The Cough Reflex Intensity Score in Critically Ill Patients' Airway Management: Study Protocol for a Multicenter, Prospective, Observational Trial

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Research Article

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Abstract

Background

A patient’s ability to cough is important for assessing a patient’s airway condition and likely mechanical ventilation outcome,there is still a lack of data comparing patients’ initial cough ability and outcomes.

Methods

The study is a prospective, observational trial which includes 144 patients from Xinjiang Medical University. After a patients is assigned a cough strength score, the cough intensity assessments will be implemented every other day for a week. The primary endpoint is whether the patient requires endotracheal intubation (including tracheostomy). Secondary endpoints include time spent under mechanical ventilation (excluding noninvasive ventilation), ICU and hospital lengths of stay, hospital expenses and in-hospital 30-day mortality.

Discussion

Anecdotally in our practice, we found that patients with a high Cough Reflex Intensity Score don't require endotracheal intubation, while patients with a low score always need to be intubated. This trial will test to what degree cough intensity is correlated to patient’s outcomes.

Trial registration:

Chinese Clinical Trial Registry,ChiCTR1900028265. Registered 16 December 2019

Background

Airway management in the care of critically ill patients is of paramount importance. It is a foundational part of treatment for all critically ill patients. Improper airway management can directly threaten patients' lives [1–4], while effective airway management can reduce mortality[24–25]. A key element in managing a patient’s airway is determining their ability to protect their airway via coughing. A patient’s ability to cough is a function of their respiratory center drive and respiratory muscle strength [7], and is important for assessing a patient’s airway condition and likely mechanical ventilation outcome [5]. At present, a study[8] has classified patients’ cough ability according to cough strength and secretions. This classification is divided into three grades: strong, medium, and weak. There have also been four[8,9,12,17] studies which looked for any correlation between a patient’s cough ability and the effectiveness of noninvasive mechanical ventilation [10]. These studies demonstrated that the worse the cough ability, the higher their risk of failing noninvasive mechanical ventilation, and the higher their in-hospital mortality [15–16]. Some

studies have tested the efficacy of cough ability to predict extubation outcome [6,8,12–14,], which showed that the stronger an ability to cough, the higher the rate of successful extubation [18,19]. However, these studies mainly focused on the cough ability of patients receiving mechanical ventilation, there is still a lack of data comparing patients' initial cough ability and outcomes. This will be a prospective, observational study using the Cough Reflex Intensity Score, which is based on a previously proposed cough strength classification [17,21,23]. This study will aim to determine whether the Cough Reflex Intensity Score is effective at assessing a patient's risk for airway sputum obstruction, respiratory infection, or mechanical ventilation.

Methods

Trial design and setting

The study is a prospective, observational trial which includes 144 patients from Xinjiang Medical University. The Ethics Committee of the First Affiliated Hospital of Xinjiang Medical University approved the trial protocol on August 28, 2019 (reference number K201908-03).And the named ethics committee which approved the study also approved the waiving of/need for consent to participate in the study. The schedule for enrolment, intervention, and assessment will follow the Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT) guidelines (see Additional File 1) and is presented in Fig. 1.

Population

Inclusion criteria are: critically ill patients who stay in either the Emergency Resuscitation Unit or the Intensive Care Unit of a hospital. Exclusion criteria are: (1) uncooperative patients, (2) patients with heart failure or multiple organ failure, (3) patients post-cardiopulmonary resuscitation, (4) patients with severe asthma, and (5) pregnant or lactating women.

There is a research coordinator at each hospital to monitor and coordinate the trial. This is a non-interventional study, so informed consent was waived for this observational trial.

Study Tool

The cough reflex intensity tool, based on the Semi-quantitative Cough Strength

Score first proposed by Khamiees in 2001 [11], was formulated using the Delphi method [20].

Grade one: No cough. The patient is conscious but has no strength to cough, is unable to make a coughing sound, is unconscious (such as in a coma), is unable to follow instructions, or has no cough reflex when presented with an external stimulation (such as sputum aspiration and pressing on the cricothyroid membrane).

Grade two: Has a weakly audible cough. The patient is conscious and able to follow instructions, but with only a faint sound and unable to produce sputum out of the glottis.

Grade three: Has a clearly audible cough. The patient can produce a clear coughing sound, able to cough sputum out of the glottis but not out of their mouth.

Grade four: Has a strong, loud cough. The patient can cough sputum out of their mouth.

End-points

The primary endpoint is whether the patient requires endotracheal intubation (including tracheostomy). Secondary endpoints include time spent under mechanical ventilation (excluding noninvasive ventilation), ICU and hospital lengths of stay, hospital expenses and in-hospital 30-day mortality.

Observation and Date-Collection Procedures

We will collect patient characteristics (age, gender, weight and height), baseline clinical characteristics (medical diagnosis, past medical and surgical histories, Glasgow Coma Scale, arterial blood gas results and vital signs), as well as cough strength score at patient enrollment.

