# The Effects of a Clinical Pathway for Endotracheal Tube Suctioning Pain Management on Pain Presence and Agitation in Surgical Intensive Care Unit Chinese Adults

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**A Thesis Submitted in Partial Fulfillment of the Requirements for the Degree of Master of Nursing Science (International Program)**

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**Thesis Title** The Effects of a Clinical Pathway for Endotracheal Tube Suctioning Pain Management on Pain Presence and Agitation in Surgical Intensive Care Unit Chinese Adults

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I hereby certify that this work has not been accepted in substance for any other degree, and is not being concurrently submitted in candidature for any other degree.

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## ABSTRACT

Even though endotracheal tube suctioning (ETS) is a necessary and frequently used procedure among intubated patients to maintain a patent airway, the pain associated with it seriously impacts patients. ETS pain can be minimized with a quality pain management program. This quasi-experimental study explored the effects of the implementation of a clinical pathway for endotracheal tube suctioning (CPETS) pain management on the level of pain presence and agitation in critically ill adult patients. Fifty-two critically ill adults admitted to the surgical intensive unit (SICU) of the second affiliated hospital of Kunming Medical university, Yunnan, China were recruited from January through March 2018. The first 26 and the next 26 patients were consecutively allocated into the usual ETS care group and the CPETS pain management group. The CPETS started before ETS with the preparation of the patient. Pain assessment and management continued during ETS through the completion of the ETS procedure. The level of pain presence was evaluated by using the Chinese-version Critical Care Pain Observation Tool (CPOT). Moreover, the Chinese-version Richmond Agitation-Sedation Scale (RASS) was used to evaluate the level of agitation. The outcomes in intervention and control groups were measured

before, during, immediately after, 5 minutes after, and 15 minutes after ETS by the research assistant (RA). A clinical characteristics questionnaire was used to collect the demographic and clinical data (S-CVI= .92). The documentation form for the ETS pain management outcomes was used to document the outcomes (S-CVI=1.00). The percentage of inter-rater reliability testing between the researcher and the RA was 100%. Descriptive and Mann-Whitney U were used to analyse the data and test the research hypothesis.

The statistical analysis of the results indicated that all of the participants experienced pain and agitation during ETS. As compare to the control group, the Mann-Whitney U test analysis revealed a statistically significant decrease in level of pain presence at during ($z = -5.97$, $p < .05$), immediately after ($z = -5.94$, $p < .05$), and 5 minutes after ($z = -2.06$, $p < .05$) the ETS procedure in the intervention group. A significantly lower level of agitation at during ($z = -3.05$, $p < .05$) and immediately after ($z = -3.91$, $p < .05$) the ETS procedure was also found in the CPETS group. No significant differences were observed between the groups in relation to the CPOT scores before and 15 minutes after the ETS ($p > .05$). The same results was true for as the RASS scores before, 5 minutes after, and 15 minutes after the ETS ($p > .05$). The findings demonstrated that the implementation of the CPETS pain management into practice could help to reduce ETS-related pain. The adoption and application of the clinical pathway (CP) across the nation as well as the establishment of in-service training programs to enhance the nurses' competence in ETS pain management are recommended.

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|---|---|
| CPETS: | Clinical Pathway for Endotracheal Tube Suctioning |
| SICU: | Surgical Intensive Unit |
| ETS: | Endotracheal Tube Suctioning |
| CP： | Clinical Pathway |
| CPOT: | Critical Care Pain Observation Tool |
| RASS: | Richmond Agitation-Sedation Scale |
| S-CVI: | Scale Content Validity Index |
| RA: | Research Assistant |
| ICU: | Intensive Care Unit |
| VAP: | Ventilator-Associated Pneumonia |
| SNS: | Sympathetic Nervous System |
| ASPMN: | American Society for Pain Management Nursing |
| HCPs: | Health Care Professionals |
| IV: | Intravenous |
| AARC: | American Association for Respiratory Care |
| OSS: | Open Suction System |
| CSS: | Closed Suction System |
| AACN: | American Association of Critical-Care Nurses |
| WOB: | Work of Breathing |
| $FiO_2$: | Fraction of Inspired Oxygen |
| PEEP: | Positive End Expiratory Pressure |
| MHI: | Manual Hyperinflation |
| VHI: | Ventilator Hyperinflation |

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|---|---|
| SSD: | Subglottic Secretion Drainage |
| PPE: | Personal Protective Equipment |
| LHD: | Local Health District |
| CTR: | Chest Tube Removal |
| NRS: | Numerical Rating Scale |
| NRS-V: | Numeric Rating Scale with Visually |
| BPS-C: | Chinese Version of the BPS |
| ICCs: | Intraclass Correlation Coefficients |
| AP: | Arterial Puncture |
| CASP: | Chinese Association for the Study of Pain |
| NNH: | Numbers Needed To Harm |
| ICUs: | Intensive Care Units |
| MICU: | Medical Intensive Care Unit |
| GCSs: | Glasgow Coma Scores |
| GCS: | Glasgow Coma Scale |
| $SpO_2$: | Oxygen Saturation |
| BMI: | Body Mass Index |
| MREC: | Medical Research and Ethics Committee |
| SPSS: | Statistical Package for Social Sciences |
| SIMV: | Synchronized Intermittent Mechanical Ventilation |
| CPAP: | Continuous Positive Airway Pressure |
| IQR: | Interquartile Range |
| PHPS: | Prince Henry Hospital Pain Scale |
| IASP: | International Association for the Study of Pain |

# CHAPTER 1

## INTRODUCTION

This quasi-experimental study aims to determine the positive effects of a clinical pathway (CP) in reducing pain presence and agitation among critically ill adults during tracheal suctioning. This chapter provides a detailed orientation of the thesis and outlines the background and significance of the problem, objective of the study, and research question. The conceptual framework underpinning this study, the research hypothesis, the definition of terms, the scope of the study, and the significance of the study are also introduced in this chapter.

### Background and Significance of the Problem

Pain is a common disturbing, distressing symptom, and a significant problem for critically ill patients. The existing evidence points to an inadequate pain management in critically ill patients (Ahlers et al., 2012; Barr et al., 2013; Czarnecki et al., 2011; Robleda et al., 2016). The major sources of pain for Intensive Care Unit (ICU) patients are underlying diseases, surgery, and nociceptive care procedures (Višnja Nesek Adam et al., 2015). Procedural pain is a common phenomenon found in critically ill adult patients (Ahlers et al., 2012; Barr et al., 2013; Czarnecki et al., 2011; Robleda et al., 2016). Although the nurses' roles in procedural pain management has been acknowledged as being crucial, inadequate procedural pain management is still existing among critically ill patients (Puntillo et al., 2014). A

recent descriptive cross-sectional study examined nurses' knowledge and principle of acute pain management in critically ill patients revealed majority of nurses perceived inadequate knowledge with less priority was given to be knowledgeable about the necessity of pain assessment during procedures (Kizza, Muliira, Kohi, & Nabirye, 2016).

Procedure-related pain is a short-lived acute nociceptive pain associated with nociceptive procedures (Višnja Nesek Adam et al., 2015). Pain relief can be expected within a given time range of the procedure's duration (Czarnecki et al., 2011; Morton, & Fontaine, 2013; Morton, Fontaine, Hudak, & Gallo, 2017; Puntillo et al., 2014). The common painful nursing care procedures included moving and turning, bathing, repositioning, sheets changing, and tracheal suctioning (Morton et al., 2017; Puntillo et al., 2014; Višnja Nesek Adam et al., 2015).

Endotracheal tube suctioning (ETS) is a frequent necessary airway clearance procedure for mechanically-ventilated adult patients in order to maintain a patent airway and prevent hypoxia (Chaseling et al., 2014; Dastdadeh, Ebadi, & Vahedian-Azimi, 2016). Effective airway clearance helps to prevent complications, such as ventilator-associated pneumonia (VAP), atelectasis, and alveolar collapse, which result in decreasing length of ICU stay, mechanical ventilation required, including mortality and morbidity rates (Chaseling et al., 2014; Sole, Klein, Moseley, Brenner, & Powers, 2017).

Although ETS is a significant procedure in the maintenance of the airway patency and prevention of a number of complications, it may have detrimental effects on patients. Potential adverse effects from ETS include mucus traumatization, infection, bronchospasms, atelectasis, increased intracranial pressure, discomfort,

agitation, and pain (Shamali et al., 2016). The invasive tracheal suctioning procedure performed with negative suction pressure applied to a client could damage the tracheal tissue and lead to pain (Shamali et al., 2016).

Tracheal suctioning has been reported as the most painful procedure experienced by critically ill adult patients (Puntillo et al., 2014; Yaman Aktaş & Karabulut, 2016). Accordingly, pain related to tracheal suctioning is a short-lived acute pain in nature and pain relief can be expected after the completion of the procedure (Czarnecki et al., 2011; Morton, & Fontaine, 2013; Morton et al., 2017; Puntillo et al., 2014). For this reason, whenever possible adequate pain control as a basic human right should be prevented and managed effectively during suctioning a client.

A variety of factors may contribute to the development of pain related to suctioning. A wide range of suctioning techniques used may aggravate the injury of tracheal tissue and make pain more intense. These include the size of suction catheter, the level of vacuum pressure applied, the depth of catheter insertion, duration on each suctioning attempt, a bag-valve-mask ventilation on each suctioning attempt, and frequency of suctioning (Ayhan et al., 2015; Bell, 2017; Chaseling et al., 2014; Majeed, 2017; Shamali et al., 2016; Sole et al., 2017).

A previous randomized controlled trial study revealed use of a suction catheter size exceed a half of inner diameter of the tracheal tube and a negative pressure exceeding 150 mmHg caused severe level of pain during suctioning (Shamali et al., 2016). In addition, higher pain during suctioning was related to insert suction catheter until resistance felt, to apply suctioning longer than 15 seconds, and to perform multiple suctioning attempts (Shamali et al., 2016).

Inadequately managed pain as well as unrelieved pain negatively impacts on patients adverse physical and psychological outcomes (Majeed, 2017; Sole et al., 2017; Yaman Aktaş & Karabulut, 2016). Pain stimulates the sympathetic nervous system (SNS), which further affects the cardiovascular system, and that can result in an increased myocardial oxygen demand and cardiovascular disorders (Sole et al., 2017). In addition, severe ETS-related pain could affect psychological responses and emotional problems such as fear, depression, anxiety, helplessness, and hopelessness (Kizza & Muliira, 2015; Yaman Aktaş & Karabulut, 2016), including long-term psychological burdens in patients (Puntillo et al., 2016; Sole et al., 2017).

ETS may lead to an increase agitation in response to pain and discomfort caused by the procedure. Agitated patients may exhibit noncompliance behaviors, such as restlessness, physical aggression, and ventilator dyssynchrony placing them at risk or potential harm to develop negative consequences, such as risk for unplanned extubation or other supportive devices, and/or a longer duration of ICU stay (Sole et al., 2017). For this reason, the nursing management strategies to effectively manage pain as well as agitation resulted from tracheal suctioning are significantly required.

Currently, few published previous studies have been conducted on the management of procedural pain as well as ETS-related pain in critically ill adult patients (Ahlers et al., 2012; Bai, Fang, & Liu, 2015; Chaveron et al., 2012; Robleda et al., 2016; Zengin et al., 2013). Presently, the clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the ICU proposed by Barr et al. (2013) provide recommendations to manage procedure-related pain.

Pre-emptive analgesia and non-pharmacological interventions (e.g., relaxation, music, and patient education) were recommended to give critically ill adult patients

prior performing invasive and potentially painful procedures (Barr et al., 2013). In 2011, the American Society for Pain Management Nursing (ASPMN) developed and released a position statement and clinical practice recommendations for procedural pain management, which provide a more specific focus for nurses (Czarnecki et al., 2011).

Procedural pain management according to Czarnecki et al. (2011), consists of procedural preparation and comfort management, which incorporates the pain management and any other discomforts that may occur with procedures in order to provide optimal comfort before, during, and after the procedure. Furthermore, planned comfort assessment with non-pharmacological and pharmacological management is recommended during all of the procedures' phases (Czarnecki et al., 2011). The existing procedural pain management guideline, however, does not provide recommendation for specific procedures-related pain, including tracheal suctioning.

Nowadays, a number of ETS guidelines have been developed, which aim at providing safe suctioning and intended to be applied in specific settings and contexts. An endotracheal suctioning guideline for adults with an artificial airway, for instance, developed by the Agency for Clinical Innovation of the New South Wales Government, aims to provide best proceeding guidance and recommendations on ETS among critically ill adults with an artificial airway in New South Wales acute-care facilities (Chaseling et al., 2014). The existing suctioning guidelines however, do not mention about ETS pain management.

At present, a few systematic and pertinent published guidelines or standards of practice regarding the management of ETS-related pain exist. Moreover, only a few studies have been conducted to test the effectiveness of different suctioning

techniques on the minimization of pain. A previous study examined effect of open and closed suction systems on pain and agitation in mechanical ventilated patients and revealed less impact of a suction system on suction-related pain and agitation (Dastdadeh, Ebadi, and Vahedian-Azimi, 2016). Results from a previous randomized controlled trial revealed the significantly less pain minimally of minimally invasive ETS compared with usual suctioning (Shamali, Babaii, Abbasinia, Shahriari, & Kaji, 2016).

Noticeably, the existing studies did not cover the whole picture of procedural pain management. As aforementioned, procedural pain management starts before the beginning of the procedure until the completion of the procedure and involves preparations, planned assessments and management using both pharmacological and non-pharmacological methods (Czarnecki et al., 2011). Nurses account for optimal pain management for patients and nursing interventions have been evidenced to promote comfort and relief pain related to tracheal suctioning (Barr et al., 2013; Czarnecki et al., 2011). Here, significant attention should be directed towards comprehensive strategies to attain adequate control pain related to suctioning in critically ill adult patients.

The Second Affiliated Hospital of Kunming Medical University has released the protocol of ETS procedure for mechanically-ventilated patients since 2012 till date. This ETS protocol focused on safe suctioning as such preventing hypoxia, infection and retention of sputum. However, intervention to prevent and reduce pain related to ETS procedure was not clearly mentioned in this protocol. In consistent with other critical care nurses, priority given is mainly valued to life-threatening

problems. For this reason, the management of ETS-related pain as well as other procedure-related pain has not been noticed in the day-to-day praxis of this ICU.

To date, there is still lack of a CP or clinical practice guideline or program for pain management associated with tracheal suctioning in global and within the context of China. Development of a CP for ETS-related pain management to control pain and improve pain management outcomes that suit the Chinese critical care context was therefore important. A research methodology that can serve both the development of a pain management pathway and implementation to evaluate the effectiveness and feasibility for Chinese patients and critical care nurses was required.

## Objective of the Study

This present study sought to compare the effects of a CPETS pain management with the usual tracheal suctioning practice on the level of pain presence and agitation in SICU Chinese adults.

## Research Question of the Study

To what extent do SICU Chinese adults who receive the CPETS pain management experience a lower level of pain presence and agitation than those who receive the usual ETS practice?

## Conceptual Framework of the Study

In order to develop a CP for management of ETS-related pain and test its effectiveness, two main concepts of procedural pain management in critically ill adult patients and the CP were simultaneously used to underpin this study. These two concepts were used in conjunction with the relevant cutting-edge evidence regarding procedural pain management as well as ETS pain management to develop a CPETS pain management as well as the research instruments of this study (see Appendix A). Then, the effectiveness of the tentative CP was tested and evaluated in terms of pain presence and agitation using the quasi-experimental study method.

### Concept of Procedural Pain Management in Critically Ill Adult Patients

Procedural pain or procedure-related pain is a type of acute pain associated with non-surgical procedures such as wound care or chest tube removal (CTR) including tracheal tube suctioning (Puntillo et al., 2014). The two existing research evidences on procedural pain management served as recommendations to construct CPETS pain management in this study: 1) a position statement and clinical practice recommendations related to procedural preparation and comfort management proposed by the ASPMN, which formed the basis of the current procedural pain management (Czarnecki et al., 2011); 2) the clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the ICU proposed by Barr et al. (2013), which have also been used to guide procedural pain management in critical care settings.

In addition, the cutting-edge evidence specifically relevant to ETS pain management was simultaneously used in conjunction with general principles of procedural pain management to develop the CPETS pain management in this study (Ahlers et al., 2012; Bai et al., 2015; Boitor, Martorella, Arbour, Michaud, & Gélinas, 2015; Casey et al., 2010; Chaseling et al., 2014; Chaveron et al., 2012; Chou et al., 2016; Fariba, Ali, Mohamad, & Sara, 2016; Hasanzadeh et al., 2016; Lee et al., 2012; Robleda et al., 2016; Saadatmand et al., 2015; Salmani et al., 2017; Schug, Palmer, Scott, Halliwell, & Trinca, 2015; Shamali et al., 2016; Yaman Aktaş & Karabulut, 2016).

According to the ASPMN, personal who experience potentially painful procedures have a right to receive the optimal pain management before, during, and after the procedure (Czarnecki et al., 2011). Before the procedure, procedural pain management consists of three recommendations: 1) establish a plan for managing the patient's comfort if the procedure is likely to painful produce; 2) prepare patients and their family members for the procedure; 3) prepare the health care professionals (HCPs) to deliver a painless procedure.

According to the ASPMN, procedural pain management during the procedure consists of seven recommendations: 1) use agreed-on coping/distraction skills; 2) measure pain using validated tools specific for the patient's status; 3) if pain is not well managed during the procedure, ask the HCPs including medical doctors and nurses, to stop doing the procedure and further evaluation can be conducted and the need for pharmacological and/or non-pharmacological interventions can be determined; 4) keep calm, confident, and do not rush, and venerably tell others to provide the same as needed; 5) deliver verbal coaching in a reliable and clam way; 6)

monitor family members and staffs' behavior, and give the feedback to make sure the surrounding remains relaxed and protected for the patient; 7) use known knowledge to minimize mucosa damage as adapted.

The after procedural phase consists of three parts: 1) consider/appraise the procedure with the client and their family members, if possible; 2) record the procedure, including evaluate the patient's experience from the patient, family members, and HCPs attitudes as well as recommendations for the future procedure, in the medical document; 3) after the procedure period, establish and utilize a comfort management scheme for the as the pain outcomes from the procedure which may not subside must be treated adequately after the procedure completion. The detailed recommendations to manage ETS-related pain using a CP were constructed based on the cutting-edge evidence-based research on ETS-related pain management.

Concerning ETS pain management, according to the procedural pain management guidelines, both pharmacological and non-pharmacological interventions are recommended to manage procedural pain in each phase (Barr et al., 2013). Before the procedure, pre-emptive analgesia is recommended (Barr et al., 2013). Intravenous (IV) opioids (e.g., morphine, sufentanil, and fentanyl) are recommended as the pre-emptive analgesia medications to cure non-neuropathic pain in critically ill adults (Barr et al., 2013). Topical anesthetics (e.g., xylocaine spray and lidocaine jelly) can also be used to relieve procedural pain (Czarnecki et al., 2011). In terms of non-pharmacological management, meditation, imagery, massage, music therapy, and cold application are recommended (Barr et al., 2013). In addition, a plan should be developed to promote the patient cope during the procedure [e.g., providing

information, distraction, relaxation techniques, deep breathing] (Barr et al., 2013; Czarnecki et al., 2011).

During the ETS procedure, analgesic should be administered if pain is anticipated as well as topical anesthetics if indicated. In addition, the delivery of non-pharmacological interventions (e.g., meditation, imagery, massage, music therapy, cold application) should be continued. Known suctioning equipments and techniques (e.g., the size of an ETS catheter not more than 50% of the internal diameter of the tracheal tube and a vacuum pressure level not exceeding 150 mmHg) should be employed as appropriate to minimize mucosa damage as adequate (Shamali et al., 2016). Other interventions include providing psychological support such as touching or holding the patient's hand, gently talking to the patient, and asking the patient for readiness [if possible] (Barr et al., 2013; Czarnecki et al., 2011). After the ETS procedure, a comfort management plan for when the procedure is completed needs to be developed and implemented. It can involve the continuation of both pharmacological and non-pharmacological managements (Czarnecki et al., 2011).

Moreover, the latest evidence regarding ETS was analyzed with a specific focus on the practices, techniques and approaches that contribute to ETS-related pain. These included: 1) a systematic review entitled, "Endotracheal suction in intubated critically ill adult patients undergoing mechanical ventilation" (Favretto et al., 2012); 2) a clinical practice guideline entitled, "Suctioning an adult ICU patient with an artificial airway" (Chaseling et al., 2014); 3) a clinical practice guideline entitled, "Endotracheal suctioning of mechanically ventilated patients with artificial airways" (American Association for Respiratory Care [AARC], 2010); 4) American Association of Critical-Care Nurses (AACN) procedure manual for high acuity,

progressive, and critical care, seventh edition (Bell, 2017); and 5) AACN procedure manual for critical care (Wiegand & American Association of Critical-Care Nurses, 2011).

According to the above research evidence, the identified recommendations on suctioning techniques and approaches involve the assessment of the criteria for suctioning, the suction tube catheter size, the level of vacuum pressure applied during suctioning, and the depth of the endotracheal suction catheter's insertion. In addition, other recommendations concern the duration of suctioning per each attempt and frequency of suctioning, adequate pre-oxygenation as well as the appropriate implementation of an open/closed suction system, and subglottic suction. However, the use of hyperinflation and normal saline instillation is not recommended (Chaseling et al., 2014). The approved CPETS pain management was implemented in Chinese critically ill adult patients with follow-up measures to test its effectiveness and feasibility. In this study, pain management outcomes served as outcome measurements as discussed later.

**Concept of Clinical Pathway (CP) Development**

The CP is a clinical decision-making instrument that operationalizes clinical practice guidelines and the best evidence recommendations in an accessible bedside format for 'care point' in a hospital setting (Jabbour, Jabbour, Govindan, Teixeira, & Freitas, 2013). According to the Performance Excellence Program Clinical Pathway Development (2011), the CP is a standardized, evidence-based, interdisciplinary care management program, which identifies an adequate consecutiveness of clinical

interventions, timelines, milestones, and expected outcomes for a specific group of patients or procedures and in this case, it is the ETS procedure.

Clinical pathways provide valuable awareness about detailed types of patients and their care as well as provide direct instruction in clinical procedure. The CP is also defined as a series of events that patients pass through from a state of the disease or phenomenon, describe the basic steps in patient care to describe how the patient is expected to progress to the restoration of a desired outcome (Rotter et al., 2010). The purpose of the CP is to standardize the clinical practice of a group of experts in order to optimize nursing care in a specific clinical situation, improve nursing quality, patient satisfaction, improve information continuity, and patient education (Lawal et al., 2016; Rotter et al., 2010). The components of the CP, according to Lawal et al. (2016), consist of a timeline, the classifications of the interventions or care, short- and long-term outcome goals, and the variance record (to allow deviations to be documented and analyzed).

In this study, the timeline of ETS-related pain was divided into three phases (before, during, and after the procedure) according to a position statement in procedural pain management (Czarnecki et al., 2011). Accordingly, the classifications of interventions or care were divided into pharmacological and non-pharmacological interventions based on a position statement in procedural pain management (Czarnecki et al., 2011) and the most up-to-date evidence on ETS pain management. The goal of ETS pain management was established according to the recommendations of Barr et al. (2013), pain during ETS as CPOT scores of < 3 (Barr et al., 2013). Importantly, mutual goal setting was performed with the patient as well as their family members before suctioning. The level of pain presence and agitation were used

as the primary and secondary pain outcome measures, respectively (Turk et al., 2006). In addition, the nursing documentation of suctioning practices-related pain was performed in a checklist form allied with the tentative CPETS pain management.

The development of a CP, according to the Performance Excellence Program Clinical Pathway Development (2011), needs to follow these steps: 1) identification of patient population that will benefit from the CP; 2) evaluation of current practices; 3) literature review of journals, texts, clinical practice guidelines, protocols as well as chart reviews; 4) establishment of important outcomes that are essential for assessing the success of the CP and consideration about how the data for the outcome variables will be collected; 5) educating and obtaining support from leadership or clinicians; 6) presentation of findings or data to leadership or clinicians, gaining consensus from leadership or clinicians and establish targets for activities of care (see Appendix A).

The principles of developing and implementing a CP were used in this study to organize the framework of developing the CPETS pain management. First, intubated critically ill adults are the target population that will receive benefit from this CPETS pain management. Second, as aforementioned, the current ETS practices in this research setting are still lack of a protocol or standardized program to manage pain-related ETS for this target population. ETS practice has been performed according to the hospital protocol, which aims at establishing patient's safety and patent of airway. Third, the integrative literature review was conducted in relation to current update of ETS pain management, in particular procedural pain management in critically ill adults. Additionally, literature regarding standardized ETS praxis was intensively reviewed. In the fourth steps, outcomes were established as the level of pain presence and agitation as the consequence of appropriate management. In step

five, development of the CPETS pain management had been consecutively informed and consulted with the ICU nurse mangers and nurse administrators and got supports and facilitation in term of ease entry to the setting and collaborations from nursing and medical staff. Finally, the CPETS pain management was got general agreement from the ICU nurse mangers and nurse administrators.

**The CPETS Pain Management**

The CPETS pain management was developed following the steps mentioned above. It utilized sequentially time-lined evidence, and its recommendations regarding interventions or care were constructed taking into account cutting-edge evidence on the management of ETS-related pain in order to achieve its desired outcomes. The mutual goal setting regarding pain management during ETS was based on either the Critical Care Pain Observation Tools (CPOT) scores of less than three and the Richmond Agitation Sedation Scale (RASS) scores of zero. This CP comprised three phases: before, during, and after ETS. The interventions in each phase were sequentially done to follow these the specific outcomes: before ETS, to prepare ETS pain management; during ETS, to control and manage the ETS-related pain; after ETS, to discuss and evaluate the quality of pain management in order to incorporate the management of pain may occur with ETS (see Appendix B).

