BIOMEDICAL RESEARCH PROTOCOL
UNIVERSITY OF MISSOURI

Project Title: **A Prospective, Randomized, Non-Blinded, Crossover Controlled Clinical Trial Evaluating the Efficacy of Face Mask Ventilation with 45 Degree Head Rotation in Anesthetized Obese (BMI ≥ 35) Adults**

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2.1 Objectives:

This prospective, randomized, non-blinded, crossover controlled clinical trial will enroll subjects with a BMI ≥ 35 who are undergoing elective surgical procedures. Subjects will be randomized to receive mask ventilation after general induction of anesthesia in either a neutral head position (practice standard position) or a head rotation position (45 degree angle) to determine:

Primary Endpoint:

1. Maximal and average expiratory tidal volume during mask ventilation

Secondary Endpoints:

1. Maximal and average inspiratory tidal volume during mask ventilation
2. Maximal and average end-tidal CO_2 ($ETCO_2$) during mask ventilation
3. Maximal and average airway flow L/min during mask ventilation
4. Lowest and delta O_2 saturation drop on SpO_2 during mask ventilation
5. Lowest and delta O_2 saturation drop on SpO_2 during intubation

2.2 Clinical Hypotheses:

Primary Hypothesis:

We hypothesize that a 45 degree head rotation during mask ventilation will:

1. Increase the efficacy of mask ventilation measured by tidal volumes

Exploratory Hypotheses:

We hypothesize that a 45 degree head rotation during mask ventilation will:

1. Decrease upper airway obstruction measured by airway flow
2. Improve oxygenation measured by SpO_2 during mask ventilation
3. Improve oxygenation measured by SpO_2 during intubation

3.1 Background & Rationale:

Mask ventilation is a foundation of airway management after the initial induction of anesthesia. It allows for adequate oxygenation of the patient to buy enough time for intubation, during which the patient is not ventilated. However, in some patients mask ventilation may be difficult – older than 55 years, heavier (BMI > 26 kg/m^2), with no teeth, having a beard or sleep apnea.[1,2,3] Inadequate ventilation, if not corrected, can result in decreasing oxygen saturation to dangerous levels – which could lead to devastating complications. As a result, the efficacy of mask ventilation is of critical importance to patient safety after the induction of anesthesia.

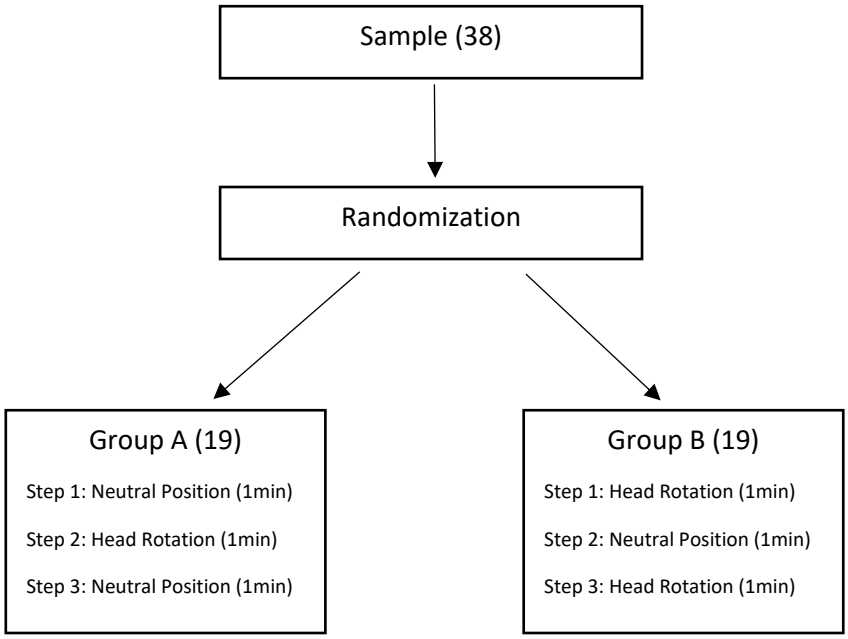
A recent study proposed that mask ventilation could be improved simply by turning a patient's head. The study showed that rotating a patient's head to a 45 degree angle significantly improved mask ventilation when compared with the head placed in a neutral position.[4] However, this study was done in patients with a BMI less than 35. As such, the effects of head rotation on the efficacy of mask ventilation has not been studied in patients with a BMI of 35 and greater.

Obesity (BMI ≥ 30 kg/m^2) affects almost 40% of US adults and is one of the most prevalent health concerns in our society.[5] It is a predictor of difficult mask ventilation because it is associated with increased upper airway obstruction, decreased airway patency, and decreased lung volumes such as functional residual capacity (FRC).[1] If previous findings in regard to the effect of 45 degree head rotation on the efficacy of ventilation hold true in the obese patient, then this study will show that head rotation could be used as a simple way to improve the efficacy of mask ventilation for patients with a BMI of 35 and above.[4]

4.1 Study Design:

This will be a prospective, randomized, crossover, non-blinded, controlled clinical trial performed at a single academic hospital.

4.2 Study Design:



4.3 Study Procedures:

I. Subject Population: this study will enroll 38 adults undergoing elective surgery requiring general anesthesia with intubation of the trachea.

