of PED with subgroup and meta-regression analysis reviewed for heterogeneity; the incidence of PED across all included studies can be concluded as the prevalence of dysphagia after endotracheal intubation in critically ill adults for 41% (95% CI 0.33-0.50, I2= 98.69%, p<0.001). STATA 16.1 was used for calculation of the sample size by the binomial test comparing one proportion to a reference value (proportion = 0.4 error = 0.1 type I error = 0.1 n = 176). With 10% dropped out included, 200 participants are needed to be enrolled.

OUTCOME ANALYSIS PLAN

All data will be calculated by STATA 16.1 software. Baseline characteristics and the results which were the continuous data are expressed as mean ± SD or as median. Categorical data are presented with frequency and percent. The clinical result in the follow-up period were compare between patients who pass the WST and patient who fail to pass the WST. Paired Student t test use for comparison for continuous variables and Fisher's exact use for categorical. The Kaplan-Meier curve will use to show time to resume oral diet after extubation and Cox regression with multivariable analysis will use to compare between pass and fail WST groups. Logistic regression analysis will perform for evaluated the outcome for risk factors of PED.

DATA MANAGEMENT

Data collection

After enrollment of participants, all of patients' baseline characteristics, intra-operative data, and extubation details are collected. After screening with WST, all the test information is recorded. In patients who do not pass the WST will be continuing to undergo FEES. All of FEES result will be recorded and evaluate the severity by PAS score. After that, the patient will be sent to OT for treatment program. FOIS score are used for evaluated the swallow function after the dysphagia therapy. Finally, at post-extubation 28 days, all of participant (both who pass and who fail of the WST) should be recorded for following up data of clinical for example time to resume oral diet, ICU stays, hospital stays and adverse outcome. If the participants are not admitted, the telephone will be call for the clinical information.

Confidentiality

Only the study code will be collected, and participants' private information will not be collected. The data will be kept confidential until they are required for analysis.

Dissemination policy

The resulted will be communicated with intensivists, critical care teams, surgical teams, swallowing therapists via academic conferences and publications.

DISCUSSION

This study proposes the protocol for a prospective observational study that investigating the incidence of PED and identifying the risk factors of PED in SICU. Although dysphagia is not a fatal disease, it is associated with an increased risk of morbidities and mortalities. The common consequences are related with pulmonary complications [1,3,8,9].

There are many possible mechanisms of PED in critically ill patients especially in the ICU. The first mechanism is the ulceration and inflammation of oropharyngeal and laryngeal mucosa that may be caused by endotracheal tube insertion. When the endotracheal tube stays inside the airway, it's leading to the impairment of airway protection. Secondly, the muscular weakness of pharyngeal muscles from disuse atrophy and decreasing oropharyngeal/laryngeal sensation caused by polyneuropathy in critically ill patients. Thirdly, the sedation and paralysis with prolonged supine position contribute to gastroesophageal reflux and impairment of sensorium, both are interrupting the swallow mechanism. Finally, the desynchrony between breathing and swallowing. When respiratory rate is increased, the peri-swallowing apnea time is shortening, the vocal cords are delayed in closure (larynx stills open) prior to food passage, resulting in aspiration [5,14,26].

The PED screening is an important procedure to detect the probability of dysphagia. Johnson XL, 2018 [8,9] suggested that the reliability and validity of a post-extubation dysphagia screening tool can help nurses to determine extubated patient's ability to swallow after prolonged endotracheal intubation. The timing and process are variable, often performed at 24 hours after extubation [3,7,16]. In stroke unit, dysphagia screening is routinely performed before starting oral feeding for prevention of aspiration complications, meanwhile it is uncommonly performed in critically ill patients in the ICU [1,11]. There are few recognitions about ICU bedside dysphagia screening test to identify the risk of PED, as a result ICU personnel are unable to detect patients at risk and lead to morbidities when start oral feeding in the ICU or after discharging form the ICU [10-12]. The Goals of PED screening in the ICU are early diagnosis the PED in ICU patients and prompt treatment the conditions leading to protection from PED complications. It is the proactive process aiming to decrease morbidities and mortalities from PED complications [4,5,8,13,14].