Pain management before ETS aimed at an ample preparing for the ETS pain management. The recommendations for pain management before ETS consisted of: 1) if the procedure is like painful procedural, develop a plan for the patient a comfort management; 2) prepare the patient for the procedure; 3) assess and identify the patient’s need for suctioning; 4) perform ETS when clinically indicated by the

relevant signs; and 5) use the CPOT scores to assess the baseline pain. In addition, before the procedure, an individualized ETS pain management plan was established that included the mutual goal setting with patients and their family members (e.g., CPOT < 3, RASS = 0).

The recommendations prior to suctioning also included providing education as the individual patient's needs, giving completely information in relation to the suctioning procedure (e.g., the need for ETS, the consequences of not ETS and the effects of ETS). Before suctioning, pharmacological management involved the administration of pre-emptive analgesia (e.g., Sufentanil 3μg) in conjunction with non-pharmacological interventions (e.g., cold application, music therapy) according to the patient's preference and experience. Importantly, the recommendations for adequate pre-emptive analgesia required the availability of appropriate and adequate prescription before the procedure to allow enough time for effectiveness.

Pain management during ETS aimed at controlling and managing the ETS-related pain using both pharmacological and non-pharmacological interventions. The recommendations for pain management during ETS were: 1) use a suction catheter size less than 50% of the internal diameter of the endotracheal tube; 2) make the duration of suctioning less than 15 seconds per each attempt which from insertion to removal of catheter with vacuum pressure; 3) have a procedure to allow for a temporary stop in order to provide additional comfort; 4) use a maximum occluded suctioning pressure limited to -80 to -150 mmHg (20kPa) for open suction system (OSS) and closed suction system (CSS), and the wall outlet should have a high pressure gauge attached; 5) use the appropriate instruments to assess level of pain presence and agitation; 6) secure and hold the endotracheal tube during suctioning and;

7) provide psychological support such as touch or hold the patient's hand, gently talk to the patient, and ask for readiness (if possible).

Pain management after ETS aimed to discuss and evaluate the quality of the CPETS pain management. These were the recommendations for this phase of the management: 1) discuss and evaluate the procedure with patients and their family members if possible; 2) record the procedure in the nursing document: duration of procedural pain, nursing interventions, an evaluation concerning the patient's experience from the perspectives of patients, their family members, and staff nurses that also includes recommendations for future procedures; 3) assess level of pain presence and agitation immediately after, 5 minutes after, and 15 minutes after suctioning in order to assess the need of further pain management.

The quasi-experimental study approach was also employed to test the effectiveness of the CPETS pain management in this study (see Appendix B). The expected pain management outcomes to prove the effectiveness of the CP consisted of the primary and secondary pain management outcomes as follows and as details in Appendix B.

**Pain Management Outcomes**

The pain management outcomes should be measured in multidimensional aspects in order to improve the means of measuring, comparing, and improving the pain management quality (Gordon et al., 2010). Since ETS-related pain is brief in nature and disappear shortly after the procedure is finished, the overall multidimensional assessment and evaluation might not be practical to evaluate. For

this reason, the level of pain presence was selected as the primary pain outcome measure of ETS pain management in this study.

The secondary pain management outcomes is defined as the outcome that happens as a consequence of adequate pain management, which varies depended on the nature of pain (Dworkin et al., 2005). In line with this, agitation is evidenced as one of the most profound adverse effects of ETS-related pain (Dastdadeh et al., 2016; Shamali et al., 2016; Sole et al., 2017). It is associated with inappropriate verbal behavior, physical aggression, increased movement (head or extremities), and ventilator dyssynchrony. Any of these could bring harm to the patient such as a higher rate of self-extubation as well as a longer duration of ICU stay (Sole et al., 2017). Agitation has also been used as an outcome measure of ETS pain management in previous studies (Dastdadeh, Ebadi, & Vaherdian-Azimi, 2016; Yaman Aktaş & Karabulut, 2016). For this reason, agitation was used as a secondary pain outcome measure in this study.

In regards to the concept of procedural pain management, of which ETS pain management is an example, pain management outcomes were simultaneously used to construct the recommendations for the CP. Appendix B delineates the steps followed in developing a quality CPETS pain management. Figure 1 illustrates the conceptual framework of the present study.

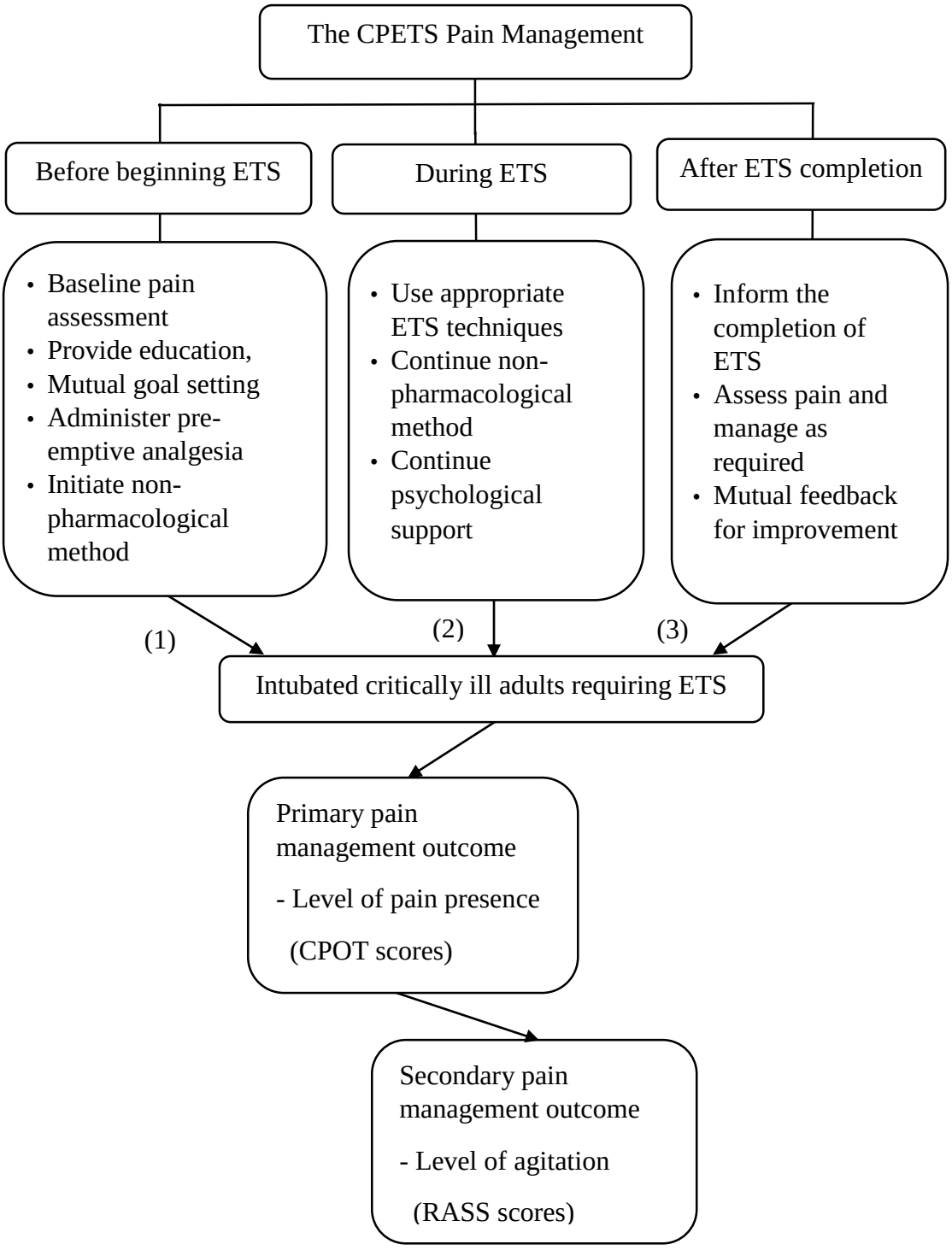


*Figure 1.* The conceptual framework of the study

## Hypothesis

SICU Chinese adults who receive the CPETS pain management experience a lower level of pain presence and agitation than those receiving the usual ETS practice.

## Definition of Terms

### The CPETS Pain Management

The CPETS pain management is a combination of evidence-based interventions carried out using a multidisciplinary approach to manage ETS-related pain (see Appendix B). The CP is applied before suctioning, throughout the duration of the procedure, and immediately after it. The components of the CP consists of nursing pain management procedures, which reflect the cutting-edge evidence regarding the management of ETS-related pain. This CP also integrated the activities of allied HCPs, the medical treatment protocols, and nursing care plans into a specific CP. Importantly, the structure underpinning this CP reflected the role that Chinese nurses play in a multidisciplinary care team in providing pain management before, during and after ETS within the Chinese hospital context and organizational culture.

### Pain Management Outcomes

The pain management outcomes in this study consisted of both primary and secondary pain outcomes. The primary pain management outcome in this study was the level of pain presence. It was measured by using the Chinese version of the CPOT for both non-communicable and communicable patients proposed by Chen et al.

(2011) and Li et al. (2012). Meanwhile, the secondary pain management outcome in this study was agitation, which was measured by using the Chinese version of the RASS proposed by Liu, Li and Herr (2015).

## Scope of the Study

This quasi-research study measured the effect of a CP on the pain management outcomes in critically ill Chinese adult patients undergoing ETS. The data collection was conducted from January through March 2018 in the SICU at the Second Affiliated Hospital of Kunming Medical University, Yunnan, China.

## Significance of the Study

The study results provided a CPETS pain management that is sustainable and feasible for the critical care context in China. It was shown that, through it, the quality of ETS pain management for the study's patients receiving ETS in China was significantly improved. Moreover, this CP can also be utilized among patients in other applicable contexts. The knowledge developed from this study generated further recommendations as well as provided new evidence regarding ETS pain management.

# CHAPTER 2

## LITERATURE REVIEW

This chapter presents a review of the literature related to management of pain related to ETS and the concept employed in development of a CP for pain management. A critical analysis of ETS-related pain, the evidence for the effectiveness of the relevant cutting-edge pain management and pain management outcomes are addressed.

1. An Overview of ETS
2. An Overview of ETS-related Pain
    2.1 Mechanism of ETS-related pain
    2.2 Consequences of ETS-related pain
    2.3 Factors contributing to ETS-related pain
3. ETS Pain Management in Critically Ill Adult Patients
    3.1 An overview of ETS pain management in critically ill adult patients
    3.2 Assessment of ETS-related pain
    3.3 Management of ETS-related pain
    3.4 Current practices in management of ETS-related pain in China
    3.5 Pain management outcomes
4. Summary

## An Overview of ETS

Tracheal tube suctioning as well as ETS is a frequent and necessary procedure carried out in the management of adults with mechanical ventilation, in particular critically ill patients (Chaseling et al., 2014). Critically ill patients increase the production of mucic and have a damaged ability to clear secretions, which results in an increased suctioning demand. The major goals of tracheal tube suctioning are to maintain the patient's airway and assist with reducing the risk of hypoxia, atelectasis and infection from the secretion retention (Chaseling et al., 2014).

Despite being a necessary practice, ETS can lead to some profound impacts for patients such as hypoxemia, airway trauma, cardiac dysrhythmias, infection, and increased intracranial pressure (AARC, 2010; Chaseling et al., 2014; Sole et al., 2017; Wiegand & AACN, 2011). In addition, a potential aspiration of stomach contents may result from uncontrolled coughing or gagging, during tracheal tube suctioning (AARC, 2010; Chaseling et al., 2014). Moreover, fear, anxiety as well as discomfort and pain are also experienced during suctioning (Wiegand & AACN, 2011). Correct techniques and preparation can help to prevent the risks of adverse events as well as discomfort for patients and the level of pain intensity during suctioning (Shamali et al., 2016).

A number of clinical practice guidelines as well as practice standards have been developed and launched to provide guidance and best practice approaches in allocating tracheal tube suctioning. The current best available tracheal tube suctioning guidelines are a systematic review entitled, "Endotracheal Suction in Intubated Critically Ill Adult Patients Undergoing Mechanical Ventilation" conducted by Favretto et al. (2012), "A Clinical Practice Guideline for Suctioning an Adult ICU

Patient With an Artificial Airway" proposed by Chaseling et al. (2014), "A Clinical Practice Guideline for Endotracheal Suctioning of Mechanically Ventilated Patients with Artificial Airways" released by AARC (2010).

Based on the tracheal suctioning guidelines, the recommendations comprise four components: 1) patients' assessment and preparation; 2) techniques used; 3) infection prevention; and 4) recommendation for organizations or policy makers (AARC, 2010; Chaseling et al., 2014; Favretto et al., 2012; Wiegand & AACN, 2011) as detailed below.

**Patients' Assessment and Preparation**

The first step is the measurement of patients to make sure the need for suctioning an endotracheal tube. Regular assessment with chest auscultation is recommended to be implemented every two hour or more continually as clinical signs as needed and not as a routine fixed-schedule treatment. (AARC, 2010; Chaseling et al., 2014; Favretto et al., 2012; Wiegand & AACN, 2011). Therefore, the determination to suction an endotracheal tube should be maintain the patency of the tracheobronchial tree as the basis of the clinical needed. An endotracheal tube should be suctioned when only clinically demonstrated by one of the following signs: visible, palpable or audible secretions, such as mucus, pulmonary secretions, stomach or upper respiratory tract contents, and blood or foreign material (AARC, 2010; Chaseling et al., 2014; Favretto et al., 2012; Sole et al., 2017; Wiegand & AACN, 2011). In addition, an ETS should be performed due to the presence of one of these significance clinical signs: desaturation and/or deterioration of the arterial blood gas values, acute respiratory distress, rising peak inspiratory pressure (during volume-

controlled mechanical ventilation/modes), increased respiratory rate, decreased tidal volume (during pressure-controlled/modes), and increased work of breathing (WOB) or coarse breath sounds on auscultation (AARC, 2010; Chaseling et al., 2014; Favretto et al., 2012; Sole et al., 2017; Wiegand & AACN, 2011). An ETS should be also performed when clinically indicated by signs of the cardiovascular system such as increased heart rate and blood pressure (Chaseling et al., 2014; Favretto et al., 2012; Sole et al., 2017; Wiegand & AACN, 2011). A saw-tooth pattern on expiratory flow-time waveform or a flow-volume loop as clarified on the ventilator graphics is also used as a suctioning criterion (AARC, 2010; Chaseling et al., 2014; Sole et al., 2017; Wiegand & AACN, 2011).

Additional criteria for suctioning include a restless/agitated or diaphoretic patient, the need to obtain a sputum specimen, and endotracheal tube removal (AARC, 2010; Chaseling et al., 2014; Sole et al., 2017; Wiegand & AACN, 2011). When a criterion for suctioning is met, it could be done with no strict contraindication (AARC, 2010; Wiegand & AACN, 2011).

Importantly, distinct information in relation to the ETS procedure like the need for suctioning, when suctioning is required the consequences of not suctioning, and the effects of ETS should be given to the patient and/or their family members in order to reduce anxiety and increase the comprehending of, and compliance with the ETS procedure. Furthermore, this knowledge should be replayed with every suctioning procedure as some patients may not memorize previous directions (AARC, 2010; Chaseling et al., 2014; Wiegand & AACN, 2011).

Monitoring patients during suctioning is also required. This should consist of blood pressure, tidal volumes, airway reactivity, peak airway pressures, pulse

oximetry, the monitoring of cardiac rate and rhythm or intracranial pressure. Some patients ask continual monitoring of pulse oximetry and ECG before, during and after ETSprocedure (AARC, 2010; Chaseling et al., 2014; Wiegand & AACN, 2011). The documentation of the assessment and suction procedure is also required as the final step of suctioning (AARC, 2010; Chaseling et al., 2014; Favretto et al., 2012; Wiegand & AACN, 2011).

**Strategies or Techniques Used**

The common recommendations of the current tracheal suctioning guidelines include strategies or techniques used for safe suctioning as described below.

**The size of suction tube catheter.** An appropriate suction catheter size should be less than 50% of the inner chamber of the tracheal tube (AARC, 2010; Chaseling et al., 2014; Favretto et al., 2012; Wiegand & AACN, 2011). According to Chaseling et al. (2014), two formulas are suggested: 1) the size of suction catheter = [endotracheal tube size (mm) minus 1] then multiplied by 2; and 2) suction catheter size = half the internal diameter multiplied by 3.

**Duration of suction per each attempt and frequency of suctioning.** The complete ETS procedure (from insertion to removal of catheter) should take less than of 15 seconds with vacuum (-80 to -150mmHg) pressure applied repeatedly as the catheter is withdrawn from the endotracheal tube (AARC, 2010; Chaseling et al., 2014; Favretto et al., 2012). According to Chaseling et al. (2014), there is no new evidence reported to support the suggestion the number of passes of the suction catheter should be less than four.

**The depth of endotracheal suction catheter insertion.** According to Chaseling et al. (2014), for patients that are not expected at a high stake of exploiting adverse events, the suction catheter might be passed until either a cough is irritated or a point of resistance is sensed. Then the catheter should be withdrawn one to two centimeter prior to continuing suctioning. In patients that are considered at a high risk of developing adverse events as well damage to and stimulation of the carina, the depth of the catheter insertion should be minimized to reduce and/or avoid complications. Consequently, it should only be inserted below the endotracheal tube until it only emerges out of the entocoel of the tube. The depth of the endotracheal suction catheter insertion is also categorized into shallow suctioning and deep suctioning (AARC, 2010; Favretto et al., 2012; Wiegand & AACN, 2011). Shallow suctioning is delivered to prevent tracheal mucosa damage, and the suction catheter is inserted at the same length as the endotracheal tube usually the length of the artificial airway plus the adapter (Chaseling et al., 2014). Deep suctioning is the suction catheter insert of until resistance is met, followed by the pullback of the catheter by one centimeter before the utilization of vacuum pressure. It is used in cases of a huge amount of secretions in the lower airway (AARC, 2010). Moreover, some guidelines and studies have recommended to mark the length after the first time of suctioning on order to prevent touching the carina in the tracheal bifurcation, stimulate the cough reflex, sputum scabs, tracheal mucosa impairment, and pulmonary infection (Chaseling et al., 2014; Favretto et al., 2012).

**The level of vacuum pressure applied during suctioning.** The maximum vacuum suction pressure should be between - 80 and -100, and -120 and -180 mmHg

(20kPa) for both open suction system (OSS) and closed suction system (CSS) (AACN, 2011; AARC, 2010; Chaseling et al., 2014). Here, the wall outlet should have a high pressure gage attached in order to monitor the level of pressure applied.

**Appropriate pre-oxygenation implementation.** Hyper-oxygenation with a hundred percent of oxygen for 30 seconds is recommended before, during, and immediately after suctioning (AARC, 2010; Wiegand & AACN, 2011). Currently, most of mechanical ventilation devices have a 100% oxygen suction mode, which delivers up to a hundred percent of fraction of inspired oxygen (FiO2) for two-minute duration. However, pre-oxygenation should not be routinely performed on every patient requiring suctioning (Chaseling et al., 2014; Shamali et al., 2016). Pre-oxygenation with a hundred percent of oxygen is recommended if the patient receives the percentage of $FiO_2$ more than 60 or the percentage of $SpO_2$ below 95 or if the level of PEEP exceeds 5cm$H_2O$ or have history or known case of hypoxia (AARC, 2010; Chaseling et al., 2014; Wiegand & AACN, 2011). However, high FiO2, even for a several minutes, can lead to the development of absorption atelectasis in healthy individuals (Chaseling et al., 2014). This effect and the pursuant loss of lung volume may be specifically harmful for critically ill patients and those with an acute lung injury (Chaseling et al., 2014).

**Instillation of normal saline.** According to AARC (2010) and Wiegand and AACN (2011), normal saline instillation should not be regularly provided before the ETS procrdure. The current evidence reveals that a bolus instillation of normal saline may be harmful, not useful (Chaseling et al., 2014; Shamali et al., 2016; Sole et al., 2017).

**Appropriate open/closed suction system implementation.** The OSS requires splitting patients from the mechanical ventilation during suctioning. The CSS, on the other hand, closed, in-line suction catheter to the ventilator circuit, contains the attachment of a sterile, which allows the passage of a suction catheter through the artificial airway without disconnecting the patient from the ventilator. Previous studies have revealed that CSS compares with OSS decreases the risk of ventilator-associated pneumonia (VAP), but it does not impact on oxygenation, duration of ventilation artificielle, mortality rate or length of ICU stay (Favretto et al., 2012). The CSS is, however, recommended for specific indications such as for critically unstable patients receiving high levels of concentration of oxygen or positive end expiratory pressure (PEEP), patients at risk for alveolar de-recruitment, and patients for whom frequent suctioning is required such as six or more times per day (Chaseling et al., 2014). Currently, the decision to use CSS or OSS depends on institutional policy and preference of medical staff.

**Hyperinflation implementation.** Hyperinflation is a method using the ventilator has been used as of both hyper-oxygenation or a manual resuscitator bag and as a lung recruitment maneuver during extubation (AARC, 2010; Chaseling et al., 2014; Favretto et al., 2012; Sole et al., 2017; Wiegand & AACN, 2011). It can be implemented either by hand or via a respirateur artificiel depending upon the level of PEEP. Manual hyperinflation (MHI) or ventilator hyperinflation (VHI) results in an gained lung compliance in intubated patients and a reduced airway resistance in patients with VAP. However, hyperinflation should not be implemented on a regular basis before ETS. The hyperinflation with it adverse effects comprise significant

gains/reduces in cardiac output, mean arterial pressure, pulmonary airway pressure and pulmonary artery pressure (Chaseling et al., 2014).

**Appropriate subglottic suction implementation.** According to Chaseling et al. (2014), endotracheal tubes with subglottic suction competence should be used for mechanically ventilated patients who are looked forward to be ventilated for more than 72 hours. Despite strong evidence regarding the outcomes associated with the subglottic secretion drainage (SSD), this type of tubes has not been widely adopted. The chief reasons for this are the higher costs associated with the devices themselves as well as ensuring that the patients who may benefit from the tube get intubated with these specialized devices (Sole et al., 2017). A significant decrease in the prevalence of VAP with the use of subglottic suction has been reported (Chaseling et al., 2014). In addition, a Y-catheter should be used to remove "above the cuff" sputum when a tracheal tube does not have subglottic suction capability (Chaseling et al., 2014).

The strategies or techniques used to obtain a good quality and safe tracheal tube suctioning involve the suction tube catheter size, the level of negative pressure applied during suctioning, the depth of the endotracheal suction catheter insertion, duration of suction per each attempt and frequency of suctioning, appropriate pre-oxygenation implementation, appropriate open/closed suction system implementation, appropriate hyperinflation implementation, and appropriate subglottic suction implementation. However, the use of normal saline instillation is not recommended. Some of these techniques showed potential relationships with ETS-related pain; therefore, they were used as the recommendations in this CPETS pain management.

**Infection Prevention**

As discussed previously one of the significant adverse events of using mechanical ventilation as well as ETS is respiratory infection, in particular ventilator-associated pneumonia (VAP). For this reason, recommendations to prevent infection are included in the current suctioning guidelines as follows:

1. Criterion preventions ask the use of personal protective equipment (PPE) to prevent conjunctival or mucosal spatter damages and contamination, and is compulsive while suctioning patients. A mask or face shield and goggles, a gown/apron and gloves must be involved (AARC, 2010; Chaseling et al., 2014; Wiegand & AACN, 2011).

2. Clinicians must stand on the five moments of hand hygiene: prior to touching a patient, prior to doing a procedure, body fluid exposure risk or after doing a procedure, after giving a patient the touch, and after giving a patient's neighbouring environment the touch (AARC, 2010; Chaseling et al., 2014; Wiegand & AACN, 2011).

3. When using the OSS skill, non-touch approach with an aseptic technique must be followed (AARC, 2010; Chaseling et al., 2014; Favretto et al., 2012; Sole et al., 2017; Wiegand & AACN, 2011).

4. Clinicians should implement a risk measurement for particular droplet and airborne precautions before suctioning (AARC, 2010; Chaseling et al., 2014; Wiegand & AACN, 2011).

**Recommendation for Organizations or Policy Makers**

In order to obtain a high-quality and safe suctioning, the current suctioning guidelines also give recommendations for organizations or policy maker as detailed in the following (Czarnecki et al., 2011):

1. Each local health district (LHD) should use the current and good quality guidelines to exploit the specific procedure to undertake the ETS procedure.

2. To make sure first-rank patient outcomes, hospitals should regularly discuss their procedure in opposition to the guidelines.

3. Hospitals should be sure that nurses and doctors who implement this practice are capable or are first-hand conducted by the capable nurses and/or doctors.

4. Personal comment should be afforded to further the development of capacity in endotracheal suctioning.

5. Where feasibility, make a plan performance in a affected context could be beneficial in guiding and evaluating the practice of this technique.

The above recommendations will be used as strategies to inform the CPETS pain management in the present study.

## An Overview of ETS-related Pain

Pain is defined by the International Association for the Study of Pain (as cited in Barr et al., 2013) as “an unpleasant sensory or emotional experience associated with actual or potential tissue damage or described in terms of such damage”. ETS is a painful and invasive procedure performed for critically ill patients (Yaman Aktaş & Karabulut, 2016). ETS has been evidenced as a primary source of pain in critically ill

adult patients with mechanical ventilation (Yaman Aktaş & Karabulut, 2016). It is also reported as the most painful nursing procedure experienced by critically ill adult patients with mechanical ventilation (Yaman Aktaş & Karabulut, 2016). A previous study revealed that ETS causes moderate to severe pain among adult patients (Arroyo-Novoa et al., 2008). Fifty percent of adult patients undergoing ETS experience moderate to severe pain (Reardon, Anger, & Szumita, 2015; Yaman Aktaş & Karabulut, 2016).

