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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) preventedpotential pulmonary complications and reduce the duration of mechanicalventilation. Most of those studies used to set PEEP at > 5 cmH2O, and some studies did not report theinitial 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 gasexchanges. Lung injury may occur because of an inappropriate PEEP setting as aresult of either overdistention of the lung or from repeated opening andclosing of alveoli throughout the respiratory cycle. (Cressoni, Chiurazzi, Chiumello, & Gattinoni, 2017) Moreover, the effect of PEEP level inpulmonary parenchyma was most frequently studied in ARDS and ALI patients. (Brielet al., 2010) (Brower et al., 2004).

Those studies showed insight into thedifferent PEEP level on lung tissue. Most of the trials which investigate thebenefits of protective strategy for patients with ARDS recommended the use ofhigh PEEP. Meta-analysis studies by Briel et al and Phoenix et al demonstratedthat as a part of lung-protective ventilation higher level of PEEP was associatedwith an increase survival rate of patient with ARDS. (Phoenix, Paravastu, Columb, Vincent, & Nirmalan, 2009) (Briel et al., 2010) However, multiplerandomized control trials showed that there were nosignificant differences in the clinical outcomewhen high PEEP compared to low PEEP in ARDS patient.

(Broweret 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 H2Oin postoperative patients with coronary artery bypass grafting (CAPG). Allpatients were without preexisted lung injury and both groups were placed in thelow tidal setting. They found that the group with PEEP of 8cm H2Ohad longer hospitalization time.

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

They found low tidal volume with PEEP of 10 cm H2Owas associated to increase pulmonary infection and lung injury. (Hong et al., 2010) Furthermore, there were clinical trials that showed the benefit of lowtidal volume and high PEEP in patient without lung injury when it was comparedto high tidal volume without PEEP. (Wolthuis et al., 2008) (Choi et al., 2006)Wolthuiset al used tidal volume 6ml/kg of IBW and 10 cmH2O PEEP that showed reductionin pulmonary inflammation. (Wolthuis et al.

, 2008) Most clinicians selectedinitial PEEP of 5 or 8 cm H2O (Hansen et al., 2015). Manzano et alstudied the used of PEEP from 5-8cm H2O with non-injured lungs. Theyconclude PEEP between 5 to 8 cm H2O reduce ventilator associatedpneumonia significantly when compared to PEEP of 0 cmH2O.

(Manzanoet al., 2008)Several articles have describeddifferent ways of determining when the goals of PEEP have been achieved for adultmechanical ventilated patients. The consensus of these different approaches isreviewed. (Cressoni et al., 2017) Some clinicians follow a specific stepincrease in FiO2 and PEEP according to the procedure outlined in theARDSnet study.

Others followed a more rapidly increasing PEEP to FiO2table from a follow-up study. Both the low and high PEEP titration techniquesfor establishing the appropriate PEEP level appear to have similar morbidityand survival rates. PEEP setting may lead to ventilationassociated events.

It is clear if PEEP progressively increases, it will resultin stressing lung tissue leading to pulmonary completions. The studies havebeen shown that the PEEP had no significant effects on lung until 15cm H2Owas used. (Meade et al., 2008) However, according to the Centers for DiseaseControl and Prevention, Ventilators Associated Evens (VAEs) may occur with an increase of PEEPof ? 3cm 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 1hour. Thereare limited researches examining the appropriateness and impact of initial PEEP setting in non-injury lung when the lung protectivestrategy is in used.

We hypothesized that PEEP of 8cm H2O will beassociated with a decrease in VAEs and pulmonary complications. Existingstudies lack to provide definitive recommendation for the best initial PEEPwhen low tidal volume applied for patient without ARDS. 3.    Researchquestion:  Dose PEEP of 8cm H2O associatedwith a reduction in pulmonary complications when compared with initial PEEP of5cm H2O in adult mechanical ventilated patientwithout lung injury? 4.

Researchmethods: This is a randomized controlled research design. After research approval, inform consent will beobtained from all subjects. All adult patients at age of ? 18 years old and required mechanical ventilation for more than 48 hwill be eligible to participate in this study. Patients will be excluded ifthey are dying or extubatedwithin 48 hours, chronic mechanical ventilation, tracheostomized, historyof any pulmonary diseases, use of immunosppressive medication, recentinfection, brain death and ARDS. Toobtain a sample that represented the target population, participants will berandomly and voluntary self-selected. The sample size will be approximately twohundred. The ventilation protocol willconsider Pressure-Regulated Volume Control (PRVC) mode or similar mode ofmechanical ventilation with initial setting of 6ml/kg tidal volume (VT)of IBW, respiratory rate (RR) to get minute ventilation of 100ml/kg, inspiratoryto expiratory ratio (I: E) to be set not more than 1: 1, an inspiratory oxygenfraction of . 50 and pressure limits at 30 cmH2O.

Subjects will be randomlyallocated to receive initial PEEP of 8cm H2O or PEEP of 5cm H2O. After initial adjustment, the clinicians will be allowed to increase tidalvolume up to 8 ml/kg and respiratory rate up to 35 breaths per minute to managePaCO2.  Additionally, they areallowed to adjust FiO2 and PEEP according to the procedure outlinedin the ARDSnet study. Baseline clinical history anddemographic information will be obtained from the patient’s medical record. Following the initiationof mechanical ventilation, all ventilator settings andavailable hemodynamic parameters will be measured and recorded daily. Also, arterial blood gas, bronchoalveolar lavage and chest radiographic data will beperformed daily. There are eight variables will be measured within our research; threedependent variables and five independent variables. The dependent variables areVAEs incidence, ARDS incidence and duration ofmechanical ventilation.

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

All data accessible only to the investigators. The outcomedata will be collected and compared with the baselinecharacteristics of experimental and control groups to measure the association between the initial PEEP setting and the development of pulmonarycomplications. The mean and median information will be calculated, standerdivision and t-test analysis comparing the baseline result will be done todetermine the significance (P <. 05). For categorical data, the chi-squaretest will be used. The differences within the both groups will be analyzed witha Wilcoxon signed-rank test for paired sample and the Mann-Whitney U test.

Allstatistical analyses will be performed with SPSS 12. 0. 5.    Researchsignificance: 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.