Water Swallowing Test (WST) is a cost-effective screening tool for PED, using oral water ingestion to detect the swallowing-related aspiration [17,26]. This test is a part of Yale Swallow Protocol (YSP) [27]. Validation information for this test is first reported on stroke patients since 1992. The appropriate timing for evaluation using this test was reported in many studies. DYnAMICS trail 2017 [1] designed to systematic dysphagia screen and follow-up until 90 days. From this trial, systematic standardized bedside dysphagia screening was performed within 3 hours of extubation as a pragmatic bedside screening tool followed by comprehensive specialist clinical examinations in screening positive case. A systematic review and meta-analysis from Brodsky et al, 2016 [15] had evaluated screening accuracy of bedside WST. The Consecutive sip technique

(drinking large volume of water 90 ml without stopping) is the test to detect an airway response or voice change as being clinically indicative of aspiration. In this study all participants will be tested by WST. If the patients pass the test, it can assume that no PED and the patient will not have swallowing-related aspiration. Then all of test-passed patient will be follow for clinical result and compare with fail WST group. For the patients who do not pass the WST, another examination will be test.

After screening, the gold standards for diagnosis of dysphagia are VFSS and/or FEES, which allows real-time bedside imaging of all stages during swallowing. Both tests are more likely to be available at university-based hospitals than community-based hospitals [28], since using these two tests are suitable for post-operative patients in ICU. Early detection of dysphagia is essential to treat with various therapeutic options to improving swallowing function. In failed WST patients, FEES will be performed at bedside in ICU to confirm diagnosis of PED and evaluated the severity of dysphagia with PAS score. Then, the treatment program will be started by the OT to treat the PED.

In 2019, El Gharib, et al. found swallowing exercises carried out by extubated patients after prolonged endotracheal intubation increased neuromuscular recruitment of suprahyoid muscles involved with swallowing and reduced dysphagia levels [4]. In addition, study from Wu et al. Critical Care 2019 showed that swallowing and oral care intervention for patients following endotracheal extubation could be significantly higher in a likelihood of resuming total oral intake. In this study, FOIS score is used to evaluate the swallowing function after the swallowing therapy [12].

The strength of this study is the benefit for the patients who has PED. The early detection of PED could help the ICU team to provide appropriate treatment for the patients resulted in a decrease of the pulmonary complication and a reduction of morbidity and mortality. Moreover, FEES is the gold standard for diagnosis of dysphagia and will perform by the swallowing specialist which allow the accurate and reliable incidence of PED. The incidence and risk factors of PED reported in this study will be helpful in developing the protocol for screening and treatment for PED in critically ill surgical patients.

This study has several limitations. First, surgical patients frequently had gastrointestinal problems or had conditions that are needed to be NPO at that time after extubation. The exclusion of these patients could affect the accuracy of the incidence of PED in surgical ICU patients. Second, while performing WST at 3 hours after extubation and within 6 hours, it could influence time to discharge from ICU. Third, the WST is a subjective assessment and can be difficult in interpretation of some unfamiliar symptoms such as wet voice and gurgly voice.

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AUTHORS' CONTRIBUTIONS

Siriraj Institutional Review Board is in full compliance with international guideline for human research protection such as the Declaration of Helsinki, the Belmont Report, CIOMS Guidelines and the International Conference on Harmonization in Good Clinical Practice (ICH-GCP) and supervise the trial. The ethics committee will meet over the course of the trial once a year to oversee conduct and progress. Natsuda Phothikun designed the study concept, and she is responsible for the recruitment and management of patients, as well as the acquisition and interpretation of the data. Phakamas Tanvijit and Poungkaew Thitisakulchai are responsible for the acquisition and interpretation of the data. Thassayu Yuyen designed the study concept, and he is responsible for revising the manuscript. All authors have contributed to writing the manuscript, and no professional writers have been involved. The authors read and approved the final manuscript.

SUPPLEMENTARY MATERIALS

none

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