**Mechanism of ETS-related Pain**

Tracheal suctioning-related pain could be categorized under procedure-related pain or pain that is associated with a non-surgical procedure (Puntillo et al., 2014). Furthermore, ETS-related pain is also classified as an acute pain since pain can be identified and pain relief can be expected within a given time range (Czarnecki et al., 2011; Morton, & Fontaine, 2013; Morton et al., 2017; Puntillo et al., 2014). The pain experienced during ETS can be expected to the end when the treatment is completed (Morton, & Fontaine, 2013; Morton et al., 2017; Puntillo et al., 2014).

Acute pain involves the physiological and psychological responses to nociception, which transfers information from a location of tissue damage to the central nervous system (Sole et al., 2017). ETS, as a noxious stimulus causes tracheal trauma or injury as well as tissue irritation due to the negative pressure applied (Ayhan et al., 2015; Shamali et al., 2016; Sole et al., 2017). For this reason, the higher the negative pressure applied, the more frequent and the deeper the catheter insertion, the higher the pain developed during ETS (Shamali et al., 2016). ETS-related pain is

mostly reported by experienced patients as “tender”, “sharp”, “aching”, “tiring-exhaustive”, “fearful-frightening”, and “awful” (Arroyo-Novoa et al., 2008).

**Consequences of ETS-related Pain**

ETS-related pain can lead to adverse physical and psychological consequences for critically ill adults (Majeed, 2017; Sole et al., 2017; Yaman Aktaş & Karabulut, 2016). Pain increases the stress responses; for example, it activates the SNS and increase the levels of catecholamine, which can result in a significant burden on the cardiovascular system (Sole et al., 2017). The activation of the SNS also results in development of tachycardia and hypertension, which lead to an increase in the myocardial oxygen demand (Tully et al., 2015).

Besides the physical suffering, acute ETS-related pain elicits psychological responses such as fearful, depression, anxious or unpleasant feelings, helplessness, hopelessness, fatigue and loss of control (Kizza & Muliira, 2015; Yaman Aktaş & Karabulut, 2016). Suctioning is noted for its perception of being painful and discomforting, and causing fear, an unpleasant and often suffocating feeling, including situations combined with a loss of breath among patients (Sole et al., 2017; Yaman Aktaş & Karabulut, 2016). Unrelieved pain can also cause insufficient sleep and can becomes one of the main sources of psychological stress for ICU patients (Puntillo et al., 2014). Severe pain can also lead to agitation. It is link with the inadequate physical aggression, verbal behavior, increased ventilator dyssynchrony, and movement [head or extremities] (Sole et al., 2017). A failure to manage agitation may lead to negative consequences such as a higher rate of self-extubation, a longer duration of ICU stay, and the requirement of extra resources for care, all of which

inflate the hospital care costs (Barr et al., 2013). In addition, pain is associated with stress, which can persist after the discharge and may result in developing a long-term psychological burden on patients (Puntillo et al., 2016; Sole et al., 2017).

**Factors Contributing to ETS-related pain**

Procedure-related pain is influenced by a number of factors, such as age, gender, ethnicity, culture, surgery received, previous pain experience, duration of mechanical ventilation, and nursing care (Barr et al., 2013; Czarnecki et al., 2011; Puntillo et al., 2016). One of the major sources of procedural pain in critically ill adults with artificial airways is ETS-related pain (Yaman Aktaş & Karabulut, 2016). Moreover, the patient's emotions, psychological state, anxiety level, knowledge about the procedures and health status as well as environmental factors such as the hospital setting and the caregiver carrying out the procedure are also contribute to ETS-related pain (Czarnecki et al., 2011).

However, evidence regarding the effect of age on procedure-related pain is inconclusive. Previous studies have revealed lower pain scores before and after procedures among older patients (Al Sutari, Abdalrahim, Hamdan-Mansour, & Ayasrah, 2014). Yet, other studies have given notice to no difference in pain intensity between older and younger patients during procedures (Barr et al., 2013; Rawe et al., 2009; Stotts et al., 2007; Stotts et al., 2004).

Similar to the situation with age and gender, there is still controversy on the effect of ethnicity on pain as well as procedure-related pain. Ethnicity influences the perception of pain, and consequently, the self-administration of analgesics (Tan et al., 2008). Previous studies have revealed no difference in the pain intensity reports by

ethnicity both before and after procedures; however, white patients tend to report a lower pain intensity than non-white patients during procedures (Barr et al., 2013; Stotts et al., 2004; Stotts et al., 2007; Walsh, Davidovitch, & Egol, 2010). Cultural heterogeneity also influences an individual's experiences on the degree of pain perception, their pain report as well as request for pain medication (Barr et al., 2013; Narayan, 2010; Walsh et al., 2010). Additionally, language is an important factor for pain expression. Thus, the ability to describe pain due to language barriers is another factor affecting an adequate pain report (Azize, Humphreys, & Cattani, 2011).

During procedures, non-surgical patients also experience lower pain intensity than surgical patients (Arroyo-Novoa et al., 2008; Barr et al., 2013; Stotts et al., 2007; Stotts et al., 2004). ETS may also increase the pain intensity of existing pain; the thoracic and abdominal pressure as well as increased muscle contractions in the surgical wound area increase the pain levels of the wound (Majeed, 2017).

Previous pain experience among intubated patients receiving mechanical ventilation after surgery was reported as the most significant factor influencing pain during procedures (Al Sutari et al., 2014). The more experience with pain they have had the more frightened they are, which increases the risk of elevating the pain intensity in subsequent painful ETS procedures (Puntillo et al., 2014). The mechanical ventilation duration is also reported as another factors affecting ETS-related pain. According to Yamashita, Yamasaki, Matsuyama, and Amaya (2017), patients often experience pain two hours after the initiation of mechanical ventilation and more than 80% of them experience a moderate to severe pain within 48 hours after receiving mechanical ventilation. Therefore, the length of ventilator use has been found to

significantly correlate with pain in critically ill intubated adult patients (Yamashita et al., 2017).

Interestingly, nursing interventions can be applied to promote comfort and reduce the procedural pain in patients during ETS (Barr et al., 2013; Czarnecki et al., 2011). The nursing management in critically ill intubated adults is sometimes rather challenging as it requires the application of complex techniques, advanced knowledge on invasive clinical procedures, and implementation of nursing interventions to manage pain (Barr et al., 2013). Most of the nursing techniques have been understood in terms of procedures, which might influence the amount of distress experienced during procedures (Barr et al., 2013; Majeed, 2017; McNaughton, Zhou, Robert, Storrow, & Kennedy, 2009). This factor was an important reason and it became the source of inspiration in conducting this study,

e.g., to develop an effective CPETS pain management to alleviate the pain experienced by this group for patients.

## ETS Pain Management in Critically Ill Adult Patients

### An Overview of ETS Pain Management in Critically Ill Adult Patients

Procedural pain is common and important in critically ill adults (Barr et al., 2013). Procedural pain or procedure-related pain is a type of acute pain associated with non-surgical procedures such as CTR or wound care, including tracheal tube suctioning (Puntillo et al., 2014). The existing evidence on procedural pain management was used to formulate the recommendations of this CPETS pain management. First, a position statement and clinical practice recommendations related

to procedural preparation and comfort management proposed by the ASPMN have shed light on the current procedural pain management (Czarnecki et al., 2011). Next, the clinical practice guidelines for the management of pain, agitation, and delirium in adult patients in the ICU proposed by Barr et al. (2013) has also been used to guide procedural pain management in critical care settings.

These two documents in addition to the cutting-edge evidence specifically relevant to ETS pain management were simultaneously used in conjunction with the general principles of procedural pain management in order to develop the CPETS pain management in this study (Ahlers et al., 2012; Bai et al., 2015; Boitor et al., 2015; Casey et al., 2010; Chaseling et al., 2014; Chaveron et al., 2012; Chou et al., 2016; Hasanzadeh et al., 2016; Lee et al., 2012; Robleda et al., 2016; Saadatmand et al., 2015; Salmani et al., 2017; Schug et al., 2015; Shamali et al., 2016; Fariba, Ali, Mohamad, & Sara, 2016; Yaman Aktaş & Karabulut, 2016).

**Assessment of ETS-related Pain**

According to Barr et al. (2013), procedural pain should be conventionally monitored in all ICU adults using validated and reliable tools. According to Schug et al. (2015), a good reliability is fundamental to the precise assessment and measurement of pain, and it can help HCPs discern the cause of pain and provide appropriate pharmacological and non-pharmacological interventions according to the subjective patient's reception. Similarly, to pain assessment in other groups, procedural pain assessment should cover the whole picture of pain including pain location, onset of pain, pain character, and the pain intensity (pain duration, exacerbating or palliating factors).

The pain assessment should also include the concerned symptoms, impacts of pain on sleep and activities, management strategies (present and previous pain pharmaceutical, non-pharmaceutical methods, and HCPs consulted), relevant pharmaceutical history (previous pain circumstance, management outcome, previous or present medical situations) and factors that affect the pain management [belief about reason for pain, information, prospects, priority, pain management outcome prospects and so on] (Schug et al., 2015).

In addition, regarding pain assessment, the position statement of the ASPMN recommends that pain should be reported by patients themselves using validated tools; this may include asking the family members to describe the patient's pain behaviors (Herr, Coyne, McCaffery, Manworren, & Merkel, 2011). The validated tools according to the best current available evidence could be categorized into validated tools used for communicable and non-communicable patients as follows.

**Validated tools used for communicable patients.** Even though critically ill adult patents who require mechanical ventilation cannot speak out their pain, some of them still can express their pain by using their fingers to point at scales or add 1-10 or using writing tablets and computer applications (Barr et al., 2013; Herr et al., 2011; Varndell, Fry, & Elliott, 2017). The Numerical Rating Scale (NRS) is a common pain assessment scale, and it has been certified to be the most discriminative and feasible self-report scale in comparison to other formats (e.g., oral versus visual) and scales (e.g., visual analogue scale and verbal descriptor scale) for estimating pain intensity in critically ill communicable adult patients (Barr et al., 2013; Chanques et al., 2010; Rahu et al., 2015).

The NRS has been used to rate procedural pain intensity in previous studies, and its feasibility has been reported (Barr et al., 2013; Herr et al., 2011; Lee et al., 2012; Schug et al., 2015; Varndell et al., 2017). The NRS involves numbers from 0 to 10, and the patient is asked to choose which number the best describes their pain, where '0' indicates no pain and '10' describes the worst pain imaginable. More specifically, the NRS has evolved into the 0-10 Numeric Rating Scale with visually enlarged lamination (NRS-V).

In order to utilize the NRS-V to indicate their pain level, the critically ill adult patients can point their fingers to the digital rapidly on the scale or add 1-10 either with both hands, or consequently with the same hand. This tool is commonly used in the ICU setting (Barr et al., 2013; Chanques et al., 2010). For this reason, the NRS could be used to assess ETS-related pain among communicable critically ill patients before and after the ETS procedure. However, NRS is inappropriate for use in the assessment of pain during ETS because, during the procedure, the communicable critically ill adults could not self-report their pain scores with their fingers or hands.

**Validated tools used for non-communicable patients.** It is a challenge to assess pain in critically ill patients because the majority of them cannot communicate (Barr et al., 2013). The factors that alter verbal communication in critically ill patients include endotracheal intubation, an altered level of consciousness, restraints, sedation, delirium, and therapeutic paralysis (Sole et al., 2017; Varndell et al., 2017). Therefore, pain assessment in non-communicable patients requires the use of the pain behavior scale in order to identify the best pain score (Barr et al., 2013; Schug et al., 2015; Sole et al., 2017; Varndell et al., 2017). The current research recommends to use the CPOT and the Behavioral Pain Scale (BPS) to assess the level of pain presence in critically

ill adults (Barr et al., 2013; Rahu et al., 2015; Schug et al., 2015; Sole et al., 2017; Varndell et al., 2017).

***Behavioral Pain Scale (BPS*).** The BPS was initially invented in France, and it has been translated into English (Payen et al., 2001), Chinese (Chen et al., 2011) and other languages. It has been reported to have a good validity, reliability, feasibility and utility among critically ill adults with mechanical ventilation (Varndell et al., 2017). The BPS has three sections: facial expression, upper limbs, and compliance with ventilation. Each item is measured from 1 (no reception) to 4 (full reception), with higher scores reflecting more pain and a score range from 3 to 12 (Barr et al., 2013; Schug et al., 2015; Varndell et al., 2017).

Furthermore, according to Chen et al. (2011), reliability and validity of the Chinese- version BPS is used among adults with mechanical ventilation in MICU. The test-retest and inter-rater reliabilities were identified by good high agreement percentages (73%-100%) and Pearson correlations ($r = .50\text{-}1.00$, $p < .001$). Similarly, according to Chen et al. (2016), the Chinese-version BPS (BPS-C) is adequate for pain measurement among non-intubated and intubated ICU adults. The internal consistency was established through Cronbach's alpha coefficients ($\alpha = .70$ - .76 in non-intubated patients, $\alpha = .72$ - .74 in intubated patients). The inter-rater reliability was sustained through intraclass correlation coefficients (ICCs) [.96 - 1.00] in both non-intubated and intubated patients with high agreement percentages (95%-100% in non-intubated patients and 95%-100% in intubated). The validity-related criterion was sustained by tough positive correlations between NRS and BPS-C scores [Pearson's correlations $r = .76$ - .90 for non-intubated patients, Pearson's correlations $r = .82$ - .94 for intubated patients] (Chen et al., 2011).

***Critical-Care Pain Observation Tool (CPOT).*** The CPOT was initially invented in France (Gélinas, Fillion, Puntillo, Viens, & Fortier, 2006), and it too has been translated into English (Gélinas & Johnston, 2007), Chinese (Li et al., 2012) and so on. Similar to BPS, the CPOT has a good validity and reliability in critically ill patients with mechanical ventilation (Varndell et al., 2017). The CPOT has four sections: facial expression, body movements, muscle tension in upper extremities, and compliance with the mechanical ventilation. Each item is measured from 0 (no reception) to 2 (full reception), with higher scores reflecting more pain and a score range from 0 to 8 (Barr et al., 2013; Schug et al., 2015; Varndell et al., 2017).

Moreover, according to Liu, Li and Herr (2015), reliability and validity of the BPS and the CPOT to measure pain in non-intubated and intubated critically ill Chinese adults. In that study, a total of 608 measurements were acquired using the BPS and the CPOT. The overall Cronbach's alpha coefficients for the CPOT and the BPS were .80 and .79, respectively. The test-retest reliability was .94 and .95 for the BPS and the CPOT, respectively (Liu, Li, & Herr, 2015). The overall weighted kappa values between the two raters of the CPOT and the BPS were .97 and .96, respectively. The BPS and the CPOT scores at rest before painful procedures and during non-painful procedures were significantly lower than those during painful procedures (Liu, Li & Herr, 2015).

Likewise, according to Li et al. (2014), reliability and validity of the CPOT has good psychometric properties for pain measurement in critically ill Chinese intubated adults. The measurement of Cronbach's α coefficient of the internal consistency (.57 to .86); the intraclass correlation coefficients as a measure of the inter-rater reliability (.80 to .91); and the measurement of Spearman nonparametric

coefficients of test-retest reliability (.81 to .93). The BPS has been used in many studies (Li et al., 2014).

However, a recent systematic review conducted by Varndell et al. (2017) reported that the CPOT might be more feasible and practical to use in ICU patients than the BPS. The CPOT has also been tried out in both nonverbal and verbal patients, including populations with delirium, and has one more domain on muscle tension, which provides more information than BPS. Furthermore, the algorithm used in CPOT is allied with the NRS, which can further guide the determination for pain management (Gélinas, 2016).

Pain is identified or diagnosed if the cutoff score of the BPS is more than 5 (BPS > 5), that of the CPOT is more than 2 (CPOT ≥ 3), and that of the NRS is more than 3 [NRS ≥ 4] (Barr et al., 2013). In the present study, as CPOT was used to assess the presence of pain in both communicable and non-communicable critically ill adult patients.

**Management of ETS-related Pain**

According to Czarnecki et al. (2011), the procedure is to be allowed biopsychosocial experiences for patients rather than brief works to be achieved by the HCPs. Health care team must facilitate a good quality of life as characterized by the client by delivering adequate comfort management, knowing and employing managements that minimize pain and damage, measuring comfort regularly, and engaging the patient in the intervention determinations and procedure (Czarnecki et al., 2011). In accordance with the ASPMN, personals who experience potentially the

painful procedure have the right to obtain optimal pain management before, during, and after the procedure (Czarnecki et al., 2011).

**Before the ETS procedure.** The procedure is probably to produce pain and/or anxiety, a program for managing patient comfort must be created (Czarnecki et al., 2011). Pain management before ETS aims at preparing the patient to receive the ETS procedure as well as decreasing pain during the ETS procedure. The recommendations for pain management before ETS consist of: 1) ETS should be considered a bio-psychosocial experience for the patient; 2) assess and identify the patient's need for suctioning; 3) perform ETS when clinically indicated by the relevant signs and; 4) assess the baseline pain using appropriate instruments. In addition, before the procedure, an individualized ETS pain management plan should be established, which includes the mutual goal setting with the patient and family [e.g., CPOT< 3 or NRS< 4] (Barr et al., 2013; Czarnecki et al., 2011).

The recommendations prior to suctioning also consist of give education tailored to meet the patient's needs, and giving distinct knowledge of regarding the ETS procedure (e.g., the need for suctioning, when suctioning is required the consequences of not suctioning, and the effects of suctioning). Before suctioning, the attending staff should select appropriate pharmacological and non-pharmacological interventions (Czarnecki et al., 2011). The pharmacological management entails the administration of pre-emptive analgesia (e.g., Fentanyl). Importantly, the recommendations for adequate pre-emptive analgesia involve the availability of appropriate and adequate prescriptions to afford for adequate time for their effectiveness prior to the procedure (Czarnecki et al., 2011).

In conjunction with pharmacological interventions, non-pharmacological interventions (e.g., relaxation, distraction, cold application, music therapy, and guided imagery coping techniques) are recommended according to the patient's preference and experience in order to help them cope during the procedure.

***Provide coping skills, distraction, and relaxation based on patient favor, competences, and experience.*** According to Jafari Tadi, Koivisto, Pänkäälä, and Paasio (2014), slow deep breathing (six breaths per minute) is a good way to reduce the patients' pain and anxiety. Moreover, Meyer, Jeevendra Martyn, Wiechman, Thomas, and Woodson, (2018) reported the effect of deep breathing and brought forward a possible mechanism behind the breathing-induced hyperalgesia. The steps of deep breathing are presented below:

1. Find a comfortable condition. Lights should be dimmed and curtains closed to minimize disturbance. Close eyes.

2. Put one hand on the chest. Put the other hand on the abdomen, just under the ribs (if patient does not have restrictions).

3. Take a normal breath.

4. Take a deep and slow breath. Breathe in lentamente through you nose. Pay attention as the abdomen fill under the hand.

5. Holding your breath, hold for one or two seconds.

6. Breathe slowly out through the mouth. Stay on the ball as the hand on the abdomen goes in with the breath.

7. Perform this a few times until you have a steady rhythm.

8. Add images to the breathing. Imagine and breathe in the air you are breathing is disseminating equilibrium and relaxation throughout the body.

9. As you expiration, imagine that your breath is whooshing away pressure and stress.

10. Try to deep inspiration for until you feel easy and less stressed or 10 minutes. Work your way step by step up to 15-20 minutes.

***Guided imagery.*** According to Sole et al. (2017), guide imagery is a intervention proposed to relieve anxiety and develop a sense of tranquility and calm. It includes a form of directed daydreaming. It is a method of consciously focusing and diverting thoughts. Critically ill patients may be instructed in the use of guided imagery during painful procedures. For example, when performing the ETS, instruct the patient to imagine walking on the beach or other pleasant sensation. Guided imagery accompanied by a gentle touch or light massage decreases the pain and tension in critically ill patients (Papathanassoglou, 2010). Guided imagery is a inexpensive and simple method that all HCPs can clearly merge into their routine procedure during most interventions and practices (Sole et al., 2017).

***Music therapy.*** Similarly, a music therapy program as guided imagery, it offers clients a diversionary skill for pain relief. The soothing music may produce relief, and peaceful in the personal, and increase a response of relaxation, thus overturning the harmful effects of the pressure response (Yaman Aktaş & Karabulut, 2016). Faigeles et al. (2013) reported that a calming voice, providing information, and deep breathing are the three most generally-performed, non-pharmacological interventions among hospitalized adults.

A study conducted by Yaman Aktaş and Karabulut (2016), revealed that music therapy can reduce ETS-related pain in critically ill adult, mechanically ventilated patients. Music therapy is recommended for use in the routine nursing care and can be

allocated before, during, and after the ETS procedure (Yaman Aktaş & Karabulut, 2016). Saadatmand et al. (2015) found that listening to nature sounds could also relieve the pain of mechanically ventilated ICU patients. Listening to music affects pain, memory and mood by adding the amount of endogenous opioid released from the hypophysis; thus, it is an effective intervention for critically ill adult patients (Chlan, Engeland, Anthony, & Guttormson, 2007; Fredriksson, Hellström, & Nilsson, 2009; Koelsch et al., 2004; Solanki, Zafar, & Rastogi, 2013; Yaman Aktaş & Karabulut, 2016).

***Aromatherapy.*** Creating a calm and soothing environment is an independent nursing intervention that helps decrease the pain associated with anxiety as well as critically ill adult patients. A study conducted by Boitor et al. (2016) revealed that applying the lavender cream combined with a 5-minute hand massage can reduce procedural pain among adults in the ICU. Moreover, lavender oil inhalation and cold application can reduce pain in cardiac surgery patients undergoing CTR (Hasanzadeh et al., 2016). Currently, the published evidence regarding the effect of aromatherapy on ETS-related pain is scarce.

***Cold application.*** According to Chou et al. (2016), cold application is defined as a simple and inexpensive therapy, and it may compress or equip the skin and can recycle automatically for relatively low temperature conservation. It should be topically applied in the management of acute pain after surgery due to its effect on tissue temperature reduction at the surgical site, hence, furnishing regional pain relief and edema reduction. Moreover, one study reported that providing cold application (e.g., ice bag) three minutes before arterial puncture (AP) revealed that it was well-tolerated and could reduce AP-related pain (Haynes, 2015). The application of cold

compression before CTR has been reported to alleviate the CTR-related pain in critically ill patients (Ertuğ & Ülker, 2012). Currently, few published studies examining the relationship between cold application and ETS-related pain exist.

***Prepare patient and family.*** Such preparation should follow these steps:

1. Give education tailored to meet patients and their family members' needs (e.g., discussion, written materials, videos, etc.).

2. Inform patients' concerns/nervous and alter the comfort management plan accordingly. According to Sole et al. (2017), delivering continuous reorientation and repeat of interpretation and information is a good method to decrease pain and anxiety. Clear information should be given to the patient to provide information in order to reduce anxiety and promote their understanding of and compliance with, the suctioning procedure. The information given to the patients should include the need for suctioning, consequences when suctioning is required but not perform. Furthermore, the information should be reduplicated with each ETS procedure as some patients may not recollection previous information (Chaseling et al., 2014).

3. Deliver guiding to family members in relation to their position if they stay with the patient. family members' role is to support the patient (if it possible), not to interfere with or participate in the procedure, and they should be afforded to step away if needed.

4. Discuss the position and time of the procedure with client/family and health care team.

5. Consent optimal patient role.

6. Prepare coping skills, distraction, and relaxation depended on client favor, experience, and functions.

7. During the procedure, decide how the patient will report unrelieved pain or anxiety to the HCPs.

8. Negotiate the need for any pre-emptive with the health care team.

9. Make sure that pre-emptive are prescribed, effective, and implement to afford adequate time for them to be available.

***Timing and location of procedure.*** Concerning timing and location, these are the recommendations that should be followed (Czarnecki et al., 2011):

1. Discuss the position and time of the procedure with client/family and HCPs.

2. Discuss the following in decision the position (privacy right, appropriate space, verstellbar lighting, lowest interruptions and noise, approachability to pharmacological intervention, practicality of supplies for non-pharmacological interventions if adequate).

3. Agree on first-rank patient opinion. Comfort body posture can issue in close personal contact with a nurse, secure holds, a positive participation by the nurse rather than negative restraining, and decreased the number of nurse required to assist with the practice (Czarnecki et al., 2011).

***Discuss the need for any pre-medication with the health care team.***

1. Administer analgesic if pain is anticipated.

Pre-emptive analgesia relates to the “timing” of administration of the analgesic technique before the insult and is a assess in terms of pain intensity or related outcomes (Schug et al., 2015). According to Barr et al. (2013), it strongly recommends that pre-emptive analgesia should be administered to reduce pain in critically ill adult patients. In addition, pre-emptive analgesia should be used with the potentially painful and invasive procedures with no exception to ETS in critically ill

adult patients (Barr et al., 2013). IV opioids (e.g., morphine, fentanyl) are recommended as the first-line pain medications to treat non-neuropathic pain in critically ill adult patients (Barr et al., 2013). Previous studies have been conducted to test the effectiveness of pre-emptive analgesia in some procedures-related pain as well as in ETS with an inconclusive result. A study conducted by Ahlers et al. (2012), to compare different intravenous doses of morphine 2.5 mg with 7.5 mg on procedure pain relief, such as ETS and movement, revealed no significant difference. On the other hand, a study conducted to examine the effect of morphine as the pre-emptive analgesia on pain relief during ETS and movement among cardiothoracic surgery ICU patients revealed significantly different (Ahlers et al., 2012).