After a patients is assigned a cough strength score, the cough intensity assessments will be implemented every other day for a week. We will collect vital parameters, including arterial blood gas results, vital signs and Glasgow Coma Scale. Other treatments, such as antibiotics, non-invasive mechanical ventilation, physical nursing treatments (e.g. chest physiotherapy or turning the patient), atomization/nebulization treatments, and any sputum suction results will be recorded.

We will also record the rate of treatment failure, as defined by worsening dyspnea or a respiratory rate >30 breaths/min; whether the patients receive endotracheal intubation or tracheotomy; time spent under mechanical ventilation, ICU and hospital length of stay, hospital expenses and in-hospital mortality.

The decision to intubate the patient will be decided by the physician in charge of that patient's care, relying on one or more of the following criteria [23]: □ respiratory or cardiac arrest, □ $Sp0_2/FiO_2$ <200mmHg, □ apnea with loss of consciousness, □ bradycardia (heart rate <50 beats/min) with loss of consciousness, □ severe agitation, □ severe aspiration or failure in respiratory secretion clearance, □ hemodynamic instability with a systolic arterial pressure <90mmHg unresponsive to vasoactive drugs, or □ metabolic or respiratory acidosis (pH≤7.2).

Data will be collected using a standardized case report form. Data will be de-identified before being entered into the database. The study site is regularly monitored, and the database is checked to ensure the accuracy of collected data.

Data analysis

Sample size calculation

Sample size was determined based on data from a prospective study[8]. The minimal sample size is calculated to be at least 30 participants in each group. In consideration of a possible dropout rate of 10%, we will aim to recruit 144 participants in total.

Data analysis plan

Analyses will be performed using SPSS version 20.0 or above (SPSS Inc, Chicago, USA). A two-sided p-value less than 0.05 will be considered statistically significant.

For continuous data, normality tests will first be carried out. If all groups meet the test for normality and the variance between two groups is equal, the homogeneity of the variance will be tested when comparing the groups and the variance analysis will be used to compare the groups. Otherwise, the nonparametric Wilcoxon rank sum test will be applied.

Patients and public involvement

Patients and the public will not be directly involved in developing research questions or in designing the study.

Discussion

There is increasing concern about airway management, especially early management in critically ill patients. Potential airway management strategies include: airway assessment, oxygen therapy, artificial airway establishment, maintenance and removal [26]. The main purpose of airway management is to maintain good ventilation, ameliorate hypoxia and prevent respiratory failure. A proper respiratory drive, an unobstructed airway, and sufficient respiratory function are essential to achieving spontaneous breathing and preventing hypoxia. Central respiratory dysfunction, airway obstruction, or respiratory insufficiency can cause or exacerbate hypoxia, leading to emergent insertion of an artificial airway.

Advanced airway assessment plays an important role in guiding timely and accurate oxygen therapy or invasive/noninvasive ventilation strategies, which help reduce the reintubation rate of extubated patients [20]. Serving as a vital part of airway management, cough intensity is closely related to the patient's ability to expel respiratory secretions and prevent airway obstruction.

Anecdotally in our practice, we found that patients with a high Cough Reflex Intensity Score don't require endotracheal intubation, while patients with a low score always need to be intubated. This trial will test to what degree cough intensity is correlated to patient's outcomes.

Trial status

The protocol version is Version 1.0; 31 January 2020, Recruitment began on January 1, 2020. The expected date for recruitment completion is between May and June 2021.

Declarations

Funding

The study is funded by Autonomous Region Education Reform Project（batch number PT2020023）.

Related Articles

I clarify that none publications containing the results of this study have already been published or submitted to any journal.

Abbreviations

N/A

Ethics approval and consent to participate

The Ethics Committee of the First Affiliated Hospital of Xinjiang Medical University approved the trial protocol on August 28, 2019 (reference number K201908-03). The named ethics committee which approved the study also approved the waiving of/need for consent to participate in the study

Consent for publication

The authors agree the publication and claim that none of the material in the paper has been published or is under consideration for publication elsewhere.

Availability of data and material

The datasets generated and/or analyzed during the current study are available from the principal investigator (Wenbin Jia) on reasonable request.

Competing interests

On behalf of all authors, the corresponding author states that there is no conflict of interest.

Authors' contributions

WBJ drafted the manuscript. JYW, RRG and JW co-authored the writing of the manuscript. JZY designed the study and edited the manuscript. JX critically assessed the study design. All authors read and approved the final manuscript.

