Title：The Effect of Prolonged Inspiratory Time on Pulmonary Mechanics in Obese Patients

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Methods

Subjects

This study was approved by the institutional Ethics Committee (Gachon University Gil Medical Center Institutional Review Board 2016-211, Incheon, Korea) and registered at the US Clinical Trials Registry (NCT02961920). After obtaining written informed consent, we assessed 54 patients scheduled for lumbar spine surgery in our institution between November 2016 and October 2018. Fifty adult patients, ASA physical status 1 or 2 with a body mass index (BMI) of ≥ 25 kg/m2, were randomly allocated to one of two groups: CRV (n=25) or ERV (n=25). BMI was not used as the basis for the ASA classification. Patients who had severe pulmonary disease (history of chronic obstructive pulmonary disease, asthma, bronchopleural fistula, or pneumothorax) or haemodynamic instability and/or hypovoloemia were excluded. The enrolled patients were randomly allocated according to a predetermined allocation sequence to receive an I:E ratio of either 1:2 (CRV) or 1:1 (ERV). A researcher in our institution who was not involved this study generated the allocation sequence without blocking using a randomisation plan generator (http://www.randomisation.com). This study was performed in accordance with relevant guidelines and regulations including CONSORT guidelines (Fig. 1).

Anaesthesia

For anaesthesia induction, intravenous propofol 1.5 mg/kg and rocuronium 0.8 mg/kg were administered. For mechanical ventilation, volume-controlled ventilation was applied with a tidal volume of 10 mL per ideal body weight (kg), an I:E ratio of 1:2 or 1:1 according to the allocated group, and no external PEEP. For maintaining an end-tidal carbon dioxide tension ($EtCO_2$) between 33 and 36 mmHg during surgery, the respiratory rate was adjusted. For

anaesthesia maintenance, sevoflurane of an end-tidal concentration 2-2.5 vol% was used and adjusted to maintain the bispectral index score between 40 and 60. Inspired oxygen fraction (FiO_2) was 0.4 using oxygen and air. For repeated blood sampling and monitoring continuous blood pressure, radial artery catheterization was conducted.

Study design

Standard monitoring during anaesthesia included continuous electrocardiograph, systemic arterial pressure, heart rate, $EtCO_2$, and peripheral oxygen saturation. We measured intraoperative respiratory mechanics including peak airway pressure (Ppeak), mean airway pressure (Pmean), plateau airway pressure, positive end-expiratory pressure (PEEP), and arterial blood gas at three time-points: ten minutes after anaesthesia induction in the supine position (Tsupine), 30 min after in the prone position (T30), and 90 min after in the prone position (T90). We calculated driving airway pressure (Pdriving), lung compliance (Cdyn), and static lung compliance (Cstatic) from respiratory data, and alveolar to arterial oxygen gradient ($D(A\text{-}a)O_2$) from arterial gas analysis data. Pdriving was defined as the difference between plateau airway pressure and PEEP. Cdyn and Cstatic were calculated using the following formula: tidal volume/ (Ppeak-PEEP) and tidal volume/ Pdriving, respectively. Alveolar oxygen tension was calculated using the following formula: FiO_2 (PB – 47 mmHg) – ($PaCO_2$/ 0.8), where PB is the barometric pressure (760 mmHg).

Statistical analysis

A previous study reported that during CRV with an inspired oxygen fraction of 0.4, the mean value (SD) of partial arterial oxygen pressure (PaO_2) was 181 (28) mmHg in obese patients after prone positioning20. We assumed a mean difference of PaO_2 between CRV and ERV of 15%. With an α-value of 0.05 and a statistical power of 90%, a sample size of 23 patients was

required for each group. Anticipating a 10% drop out rate, we recruited 50 patients. Continuous variables are expressed as mean ± standard deviation and categorical variables as number of patients (%). Continuous variables were analysed using the Student t-test or Mann-Whitney U test. Categorical variables were analysed using the Fisher's exact test. Serial changes in respiratory variables and haemodynamic changes were analysed using repeated measures ANOVA followed by Bonferroni correction25. After analysing group x time interaction, we reanalysed serial changes in respiratory variables in each group using repeated measures ANOVA followed by Bonferroni correction. SPSS 21.0 (SPSS Inc., Chicago, IL) was used for statistical analyses.