The administration of the optimal dose of IV fentanyl (1.5µg/kg for surgical and trauma patients), as pre-emptive analgesia is recommended to administer to in critically ill mechanically-ventilated patients prior to perform turning as well as other procedures-related pains (Robleda et al., 2016). Topical anesthetics were also used to relieve the procedural pain (Czarnecki et al., 2011). Ten percent xylocaine spray, for instance, was delivered 3-5 minutes before suctioning procedure effectively reducing the throat pain (Bai et al., 2015; Czarnecki et al., 2011; Lee et al., 2012). Lidocaine jelly also effect on the postoperative sore throat patient with endotracheal tube (Lee, Lee, Son, Lee, & Kim, 2017).

Although pre-emptive analgesia prior performing procedures-related pain is mostly relied on medical doctor order, nurses are responsible and accountable for adequacy of pain medication a patient receives (Maryland Board of Nursing, 2011). Here, nurses need to collaborate with medical doctor to make pre-emptive analgesia

feasible and accessible for patients (Czarnecki et al., 2011). Table 1 illustrates the vital details of analgesics used for procedure-related pain.

2. Use anesthetics topical if referential.

3. Administer anxiolytic if anxiety is expected/present.

4. Sedate if patient is asked for the patient to be positioning for long term or if significant pain is anticipated.

5. Employ adequate monitoring strategies as required (note: it is always requested the optimal management of procedures; whereas, if the patient asks continuous procedures, it is considerable. It is appropriate to regulate maximum safe intervention for pain and anxiety during the first procedure in order to minimize anxiety before pursuant procedures).

Czarnecki et al. (2011) in order to be sure the pre-emptive analgesics are instruction, effective, and administered to afford competent time for their effectiveness before painful procedures.

Table 1

*Pre-emptive Analgesia Used for Procedure-related Pain*

| Medication Management in pain | Action/uses | Dose/route | Side effects | Nursing implication |
|---|---|---|---|---|
| Fentanyl or Sulfentanyl | Opioid; inhibits ascending pain pathway in central nervous system (CNS); increases pain threshold; alters pain perception | Dosage varies depending on desired effect<br><br>*Infusion:* in general, 1-3 µg/kg/hour; | Hypotension, muscle rigidity, decreased gastric motility; constipation, respiratory depression, bradycardia, itching | 1. Titrate infusion lentamente in increments<br>2. Monitor heart rate, blood pressure, respiratory status, and the sedation score<br>3. Administer fluids as indicated.<br>4.Give as an infusion for extended therapy<br>5. escape heat directly, which increases fentanyl release; change new one per 72 hours |
| Morphine | Opioid; depresses pain impulse transmission at spinal cord level by interacting with opioid receptors | IV patient-controlled analgesia: 1-2 mg injected 30 min after a standard IV dose of 5-20 mg; the lockout period is 6-15 min; the 4-hour limit is 30 mg | Decreased gastric motility, hypotension, constipation, , nausea and vomiting, urinary retention, respiratory depression, itching or rash | 1. Titrate infusion slowly in increments<br>2. Monitor the sedation score, heart rate, blood pressure, and respiratory status<br>3. Administer fluids as indicated<br>4. Administer lower doses in the elderly patients |

Table 1 (Cont'd.)

*Pre-emptive Analgesia Used for Procedure-related Pain*

| Medication | Action/uses | Dose/route | Side effects | Nursing implication |
|---|---|---|---|---|
| Management in pain | | | | |
| Lidocaine jelly or Xylocaine spray | Topical anesthetic: produces local anesthesia by restraining transport of ions across neuronal membranes, thereby preventing conduction of standard nerve impulses and initiation | Endotracheal (Adults): Give 2–2.5 times the IV loading dose down the endotracheal tube, followed by a 10-ml saline flush | Dermatologic, hypersensitivity: anaphylactoid reactions; Local: burning, stinging, tenderness, swelling, tissue irritation, tissue sloughing and necrosis, methemoglobinemia. | 1. Throat Spray: before allowing patient to drink or eat make sure that gag reflex is intact<br>2. Anesthetic: measure level of numbness of affected part<br>3. Transdermal: determine the sedation score, and monitor for pain presence in affected area periodically during therapy<br>3. Apply it sparingly, avoiding irritated or broken skin; do not apply heat or wrap skin to area (heating pad/electric blanket) |

***Prepare the health care team.***

1. Make sure the procedure characteristics (how long it will be take, what will be done, what kind of pain is prospected).

2. Gather adequate equipments and technique.

3. Make sure, if attached support caregivers are needed and their role.

4. Make sure somebody to lead the coping techniques and distraction so the client is not puzzled (if multiple caregivers are present).

5. Make sure how the client and their family members think the client will reply.

6. Make sure how long the procedure will need to be performed again.

**During the ETS procedure.** Pain management during ETS aims at controlling and managing the ETS-related pain using both pharmacologic and non-pharmacologic interventions. The recommendations for pain management during ETS consist of: 1) use agreed upon coping/distraction skills; 2) measure pain and anxiety (if patient is conscious); 3) if pain and/or anxiety cannot controlled during procedures, ask the HCPs delivering procedures to stop so that further estimate can be conducted and the need for extra intervention (pharmacological and/or non-pharmacological) be judged.

1. Signs that the procedure may not be developing as looked forward to include but are not limited to:

1) Restrain patients instand of supporting patients.

2) Add voices volume, voices strained.

3) Multiple people undertaking to guide, involvement.

4) Patient who is crying, moaning, or combative.

5) Family members dissatisfaction,

6) Client who voice the need to ‘‘have done with’’ as opposed to calmly delivering the procedure.

2. Do not forget to remain convinced and calm, no need to rush. Venerably remind others to do the same, as needed.

3. Perform verbal guiding in a calm responsible manner.

4. Monitor the behavior of family and nurse, and deliver feedback to make sure the surrounding remains relaxed and safe for the patient.

5. Use supplies known to minimize mucosa damage as adequate. During the procedure, if pain and/or anxiety are not controlled well, ask the HCPs providing the procedure to desist so that further assessment can be managed and the need for extra support (pharmacological and/or non-pharmacological interventions) be identified.

***The painless suctioning techniques.*** Beyond the application of general non-pharmacological management used to manage ETS-related pain, a number of techniques have been innovated to manage or reduce ETS-related pain. Appropriate suction equipments and techniques can decrease the lower airway trauma and the suction-related pain intensity (Shamali et al., 2016). These painless suctioning techniques include minimally invasive ETS technique, the use of an optimal size of suction catheter, the use of optimal degree of negative pressure, the use of an optimal depth of the suction catheter insertion, and optimal suction time and frequency, open/closed suction system, accurate assess and inappropriate implement of adjunct procedures such as hyperinflation and instillation of normal saline (Majeed, 2017; Shamali et al., 2016).

***Minimally invasive ETS techniques.*** Evidence from previous study revealed the effectiveness in using the minimally invasive ETS technique on the reduction of ETS-related pain and airway traumatization (Shamali et al., 2016). The minimally invasive ETS techniques include optimal size of suction catheter, appropriate duration of suction per each attempt and frequency of suctioning, appropriate depth of endotracheal suction catheter insertion, appropriate level of vacuum pressure applied

during suctioning, and appropriate pre-oxygenation implementation as discussed previously.

**After the ETS procedure.** Pain management after ETS aims to discuss and evaluate the quality of the CPETS pain management. The recommendations for pain management after ETS consist of: 1) discuss and evaluate the procedure with the patient and their family if applicable. This practice aims to inform the patient that the procedure is finished and that it is necessary, educate the patient and responsible caregiver about the treatment options for management of procedural pain, and reassess the outcome regarding pain management (Czarnecki et al., 2011; Schug et al., 2015). Furthermore, educate the patient how pain is reported and assessed including the use of pain assessment tools. Then, reassess the pain and the outcome regarding pain management. For pharmacological and non-pharmacological treatment, assess the previous treatment and the adverse effects related to the treatment (Chou et al., 2016; Czarnecki et al., 2011; Schug et al., 2015); 2) document the procedure: duration of procedural pain, nursing interventions, an estimate of the client's experience from the client, family members, and staff nurses with standpoint as the suggestions for future procedures in the nursing document; 3) improve and utilize a comfort management program for after the procedure as the pain-related the procedure when completion the procedure and must be treated adequately. Assess pain intensity immediately, 5 minutes after suctioning and 15 minutes after suctioning, to assess the need of further pain management. Multimodal intervention including pharmacological and non-pharmacological interventions such as opioids, adjuvants treatment may be figured. The comfort management should include care in the event the client is no longer in the health care context after the procedure.

## Current Practices in Management of Pain-related ETS in China

Pain management in China, like global pain management, has gained attention to establish quality pain management. The Chinese Association for the Study of Pain (CASP) was established in 1989 aims at launching the standardized of pain treatment and improve the quality of life for patients with pain (Han, 2011). Moreover, quality pain management has been used as one of the quality tertiary hospital indicator in China with a specific focused on adequate treatment, continuing quality improvement, and allocation of pain management training (Yu et al., 2016).

The current evidence of pain management in China is mainly focused and made great affords on cancer pain management (Sun, 2017; Yang et al., 2014; Yu, 2016). However, there was still limited evidence on pain management in critically ill patients as well as procedural pain management in China. The Chinese-language version of the CPOT was conducted to measure ventilated, critically ill patients' pain and to test its psychometric properties (Chen et al., 2011). However, still lack of evidence on the utilization of this tool. To date, no evidence has been found of an evidence-based care program as well as any pertinent published guideline or standard of practice to manage ETS-related pain within the context of China.

## Pain management outcomes

Pain management outcomes are used to evaluate and improve the quality of pain research (Turk et al., 2006). Pain outcomes are difficult to measure because of the multifaceted and subjective nature of pain. The proper pain outcomes measure is significant to demonstrate scientifically valid of treatment efficacy (Younger, McCue, & Mackey, 2009). In order to improve and achieve high quality pain management,

pain outcomes measures should include measurement of the appropriateness of assessment, treatment, cultural background, cooperative and interdisciplinary care planning, safety, cost effectiveness and come close to specialty care (Turk et al., 2006).

The ETS-related pain examined in this study was categorized as acute pain. For this reason, acute pain outcomes will be measured to valid the efficacy of the clinical pathway for ETS pain management. Additionally, the pain management outcomes should be measured both in terms of primary and secondary pain outcomes to improve means of measuring, comparing and improving pain management quality (Turk et al., 2006). According to Turk et al. (2003), primary pain management outcomes consist of pain, emotional and physical functioning, participant grades of satisfaction and amendment with intervention, adverse events and symptoms, and participant preference. ETS-related pain is of a short duration in nature and will disappear shortly after the procedure is finished. Pain intensity and relief are recommended to use to evaluate as the primary pain management outcomes. Whereas the secondary pain management outcomes are the outcomes measures that are the consequences of adequate or quality pain management (Dworkin et al., 2005). With regard to ETS-related pain, one of the major profound impacts of unmanaged ETS-related pain is agitation (Shamali et al., 2016; Sole et al., 2017). Agitation is defined as associated with inappropriate verbal behavior, physical aggression, increased movement (head or extremities), and ventilator asynchrony, any of which may harm the patient (Sole et al., 2017). Further, the failure to manage agitation may have negative consequences or cause harm to the patient, such as a higher rate of self-extubation as well as a longer duration of ICU stay (Sole et al., 2017). For this reason,

agitation will be used as a secondary pain outcome measure in this study. Thus, the primary pain outcomes in this study will include the severity and relief, while the secondary pain outcome in this study will be agitation.

## Summary

The literature review in this chapter provides information associated with the overview of ETS, the overview of ETS-related pain, and ETS pain management in critically ill adults. Tracheal suctioning is a frequent and necessary invasive procedure, which may lead to some profound impacts for patients, including pain. ETS pain is resulted from trauma or injury around tracheal as well as tissue irritation from negative pressure applied. ETS pain lead to adverse physical and psychological consequences. A number of clinical practices guidelines as well as practice standards have been developed and launched to provide guidance and best practice in allocating tracheal tube suctioning with not specific or focused on pain control.

Nurses perform a key position in the pain assessment, administration of the prescribed analgesics and assisting patients with providing non-pharmacological methods to develop the quality of pain management. Nursing interventions have been evidenced to promote comfort and relieve pain related to suctioning. A CPETS pain management was developed based on the principle of CP development and integrated the relevant cutting-edge evidence served to manage ETS pain using a combination of pre-emptive analgesia with non-pharmacological interventions.

The CP starts from before the beginning of suctioning until the completion of suctioning. The quasi-experimental approach was employed in the implementation

and evaluation phase to test the efficacy of the clinical pathway on primary and secondary pain management outcomes. The Chinese version of CPOT, a validated pain assessment tool, was used to measure pain presence as a primary pain management outcome. The secondary pain management outcome was measured as agitation using the Chinese-version RASS

# CHAPTER 3

# RESEARCH METHODOLOGY

This chapter presents a detailed description of the research methodology including research design, research setting, population and sample, research instruments, data collection procedure, ethical considerations, and data analysis.

## Research Design

This study was a quasi-experimental study with a two-group posttest design to examine the effects of the tentative CPETS pain management on pain presence and agitation in critically ill Chinese adult patients. Types of quasi-experimental study designs are mainly depended on the number of groups and the frequency of measurement (LoBiondo-Wood & Haber, 2017). The two-group posttest design was used in determining the differences between two groups after the intervention or treatment. One group received the treatment or the CPETS pain management (the X) and the other group received the standard or typical treatment and care. This type of the study design fitted with the present study that aimed at comparing the pain outcomes between the experimental group receiving the CPETS pain management and the control group receiving the typical ETS pain management.

In this study, the researcher sequentially compared pain management outcomes between the control group or critically ill Chinese adult patients who received the usual ETS from the staff nurses in the setting and the experimental group

or critically ill Chinese adult patients who received the tentative CPETS pain management (the X) from the researcher. The CPETS pain management (the X) was allocated according to phases of procedural pain management from before, during, and after ETS procedure.

The selected times of outcome measurements (the O) were guided by a previous study at before, during, immediately after, 5 minutes after, and 15 minutes after the ETS procedure in both groups (Dastdadeh, Ebadi, & Vahedian-Azimi, 2016; Lee et al., 2013). The pain assessment before procedure aimed at measuring the baseline pain of the patient. While pain assessment during and after procedure aimed at measuring procedure-related pain as well as the outcomes of pain management (Czarnecki et al., 2011). Figure 2 shows a schematic of research design followed for carrying out this study.

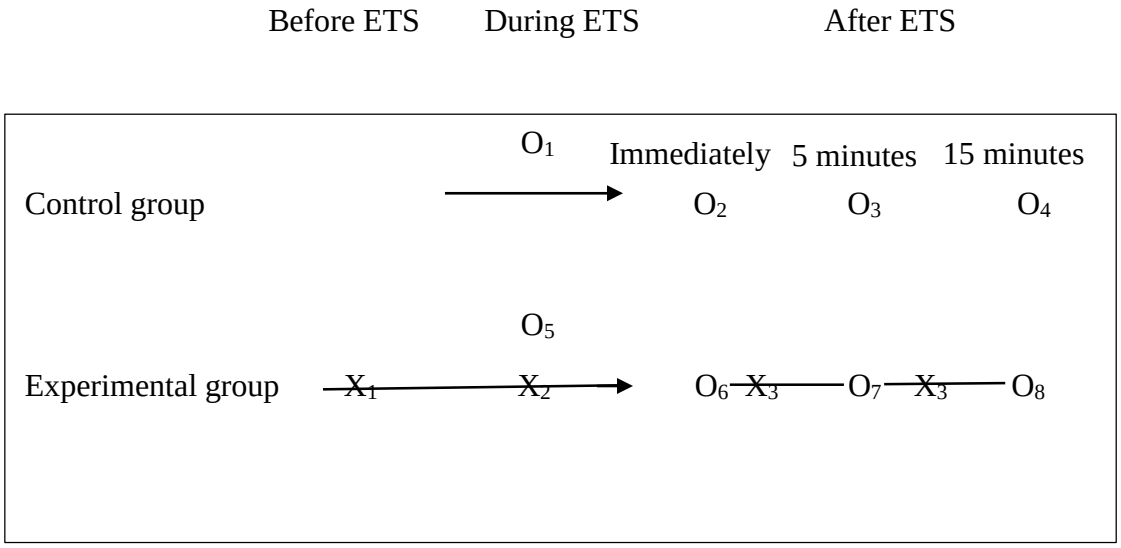


*Figure 2.* A schematic of research design

$X_{1, 2, 3}$ refer to the interventions given before the beginning of ETS, during ETS, and after the completion of ETS, respectively.

$O_{1, 5}$ refer to the measurement of the level of pain presence and agitation during ETS in the control and experimental group, respectively.

$O_{2, 3, 4}$ refer to the measurement of the level of pain presence and agitation in the control group immediately after, 5 minutes after, and 15 minutes after the ETS, respectively.

$O_{6, 7, 8}$ refer to the measurement of the level of pain presence and agitation in the experimental group immediately after, 5 minutes after, and 15 minutes after the ETS, respectively.

## Research Setting

This present study was conducted at the SICU of the Second Affiliated Hospital of Kunming Medical University, Yunnan, China. This hospital is a 1,500-bed tertiary public hospital in Yunnan Province. It serves as a teaching hospital for all health sciences as well as a research center. The Intensive Care Units (ICUs) under the department of anesthesiology, provide care for patients in critical conditions. Adult ICUs consist of a 20-bed SICU and a 10-bed Medical Intensive Care Unit (MICU). Forty-seven registered nurses in SICU and 11registered nurses in MICU. Patients after surgery are usually admitted to SICU with short duration of intubation and light dose of sedatives. However, patients admitted to MICU with long duration of intubation, high dose sedative, low consciousness level and have chronic condition with chronic pain experience, which cannot met the

inclusion criteria in this study, and can also affect their pain perception and response to analgesics. Therefore, in this study the participants only recruited in SICU.

The patient beds are parallel with the nurses' station. The nurses' station is in a "U" shape and is situated between the patient beds. Three nursing care teams are set in each ICU. Each team consists of three registered nurses. The nursing system used in the ward is that of the primary care system with 1:2-3 nurse-patient ratios. The primary nurse establishes the plan for patient care and is responsible for the implementation of the plan. After each shift handover report, a team meeting addresses the patients' problems and plans of care. Any medical doctor orders and patient records are kept at the counter in front of the charge nurse of each team.

The common causes of endotracheal tube intubation in critical ill adult patients in this setting are the need to protected or sustain a patent airway, to assist in the delivery of mechanical ventilation support, and failure to use non-invasive ventilation. In addition, endotracheal tube intubation often uses to facilitate the removal of tracheal secretions among patients with seriously ill such as multi-organ failure/sepsis, to reduce the risk of aspiration, and in order to deliver high concentrations of oxygen.

Patients with an artificial airway or endotracheal tube will receive tracheal tube suctioning by the primary nurse as needed such as audible of secretion sounds, the collection of a sputum culture as prescribed, before the arterial blood gas testing or endotracheal tube removal. An OSS is generally used for every patient in this setting. However, the closed suction system may be occasionally used for specific

indications such as for critically unstable patients receiving high oxygen concentration or $FiO_2$ more than 60% including patients who have potentially require mechanical ventilation more than three days.

## Population and Sample

### Target Population

In this study, the target population was SICU adult patients receiving ETS in the Second Affiliated Hospital of Kunming Medical University, Yunnan, China.

### Sample and Sampling Procedure

The pain management outcomes in SICU adult patients receiving regular ETS (Group I, *n*=26) was compared with the SICU adult patients receiving the clinical pathway for ETS pain management (Group II, *n*=26) in the same SICU. All of the patients undergoing ETS during the CP implementation that met the inclusion criteria were included. The process of random sampling selection is presented in Figure 3.

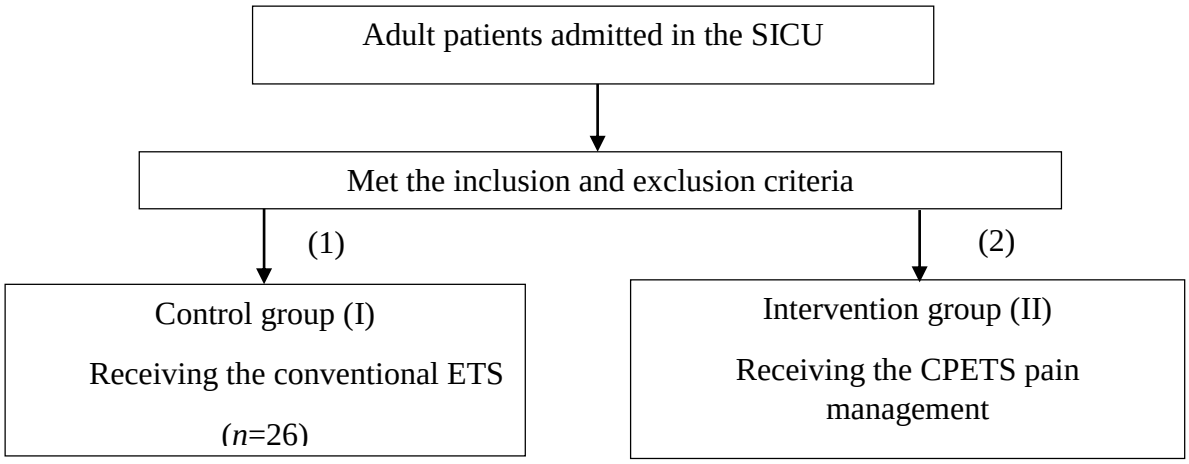


*Figure 3.* The process of sample selection

The quasi-experimental design allowed the researcher to control the assignment to the treatment condition using particular criteria other than random assignment.

The criteria for entering the study included the following: 1) adults over 18 years of age; 2) requiring ETS; 3) consciousness level with a Glasgow Coma Scores (GCSs) of 7 or higher; 4) not deep sedation with high-dose sedatives or tranquilizers during the previous six hours; 5) no severe facial trauma; 6) no neurological damage affecting breathing (such as quadriplegia); 7) no record of mental illness or neuromuscular diseases; 8) communicable and no history and current hearing deficit and cognitive impairments; 9) obtaining written informed consent from the family member of patient. The exclusion criteria consisted of the following: 1) require suctioning at interval shorter than 20 minutes; 2) development of dysrhythmia, and reduced oxygen saturation ($SpO_2$) level by more than 10% during suctioning.

**Sample Size Estimation**

In order to control the accuracy of the experiment or treatment, the strength of the statistical power was required. The statistical power, or the probability of rejecting a false null hypothesis can be affected by the level of significance (α), the magnitude or size of the treatment effect (effect size), and the sample size ($n$). In this study, significance level was set at .05 and the power equal to .80. In this study, the effect size calculation was calculated based on the findings from previous relevant studies conducted by Saadatmand et al. (2015) entitled, “The effects of natural sounds on pain: a randomized controlled trial with patients receiving mechanical ventilation support” and Shamali et al. (2016) entitled, “Effect of minimally invasive ETS on

suction-related pain, airway clearance and airway trauma in intubated patients: a randomized controlled trial". Currently, the average of patients admitted in SICU of this hospital setting is between 130 to 240 patients per month. Here, a-priori sample size calculation was employed to estimate the sample size for this study.

According to Cohen (1992), the a-priori sample size calculation is the estimation of the sample size required to achieve the set alpha value and desired power as well as the estimated effect size done by the researcher while planning the research. According to Wood, Kerr, and Ross-Kerr (2010), the sample size for a study should be as large as possible to reduce the chances of type II error with consideration to practicality. Using the a-priori sample size calculation, according to Polit and Beck (2014), the minimum sample size was calculated for an effect size of weighted averaging .70 with the power was set at .80 and the level of significance at .05. Totally, fifty-two participants were required in the experimental and the control groups (see Appendix C).

The first 26 adult participants receiving ETS who met the inclusion criteria were assigned into the control group and the data were completely collected first in this group. Then the next 26 adult participants receiving ETS and who met the inclusion criteria were further assigned into the experimental group to prevent and minimize contamination of the causal effect of the intervention.

## Research Instruments

The following instruments were used in this research study: 1) intervention instrument; 2) data collection instruments.

**Part I: Intervention Instrument**

The intervention instrument was the CPETS pain management in adults (see Appendix B). It was a set of nursing interventions as well as a combination of evidence-based interventions carried out using a multidisciplinary approach to manage ETS-related pain developed by the researcher. The CPETS pain management in adults in this study was developed using the steps in developing a CP. This CPETS pain management in adults was based on sequentially time lined evidence and recommendations of interventions or care constructed from the cutting-edge evidence to manage ETS-related pain in order to achieve the outcomes. The detailed of the CP development was presented in Appendix A (see Appendix A). The CP consisted of three phases starting from before the ETS, during until after ETS as follows.

The usual care of ETS in the setting is allocated based on the ETS protocol proposed and revised by the Second Affiliated Hospital of Kunming Medical University in 2012. This protocol aims to prevent hypoxia, infection and atelectasis due to the retention of sputum among mechanically-ventilated patients. Accordingly, the nursing department allocates a special in-service training on the open tracheal suction system for all ICU nurses in this setting with a focused on safety suctioning.

The data derived from personal interviews with the SICU staff nurses revealed ETS praxis has been performed regardless to pain. Further, ETS pain management is sometimes initiated just in case that patient presents restlessness or noncompliance during the ETS or family members' complaint and request pain management during suctioning. The notification of medical doctor to prescribe extra dose analgesia is also varies depended on the attending nurses and medical doctors. Aftermath, in case that nurses made decision to give extra dose analgesia; they usually administer analgesics

after the completion of suctioning. Moreover, some nurses assessed pain prior to suctioning and if the pain score below Prince Henry Hospital Pain Scale (PHPS) 2, they usually interpret as no pain management needed during suctioning.

Noticed with respect, the usual ETS praxis data derived from the researcher first-hand experience while working in this area in combination with data gathered from the comparison group revealed the current ETS praxis might worsen pain-related ETS procedure. For instance, common criteria for suctioning used in this setting are visible, palpable or audible secretions and coughing, including high pressure ventilator alarm. Further, there was no evidence exist in relation to preparedness patient prior suctioning as such information given towards the need for suctioning or the consequences of not suctioning, detailed procedure, pain-related ETS and management.