II. Inclusion Criteria:

a. Age ≥ 18 years
b. ASA I-III
c. BMI ≥ 35 kg/m2

III. Exclusion Criteria:

a. Inability to obtain written informed consent
b. Pregnant or breastfeeding
c. Limited head rotation or neck extension
d. Subjects with expected or history difficult intubation
e. Large beard
f. OG/NG tube
g. GERD

IV. Randomization: On the day of surgery, before the induction of anesthesia subjects will be randomized into either Group A or Group B. Randomization will be accomplished by the method of randomized permuted block. The two groups will be stratified so that obese subjects with a BMI ≥ 35 and ≤ 44 and those with a BMI ≥ 45 are equally distributed between both groups. Groups will be additionally stratified by the presence or lack of obstructive sleep apnea (OSA).

V. Blinding: Group assignment will not be known by research staff at the time of subject recruitment. No blinding will occur during the clinical portion of the study or during data analysis.

VI. Preoperative Data Collection and Measurements: Before the subject is taken into the operating room, we will record and measure age, BMI, sex, ASA status, preop diagnoses, OSA, procedure being done, Mallampati score, mouth opening, thyro-mental distance, neck circumference, neck range of motion, lack of teeth, presence of beard, and history of snoring.

VII. Anesthetic Management

a. Monitoring

1. All subjects will be monitored with standard perioperative monitors: ECG, non-invasive blood pressure, pulse oximetry, esophageal temperature, and capnography.

b. Anesthetic Technique

1. All subjects will receive a standardized general anesthetic technique and all anesthetic medications will be dosed on the ideal body weight rather than actual body weight.
2. Preoxygenation – 100% oxygen delivered via face mask for a minimum of 3 minutes

3. Induction – intravenous delivery of propofol, 1.5-2.0 mg/kg, fentanyl, 1 µg/kg, and rocuronium, 0.6 mg/kg. Additional propofol or fentanyl may be administered at the discretion of the anesthesia provider.
4. Mask Ventilation – start when subject loses consciousness. Ventilation settings will be pressure controlled ventilation 20 cmH_2O. Respiratory Rate will be 16. Group A will receive 1 minute of neutral head position followed by 1 minute of 45 degree head rotation to the right and then 1 minute of neutral head position. Group B will be the opposite. If mask ventilation is difficult or SpO2 saturation drops below 90% the subject will be excluded from the study. Immediately after exclusion the standard of care ventilation will be resumed.
5. Intubation – will be in the standard of care fashion after the 3 sets of head positions are completed. Usually the endotracheal intubation is after 2-3 minutes after induction. Our study may increase that time by 1 or 2 minutes.
6. The study will conclude with intubation of the trachea. The rest of the subject management will be per anesthesia clinical team standard of care.

c. Extubation
    1. Standard of care.

VIII. Postoperative Pain Management

a. Standard of care.

4.4 Costs:

The cost of the Medline Top Valve Anesthesia Mask used in this study will be billed to subjects' insurance as normal standard of care at University Hospital. Face masks are used on surgical patients as standard of care following University Hospital Department of Anesthesiology and Perioperative Medicine protocol. They are necessary for

preoxygenation of patients before surgical procedures. Taking part in this study will bring no additional cost to subjects.

4.5 Study Duration:

Study will start in September 2018 and last one year.

5.1 Statistical Analysis and Sample Size Justification:

A power analysis using a predicted tidal volume of 450 ml for group A and 520 ml for group B, with a standard deviation of 75 ml, determined that 19 subjects per group would be needed to achieve a power of 80% with an alpha error of 5%.

6.1 Publication Plan

We plan to present this data at anesthesiology meetings. We will target the American Society of Anesthesiologists Annual meetings for abstract presentations and the journal *Anesthesiology* for publication of the final data.

7.1 References:

1. Langeron O, Birenbaum A, Le Sache F, & Raux M. Airway management in obese patient. *Minerva Anestesiol*. 2014; 80:382-392.

2. Kheterpal S, Han R, Tremper KK, Shanks A, Tait AR, O'Reilly M, & Ludwig TA. Incidence and predictors of difficult and impossible mask ventilation. *Anesthesiology* 2006; 105:885–891.

3. Kheterpal S, Martin L, Shanks AM, & Tremper KK. Prediction and outcomes of impossible mask ventilation: A review of 50,000 anesthetics. *Anesthesiology* 2009; 110:891–897.

4. Itagaki T, Oto J, Burns SM, Jiang YJ, Kacmarek RM, & Mountjoy JR. The effect of head rotation on efficiency of face mask ventilation in anaesthetised apnoeic adults. *European Journal of Anesthesiology*. 2017; 34:432-440.

5. Hales CM, Carroll MD, Fryar CD, & Ogden CL. Prevalence of obesity among adults and youth: United States, 2015-2016. *National Center for Health Statistics* 288th ed. CDC; 2017:1-8.

6. Chapter 19. Airway Management. In: Butterworth JF, IV, Mackey DC, Wasnick JD. eds. *Morgan & Mikhail's Clinical Anesthesiology, 5e* New York, NY: McGraw-Hill; 2013.