

Research vt of 6-8ml kg of ideal body

Business, Strategy



ResearchProject ProposalTitle: The Association between the InitialPEEP Setting and the Development of Pulmonary Complications in Adult Patients WithoutLung Injury: a randomized controlled trial1. Abstract: Background: Over the last few decades, the lungprotective strategy has become stander of care for ARDS patients and proved tobe a strategy to prevent Acute-lung injury (ALI) for patients with no previouslung injury. The current data regarding theinitial PEEP setting with lung protective ventilation for adult patient withoutARDS are conflicting. Objective: The main aim of this study is to investigate the associationbetween the initial PEEP setting (8cm H2O vs. 5cm H2O) andthe development of pulmonary complications in adult patients without lung injury.

Methods: This is a randomized controlled research design. All adult patients at age of ? 18years old and required mechanical ventilation for more than 48 h will beeligible to participate in this study. Subjects will be randomly allocated to receiveinitial PEEP of 8 cm H2O or PEEP of 5 cm H2O. The primaryoutcome will be pulmonary complications and duration of mechanical ventilation.

2. Context: Over last few decade lung protectivestrategy has become stander of care for ARDS patients and proved to be the beststrategy to prevent ALI for patients with no previous lung injury. (AcuteRespiratory Distress Syndrome Network et al.

, 2000) (Serpa Neto et al., 2012)Several studies showed that the use of low tidal volume for adult mechanicallyventilated patient without ARDS improved the clinical outcomes and decrease therisk of pulmonary complication.

(Fuller, Mohr, Drewry, & Carpenter, 2013) (Gu, Wang, & Liu, 2015) (Yang, Grant, Stone, Wu, & Wick, 2016) (Choi et al., 2006) They concluded that VT of 6-8ml/kg of ideal body weight (IBW) prevented potential pulmonary complications and reduce the duration of mechanical ventilation. Most of those studies used to set PEEP at > 5 cmH₂O, and some studies did not report the initial PEEP. (Fuller et al., 2013) (Gu et al.

, 2015) (Yang et al., 2016) (Choi et al., 2006) When low tidal volume of 6ml/kg used; adequate PEEP level will be needed to prevent atelectrauma and improves gas exchanges. Lung injury may occur because of an inappropriate PEEP setting as a result of either overdistention of the lung or from repeated opening and closing of alveoli throughout the respiratory cycle. (Cressoni, Chiurazzi, Chiumello, & Gattinoni, 2017) Moreover, the effect of PEEP level in pulmonary parenchyma was most frequently studied in ARDS and ALI patients. (Brielle et al., 2010) (Brower et al., 2004).

Those studies showed insight into the different PEEP level on lung tissue. Most of the trials which investigate the benefits of protective strategy for patients with ARDS recommended the use of high PEEP. Meta-analysis studies by Briel et al and Phoenix et al demonstrated that as a part of lung-protective ventilation higher level of PEEP was associated with an increase survival rate of patient with ARDS. (Phoenix, Paravastu, Columb, Vincent, & Nirmalan, 2009) (Briel et al., 2010) However, multiple randomized control trials showed that there were no significant differences in the clinical outcome when high PEEP compared to low PEEP in ARDS patient.

(Brower et al., 2004) (Meade et al., 2008) (Mercat et al., 2008) (Villar, Kacmarek, Perez-Mendez, & Aguirre-Jaime, 2006) Additionally, Hansen et al compared initial PEEP of 5cm H₂O and PEEP of 8cm H₂O in postoperative patients with coronary artery bypass grafting (CABG). All patients were without preexisting lung injury and both groups were placed in the low tidal setting. They found that the group with PEEP of 8cm H₂O had longer hospitalization time.

However, there were no significant differences between both groups in hospital death and aspiration pneumonia (Hansen et al., 2015). Hong and colleagues published a study examining different levels of PEEP with low tidal volume.

They found low tidal volume with PEEP of 10 cm H₂O was associated to increase pulmonary infection and lung injury. (Hong et al., 2010)

Furthermore, there were clinical trials that showed the benefit of low tidal volume and high PEEP in patients without lung injury when it was compared to high tidal volume without PEEP. (Wolthuis et al., 2008) (Choi et al., 2006) Wolthuis et al used tidal volume 6ml/kg of IBW and 10 cm H₂O PEEP that showed reduction in pulmonary inflammation. (Wolthuis et al.

, 2008) Most clinicians selected initial PEEP of 5 or 8 cm H₂O (Hansen et al., 2015). Manzano et al studied the use of PEEP from 5-8cm H₂O with non-injured lungs. They conclude PEEP between 5 to 8 cm H₂O reduce ventilator associated pneumonia significantly when compared to PEEP of 0 cm H₂O.