Moreover, pre-oxygenation (100%) was evidenced to provide to every patient prior and during suctioning. However, the pre-emptive analgesia and non-pharmacological pain management before the beginning of ETS have not been noticed in this setting. Notably, equipment and techniques used during the ETS praxis prose to certain question of worsen pain. For instances, the size of suction catheter, level of vacuum pressure applied, the depth of catheter insertion, the duration of ETS, including psychological support provided. In regard to pain management after the completion of the ETS, as aforementioned earlier, this is performed inconsistently relied on the attending nurses and medical doctors.

**Part II: Data Collection Instruments**

The data were collected using the following instruments: 1) the demographic and clinical characteristics questionnaire; 2) documentation form for ETS pain management outcomes.

**Demographic and Clinical Characteristics Questionnaire.** The demographic and clinical characteristics information were developed by the researcher based on literature reviews to collect demographic and clinical characteristics data. This questionnaire composed of 22 questions including demographic information, pain-related information, details of ETS and mechanical ventilation information, health-related information, and the information related to prescription. The demographic data of the participants consisted of six items including age, gender, ethnicity, marital status, educational attainment, and occupation or employment status.

The pain-related information consisted of three items including pain experiences or primary pain, existing pain, history of taking pain medication. Details of ETS and mechanical ventilation information consisted of eight items including history of mechanical ventilation, date and times of intubation, duration of intubation, duration mechanical ventilation, modes of mechanical ventilation, suction tube size, suction system, and suction catheter size (see Appendix D). The information related to prescriptions as well as health-related information were collected from nursing and medical records or medical profiles including body mass index (BMI), surgical procedure, reason for using mechanical ventilation as well as intubated, other medical devices or surgical procedure. The information related to prescription consisted of

current prescription of pain medications, and regular pain medication administration (see Appendix D).

**Documentation Form for ETS Pain Management Outcomes**. In this study, the pain management outcomes were measured according to the concept of pain management outcomes (Turk et al., 2003). Since ETS-related pain is of a short duration in nature and will disappear shortly after the procedure is finished, level of pain presence was selected as the primary pain management outcome to measure in this study. Whereas the secondary pain management outcomes are the outcome measures that are indirectly related to pain (Dworkin et al., 2005). One of the profound impacts of ETS-related pain is agitation (Dastdadeh, Ebadi, & Vahedian-Azimi, 2016; Shamali et al., 2016; Sole et al., 2017). For this reason, the assessment of agitation using the RASS was used as a secondary pain outcome measurement in this study.

This form was developed by the researcher to document the CPETS pain management outcomes. The documentation was divided into three phases (before, during, and after the ETS procedure). Before ETS, the pain management outcomes were: 1) assessment of the existing baseline pain using CPOT; 2) assessment of agitation using RASS. During ETS, the pain management outcomes were: 1) assessment of the existing pain using CPOT; and 2) assessment of agitation using RASS. After ETS, the pain management outcomes were: 1) assessment of the existing pain using CPOT; 2) assessment of agitation using RASS (see Appendix E).

The documentation during ETS based on the literature reviews was developed by the researcher, the number of passes of the suction catheter to maximum of three. The frequency of documentation of the ETS pain management outcomes during

suctioning was calculated based on findings from a previous relevant study conducted by Shamali et al. (2016) entitled, “Effect of minimally invasive ETS on suction-related pain, airway clearance and airway trauma in intubated patients: a randomized controlled trial”. The pain management outcomes (level of pain presence and level of agitation) were assessed and recorded only in the first time of suctioning. The outcomes of the second and third times were also measured and recorded as the additional data. After ETS, the documentation was done in terms of interventions given and evaluation of pain management outcomes. As discussed above, the CPOT and the RASS were used to assess the level of pain presence and level of agitation in this study.

The original CPOT was proposed by Gélinas et al. (2006), and the Chinese-version CPOT that using the back translation skill to translate the original one proposed by Chen et al. (2011). The Chinese-version CPOT was used to assess the level of pain presence for both communicable and non-communicable patients in this study. The CPOT measure with the scores and record the detail in the four items of facial expression, body movements, compliance with the ventilator, muscle tension (see Appendix B). Each item scored from 0 equal to ‘not at all’ to 2 equal to ‘very much’. The item scores are summed to obtain the total score. The total scores ranged from 0 to 8. Here, higher scores represent the higher level of pain presence.

According to Liu, Li and Herr (2015), the Chinese-version CPOT is reliable and valid tool to measure pain in critically ill Chinese adults (intubated and non-intubated). The CPOT were obtained total of 608 assessments. Overall Cronbach’s alpha coefficient the Chinese-version CPOT was .08 and the test-retest reliability was .95 (Liu, Li & Herr 2015). Overall inter-rater of the Chinese version CPOT

between the raters was .97 (Liu, Li & Herr 2015). The Chinese-version CPOT scores were both significantly higher during the painful procedures than those the non-painful procedures, and those at rest before the painful procedures (Liu, Li & Herr 2015).

Likewise, according to Li et al. (2014), the Chinese-version CPOT has good reliability, validity and psychometric properties for pain measurement in critically ill Chinese intubated adult patients. Cronbach's α coefficient assess the internal consistency ranged from .57 to .86, Spearman nonparametric coefficients as a assess for test-retest reliability ranged from .81 to .93, intraclass correlation coefficients assess for inter-rater reliability ranged from .80 to .91(Li et al., 2014).

The original RASS was proposed by Sessler et al. (2002), the Chinese-version RASS that use back translation technique to translate the original one proposed by Yang et al. (2016) was used to assess agitation related ETS in this study (see Appendix B). The Chinese-version RASS measured with the score and recorded the detail of the item of combative, very agitated, restless, alert and calm, drowsy, light sedation, moderate sedation, deep sedation, unarousable (Yang et al., 2011). Score 0 to + 4 equal to 'patient is alert, restless, or agitated', score -1 equal to 'patient awakens with sustained eye opening and eye contact', score -2 equal to 'patient awakens with eye opening and eye contact, but not sustained', score -3 equal to 'patient has any movement in response to voice but no eye contact', score -4 equal to 'patient has any movement to physical stimulation', score -5 equal to 'patient has no response to a stimulation'. Here, higher scores represent more agitation, lower scores represent more sedation. Moreover, according to Yang et al. (2016), RASS has good reliability, validity and psychometric properties for pain assessment in critically ill

Chinese ventilated adult patients. Cronbach's α coefficient as a assess measurement for the internal consistency ranged from .53 to .84; Spearman nonparametric coefficients as a assess measurement for the test-retest reliability ranged from .84 to .92; intraclass correlation coefficients as a assess measurement for inter-rater reliability ranged from .83 to .90; and the (Yang et al., 2016).

## Validity and Reliability of the Instruments

According to LoBiondo-Wood and Haber (2017), prior collecting data, the validity and reliability of the instruments were evaluated and approbated. The validity of the research instrument was recognized as the ability of an instrument to estimate the attributes of a variable. On the other hand, the reliability of a research instrument was recognized as the extent to which an instrument estimate the attributes of a concept precisely.

### Validity of the Instrument

The content validity, which was concerned with the adequacy and suitability of the items of the variables in the instruments, was used to test the validity of the research instruments in this study that included: 1) the clinical characteristics questionnaire; 2) The CPETS pain management in adults, and 3) documentation form for ETS pain management outcomes. Four experts approved the content validity of the instruments (see Appendix F). The experts were consisted of: 1) a specialist pain doctor from department of anesthesiology, Songklanagarind Hospital, Thailand; 2) a pain specialist nurse from Songklanagarind Hospital, Thailand; 3) a specialist pain

doctor from department of anesthesiology, the Second Affiliated Hospital of Kunming Medical University ICU Kunming, Yunnan, China; and 4) a critical care nurse specialist from the Second Affiliated Hospital of Kunming Medical University ICU Kunming, Yunnan, China. Each research instrument was evaluated for the adequacy and suitability with the relevant content. The modification of each research instrument were done thereafter based on the feedback and recommendations from the experts.

According to the validity test of the instruments and the intervention of the CPETS pain management in adults, the scale content validity index (S-CVI) of the clinical characteristics questionnaire was .92, the documentation form for ETS pain management outcomes was 1.00, and the intervention of the clinical pathway for ETS pain management in adults was 1.00.

**Reliability of the Instrument**

The reliability of the instrument refers to the consistency of the measurement of the construct the instrument intends to measure (Polit & Beck, 2014). The inter-rater reliability evaluation is used to determine the consistency of two different raters who classify a specified group of persons using the same measurement occasion (Waltz, Strickland & Lenz, 2010). In this study, inter-rater procedures used to determine the consistency of the two different raters establish whether the research assistant (RA) in the study had completed the training and had the necessary competency to utilize the ETS pain management outcomes assessment tools (CPOT and RASS). The percent agreement between the RA and the raters was 100%.

### A pilot study

A pilot study is a miniature version or testing conducted before the major research to see the plausibility and feasibility of the study (Polit & Beck, 2014). The primary purpose of a pilot study is to refine the protocol for the full-scale study by shedding light on the strengths, inadequacies, or omissions of the preliminary plan (Polit & Beck, 2014). However, few evidence to guide the researcher to calculate the sample of a pilot study. In this study, the researcher decided the CPETS pain management in adults was tested with 10 participants that had the same inclusion criteria as the research samples. In addition, in this study, the data collection instruments were tested with 10 participants to see the feasibility and appropriateness. The CP and data collection instruments were finally revised based on analysis and feedback derived from the study pilot for appropriateness with the context.

## Data Collection Procedures

The emergent design had resulted in two distinct study phases (see Figure 1). Phase one was the CP development phase in which the information from the literature review of the relevant concepts as well as the cutting-edge evidence was used to develop the CPETS pain management to manage ETS pain in critically ill Chinese adult patients. Phase two, the implementation and evaluation phase, aimed to test whether designing the CPETS pain management could improve the pain management outcomes during and/or after ETS in critically ill Chinese adult patients. The approved model was tested by implementing and evaluating the measurable outcomes in the Second Affiliated Hospital of Kunming Medical University SICU, Yunnan,

China by using a quasi-experimental study. The key stakeholders was engaged to ensure the utility of the CP. The algorithm of this clinical pathway for ETS pain management is presented in Figure 4. In this study, the data collection was conducted in two phases, the preparation phase and the implementation phase. The process of data collection is presented in Figure 5.

**Preparation Phase**

The preparation phase consisted of the following steps: 1) obtained the ethical approval from the Research Ethics Committee of the Faculty of Nursing, Prince of Songkla University (PSU); 2) obtained ethical approval and official permission for data collection from the Medical Research and Ethics Committee (MREC), Ministry of Health, China; 3) prepared all research instruments and documents, including the informed consent form; 4) conducted a pilot study; and 5) recruited the research assistant (RA). In this study, the research assistant (RA) collected the data related to the ETS pain management outcomes (level of pain presence and agitation) and provided psychological support. The RA is a nurse who holds a Bachelor Degree in Nursing, currently works in the SICU of the hospital where the study was conducted, and has 20 years of experience. There were three steps in the training of the RA. First, the researcher clarified the objective, protocol and tools used in this study. Second, the researcher explained clarification about the roles and responsibilities of the RA. Lastly, the researcher and the RA reviewed the

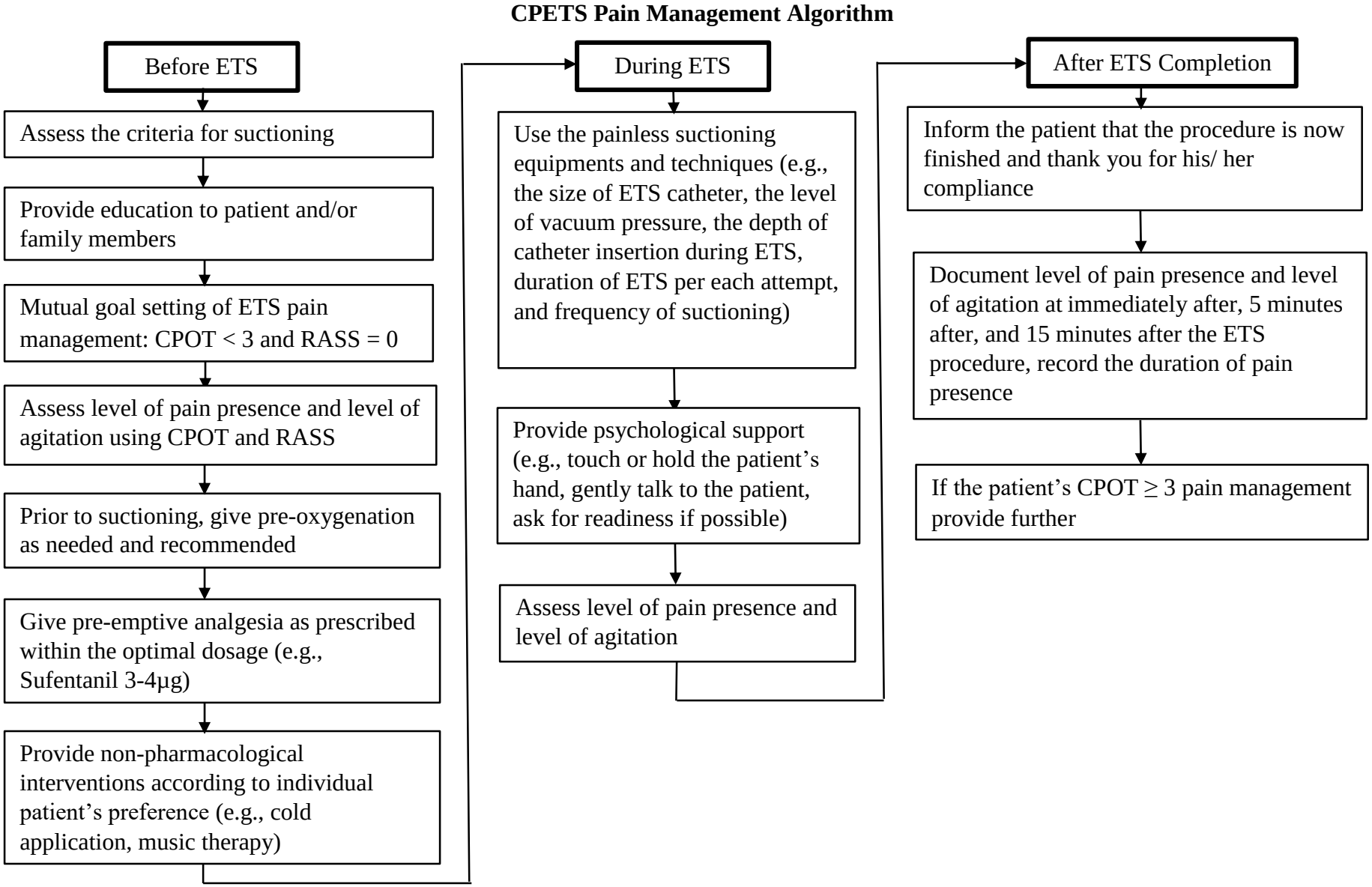


*Figure 4.* Algorithm of CPETS pain management procedure

questionnaire and the documentation form. The RA was encouraged to ask about anything she did not understand and/or if she required further detail or explanation, and the researcher ensured everything was made clear to the RA's satisfaction during this process in order to ensure that she was able to answer any question during data collection. This training process took about 5 hours.

In this study, the researcher implemented the intervention and collected the demographics and clinical characteristics questionnaire. The RA collected the data about pain management outcomes (level of pain presence using the CPOT and agitation using the RASS) and was not informed about the group allocation of each participant.

**Implementation Phase**

The implementation phase included the recruitment process of the samples and the sequential steps in implementing the CP and collecting data.

**The recruitment processes.**

1. The researcher established a good relationship with the staff at the SICU of the hospital setting and explained the purpose of the access to the unit.

2. The SICU staff individually approached the patient with endotracheal tube and the family members admitted during collecting data and asked for permission for the researcher to approach and to inform about this study.

3. After getting permission from the family members of the patients, the researcher together with the attending SICU staff assessed for eligible.

4. The researcher informed family member as well as the patient using inform consent form (see Appendix I) including well and definitely explained the aim of the

study, potential risks and harm, and gave time for them to ask any questions. In addition, the family members of the participant were informed to assess the normal facial expression before ETS.

5. The research left from the participants and family members about 30 minutes or whenever they ready to make freely decision to participate in the study and if they agree or willing to participate in the study the researcher asked family member of the participants to sign in an informed consent release form.

**Process of data collection.**

1. After the family member of participants agreed and willing to join the study and give the written consent in the informed consent form, the researcher began to collect data using the demographics and clinical characteristics questionnaire for both the control and experimental groups.

2. The control group received the usual ETS care by the SICU nurses. While the researcher initiated the ETS pain management to the experimental group as detailed in the CPETS pain management in adults.

3. The pain management outcomes were measured in both groups at the same specific point of time by RA, using the pain management outcomes documentation form (see Appendix E).

## Ethical Considerations

The ethical considerations in nursing research and ethical principles, which include beneficence, non-maleficence, respect for human dignity, justice, and informed consent were used to underpin every process in this study (Polit & Beck,

2012). The researcher got permission for data collection from the Research Ethics Committee of the Faculty of Nursing, Prince of Songkla University, Thailand (see Appendix G), and from the Medical Research and Ethics Committee (MREC), Ministry of Health, China prior collecting data (see Appendix H).

The researcher explained to the patients and their family members that they have the right to participate or not to participate. Moreover, the researcher gave information about their right to withdraw at any time during the study without any negative consequences or penalty. The researcher explained the purpose of the study, procedures, potential risks and the benefits of the study. Very well consent was informed to patient and family member and written inform consent was gained from the family member (see Appendix I). For the participants in the experimental group, the researcher explained to them and their family members the procedures of the CPETS pain management. All of the information from the participants and the identity of the participants were kept confidential. The researcher used a coding system to identify the participants to maintain anonymity. As the ETS-related pain happened during suctioning, in order to assess the area in body movement of the CPOT, the participants did not use the wrist restrains during this study. To avoid the risk (e.g., self-extubation) of the participants' protection and agitation, the researcher provided the participants education about the consequence of self-extubation, well explained this risk to the primary physician, primary nurse, and family members. During ETS, the primary nurse was bedside to monitor and was sure the participant's safety. During data collection procedure, no unplanned extubation event happened.

## Data Analysis

The data was analysed with computer software called IBM statistical package for social sciences (SPSS) version 22. The researcher used descriptive and Mann-Whitney U test to analyse the data to answer the research questions and to test the research hypothesis. For the descriptive statistics, frequencies, percentage, mean and standard deviation were used to depict and evaluate demographic and clinical characteristics in the both groups. Likelihood test, Independent t-test, and Pearson Chi-Square test were used to identify the significant difference of demographic and clinical characteristics of the participants between the experimental and the control groups.

For inferential statistics, the assumption of ANOVA (e.g., normality, homogeneity) of variance were examined before the adequate statistical analysis enforced. Using skewness and kurtosis value tested the assumption of the normality, while the Levene's test tested the homogeneity of variance. The assumption test result analysis showed that the data sets were not met, and there were significance score from the Levene's test ($p < .05$), that demonstrated that the outcomes variables assumption test in both groups were not met (see Appendix J). Then, the Mann-Whitney U test was used to evaluate the median differences of level of pain scores and agitation scores between receiving the CPETS pain management group and receiving the usual ETS care group.

# CHAPTER 4

# RESULTS AND DISCUSSION

This chapter presents and discusses the findings of the present study. The results are divided into two parts: 1) the demographic and clinical characteristics of the study participants, 2) level of pain presence and agitation in critically ill Chinese adult patients who received the CPETS pain management compared with those received usual ETS. The discussions of research findings are drawn thereafter to highlight, interpret, and justify the significant findings focused on the study hypothesis.

## Results

### The demographic and clinical characteristics of the study participants

A total of 52 critically ill Chinese adult patients, who were admitted from January through March 2018 and met the inclusion criteria were enrolled in this study. The first 26 participants and the following 26 participants were assigned into the control group and experimental group, respectively. In order to avoid selection bias, the significance testing of the baseline differences between the two groups was conducted in terms of demographic characteristics. The demographic characteristics of the study participants in both groups were compared regarding age, gender, ethnicity, marital status, educational attainment, and employment status using frequencies, percentages, mean, and standard deviation.

As shown in Table 2, there were no significant differences between the groups in terms of demographic characteristics ($p > .05$). There were 10 men (38.5%) and 16 women (61.5%) enrolled into each group. The age of the participants ranged between 41 and 78 years, the mean age was 61.35 (*SD*=11.42) and 61.38 years (*SD*=11.37) in the experimental and control group, respectively. All participants in this study were Han Chinese ethnicity. The majority of the participants in the experimental (73.1%) and control groups (88.5%) were married. Among the participants, the educational attainment of the majority was junior middle school (experimental group 34.6%, control group 38.5%). More than half of the participants in the experimental group was agriculturists (57.7%), meanwhile in the control group, the majority of the participants was agriculturists (38.5%) and retired (34.6%). Table 2 displays the demographic characteristics of the study participants.

Table 2

*Demographic Characteristics of the Study Participants in the Control and Intervention Groups (N = 52)*

| Characteristics | Intervention group (*n* = 26) | | Control group (*n* = 26) | | Statistic value | *P* value |
|---|---|---|---|---|---|---|
| | n | % | n | % | | |
| Age (Min-Max= 41-78) | *M*=61.35 | *SD*=11.42 | *M*=61.38 | *SD*=11.37 | .01[t] | .98 |
| Gender | | | | | .00[a] | 1.00 |
| Male | 10 | 38.5 | 10 | 38.5 | | |
| Female | 16 | 61.5 | 16 | 61.5 | | |
| Ethnicity | | | | | | |
| Han Chinese | 26 | 100.0 | 26 | 100.0 | | |
| Marital status | | | | | 2.03[b] | .16 |
| Married | 19 | 73.1 | 23 | 88.5 | | |
| Widowed | 7 | 26.9 | 3 | 11.5 | | |
| Educational attainment (age) | | | | | 2.00[b] | .74 |
| Primary school (6-12) | 8 | 30.8 | 6 | 23.1 | | |
| Junior middle school (12-14) | 9 | 34.6 | 10 | 38.5 | | |
| Senior high school (14-18) | 6 | 23.1 | 4 | 15.4 | | |
| Non-degree zhuanke (17-21) | 1 | 3.8 | 3 | 11.5 | | |
| Bachelor degree (17-23) | 2 | 7.7 | 3 | 11.5 | | |
| Occupation or employment status | | | | | 2.01[b] | .56 |
| Self-employee | 4 | 15.4 | 5 | 19.2 | | |
| Public employee | 1 | 3.8 | 2 | 7.7 | | |
| Agriculturist | 15 | 57.7 | 10 | 38.5 | | |
| Retired | 6 | 23.1 | 9 | 34.6 | | |

*Note: M* = Mean, *SD* = Standard Deviation, [a] = Chi-Square, [b] = Likelihood Ratio, [t] = Independent *t*-test

As shown in Table 3, there were no significant differences between the groups in terms of clinical characteristics ($p > .05$). All of the participants were admitted to the SICU immediately after surgery, the predominant GCSs was 10T. The most common surgical procedures for the experimental and control groups were partial hepatectomy (30.8% and 26.9%) followed by cholecystectomy (34.6% and 23.1%). The majority of the participants' average BMI was 18.5-24.9 kg/m$^2$ in both groups (73.1% in the experimental group and 80.8% in the control group). None of the

participants had previous pain experience, but all of them experienced intense postoperative incisional pain intensity (100%). The most commonly used invasive procedures for both groups were the central venous line and the arterial line (experimental 92.3%, control 96.2%).

More than half of the participants in both groups received mechanical ventilation in the Synchronized Intermittent Mechanical Ventilation (SIMV) and the Continuous Positive Airway Pressure (CPAP) mode with 2-4 hours duration (experimental 53.9%, control 57.8%). An endotracheal tube size of 7.0 with 8-12 hours length of intubation were employed in more than half of the participants in both groups (intervention 53.9%, control 65.4%). An OSS with a suction catheter French sizing (Fr) of 14 was used for all of the participants in both groups (100%). The majority of the participants received prescriptions for Sufentanil and Dexmedetomidine with equivalents doses and continuous infusion modes of administration for 3-4 days (intervention 53.9%, control 80.8%). Table 3 shows the clinical characteristics of the study participants that might have an impact on the effectiveness of the intervention.