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Supplementary Files

Additional File 1 is not available with this version

Figures

	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT**	$-t_1$	0	*Day 1*	*Day 3*	*Day 5*	*Day 7*	*Hospital Discharge*
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
NO INTERVENTIONS:							
ASSESSMENTS:							
characteristics	X						
baseline clinical characteristics	X		X	X	X	X	X
Primary outcome			X	X	X	X	X
Secondary outcome							X
Other treatments			X	X	X	X	X

Figure 1

Standard Protocol Items: Recommendation for Interventional Trials (SPIRIT) schedule of enrolment, intervention and assessments. Characteristics: age, gender, weight and height. Baseline clinical characteristics :(medical diagnosis, past medical and surgical histories, Glasgow Coma Scale, arterial blood gas results and vital signs. Primary outcome:endotracheal intubation. Secondary outcome:time spent under mechanical ventilation (excluding noninvasive ventilation), ICU and hospital lengths of stay, hospital expenses.Other treatments:antibiotics, non-invasive mechanical ventilation, physical nursing treatments (e.g. chest physiotherapy or turning the patient), atomization/nebulization treatments, and sputum suction.

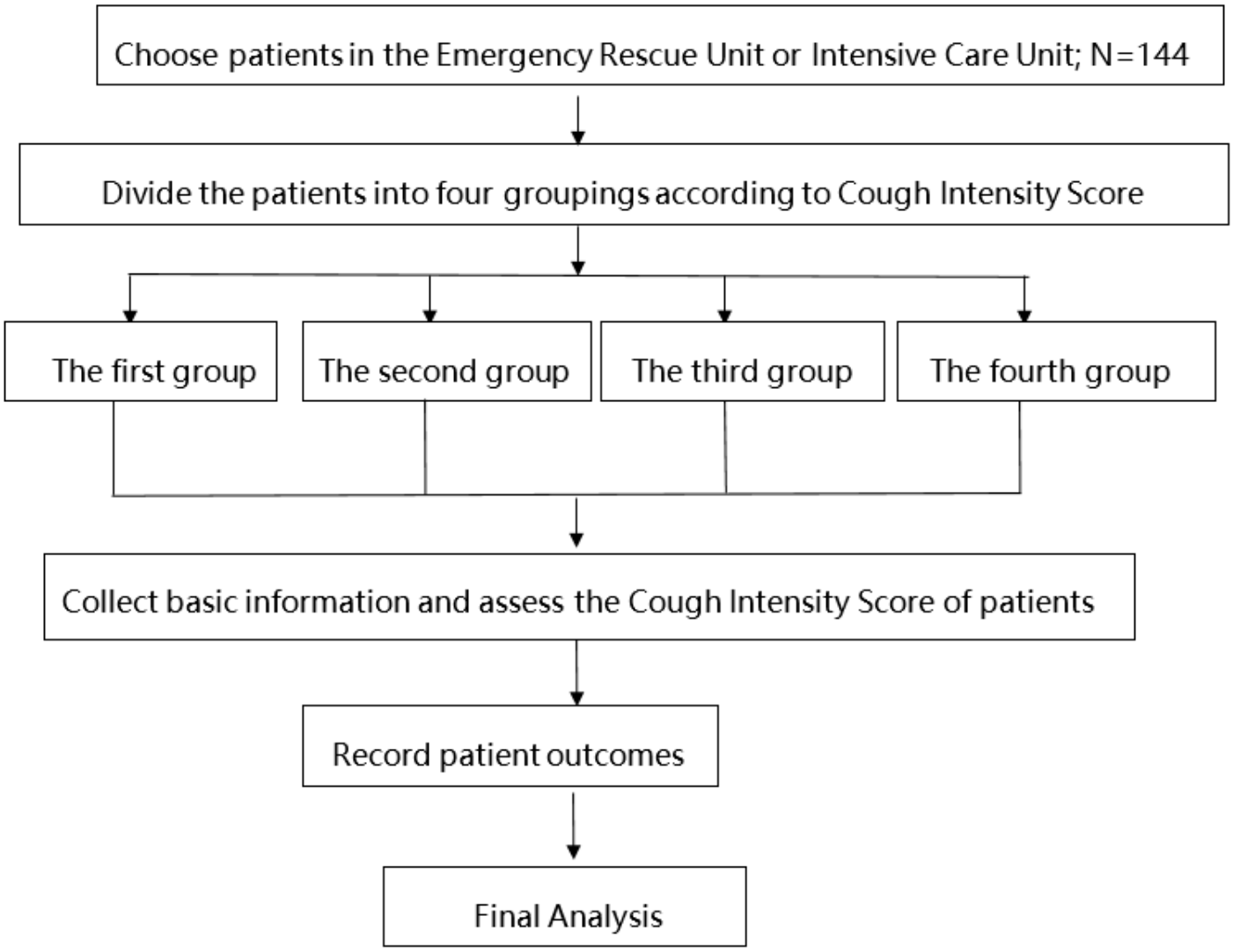

Figure 2

Technology Roadmap