(Manzano et al., 2008) Several articles have described different ways of determining when the goals of PEEP have been achieved for adult mechanical ventilated patients. The consensus of these different approaches is reviewed. (Cressoni et al., 2017) Some clinicians follow a specific step increase in FiO₂ and PEEP according to the procedure outlined in the ARDSnet study.

Others followed a more rapidly increasing PEEP to FiO₂ table from a follow-up study. Both the low and high PEEP titration techniques for establishing the appropriate PEEP level appear to have similar morbidity and survival rates. PEEP setting may lead to ventilation associated events.

It is clear if PEEP progressively increases, it will result in stressing lung tissue leading to pulmonary complications. The studies have been shown that the PEEP had no significant effects on lung until 15 cm H₂O was used. (Meade et al., 2008) However, according to the Centers for Disease Control and Prevention, Ventilator Associated Events (VAEs) may occur with an increase of PEEP of 3 cm H₂O over the daily minimum PEEP in the baseline period, for 2 days.

(Magill et al., 2013) It also has to be maintained for at least 1 hour. There are limited researches examining the appropriateness and impact of initial PEEP setting in non-injury lung when the lung protective strategy is in used.

We hypothesized that PEEP of 8 cm H₂O will be associated with a decrease in VAEs and pulmonary complications. Existing studies lack to provide definitive recommendation for the best initial PEEP when low tidal volume applied for patient without ARDS. 3. Research question: Dose PEEP of 8 cm H₂O

associated with a reduction in pulmonary complications when compared with initial PEEP of 5 cm H₂O in adult mechanical ventilated patients without lung injury? 4.

Research methods: This is a randomized controlled research design. After research approval, informed consent will be obtained from all subjects. All adult patients at age of \geq 18 years old and required mechanical ventilation for more than 48 h will be eligible to participate in this study. Patients will be excluded if they are dying or extubated within 48 hours, chronic mechanical ventilation, tracheostomized, history of any pulmonary diseases, use of immunosuppressive medication, recent infection, brain death and ARDS. To obtain a sample that represented the target population, participants will be randomly and voluntarily self-selected. The sample size will be approximately two hundred. The ventilation protocol will consider Pressure-Regulated Volume Control (PRVC) mode or similar mode of mechanical ventilation with initial setting of 6 ml/kg tidal volume (VT) of IBW, respiratory rate (RR) to get minute ventilation of 100 ml/kg, inspiratory to expiratory ratio (I: E) to be set not more than 1: 1, an inspiratory oxygen fraction of .50 and pressure limits at 30 cmH₂O.

Subjects will be randomly allocated to receive initial PEEP of 8 cm H₂O or PEEP of 5 cm H₂O. After initial adjustment, the clinicians will be allowed to increase tidal volume up to 8 ml/kg and respiratory rate up to 35 breaths per minute to manage PaCO₂. Additionally, they are allowed to adjust FiO₂ and PEEP according to the procedure outlined in the ARDSnet study. Baseline clinical history and demographic information will be obtained from the

patient's medical record. Following the initiation of mechanical ventilation, all ventilator settings and available hemodynamic parameters will be measured and recorded daily. Also, arterial blood gas, bronchoalveolar lavage and chest radiographic data will be performed daily. There are eight variables will be measured within our research; three dependent variables and five independent variables. The dependent variables are VAEs incidence, ARDS incidence and duration of mechanical ventilation.

While, the independent variables are age, gender, diagnosis, BMI and smoking history. The primary outcome will be pulmonary complications and duration of mechanical ventilation. Pulmonary complications will include ARDS and VAE. All personal information will be kept completely confidential. The records will not have any identifying information on them.

All data accessible only to the investigators. The outcome data will be collected and compared with the baseline characteristics of experimental and control groups to measure the association between the initial PEEP setting and the development of pulmonary complications. The mean and median information will be calculated, standard deviation and t-test analysis comparing the baseline result will be done to determine the significance ($P < .05$). For categorical data, the chi-square test will be used. The differences within the both groups will be analyzed with a Wilcoxon signed-rank test for paired sample and the Mann-Whitney U test.

All statistical analyses will be performed with SPSS 12.

0. 5. Research significance: The finding of this study will present

anevidence about the association between the initialPEEP setting and the development of pulmonary complications in adult patientwithout lung injury.

Currently, there are limited researchesexamining the appropriateness and impact of initialPEEP setting in healthy lung when the lung protective strategy is in used(6ml/kg of IBW). Existing studies lack to provide definitive recommendation forthe best initial PEEP when low tidal volume applied for patient without ARDS. We hypothesized that PEEP of 8cm H₂O will be associated with adecrease in pulmonary complications.