Table 3

*Clinical Characteristics of the Study Participants in the Control and Intervention Groups*
*(N = 52)*

| Characteristics | Intervention group (n = 26) | | Control group (n = 26) | | Statistic value | *P* value |
|---|---|---|---|---|---|---|
| | n | % | n | % | | |
| Surgical procedure | | | | | 3.58[b] | .83 |
| Partial hepatectomy | 8 | 30.8 | 7 | 26.9 | | |
| Cholecystectomy | 9 | 34.6 | 6 | 23.1 | | |
| Choledochoscopy | 3 | 23.1 | 5 | 23.1 | | |
| Pancreaticoduodenectomy | 2 | 23.1 | 4 | 19.2 | | |
| Colectomy | 1 | 3.8 | 2 | 7.7 | | |
| Rectectomy | 1 | 3.8 | 1 | 3.8 | | |
| Splenectomy | 1 | 3.8 | 1 | 3.8 | | |
| Excision of abdominal mass | 1 | 3.8 | - | - | | |
| BMI (kg/m$^2$) | (*M* = 21.93, *SD* = 3.22) | | (*M* = 21.69, *SD* = 3.07) | | .28[t] | .78 |
| Underweight (<18.5) | 1 | 7.7 | 2 | 7.7 | | |
| Normal weight (18.5–24.9) | 19 | 73.1 | 21 | 80.8 | | |
| Overweight (25–29.9) | 5 | 19.2 | 2 | 7.7 | | |
| Obesity (≥ 30) | - | - | 1 | 3.8 | | |
| GCSs | | | | | .00[t] | 1.00 |
| 9T | 1 | 3.8 | 1 | 3.8 | | |
| 10T | 25 | 96.2 | 25 | 96.2 | | |
| Previous pain experiences or primary pain | | | | | .00[t] | 1.00 |
| No | 26 | 100.0 | 26 | 100.0 | | |
| Existing pain | | | | | .00[t] | 1.00 |
| Postoperative incisional pain | 26 | 100.0 | 26 | 100.0 | | |
| Duration of intubation (hours) | | | | | 1.15[t] | .26 |
| < 8 | 8 | 30.8 | 7 | 26.9 | | |
| 8 - 12 | 14 | 53.9 | 17 | 65.4 | | |
| 13 - 24 | 1 | 3.8 | - | - | | |
| 25 - 48 | - | - | - | - | | |
| 49 - 72 | - | - | - | - | | |
| > 72 | 3 | 11.5 | 2 | 7.7 | | |

*Note: M* = Mean, *SD* = Standard Deviation, BMI = body mass index,
GCS = Glasgow Coma Scores, [b] = Likelihood Ratio, [t] = Independent *t*-test

Table 3 (Cont'd)

*Clinical Characteristics of the Study Participants in the Control and Intervention Groups (N = 52)*

| Characteristics | Intervention group (n = 26) | | Control group (n = 26) | | Statistic value | *P* value |
|---|---|---|---|---|---|---|
| | n | % | n | % | | |
| Duration of mechanical ventilation (hours) | | | | | 1.14[t] | .26 |
| 2 - 4 | 14 | 53.9 | 15 | 57.8 | | |
| 5 - 8 | 9 | 34.6 | 8 | 30.8 | | |
| 9-24 | - | - | 1 | 3.8 | | |
| 25-48 | - | - | - | - | | |
| 49-72 | 1 | 3.8 | 1 | 3.8 | | |
| > 72 | 2 | 7.7 | 1 | 3.8 | | |
| Modes of mechanical ventilation | | | | | 3.66[b] | .16 |
| SIMV + CPAP | 21 | 80.8 | 24 | 92.3 | | |
| CPAP | 4 | 96.2 | 2 | 100.0 | | |
| BiPAP | 1 | 3.8 | - | - | | |
| Endotracheal tube size | | | | | .00[t] | 1.00 |
| 7.0 | 16 | 61.5 | 16 | 61.5 | | |
| 7.5 | 10 | 38.5 | 10 | 38.5 | | |
| Suction system | | | | | .00[t] | 1.00 |
| Open suction system | 26 | 100.0 | 26 | 100.0 | | |
| Suction tube catheter size (French) | | | | | .00[t] | 1.00 |
| 14 | 26 | 100.0 | 26 | 100.0 | | |
| Other invasive medical devices | | | | | 1.73[b] | .42 |
| Central venous line | 2 | 7.7 | 1 | 3.8 | | |
| Central venous line + Arterial line | 24 | 92.3 | 25 | 96.2 | | |
| Current analgesic prescription medication | | | | | | |
| Sufentanil continuous intravenous infusion 4-6µg per hour | | | | | 1.41[b] | .005 |
| | 7 | 26.9 | 3 | 11.5 | | |
| Sufentanil continuous intravenous infusion 4-6µg per hour +1% Propofol continuous intravenous infusion 2-6 mg per hour | | | | | 1.21[b] | .014 |
| | 5 | 19.2 | 2 | 7.7 | | |
| Sufentanil continuous intravenous infusion 4-6µg per hour +Dexmedetomidine continuous intravenous infusion 8-24 µg per hour | | | | | -2.12[b] | .000 |
| | 14 | 53.9 | 21 | 80.8 | | |

*Note:* BiPAP = Bilevel Positive Airway Pressure, CPAP = Continuous Positive Airway Pressure, SIMV = Synchronized Intermittent Mechanical Ventilation.
[b] = Likelihood Ratio, [t] = Independent *t*-test

**The effects of CPETS pain management on pain presence and agitation in SICU Chinese adults**

The hypothesis of this study was that SICU Chinese adults who receive the CPETS pain management have lower level of pain presence and agitation than those who did not receive such intervention. In this study, level of pain presence and agitation were measured using the CPOT and the RASS, respectively. In order to evaluate the effects of a new CPETS pain management compared to the usual ETS care, analyzing differences between groups was tested to determine the between-group effects on level of pain presence and agitation.

Table 4

*Comparison of Pain Presence (CPOT Scores) Between the Usual Care Group and the Intervention Group (N = 52)*

| CPOT scores | n | Median (0-8) | Interquartile Range (IQR) | Mean Rank | Min - Max | Mann-Whitney U Test | |
|---|---|---|---|---|---|---|---|
| | | | | | | z | *P* |
| Before ETS | | | | | | .00 | 1.000 |
| Intervention group | 26 | 0 | - | 26.50 | 0 | | |
| Usual care group | 26 | 0 | - | 26.50 | 0 | | |
| During ETS, the first time | | | | | | -5.97 | .000 |
| Intervention group | 26 | 2 | 1 | 14.31 | 1-3 | | |
| Usual care group | 26 | 4 | 1 | 38.69 | 3-6 | | |
| Immediately after ETS | | | | | | -5.94 | .000 |
| Intervention group | 26 | 0 | 0 | 14.98 | 0-1 | | |
| Usual care group | 26 | 1 | 1 | 38.02 | 0-3 | | |
| 5 minutes after ETS | | | | | | -2.06 | .039 |
| Intervention group | 26 | 0 | - | 24.50 | 0 | | |
| Usual care group | 26 | 0 | 0 | 28.50 | 0-2 | | |
| 15 minutes after ETS | | | | | | .00 | 1.000 |
| Intervention group | 26 | 0 | - | 26.50 | 0 | | |
| Usual care group | 26 | 0 | 0 | 26.50 | 0 | | |

As seen from Table 4, the CPOT scores were similar before suctioning in both groups. During suctioning, the median of the CPOT scores increased to 4 (*IQR*= 1) and 2 (*IQR*= 1) in the usual and the CPETS pain management groups, respectively ($z = -5.97$, $p < .05$). Immediately after ETS, the median of the CPOT scores decreased to 1 (*IQR*= 1) and 0 (*IQR*= 0) in the usual and the CPETS pain management groups, respectively ($z = -5.94$, $p < .05$). The CPOT scores decreased to 0 (*IQR*= 0) and 0 at 5 minutes after the ETS in the usual and the CPETS pain management groups, respectively ($z = -2.06$, $p < .05$). The CPOT scores were also similar at 15 minutes after the ETS procedure in both groups.

The CPOT scores revealed a significant difference during ($z = -5.97$, $p < .05$), immediately after ($z = -5.94$, $p < .05$), and 5 minutes after ($z = -2.06$, $p < .05$) the ETS procedure between the usual and the CPETS pain management groups. There was no statistically significant difference in the CPOT scores before and 15 minutes after the ETS procedure ($z = .00$, $p > .05$).

Table 4 displays the level of agitation (RASS scores) over different time measurements in the usual group compared with the CPETS pain management group.

Table 5

*Comparison of Agitation (RASS scores) Between the Usual Care Group and the Intervention Group (N = 52)*

| RASS scores | n | Median (0 - +4) | Interquartile Range (IQR) | Mean Rank | Min - Max | Mann-Whitney U Test | |
|---|---|---|---|---|---|---|---|
| | | | | | | z | *P* |
| Before ETS | | | | | | .00 | 1.000 |
| Intervention group | 26 | 0 | - | 26.50 | 0 | | |
| Usual care group | 26 | 0 | - | 26.50 | 0 | | |
| During ETS, the first time | | | | | | -3.05 | .002 |
| Intervention group | 26 | 1 | 1 | 22.50 | 0-1 | | |
| Usual care group | 26 | 1 | - | 30.50 | 1 | | |
| Immediately after ETS | | | | | | -3.91 | .000 |
| Intervention group | 26 | 0 | - | 20.50 | 0 | | |
| Usual care group | 26 | 0 | 1 | 32.50 | 0-1 | | |
| 5 minutes after ETS | | | | | | .00 | 1.000 |
| Intervention group | 26 | 0 | - | 26.50 | 0 | | |
| Usual care group | 26 | 0 | - | 26.50 | 0 | | |
| 15 minutes after ETS | | | | | | .00 | 1.000 |
| Intervention group | 26 | 0 | - | 26.50 | 0 | | |
| Usual care group | 26 | 0 | - | 26.50 | 0 | | |

As seen from Table 5, RASS scores were similar before suctioning in both groups. During suctioning, the median of the RASS scores increased to 1 and 1 (*IQR*= 1) in the usual and the CPETS pain management groups, respectively ($z = -3.05$, $p < .05$). Immediately after ETS, the median of the RASS scores decreased to 0 (*IQR*= 1) and 0 in the usual and the CPETS pain management groups, respectively ($z = -3.91$, $p < .05$). The RASS scores were also similar at 5 minutes and 15 minutes after the ETS procedure in both groups.

The RASS score analysis revealed a significant difference during ($z = -3.05$, $p < .05$) and immediately after ($z = -3.91$, $p < .05$) the ETS procedure in the usual and the CPETS pain management groups. There was no statistically significant difference,

however, in the level of agitation or RASS scores before, 5 minutes after, and 15 minutes after the ETS procedure ($z = .00$, $p > .05$).

The study results are consistent with the hypothesis of this study that critically ill Chinese adult patients who received the CPETS pain management exhibited a lower level of pain presence and agitation compared with those in the usual ETS care group.

## Discussion

This study implemented and evaluated the effectiveness of the CPETS pain management on the level of pain presence and agitation in critically ill Chinese adult patients compared with the usual ETS pain management. The study results indicated that the CPETS pain management significantly lower level of pain presence ($p < .05$) and agitation ($p < .05$) in critically ill Chinese adult patients from during suctioning to 15 minutes after suctioning. The study finding of insignificant differences in the demographic and clinical characteristics of the study participants in both groups infer the effectiveness of the CPETS pain management with no between-group effects ($p > .05$).

The majority of the study participants were between 41 and 78 years of age with the average age of over 60 years. This result is consistent with age of participants reveled in previous studies conducted in Chinese ICUs (Du et al., 2013; Ye et al., 2017; Li et al., 2014; Liu, Li, & Herr, 2015; Liu, Lyu, Zhao, & An, 2017) and global reports (Vincent et al., 2014). A popular explanation is that the number of elderly patients currently admitted to ICUs has been increasing due to the rapidly increasing

aging population in China (Du et al., 2013). Older adults are susceptible to develop health conditions and ICUs are witnessing an increase in the amount of care offered to older patients as a result of comorbidities (Kim et al., 2016; Kirksey et al., 2015).

In consistent with global trends, elder adults account for the high proportion of the ICU admissions in Chinese ICUs, a number of issues regarding elderly and pain assessment and treatment in ICU should be taken and paid into clinical attention and considerations but not stigmatization, in particular pain experience and pain beliefs. Importantly, nurses should explore his/ or her own personal perception, believes, values, prejudices, or biases towards pain in elder adults to avoid developing influence on pain assessment and pain management praxis. Till date, there is till lack of high quality evidence to support that older adults experience less pain than younger, even though they may have a marginally higher pain threshold. Moreover, some literature suggests that although pressure-pain thresholds decrease with age, there is no current published evidence supported that old reduces the sensation of pain (Botwinick, 2013; Sigakis & Bittner, 2015).

Furthermore, older people may show increased stoicism or reluctant to report pain and express pain as well as fear of analgesics side effects. However, pain is actually not a natural consequence of aging. Elderly patients may have a more rapid response to them and may require lower dosing of opioid analgesics. Another addition point to concern, elderly people may development of analgesic retention and side effects from impaired of renal and/ or hepatic function resulted from physical deterioration with advanced age. This is however, varies depended on individual (Botwinick, 2013; Sigakis & Bittner, 2015).

With regard to pain, the literature revealed most of older adults have chronic conditions with chronic pain experience, which can exacerbate in acute conditions. An increase in fat mass, a decrease in muscle mass, diminished renal and liver function, and a decrease in the cerebral vascular flow in the older adults can also affect pain perception and response to analgesics (Kirksey et al., 2015). Contrary to this findings, none of the study participants recalled any previous pain experience and every participant had normal liver function. Meanwhile the association of gender differences with pain remains inconclusive (Al Sutari et al., 2017; Racine et al., 2012; Zheng et al., 2017). A study of pain among mechanically-ventilated patients in critical care units revealed that older patients tend to have less pain than younger ones during routine nursing interventions (Al Sutari et al., 2014). Another study revealed that a greater pain intensity was significantly associated with obesity (BMI $\geq$ 30 kg/m$^2$) in older women (Eslami et al., 2017).

Since of all of the participants in this study were of Han Chinese ancestry, the influence of ethnic differences on pain and pain management was very limited. Cultural backgrounds affect disparities in pain perception, expression of pain, and responses to pain treatment such as the metabolism and the effectiveness of morphine (Campbell1, & Edwards, 2012). For instance, Caucasian patients report lower pain intensity during procedures than non-white patients (Walsh et al., 2010). Other studies have revealed that Chinese patients require less opioids, experience greater pain intensity (Konstantatos et al., 2012), and reported higher pain intensity than do white patients (Hsieh, Tripp, Ji, & Sullivan, 2010) .

The results revealed that every participant majority had undergone surgery and experienced acute post-surgical pain. The majority of them had moderate pain during

the ETS procedure after surgery. Postoperative pain intensity also varies with types of surgery (Pinto, McIntyre, Araújo-Soares, Costa, & Almeida, 2015). However, the study participants in both groups of this study were similar in terms of types of surgery. The existing postoperative pain worsened or increased during ETS as a result of muscle contraction around the surgical site area (Majeed, 2017).

The study participants in both groups were intubated because they had undergone surgery. They experienced a similar duration of intubation and mechanical ventilation received between 8 and 12 hours, and 2 and 4 hours, respectively. The neuroendocrine responses of the human body after tracheal intubation can cause tissue injury and induce sore throat pain (Puyo et al., 2017). The longer the duration of tracheal intubation or mechanical ventilation and coupled with the tracheal tube size and cuff pressure increase endotracheal tube-induced sore throat pain (El-Boghdadly, Bailey, & Wiles, 2016; Georgiou, Hadjibalassi, Lambrinou, Andreou, & Papathanassoglou, 2015) and worsen pain during ETS.

All of the study participants in both groups received an OSS during the short-term endotracheal intubation after surgery. Currently, open versus closed endotracheal suction tube systems has not been proved from previous studies on effect on the level of pain intensity and agitation of patients (Mohammadpour, Amini, Shakeri, & Mirzaei, 2015; Dastdadeh et al., 2016). In line with previous studies, the majority of the this study's participants received central venous and artery catheterization for continuous ICU monitoring purposes, which constitute a significant pain source in ICU patients (Kotfis, Zegan-Barańska, Szydłowski, Żukowski, & Ely, 2017).

Most of the study participants had received the same regimen of analgesic and sedative combination aiming to achieve a target sedation level of RASS score of 0

regardless of the optimal pain level. An analgesic-based sedation protocol was used to decrease the doses of sedatives in order to reduce the occurrence of delirium in mechanically-ventilated patients (Liu, Lyu, Zhao, & An, 2017). A similar pattern of analgesic and sedative regimen was reported by a national multicenter survey from China concerning the management of pain, agitation, and delirium in ICUs (Wang et al., 2017). Accordingly, the first choices of medication for analgesic, sedation, and delirium treatment in ICUs in China are fentanyl, midazolam, and dexmedetomidine (Wang et al., 2017). Similarly, intravenous administration is preferred because of the altered GI tract function in critically ill patients (Nesek Adam et al., 2015). This was particularly the case after abdominal surgery in this study.

The Chinese expert consensus on enhancing recovery after hepatectomy, the most common surgical procedure conducted in this study, which recommends to use of prophylactic and multimodal analgesia to reduce the postoperative pain severity and the dosage of opioids used (Jia, Liu, & Qiao, 2018). Since opioids were commonly used in this study setting, this may raise concerns about the adverse reactions of opioids in inhibiting intestinal function after surgery and delaying recovery (Jia et al., 2018). Current postoperative pain management methods in the hospital setting, however, can be considered as effective to manage pain in critically ill Chinese adult patients after surgery as indicated by the CPOT and RASS scores in both groups before ETS reaching zero.

The key findings that emerged from this study concerning the level of pain presence and agitation were that they were significantly lower during and immediately after ETS in the CPETS pain management group than in the usual ETS ($p < .05$). From the results and discussion presented above, it can be concluded that

the critically ill Chinese adult patients in both groups were similar in terms of the demographic and clinical characteristics, which may influence the level of pain presence and agitation related to ETS. The study results indicated that the PCETS pain management is effective in reducing the level of pain presence and agitation associated with ETS among intubated critically ill Chinese adult patients.

Previous studies have examined the factors related to pain during tracheal suctioning and tested the effects of music, open and closed endotracheal suction tube systems (Dastdadeh, Ebadi, & Vahedian-Azimi, 2016; Saadatmand et al., 2015; Yaman Aktaş & Karabulut, 2016), minimally invasive suctioning (Shamali et al., 2016), two different suction catheter sizes 12 and 14 (Javadi, Hejr, Zolad, Khalili, & Paymard, 2017), lavender inhalant (Taheri Rezgh Abadi, Mohammadpour, & Sajadi, 2017), and standard suctioning versus routine methods (Keykha et al., 2016) on pain and/or agitation related to ETS. The result have revealed that music therapy and a catheter size of 12 lower pain intensity, while lavender inhalation lowers pain intensity and agitation (Keykha et al., 2016; Dastdadeh et al., 2016; Saadatmand et al., 2015; Shamali et al., 2016; Taheri Rezgh Abadi et al., 2017; Yaman Aktaş & Karabulut, 2016). However, the use of open and closed suction systems has no effect on the level of pain and agitation (Javadi et al., 2017).

The pain associated with tracheal suctioning is still an essential issue in intubated patients. The results of the present study showed that the CPOT scores and RASS scores of the study participants in both groups increased from the baseline score during suctioning and returned to baseline after the procedure, which is consistent with the findings reported by previous studies (Dastdadeh et al., 2016; Shamali et al., 2016). Furthermore, pain related ETS can be reduced by good

preparation and correct suctioning technique (Dastdadeh, Ebadi, & Vaherdian-Azimi, 2016; Yaman Aktaş & Karabulut, 2016).

The usual ETS techniques used in the clinical research setting have focused on secretion clearance, airway patency, oxygenation and ventilation maintenance regardless of pain management comparable to tracheal suctioning practices in other literature (AARC, 2010; Chaseling et al., 2014; Wiegand & AACN, 2011). According to Chaseling et al. (2014), pain in ICU patients is not always considered of an utmost importance as is the severity of the patient's illness. As mentioned earlier, none of the participants in the usual ETS care group received analgesics and non-pharmacological intervention before the ETS procedure.

Some routine interventions are still performed regardless of evidence; for example, delivering pre-oxygenation (100%) to every patient, which can lead to the development of atelectasis in healthy individuals (Chaseling et al., 2014). Some routine ETS practices in the setting of this study might worsen pain. A few of participants in usual care group received exceed necessary level of negative pressure applied, the use of deep suctioning, the employment of one suction catheter size 14 (Fr) in every participant, and manual ventilation with a bag-valve-mask. As discussed by Shamali et al. (2016) all of these usual practices can cause agitation and discomfort for patients.

As aforementioned, the CPETS pain management in this study was developed based on the cutting-edge evidence of procedural pain management and ETS pain management. For this reason, all potential ETS-related pain factors such as induced tear, traumatized or damaged tracheal mucosa or tissue that can contribute to more tracheal suctioning pain were managed in this present study. For instances, an optimal

level of vacuum pressure, depth of suction catheter insertion, number and duration of suctioning on each attempt were controlled in the clinical pathway. Psychological support, immobilization of the endotracheal tube, and ongoing pain assessment were also performed during and after suctioning.

The main differences concerning interventions in the CP compared with the usual ETS protocol were the administration of pre-emptive analgesia and application of non-pharmacological interventions. As seen from the results, a 3-4µg Sufentanil intravenous injection was administered to every participant in the intervention group 5 minutes prior to suctioning in order to reduce the sensitization of the peripheral and central pain pathways during the procedure (Barr et al., 2013; Robleda et al., 2016).

Currently, effective analgesia using multimodal analgesia for effective pain relief and minimal sedation for ICU patients in the absence of recognized sedation required is recommended to increase the communication of patients with staff and relatives and early mobilization (Vincent et al., 2016). However, majority of participants in this research setting was still prescribed with sedative agents.

Surprisingly, although a higher proportion of study participants in the usual care group received an analgesic plus sedative combination (80.8%) than those in the experimental group received (53.9%), the level of pain presence and agitation were significantly lower ($p < .05$) in the intervention group. This result provides evidence for the value and effectiveness with special attention of the pre-emptive analgesia to prevent and/or reduce procedural-related pain.

Non-pharmacological intervention including patient education, use of music therapy or cold application were allocated to participants in the intervention group prior and after suctioning, which supports the notion of its efficacy to obtain an

analgesic effect (Barr et al., 2013; Boitor et al., 2015; Yaman Aktaş & Karabulut, 2016).

The gold standard in pain evaluation is patient self-reporting (Dansie & Turk, 2013). However, it might not always be possible and feasible in a setting such as that of this study to ask patients under sedation to rate their pain during a procedure. The CPOT was used to assess the occurrence of pain in this study. The Chinese-versions of the CPOT have been proven to sensitively discriminate the occurrence of pain and predict pain during a nociceptive procedure in critically ill patients (Cheng, Tsai, Wang, & Tsay, 2018). Pain assessment tool used in this setting as well as widely used in other Chinese surgical intensive care units, is a self-report PHPS regardless non-communicable patients.

The results of the present study suggest that the CPETS pain management provides positive effects in reducing the occurrence of ETS-related pain and agitation with sufficient effectiveness to remove airway secretions. Finally, the key success factor of the CPETS pain management in this study could be acknowledged and valued of utilization evidence-based nursing practice on effective, safe, and efficient patient outcomes.

Nowadays, nurses have proactive attitudes toward evidence-based nursing practice and the ambition to gain more knowledge and learn new techniques. Nevertheless, they still face barriers in utilizing evidence-based nursing in their practice (Melnyk, Fineout-Overholt, Gallagher-Ford, & Kaplan, 2012). The significant progresses made have been certified by the effectiveness of increasing the patients' safety by means of highly developed education and training (Bowie, McKay, McNab, & Wet, 2016). Evidence-based nursing practice accords research evidence

with clinical expertise and stimulates the individualization of care including the patient preferences (Bowie et al., 2016). Therefore, evidence-based nursing practice could benefit the attainment of positive patient outcomes.

# CHAPTER 5

# CONCLUSION AND RECOMMENDATIONS

This chapter presents the summary of the findings, conclusions, recommendations and implications for nursing practice, ongoing nursing education, and nursing research based on the data analyzed in the previous chapter. Some strengths and limitations are also identified and discussed.

## Conclusion

The focus of this study was to determine the efficacy of the CP in managing ETS-related pain, e.g., pain presence and agitation, in critically ill Chinese adults who were intubated for less than 12 hours. The research approach used in this study followed a quasi-experimental with a two-group posttest design. Data collection was conducted at the Second Affiliated Hospital of Kunming Medical University SICU, Yunnan, China from January through March 2018. Fifty-two critically ill Chinese adults participated in this study. The first 26 were sequentially assigned into the control group and the rest into the experimental group. A written consent was obtained from all of the participants' family members prior to the study's commencement.

The demographic and clinical characteristics questionnaire was developed and used to collect the baseline data of the participants. The consistency testing for the S-CVI and the inter-rater reliability of the questionnaire results were: S-CVI= .92 and the percentage of agreement for the RA and the two raters=100%.

The CP for managing ETS-related pain started before the tracheal tube suctioning began, and it was considered finished at 15 minutes following its completion. The CP was developed based on the best evidence available, and it consisted of nursing interventions, analgesia, and patient monitoring throughout the intervention, and it was applied sequentially to the patients. The CPOT and RASS scores were measured as outcomes in both groups at specific time points; before ETS commencement, during the procedure, immediately after, 5 minutes after, and 15 minutes after its completion.

The demographic and clinical characteristics of the participants were analyzed using descriptive statistics. The Mann-Whitney U test was used to investigate the efficacy of the CP on alleviating the level of pain presence and agitation. The demographic and clinical characteristics data were tested to compare the baseline differences, and no significant differences between two groups was detected ($p > .05$). Moreover, no new program affecting the presence of pain and agitation was applied during the implementation of the PCETS.

The results indicated that all of the participants experienced pain during ETS as the level of pain presence increased from a CPOT score of zero before ETS to two in the CP group and four in the usual care group. Overall, the findings demonstrated the efficacy of the ETS pain management CP in significantly reducing the level of pain presence and agitation. The CPOT scores of the CP group were significantly lower during suctioning ($z = -5.97$, $p < .05$), immediately after ($z = -5.94$, $p < .05$), and 5 minutes after ($z = -2.06$, $p < .05$) the ETS. Furthermore, significantly lower RASS scores were also detected in the CP group during ($z = -3.05$, $p < .05$) and immediately after ($z = -3.91$, $p < .05$) the ETS procedure.

The study's findings confirmed that the implementation of this CPETS can decrease pain presence and agitation related to ETS in intubated critically ill adults. The success of the utilization of the CPETS lies in integration of the best available evidence into the evidence-based nursing practice to achieve a standardization of patient care with significant improvements in the quality of care. The evidence derived from this study provides valuable insight into the utilization of this CP to relieve pain presence and agitation related to ETS with the hope of lessening the tracheal suctioning pain felt by critical care patients worldwide.

## Strengths and Limitations of the Study

The strengths and limitations in conducting this study were appraised and proposed based on the advantages and disadvantages of a quasi-experimental study in accordance with the Critical Appraisal-Checklist for Analytical Quasi-experimental Studies (Joanna Briggs Institute, 2016).

### Strengths of the Study

The strengths of this study may be the internal validity of the research instrumentation and the minimization of selection bias concerning extraneous variables. The quality assurance of the clinical pathway development can be a significant factor in controlling the validity of this study. This CP was constructed based on the integration of the best available evidence, and it was approved by the experts as well as clinical specialists of the setting.

The extraneous variables that could potentially influence the findings were considered before the initiating of the CP. No new program that could affect the measurable data outcomes was started during the study period. The patients' baseline demographic and clinical characteristics data were compared between the two groups to ensure the participants were similar and representative of the same population. Moreover, there was no presence of pain reported among the participants in the both groups prior for suctioning (CPOT 0), which reflected adequate postoperative pain management and ensured the outcomes measured in this study were not affected by the presence of pain before the commencement of the intervention.

In addition, selection criteria were employed to decrease selection bias and control the homogeneity of the participants. The measurements of the variables were conducted at the same points of times in both two groups. In this study**,** although participation occurred naturally without any control, the researcher tried to minimize contamination between the two groups by sequentially collecting data. Moreover, the experimental design, data analysis, data interpretation, and report of the findings were objectivity and honesty performed in order to avoid potential biases.

**Limitations of the Study**

While this study was carefully prepared, its objective was attained, and it generated evidence regarding ETS-related pain management in the Chinese critical care context, there were some unavoidable limitations and shortcomings. The lack of random assignment into the intervention group leads to non-equivalent test groups, which can limit the generalizability of the results to a larger population.

Another limitation detected might be the generalization of this study. During data collection, the majority of intubated patients were only admitted at the SICU with a duration of intubation of less than 12 hours. In addition, the participants were selected purposively; thus, those who were not selected might have had different responses in terms of presence of pain and agitation related to suctioning. This might not represent the situation related to ETS pain in other ICU patients with a longer period of or prolonged intubation, and some potential responses by such patients were not included. In addition, since the researcher implemented the CP only during the day shift and the staff nurses still followed the usual ETS practices thereafter, other confounding factors such as discontinuation might have been present.

Certain conflicts arose during data collection. One of them was the principle of human subject protection to minimize harms and risks and maximize benefits, in particular concerning vulnerable populations; however, the researcher did not protect the control group participants. Some common ETS practices applied to the control group such as the depth and size of suction of catheters inserted have been proven from research to damage tissues and worsen pain. The CPOT was used to measure the pain presence outcome in this study, while the gold standard of pain assessment is a self-report. Even though most of the participants in this study were full conscious, self-reporting was not used to measure pain. Moreover, the staff nurses of the setting used the PHPS to assess pain among patients in SICU, which raised concerns regarding the accuracy of the pain assessment document.

# Implications and Recommendations

The findings of this research provide insights for recommendations and implications into nursing education, practice, and research, which can help address the gap founded.

## Nursing Education

The year 2018 has been launched by the International Association for the Study of Pain (IASP) as the global year for excellence in pain education. Adequate provision of evidence-based pain education content in the curricula of nursing education at all levels to ensure quality pain management is the essential mission.

The cultivation of a sound foundation regarding effective pain management should begin with nursing students that later became nurses in order for them to be able to address the pain needs of their patients adequately. Nursing faculties should be knowledgeable about procedural pain management and keep abreast with current best evidence to educate and prepare students well on procedural pain management in clinical settings. Holistic pain management should be clearly incorporated in the core nursing curriculum.

Moreover, continuing education and in-service training programs on painless and safe suctioning based on the best available evidence, including competency in applying non-pharmacological intervention, should be allocated for intensive care nurses. The National Nursing Council should also launch and support programs and career tracks for pain management nurses or clinical nurse specialists in pain.

**Nursing Practice**

The findings of the study provided a practical and applicable intervention for pain relief and agitation reduction related to tracheal suctioning. This calls for institutions to launch and utilize this CPETS across the hospitals nationwide. Nurse executives should facilitate and support staff nurses to promote this evidence-based CP and encourage its sustained utilization. Furthermore, hospitals should use the validated pain-assessment tools in both patients able and unable to self-report based on the best available evidence.

This research has also highlighted the need for critical care nurses to consider not only the airway clearance of the intubated patients, but also the pain associated with ETS. In combination with pre-emptive analgesia, non-pharmacological approaches should be integrated into the routine nursing care for intubated patients in order to relieve procedure-related pain and enhance comfort.

Some usual tracheal suctioning practices that do not benefit and might even harm the patient should heighten the awareness of nurse administrators and the concern of staff nurses regarding the utilization of the best evidence available to inform their practice. For instance, tracheal suctioning should not only be performed as a ward routine. Rather, the clinical condition and requirements of the individual patient should be the guiding force in make these decisions. The usual tracheal suctioning practices should be revised based on the best up-to-date evidence. Current ETS practice could be cultivated from the nurses' own experiences and a culture of tracheal suctioning practice. Here, the challenge remains for nurses as well as nurse executives to move beyond their experiences towards ETS pain management.

**Nursing Research**

This quasi-experimental study was conducted to examine the effect of a CP on the presence of pain and agitation during ETS among critically ill Chinese adult patients. This CP can be effectively used to reduce the level of pain presence and agitation during suctioning.

Its effectiveness was tested in one SICU and the outcomes were only measured at the first attempt of suctioning. For these reasons, this study should be repeated on different ICU patients as well as the subsequent attempts of suctioning in order to measure the generalizability of the CP to the broader population. Since the PHPS was used to assess pain in this setting, future research should take into account the comparison of reliability and correlations between the CPOT and the PHPS in order to predict the behavioral pain rating scale with the aim of obtaining support for the use of the PHPS.

The finding that the majority of those admitted in the ICU are older adults, future research regarding non-pharmacological interventions should focused on traditional non-pharmacological approaches used in the Chinese context. Finally, additional research involving randomized controlled trials is needed in order to increase the generalizability and causality of the results to a larger population.

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# APPENDICES

# APPENDIX A

## The CPETS Pain Management

### Panel Composition

The developers of this CP comprised the researcher (Masters of Nursing student), an assistant professor of nursing with specialty in pain management in critically ill adult patients (advisor), and an expert with specialty in critically ill adult patients (co-advisor).

### Target Audience and Scope

The intent of this CP was the provision of evidence-based nursing interventions for procedural pain in critically ill adult patients who utilize a mechanical ventilator. The target audience were nurses who perform ETS. The management of non-ETS-related pain was out of the scope of this CP.

### The Process of Model CP Development

The pertinent steps of the CP for the development of this CP were:

1. Determine interest and select the CP to develop: The interest and selected CP were the CPETS pain management.

2. Identify patient population that benefits from the CP: The population that benefits from this CP are patients receiving ETS.

3. Educate and obtain support from leadership/clinicians: This CP, as an evidence-based multidisciplinary approach, involved nurses (the researcher and the ward nurses) and medical doctors. Thus, the support of the ward nurses and medical

doctors involved in patient care were solicited and adequate education on both the CP and the roles they play in affecting the CP for patients was provided.

4. Conduct literature review of journals, texts, clinical practice guidelines: This step consisted of reviewing literature, identifying and forming 'expert panels,' drafting a model, engaging in a consulting or approving process, and revising and launching a model. The CP was developed from literature review that complied with the analysis of the existing pain management for patients receiving ETS at the research setting. An extensive review of literature was performed at first. The literature search was undertaken by the researcher to review the most up-to-date and best available evidence from previous studies on current ETS pain management and the effectiveness of various treatment modalities to prevent and manage ETS-related pain. Then the researcher critiqued and synthesized this information for use in the development of the CP. This was limited to English publications, using both electronic and manual methods.

Seven electronic databases were used: 1) The Cochrane Library; 2) National Library of Medicine – Medline Ovid; 3) Cumulative Index of Nursing and Allied Health Literature (CINAHL); 4) Science Direct; 5) Scopus and Scopus journal analyser; 6) ProQuest Nursing and; 7) Allied Health for systematic reviews, evidence-based clinical practice guidelines, fast track or multimodal care, and randomized controlled trials related to postoperative pain management. The fields of focus were patient-related and intervention-related within the search terms of examined or discussed ETS-related pain, tracheal suctioning-related pain, procedural pain, and ETS being reviewed. A manual search was also conducted to find related articles and textbooks on this topic.

5. Evaluate current practices: the researcher evaluated the cutting-edge evidence regarding ETS specifically focusing on practices or techniques.

6. Present findings/data to leadership/clinicians: the model was reviewed for appropriateness by the ‘expert panel’ and improved until consensually approved by the experts.

7. Gain consensus from leadership/clinicians and establish targets for care activities: the approved CP was piloted with patients that have the same characteristics as the participants. Reflection on the CP was done with attending anaesthesiologists, SICU nurses, patients, ‘clinical experts’ and the researcher. Then the CP was revised, and the lists of changes were recorded. Finally, the CP was implemented among patients receiving ETS in the SICU of the Second Affiliated Hospital of Kunming Medical University, Yunnan, China.

**Grading of Evidence and Recommendations**

The researcher used the Joanna and Briggs Institute’s (JBI) grading for evidence and recommendations 2014 and 2016 respectively. Each recommendation received a grade of strength (strong or weak) and a quality of evidence (high, moderate and low). The strength of the recommendation was based on the JBI and it laid out features like the benefits outweigh the harm, cost-effectiveness, and practicability.

# Recommendations

## Procedural Pain Assessment

Pain assessment is the first element of pain management, with comprehensive history taking before procedures as an important part, which provides baseline information about critically ill adult patients and helps to individualise care with respect to the history taken (Czarnecki et al., 2011). Therefore, the following are recommended for procedural pain assessment:

1. Assess procedural pain using an appropriate tool in critically ill adult patients. It is recommended to use valid and reliable tools such as the NRS to assess patients that are able to communicate, and the BPS and the CPOT to assess those who are unable to communicate. Moreover, the CPOT has been tested on both nonverbal and verbal patients, including populations with delirium (strong recommendation, high-quality evidence).
2. Besides, “A Position Statement with Clinical Practice Recommendations” highlighted that procedural pain should be assessed at three phases: before, during, and after procedures (strong recommendation, high-quality evidence).

## Pain Management before the Procedure

1. Collect a detailed medical history comprising pain and intubation experience in order to devise an individually feasible pain management plan through the ability to participate in pain treatment decisions in critically ill adult patients. Develop an individually tailored pain management plan through shared decision-making (strong recommendation, high-quality evidence).

2. Assess any underlying misperceptions about procedural pain and pre-emptive analgesia; for example, the patient might believe that pain before the procedure does not need treatment, that the caregiver will only respond to serious emotions and report descriptions of pain, that pharmacological intervention is always required for procedural pain, or that analgesics use ineluctably leads to addiction (strong recommendation, high-quality evidence).
3. The perception that procedural pain is influenced by an individual's age, gender, genetic makeup, cultural factors, educational level, fear and anxiety, and experience of procedural pain factors (strong recommendation, high-quality evidence).
4. Educate the conscious patient about treatment selections for the management of procedural pain, make a goal regarding procedural pain management during and after procedures (strong recommendation, high-quality evidence).
5. Educate the patient how pain is reported and assessed including the use of appropriate pain assessment tools (strong recommendation, high-quality evidence).
6. Educate the patient regarding risk factors that influence procedural pain assessment and management such as previous experiences with intubation and procedural management, medication allergies and intolerances, cognitive status, comorbidities, preferences for intervention, and outcome of management (strong recommendation, high-quality evidence).
7. Pre-emptive analgesia should be delivered 5-10 minutes before procedures (e.g., 1.5 μg/kg of intravenous fentanyl 5-10 minutes before the procedure for surgical and traumatic patients. In addition, 30 minutes before turning and

CTR, 2.5 mg of intravenous morphine for procedural pain management (strong recommendation, high-quality evidence).

8. Provide patients with some non-pharmacological treatment such as cold application, relaxation techniques, music therapy, and massage (strong recommendation, low-quality evidence).
9. Consider procedural sedation (strong recommendation, high-quality evidence).
10. Assess previous treatments and adverse effects related to them (strong recommendation, low-quality evidence).

**Pain Management during the Procedure**

1. Continue providing patients with alternative non-pharmacological interventions such relaxation techniques, meditation, imagery, thermal measures, positioning, cold application, music therapy, and massage (strong recommendation, high-quality evidence).
2. Provide psychological support such as touch or hold the patient's hand, gently talk to the patient, and ask for readiness if possible (strong recommendation, high-quality evidence).

**Pain Management after the Procedure**

1. Educate the patient and responsible caregiver about the treatment options for the management of procedural pain, and reassess the outcomes regarding pain management (strong recommendation, low-quality evidence).
2. Educate the patient how pain is reported and assessed including the use of pain assessment tools (strong recommendation, low-quality evidence).

3. Assess previous treatments and the adverse effects related to them (strong recommendation, low-quality evidence).
4. For pharmacological treatment, reassess pain presence 5-10 minutes after parenteral drug therapy (strong recommendation, low-quality evidence).
5. Discuss/evaluate the patient's procedural pain experience from the patients' perspectives, including recommendations for future procedures in the medical record (strong recommendation, high-quality evidence).
6. Develop and implement a comfort management plan for after the procedure as the pain resulting from the procedure itself may not subside when the procedure is completed and must be treated appropriately (strong recommendation, high-quality evidence).

**Conclusions**

1. The current evidence regarding procedural pain management provides a basis for the general procedural pain management, which is divided into 3 phases: before, during, and after procedures.
2. The procedural pain management consists of pain assessment, pain management, and patient education.
3. Pharmacological or pre-emptive analgesia as well as non-pharmacological areas play vital roles in procedural pain management.
4. The overall quality of evidence here is high and associated with strong recommendations.

## APPENDIX B

## The Clinical Pathway for Endotracheal Tube Suctioning (CPETS) Pain Management in Adults

**Date……..…Time……..…..** **Code……**

| | Before ETS | During ETS / Start time ……. | After ETS |
|---|---|---|---|
| **Goal** | To prepare ETS pain management | To control and manage the ETS-related pain | To discuss and evaluate the quality of pain management in order to incorporate the management of pain may occur with ETS |
| **Assessment**<br>• Regular assess criteria for suctioning every 2 hours and as needed as follows:<br>□ Visible, palpable or audible secretions<br>□ A saw-tooth pattern on a flow volume loop or expiratory flow time waveform as illustrated on the ventilator graphics<br>□ Sputum culture prescription<br>□ Before endotracheal tube removal/ extubation<br>• The one that might need suctioning, if presence, check the criteria for suctioning as above:<br>□ Before/after oral hygiene<br>□ After turning and/or percussion<br>□ Before tube feeding | | • Use the following suctioning equipments and techniques:<br>□ The size of the suction tube catheter should be less than the half internal diameter of tracheal tube ……<br>□ The level of vacuum pressure should be -80 to -150 mmHg …….. mmHg<br>□ The depth of endotracheal suction catheter insertion<br>□ In patients considered at high risk of adverse events**, trauma to, and stimulation of, the carina | □ Inform patient that the procedure is now finished and thank you for his/her cooperation<br>□ Ask for other help as patient's needs<br>**Document pain management outcomes**<br>Pain assessment<br>□ CPOT<br>Score: Immediately……<br>5 minutes ……...<br>15 minutes ……. |

| | | |
|---|---|---|
| □ Before/after bronchodilation<br>□ Patient ask for suctioning<br>*Respiratory:<br>□ Desaturation ($SpO_2$ < 95% or $SpO_2$ < baseline)<br>□ Rising peak inspiration pressure (PIP > 40 $cmH_2O$)<br>□ High-pressure ventilator alarm<br>□ Decreased tidal volume ($V_T$ decrease > 50mL)<br>□ Increased respiratory rate (> 20 beats/minute)<br>□ Increased coarse breath sounds on auscultation<br>*Cardiovascular:<br>□ Increased heart rate (HR > 100 beats/minute or HR > 20% of baseline)<br>□ Blood pressure (BP > 120/80 mmHg or BP > 20% of baseline)<br>□ Restless/agitated<br>□ Diaphoresis<br>*(*Suctioning criteria should confirm with the respiratory, cardiovascular assess and rely on the baseline of each patient)*<br><br>If a patient present with the suctioning criteria, give education to the patient as follows: | should be minimized to prevent complications.<br>Therefore, the suction catheter should only be inserted down a tracheal tube until it just emerges out of the lumen of the tube, usually, it is the length of the artificial airway plus the adapter.<br>**The patients considered at high risk of adverse events you can see additional details as above:<br>Respiratory:<br>- Decreased in dynamic lung compliance and functional residual capacity which may put patient at risk of acute pulmonary hemorrhage.<br>- Atelectasis which may put patient at risk of acute lung injury/PEEP dependent or high oxygen requirements.<br>- Hypoxia or hypoxemia which may put patient at risk of lack of cough reflex. | □ The duration of ETS-related pain<br>…… minutes<br><br>Agitation assessment<br>□ RASS<br>Score: Immediately……<br>5 minutes ……..<br>15 minutes …….<br><br>If patient's CPOT ≥ 3 after suctioning, need further pain management as prescription as notify medical doctor to prescribe additional pain medication |

| | | |
|---|---|---|
| • The first time before suctioning:<br>□ Educate patient the need for suctioning<br>□ To prevent hypoxia<br>□ To prevent infection<br>□ To prevent atelectasis from retention of sputum<br>□ others are according to the suctioning criteria or reasons for suctioning<br><br>□ Educate patient the consequences of not suctioning when it is required<br>□ Patient might develop difficulty breathing or choking<br>□ Patient might increase the duration of mechanical ventilation<br>□ Patient might increase the length of ICU stay<br><br>• Every time before suctioning:<br><br>□ Explain to a patient that the procedure might be uncomfortable or pain, suctioning will be short but may need to be done more than once. Importantly, pain during suctioning can be controlled and managed by using both pharmacologic and non-pharmacologic interventions.<br><br>• Mutual goal setting for ETS pain management including CPOT < 3 and RASS = 0. | - Tissue damage to the tracheal and/or bronchial mucosa which may put patients at a high risk of bronchospasm or reactive airways.<br>Cardiac:<br>- Hypertension or hypotension, or cardiac dysrhythmias which may put patient at a high risk of unstable cardiovascular system.<br>Neurological:<br>- Increased intracranial pressure and changes of cerebral blood flow which may put patient at a high risk of unstable or high intracranial pressure or spinal injury with autonomic dysreflexia.<br>Hematological:<br>- An ETS may have the complications which may put patient at risk with hematological system such as coagulopathy. | |

| | | |
|---|---|---|
| • Baseline pain measurement before suctioning:<br>Pain assessment<br>□ CPOT Score …….<br>Agitation assessment<br>□ RASS Score …….<br>• Prior to suctioning:<br>□ Give pre-oxygenation (when patient received $FiO_2$ > 60% or $SpO_2$ < 95% or PEEP > 5cm$H_2O$ or have history or known case of hypoxia)<br>• **Pharmacological pain management**<br>□ Collaborate with medical doctor and provide the pre-emptive analgesia as prescribed deliver 5-10 minutes before suctioning within the optimum dosage: | Infection prevention:<br>- Increased microbial colonization of the lower airways which may put patient at risk with immunocompromised.<br>□ In patients not considered at high risk of adverse events, the endotracheal suction catheter could be passed until either a point of resistance is felt or a cough is stimulated, then the catheter should be withdrawn 1-2cm prior to suctioning.<br>□ The duration of suctioning < 15 seconds per each attempt<br>□ Secure and hold the endotracheal tube during suctioning<br>□ Provide psychological support such as touch or hold patient's hand, gently talk to patients, ask for readiness if possible. | |

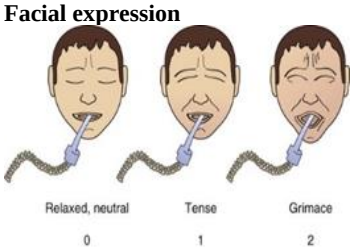
| | | |
|---|---|---|
| □ Fentanyl 1.5µg/kg<br>(*Do not more than 100µg per each attempt)*<br>□ Sufentanil 0.15-0.4µg/kg<br>(*Do not more than 0.4µg/kg per each attempt)*<br>□ Remifentanil 0.5-1µg/kg<br>(*Do not more than 1µg/kg per each attempt)*<br>□ Morphine 0.15 mg/kg<br>□ Xylocaine Spray10% 2-4µg/ml<br>(*Safe and effective dose: 127-320mg*)<br><br>The optimum dosage you should provide and the side effects of the analgesics you can see additional details as above:<br><br>**Pre-emptive analgesia** / **Optimum dosage** per each attempt / **Side effects**<br>Fentanyl — 30 µg — Respiratory depression<br>Sufentanil — 3-8µg — Bradycardia<br>Remifentanil — 15µg — Hypotension<br>Morphine — 3 mg | • Pain and agitation assessment when suction catheter insert into endotracheal tube of each attempt<br><br>Pain assessment<br>□ CPOT<br>Score: ① …… ② …… ③ …….<br><br>Agitation assessment<br>□ RASS<br>Score: ① …… ② …… ③ ……. | |

| | | |
|---|---|---|
| • **Non-pharmacological pain management according to individual patient's preference**<br>□ Cold application<br>- Apply ice pack to patient's neck for 3 minutes before suctioning.<br>- After suctioning 1-2 minutes remove the ice pack.<br>□ Music Therapy<br>- Provide music to patient with earphones 5 minutes before suctioning.<br>- Provide music until 15 minutes after suctioning. | | |

CPOT= Critical Care Pain Observation Tools, RASS= Richmond Agitation Sedation Scale, VAP= Ventilator-associated Pneumonia, PEEP= Positive End-expiratory Pressure.

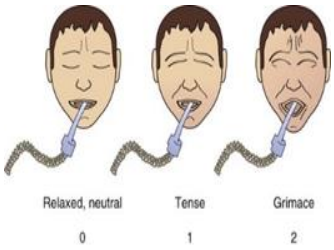
# The Critical-Care Pain Observation Tool (CPOT)

## (Gélinas et al., 2006)

| Indicator | Score | Description |
|---|---|---|
| **Facial expression**   | Relaxed, neutral 0 | No muscle tension observed |
| | Tense 1 | Presence of frowning, brow lowering, orbit tightening and levator contraction or any other change (e.g. opening eyes or tearing during nociceptive procedures) |
| | Grimacing 2 | All previous facial movements plus eyelid tightly closed (the patient may present with mouth open or biting the endotracheal tube) |
| **Body movements** | Absence of movements or normal position 0 | Does not move at all (doesn't necessarily mean absence of pain) or normal position (movements not aimed toward the pain site or not made for the purpose of protection) |
| | Protection 1 | Slow, cautious movements, touching or rubbing the pain site, seeking attention through movements |
| | Restlessness/Agitation 2 **(RASS)**<br>+4 Combative<br>+3 Very agitated<br>+2 Agitated<br>+1 Restless<br>0 Alert and calm<br>-1 Drowsy<br>-2 Light sedation<br>-3 Moderate sedation<br>-4 Deep sedation<br>-5 Unarousable | Pulling tube, attempting to sit up, moving limbs/thrashing, not following commands, striking at staff, trying to climb out of bed |
| **Compliance with the ventilator (intubated patients)** | Tolerating ventilator or movement 0 | Alarms not activated, easy ventilation |
| | Coughing but tolerating 1 | Coughing, alarms may be activated but stop spontaneously |
| | Fighting ventilator 2 | Asynchrony: blocking ventilation, alarms frequently activated |
| **Muscle tension**<br>Evaluation by passive flexion and extension of upper limbs when patient<br>is at rest or evaluation when patient is being turned | Relaxed 0 | No resistance to passive movements |
| | Tense, rigid 1 | Resistance to passive movements |
| | Very tense or rigid 2 | Strong resistance to passive movements or incapacity to complete them |
| **TOTAL** | **---------- / 8** | |

# 中文版重症监护疼痛观察工具(CPOT)

（李青栋等译， 2012）

| 指标 | 条目 | 描述 | 得分 |
|---|---|---|---|
| 1. 面部表情   | 放松，自然 | 无肌肉紧张表现 | 0 |
| | 表情紧张 | 皱眉、眉毛下垂、眼窝紧缩、轻微的面部肌肉收缩，或其它改变（如侵害操作中睁眼或流泪） | 1 |
| | 脸部扭曲<br>表情痛苦 | 出现上述所有面部运动，并有眼睑紧闭（可以表现出张口或紧咬气管插管） | 2 |
| 2. 身体活动 | 没有活动<br>或正常体位 | 根本不动或正常体位 | 0 |
| | 防卫活动 | 缓慢、小心的活动，触摸或摩擦痛处，通过活动寻求关注 | 1 |
| | 躁动不安 | 拔管，试图坐起，肢体乱动/翻滚，不听指令，攻击医务人员，试图爬离床 | 2 |
| 3. 肌肉紧张度 | 放松 | 被动运动时无抵抗 | 0 |
| | 紧张，僵硬 | 被动运动时有抵抗 | 1 |
| | 非常紧张或僵硬 | 强烈抵抗，无法完成被动运动 | 2 |
| 4. 机械通气顺应性<br>（插管患者） | 耐受呼吸机或活动 | 无报警，通气顺畅 | 0 |
| | 咳嗽但可耐受 | 咳嗽，可触发报警但自动停止报警 | 1 |
| | 人机对抗 | 不同步：人机对抗，频繁引起报警 | 2 |
| 总分 | | | |

## Richmond Agitation Sedation Scale (RASS) *

| Score | Term | Description | |
|---|---|---|---|
| +4 | Combative | Overtly combative, violent, immediate danger to staff | |
| +3 | Very agitated | Pulls or removes tube(s) or catheter(s); aggressive | |
| +2 | Agitated | Frequent non-purposeful movement, fights ventilator | |
| +1 | Restless | Anxious but movements not aggressive vigorous | |
| 0 | Alert and calm | | |
| -1 | Drowsy | Not fully alert, but has sustained awakening (eye-opening/eye contact) to *voice* **(≥10 seconds)** | Verbal Stimulation |
| -2 | Light sedation | Briefly awakens with eye contact to *voice* **(<10 seconds)** | |
| -3 | Moderate sedation | Movement or eye opening to *voice* **(but no eye contact)** | |
| -4 | Deep sedation | No response to voice, but movement or eye opening to *physical* stimulation | Stimulation Physical |
| -5 | Unarousable | No response to *voice or physical* stimulation | |

**Procedure for RASS Assessment**

1. Observe patient
   a. Patient is alert, restless, or agitated. **(score 0 to +4)**
2. If not alert, state patient's name and *say* to open eyes and look at speaker.
   b. Patient awakens with sustained eye opening and eye contact. **(score –1)**
   c. Patient awakens with eye opening and eye contact, but not sustained. **(score –2)**
   d. Patient has any movement in response to voice but no eye contact. **(score –3)**
3. When no response to verbal stimulation, physically stimulate patient by shaking shoulder and/or rubbing sternum.
   e. Patient has any movement to physical stimulation. **(score –4)**
   f. Patient has no response to any stimulation. **(score –5)**

* Sessler CN, Gosnell M, Grap MJ, Brophy GT, O'Neal PV, Keane KA et al. The Richmond Agitation-Sedation Scale: validity and reliability in adult intensive care patients. Am J Respir Crit Care Med 2002; 166:1338-1344.

* Ely EW, Truman B, Shintani A, Thomason JWW, Wheeler AP, Gordon S et al. Monitoring sedation status over time in ICU patients: the reliability and validity of the Richmond Agitation Sedation Scale (RASS). JAMA 2003; 289:2983-2991.

# Richmond 躁动-镇静量表 (RASS)

| | 术语 | 描述 | |
|---|---|---|---|
| 4 | 攻击行为 | 明显的好战行为、暴力行为、对工作人员构成直接的危险 | |
| 3 | 非常躁动不安 | 抓或拔出引流管或各种插管,具有攻击行为 | |
| 2 | 躁动不安 | 频繁的无目的动作,于呼吸机抵抗 | |
| 1 | 烦躁不安 | 焦虑不安,但动作不是猛烈地攻击 | |
| 0 | 清醒状态且平静 | | |
| -1 | 昏昏欲睡 | 不能完全清醒，但声音刺激能够叫醒并维持觉醒状态 睁眼/眼睛接触，≥ 10 秒) | 声音刺激 |
| -2 | 轻度镇静状态 | 声音能叫醒并有短暂的眼睛接触(<10 秒) | |
| -3 | 中度镇静状态 | 声音刺激后有动静或睁眼反应（但无眼睛接触) | |
| -4 | 深度镇静状态 | 对声音刺激无反应.但身体刺激后有动静或睁眼反应 | 身体刺激 |
| -5 | 不可叫醒状态 | 对声音或身体刺激均无反应 | |

**Glasgow Coma Scale (GCS)**
**(Teasdale et al., 2014)**

| | |
|---|---|
| **Eye opening** | |
| Spontaneous | 4 points |
| To sound | 3 points |
| To pressure | 2 points |
| None | 1 point |
| **Verbal response** | |
| Orientated | 5 points |
| Confused | 4 points |
| Words | 3 points |
| Sounds | 2 points |
| None | 1 point |
| **Motor response** | |
| Obeys commands | 6 points |
| Localizing | 5 points |
| Normal flexion | 4 points |
| Abnormal flexion | 3 points |
| Extension | 2 points |
| None | 1 point |
| Total | |

# APPENDIX C

## Sample Size Estimation

Sample size was estimated by using data from the study entitled conducted by Saadatmand et al. (2015).

Effect Size (d) = $M_1$-$M_2$ / pooled SD

Where, Pooled SD = $\sqrt{SD_1^2 + SD_2^2 /2}$

Definition:

$M_1$, $M_2$ & SD from previous study

$M_1$ = Mean of experimental group

$M_2$ = Mean of control group

Pooled SD: Standard deviation of the control group and experimental group

In this study, researcher used previous study $M_1$ =3.93, $M_2$ = 4.83 and $SD_1$ =0.94, $SD_2$ =0.91

Pooled SD = $\sqrt{SD_1^2 + SD_2^2 /2}$

= $\sqrt{(0.94^2 + 0.91^2) /2}$

= 0.93

Effect Size (d) = $M_1$-$M_2$ / pooled SD

= (3.93-4.83) / 0.93

= 0.97

Effect Size of this study is: 0.97

## Sample Size Estimation

Sample size was estimated by using data from the study entitled conducted by Shamali et al. (2016).

Effect Size (d) = $M_1$-$M_2$ / pooled SD

Where, Pooled SD = $\sqrt{SD_1^2 + SD_2^2 /2}$

Definition:

$M_1$, $M_2$ & SD from previous study

$M_1$ = Mean of experimental group

$M_2$ = Mean of control group

Pooled SD: Standard deviation of the control group and experimental group

In this study, researcher used previous study $M_1$ =1.84, $M_2$ = 2.43 and $SD_1$ =1.29, $SD_2$ =1.26

Pooled SD = $\sqrt{SD_1^2 + SD_2^2 /2}$

= $\sqrt{(1.29^2 + 1.26^2) /2}$

= 1.27

Effect Size (d) = $M_1$-$M_2$ / pooled SD

= (1.84 – 2.43) / 1.27

= 0.46

The weighted averaging effect Size of this study is: 0.7.

Expected Alpha (α) =.05, expected power =.80, thus, approximate sample size in each group =26.

## APPENDIX D

### Demographic and Clinical Characteristics Questionnaire

**Approach Date &Time ……..……. Code ……**

**Demographic Information**

1. Age: …… years

2. Gender: ( ) Male ( ) Female

3. Ethnicity ……...

4. Marital status

( ) Single ( ) Married ( ) Widowed ( ) Divorced

5. Educational attainment

( ) Primary school ( ) Junior middle school ( ) Senior high school

( ) Non-degree zhuanke ( ) Bachelor degree ( ) Master degree

( ) Other (Please specify)…….

6. Occupation or employment status

( ) Student ( ) Self-employee ( ) Public employee ( ) Agriculturist

( ) Other (Please specify)……...

**Pain-related Information**

7. Previous pain experiences or primary pain

( ) No ( ) Yes (Please specify) ……

8. Existing pain

( ) No ( ) Yes (Please specify) ……

9. Pain medication took previously

( ) No ( ) Yes (Please specify) ……

**Details of Endotracheal Tube Intubation & Mechanical Ventilation**

10. History of mechanical ventilation

( ) No ( ) Yes (Please specify)

……..

11. Date & Times of intubation

……..

12. Duration of intubation

……

13. Duration of mechanical ventilation

……

14. Modes of mechanical ventilation

……

15. Endotracheal tube size

……

16. Suction system

( ) Open ( ) Closed

17. Suction tube catheter size

( ) 12 ( ) 14 ( ) Other

**Health-related Information**

18. Body mass index (BMI)

…….

19. Surgical procedure

……

……

20. Reason for using mechanical ventilation as well as intubated

……..

……

21. Other medical devices or surgical procedures used …….

……

**The Information Related to Prescription**

22. Current prescribed medications

Analgesics

( ) Sufentanil ……..……

( ) Morphine …….

( ) Other ……

Sedatives/tranquilizers

( ) Propofol …….

( ) Dexmedetomidine ……

( ) Midazolam ……..……

( ) Combination of several drugs ……..……..

## APPENDIX E

### Documentation Form for Endotracheal Tube Suctioning (ETS) Pain Management Outcomes

**Date……..…Time……..…** **Code……**

| **Times** | **Tools** | **Before EST** (1-2min) | **During ETS** | | | **After ETS** | | | **Duration of pain** |
|---|---|---|---|---|---|---|---|---|---|
| | | | ① | ② | ③ | Immediately | 5 minutes | 15 minutes | |
| **1** | **CPOT** | | | | | | | | |
| | **RASS** | | | | | | | | |
| **2** | **CPOT** | | | | | | | | |
| | **RASS** | | | | | | | | |
| **3** | **CPOT** | | | | | | | | |
| | **RASS** | | | | | | | | |
| **4** | **CPOT** | | | | | | | | |
| | **RASS** | | | | | | | | |
| **5** | **CPOT** | | | | | | | | |
| | **RASS** | | | | | | | | |

**Note: other behaviors** _____

# APPENDIX F

## List of Content Validity Experts

1. Miss Sarunya Tukchoosaeng

   MICU Head Nurse, Pain specialist nurse, Expert in critical care nursing

   Songklanagarind Hospital, Songkhla, Thailand

2. Assoc. Prof. Dr. Sasikaan Nimmaanrat

   Anesthesiologist, Department of Anesthesiology,

   Songklanagarind Hospital, Songkhla, Thailand

3. Assoc. Prof. Dr. Qingqing Huang

   Anesthesiologist, Department of Anesthesiology,

   The Second Affiliated Hospital of Kunming Medical University

   Kunming, Yunnan, China

4. Head nurse, Miss Qing Zhang, Lecturer

   ICU Head Nurse, Critical care nurse specialist, Expert in critical care nursing

   The Second Affiliated Hospital of Kunming Medical University

   Kunming, Yunnan, China

# APPENDIX G

## Ethics Committee Approval Letter

## 1. Ethic Committee Approval of Prince of Songkla University

Certificate of Approval of Human Research Ethics
Center for Social and Behavioral Sciences Institutional Review Board,
Prince of Songkla University

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**Document Number:** 2017 NSt – Qn 045

**Research Title:** The Effects of Clinical Pathway for Endotracheal Tube Suctioning (ETS) Pain Management on Pain Management Outcomes in Critically Ill Chinese Adult Patients

**Research Code:** PSU IRB 2017 – NSt 036

**Principal Investigator:** Qianwen Ruan

**Workplace:** Master of Nursing Science (International Program) Faculty of Nursing, Prince of Songkla University

**Approved Document:**
1. Human Subjects
2. Instrument
3. Invitation and Informed Consent

**Approved Date:** 27 November 2017

**Expiration Date:** 27 November 2019

The Research Ethics Review of Center for Social and Behavioral Sciences Institutional Review Board, Prince of Songkla University approved for Ethics of this research in accordance with Declaration of Belmont.

(Assoc. Prof. Dr. Aranya Chaowalit)
Committee Chairman of Center for Social and Behavioral Sciences
Institutional Review Board, Prince of Songkla University

## 2. Ethic Committee Approval of the Second Affiliated Hospital of Kunming Medical University ICU Kunming, Yunnan, China



### 伦理审查意见

审-YJ- 2018-01

| | | | |
|---|---|---|---|
| 项目名称 | 气管插管吸痰疼痛管理临床路径对中国成人重症患者疼痛管理的实效性研究 | | |
| 项目申办方 | 本院 | | |
| 主要研究者 | 阮倩雯 | 申请研究科室 | 重症医学科 |
| 审查类别 | 复审 | 审查方式 | 快速审查 |
| 审查日期 | 2018. 02. 08 | 审查地点 | 不适用 |
| 审查委员 | 王琳、刘文军 | | |
| 审查文件 | 1. 临床试验方案(版本号、日期：20180122 版，2018. 01. 22)<br>2. 知情同意书（版本号、日期：20180122 版，2018. 01. 22） | | |

审查意见

根据国家卫生计生委《涉及人的生物医学研究伦理审查办法》、CFDA《药物临床试验质量管理规范》、《医疗器械临床试验规定》、WMA《赫尔辛基宣言》和 CIOMS《人体生物医学研究国际道德指南》的伦理原则，经本伦理委员会审查，意见如下：

☑同意

此研究项目已于 2017 年 12 月 28 日经昆明医科大学第二附属医院医学伦理委员会审批。审批意见为：作必要修正后重审。

此次提交的材料，经主审委员审核，符合会议审查提出的修改意见，同意项目实施。

按审查意见修改后的文件，或对审查意见不同观点的陈诉，请提交“复审申请”，方案/知情同意书请注明新的版本号和版本日期，并以阴影和/或下划线方式标注修改部分，报伦理委员会审查，经批准后执行。

| | |
|---|---|
| 调整的年度/定期跟踪审查频率 | 6 个月 |
| 伦理委员会（盖章） | 昆明医科大学第二附属医院医学伦理委员会 |
| 主任委员或副主任委员签字（盖章） | |
| 日期 | 2018.2.11 |

# APPENDIX H

## Permission Letter for Data Collection

### Permission Letter for Collecting Data

28 December, 2017

To the chairman
The medical ethical committee, the Second Affiliated Hospital of Kunming Medical University, Kunming, China

Subject: Asking permission for collecting data

Dear Sir,

With due respect, I beg to state that I am Qianwen Ruan, a nurse of the Second Affiliated Hospital of Kunming Medical University. Now I am studying Master grogram in nursing at Prince of Songkla University (PSU), Thailand. To fulfill the partial requirement of my master degree, I will conduct a research entitled "The effects of clinical pathway for endotracheal tube suctioning (ETS) pain management on pain management outcomes in critically ill Chinese adult patients". This study has been reviewed and approved by the Institutional Review Board (IRB), Faculty of Nursing, PSU. I would like to collect data from the patients admitted in SICU. The estimated duration of data collection is about 3 months. Therefore, I am applying for your kind permission to collect data in this department to complete my master study.

I am looking forward to your kindness to give me permission to collect data.

Yours sincerely,

Qianwen Ruan
(Qianwen Ruan)
Nurse
The Second Affiliated Hospital of
Kunming Medical University,
Kunming, China, and

Student of Master degree in nursing
Faculty of Nursing, Prince of Songkla University
Hat Yai, Songkhla, Thailand

此论题已经医院伦理委员会审核通过.
2017.12.29.

# APPENDIX I

## Informed Consent Form

Informed Consent Form

My name is Qianwen Ruan. I am a master student of the nursing science international program at the Faculty of Nursing, Prince of Songkla University, Thailand. I am also a nurse at ICU of the Second Affiliated Hospital of Kunming Medical University ICU. I am conducting a research entitled, "The Effects of a Clinical Pathway for Endotracheal Tube Suctioning Pain Management on Pain Presence and Agitation in Surgical Intensive Unit Chinese Adults". It is expected that the findings of this study will contribute to the improvement of procedural pain management in critically ill patients.

This study has been approved by the Institutional Review Board of Prince of Songkla University, Thailand. You are asked to participate in this study. If you decided to participate, I will proceed with the following:

Explanation regarding procedures:

1. You will be assigned into either the control group or the experimental group.
2. If you are in the control group, you will be provided with the usual care offered at this hospital.
3. If you are in the experimental group, you will undergo the CPETS pain management during the study period.
4. Before suctioning, the researcher will provide knowledge to the experimental group about the need for suctioning, explain to them that the procedure might be uncomfortable or painful, and that suctioning will be short, but it may need to be

performed more than once. Importantly, pain during suctioning can be controlled and managed using both pharmacological and non-pharmacological interventions. The researcher will collaborate with medical doctors and provide pre-emptive analgesia as prescribed, which will be administered before suctioning and within the optimal dosage. In addition, non-pharmacological pain management will be provided in accordance with your individual preferences.

5. During suctioning, the researcher will perform the suctioning on those in the experimental group, the research assistant (RA) will record the outcome data regarding of your pain and agitation, non-pharmacological interventions will continue to be administered to minimize the suctioning-related pain, and the RA and nurse will stay by your bedside to keep your safe. You should cooperate, relax, and not touch your endotracheal tube.
6. After suctioning, the researcher will inform you that the procedure is now finished, and follow-up on your pain management outcomes as well as plan for further pain management.

Risk, Comfort and Compensation

To avoid potential risks (e.g., self-extubation) of patient's protection and agitation, the researcher should educate the patient about the consequences of self-extubation as well as explain this risk to the primary physician, primary nurse, and family members. During ETS, the primary nurse should be bedside to monitor and ensure the patient's safety. Any unplanned extubation should be reported, and preparations should be in place in order to minimize the complications of an unplanned extubation. If you feel discomfort or fatigue during suctioning, you can ask

for a break to rest for a while. There will be neither cost nor payment to you or your family for participating in this study.

Alternative Procedures/Treatment

Except for not participating, there are no alternatives to participation. You will always receive nursing care in any case.

Your rights

Your personal identity and all of your answers will be confidential. The information gathered will be revealed, but both anonymity and confidentiality will be maintained. You may withdraw from the research at any time if you perceive any potential harm to you. Your participation in this study is voluntary. There are no costs or financial awards to participate in this study. Your signature on this form will indicate that you understand the contents of this form, and that you are willing to participate in this research.

Benefits

This study will try to identify the effects of a clinical pathway for ETS pain management on improving pain management, understand your pain experience and satisfaction with care as well as involve you in the process of nursing care. The results of this study can be used as a guideline for nurses to provide alternative interventions that may enhance ETS pain management in critically ill Chinese adult patients. It also will provide useful information for future research related to this area.

Participation and Withdrawal from Participation

Your participation in this study is voluntary. Singing the informed consent or agreeing verbally to participate and returning the form given to you indicate that you understand what is involved and you consent to participate in this study project. At any time during this study, you have the right to withdraw without any repercussion whatsoever.

Thank you very much for your kind cooperation. If you need information or have any questions, please contact with me, Miss Qianwen Ruan, at Faculty of Nursing, Prince of Songkla University, Thailand. Mobile number: 064 0375518 or e-mail: rqw746766375@vip.163.com. My thesis advisors' contact is given below:

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Address: Center for Social and Behavioral Sciences Institutional Review Board, Prince of Songkla University (SBSIRB-PSU).

Miss Qianwen Ruan

Researcher

**Informed Consent Form**

Title: The Effects of a Clinical Pathway for Endotracheal Tube Suctioning Pain Management on Pain Presence and Agitation in Surgical Intensive Unit Chinese Adults

Researcher: Miss Qianwen Ruan (Master student, Faculty of Nursing, Prince Songkla University, Thailand)

Patient name: ……. Age: ……

Patient's or his/her family member's Consent

I, ……, was informed about the details of the research entitled "The Effects of a Clinical Pathway for Endotracheal Tube Suctioning Pain Management on Pain Presence and Agitation in Surgical Intensive Unit Chinese Adults." It was guaranteed that no part of my personal information will be exposed to the public. If any concerns or issues come up, I can discuss them with the researcher. I also have the right to withdraw from this study at any time without any effect on the medical services rendered to me. I am willing to participate in this research study and hereby append my signature.

Given by…… (consenter) date: …….

Researcher's note

I have given detailed information regarding the research entitled, "The Effects of a Clinical Pathway for Endotracheal Tube Suctioning Pain Management on Pain Presence and Agitation in Surgical Intensive Unit Chinese Adults." The signature and returned form indicate that the participant understands what is involved and agrees to participate in this study voluntarily. I provide opportunities for questions from the participant, while promising to give the required answers.

Signature: …… (Researcher) date: ……

## APPENDIX J

### Testing Assumptions of ANOVA

1. Normality assumptions is tested using z test for skewness and kurtosis

*The Values of the Skewness and Kurtosis Divided Their Standard Error of CPOT in the Experimental and Control Groups*

| | | Statistics (a) | Standard Error (b) | Z value = a / b |
|---|---|---|---|---|
| CPOT2 (During suctioning the first time) | | | | |
| Experimental group | Skewness | .000 | .456 | 0 |
| | Kurtosis | - .747 | .887 | - .842 |
| Control group | Skewness | .630 | .456 | 1.382 |
| | Kurtosis | .556 | .887 | .627 |
| CPOT5 (After suctioning immediately) | | | | |
| Experimental group | Skewness | 2.558 | .456 | 5.610 |
| | Kurtosis | 4.915 | .887 | 5.541 |
| Control group | Skewness | .879 | .456 | 1.928 |
| | Kurtosis | .284 | .887 | .320 |
| CPOT6 (After suctioning 5 minutes) | | | | |
| The CPOT6 of the Experimental group is constant = 0 means no pain intensity | | | | |
| Control group | Skewness | 2.676 | .456 | 5.868 |
| | Kurtosis | 7.053 | .887 | 7.951 |
| CPOT7 (After suctioning 15 minutes) | | | | |
| The CPOT7 of the Experimental group is constant = 0 means no pain intensity | | | | |
| Control group | Skewness | 5.099 | .456 | 11.182 |
| | Kurtosis | 26.000 | .887 | 29.312 |

1). The distribution of CPOT2 (During suctioning the first time) of Experimental group is normal.

2). The distribution of CPOT2 (During suctioning the first time) of Control group is normal.

3). The distribution of CPOT5 (After suctioning immediately) of Experimental group is abnormal.

4). The distribution of CPOT5 (After suctioning immediately) of Control group is abnormal.

5). The distribution of CPOT6 (After suctioning 5 minutes) of Control group is abnormal.

6). The distribution of CPOT7 (After suctioning 15 minutes) of Control group is abnormal.

*The Values of the Skewness and Kurtosis Divided Their Standard Error of RASS in the Experimental and Control Groups*

| | | Statistics (a) | Standard Error (b) | Z value = a / b |
|---|---|---|---|---|
| RASS2 (During suctioning the first time) | | | | |
| Experimental group | Skewness | -.885 | .456 | -1.941 |
| | Kurtosis | -1.325 | .887 | - 1.494 |
| The RASS2 of the Control group is constant = 1 means Restless | | | | |
| RASS5 (After suctioning immediately) | | | | |
| The RASS5 of the Experimental group is constant = 0 means Alert and calm | | | | |
| Control group | Skewness | .164 | .456 | .360 |
| | Kurtosis | -2.145 | .887 | - 2.418 |
| RASS6, RASS7 of both Experimental group and Control group is constant = 0 means Alert and calm | | | | |

1). The distribution of RASS2 (During suctioning the first time) of Experimental group is normal.

2). The distribution of RASS5 (After suctioning immediately) of Control group is abnormal.

2. Homogeneity assumption is checked by Levene's test

ANOVA

| | | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|---|
| CPOT 2 | Between Groups | 50.019 | 1 | 50.019 | 92.760 | .000 |
| | Within Groups | 26.962 | 50 | .539 | | |
| | Total | 76.981 | 51 | | | |
| CPOT 5 | Between Groups | 22.231 | 1 | 22.231 | 65.385 | .000 |
| | Within Groups | 17.000 | 50 | .340 | | |
| | Total | 39.231 | 51 | | | |
| CPOT 6 | Between Groups | .481 | 1 | .481 | 3.981 | .051 |
| | Within Groups | 6.038 | 50 | .121 | | |
| | Total | 6.519 | 51 | | | |
| CPOT 7 | Between Groups | .019 | 1 | .019 | 1.000 | .322 |
| | Within Groups | .962 | 50 | .019 | | |
| | Total | .981 | 51 | | | |

1. COPT2 (during suctioning the first time)

There is a significant different between group on pain intensity (CPOT) $F(1,50)=92.760$, $p = .000 < .05$. Testing assumption show homogeneity, determined by the Fmax = variance max/variance min are in the range of $\leq 3$. Fmax> 3.

2. CPOT5 (after suctioning immediately)

There is a significant different between group on pain intensity (CPOT) $F(1,50)=65.385$,

$p = .000 < .05$. Testing assumption show homogeneity, determined by the Fmax = variance max/ variance min are in the range of $\leq 3$. Fmax > 3.

3. CPOT6 (after suctioning 5 minutes)

There is no significant different between group on pain intensity (CPOT) $F(1,50)=3.981$,

$p = .051 > .05$.

4. CPOT7 (after suctioning 15 minutes)

There is no significant different between group on pain intensity (CPOT) $F(1,50)=1.000$,

$p= .322 > .05$.

ANOVA

| | | Sum of Squares | df | Mean Square | F | Sig. |
|---|---|---|---|---|---|---|
| RASS2 | Between Groups | 1.231 | 1 | 1.231 | 11.111 | .002 |
| | Within Groups | 5.538 | 50 | .111 | | |
| | Total | 6.769 | 51 | | | |
| RASS5 | Between Groups | 2.769 | 1 | 2.769 | 21.429 | .000 |
| | Within Groups | 6.462 | 50 | .129 | | |
| | Total | 9.231 | 51 | | | |
| RASS6 | Between Groups | .000 | 1 | .000 | . | . |
| | Within Groups | .000 | 50 | .000 | | |
| | Total | .000 | 51 | | | |
| RASS7 | Between Groups | .000 | 1 | .000 | . | . |
| | Within Groups | .000 | 50 | .000 | | |
| | Total | .000 | 51 | | | |

1. RASS2 (during suctioning the first time)

There is a significant different between group on agitation (RASS) $F(1,50) = 11.111$, $p = .002 < .05$. Testing assumption show homogeneity, determined by the Fmax = variance max/ variance min are in the range of $\leq 3$. Fmax >3.

2. RASS5 (after suctioning immediately)

There is a significant different between group on agitation (RASS) $F(1,50) = 21.429$, $p = .000 < .05$. Testing assumption show homogeneity, determined by the Fmax = variance max/ variance min are in the range of $\leq 3$. Fmax >3.

# VITAE

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**List of Publications and Proceedings**

Ruan, Q., Khasanah, I. H., Kongkeaw, O., & Maneewat, K. (2017). Pain management during endotracheal tube suctioning: An evidence-based approach for nurses. *Journal of Healthcare Communications*. https://doi.org/10.4172/2472-1654-C1-002.

Ruan, Q., Khasanah, I. H., Kongkeaw, O., & Maneewat, K. (2017, July). Pain management during endotracheal tube suctioning: An integrative review. Abstract poster presented at the 2017 International Nursing Conference on Ethics

Esthetics, and Empirics in Nursing Driving Force for Better Health, Prince of Songkla University, Thailand.