Title: Improvement of Manual Ventilation Efficacy with Ventilation Grip Device: a manikin study

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1) **Protocol Title**

Improvement of Manual Ventilation Efficacy with Ventilation Grip Device: a manikin study.

Principal Investigator: Alecia L. Stein, MD

Setting: Center for Patient Safety, University of Miami Miller School of Medicine

2) **Objectives***

PRIMARY OBJECTIVES:

Primary aim: Our primary goal is to assess the efficacy of the Mask Ventilation Grip (MVG) device via comparison of the average tidal volumes achieved during respiration using the MVG device compared to the standard two-handed V-E technique(2VE),by measuring the average tidal volume(s) achieved as well as changes in the obtained tidal volumes over a duration of two three-minute cycle in both experienced (expert) and inexperienced (novice) clinicians

Primary hypothesis: Specifically, we hypothesize that use of the MVG device when providing two-handed mask ventilation will improve the average tidal volumes achieved compared to the standard 2VE technique in both expert and novice groups in a manikin simulation setting with novices appreciating a greater increase in average tidal volume than experts

SECONDARY OBJECTIVES:

Secondary aim 2: Our second aim is to investigate the level of perceived difficulty and fatigue experienced while using of the MVG device versus the standard 2VE technique. in both expert and novice groups

Secondary hypothesis: Providing mask ventilation to a manikin is easier (subjective perception of difficulty) when using the MVG device compared to the standard 2VE technique in both groups, with the novice group demonstrating a greater ease to ventilate. Hand-fatigue is reduced by using the ventilation grip device compared to the standard 2VE technique in both expert and novice groups with the novice group appreciating a greater reduction in fatigue with the MVG compared to 2VE than the expert group.

Subjectively, participants will fill out NASA-TLX (NASA Task Load Index) and SOFI (Swedish Occupational Fatigue Inventory) questionnaires. "The NASA task load index (NASA TLX) is a tool for measuring and conducting a subjective mental workload (MWL) assessment. It allows you to determine the MWL of a participant while they are performing a task. It rates performance across six dimensions to determine an overall workload rating. The six dimensions are as follows: mental demand, physical demand, temporal demand, effort, performance, and frustration level. Dimensions will be weighted and a fatigue index score will be calculated with computer software. The SOFI questionnaire is a comprehensive assessment of a participant's subjective perception of fatigue that explores fatigue across 5 domains rated on a sliding 7 point scale: lack of energy, physical exertion,

physical discomfort, lack of motivation, and sleepiness. Participants will complete these questionnaires after providing mask ventilation with each of the two mask ventilation techniques (MVG and 2VE.)

Objectively, fatigue will be measured by recording the changes in tidal volumes achieved per machine delivered breath temporally over the course of 2 three-minute mask ventilation periods.

EXPLORATORY OBJECTIVES:

Exploratory aim 1: One of our exploratory aims is to compare the efficacy (as described above in primary objectives) of the MVG device versus standard 2VE amongst individuals with smaller hands/weaker grip and individuals with larger hands/stronger grip strength.

Exploratory hypothesis 1: Regardless of hand size and grip strength, all individuals will appreciate an increase in tidal volumes with MVG than with standard 2VE, but individuals with smaller hands/weaker grip will appreciate a greater increase in tidal volumes achieved with the MVG device compared to the 2VE technique than individuals with larger hands/stronger grip.

Exploratory aim 2: Our second exploratory aim is to compare the level of difficulty perceived and fatigue (as described above) appreciated while using the MVG device for mask ventilation compared to the standard 2VE amongst individuals with smaller hands/weaker grip strength and individuals with larger hands/stronger grip strength.

Exploratory Hypothesis 2:
Regardless of hand size and grip strength, all individuals will appreciate a decrease in difficulty and appreciate lesser fatigue with the MVG device than with standard 2VE, but individuals with smaller hands/weaker grip will appreciate a more significant decrease in difficulty and less fatigue than individuals with larger hands/stronger grip.

3) **Background***

Face mask ventilation (MV) is a basic and essential skill in airway management. It is defined as the procedure of external placement of a mask over patient's face with adequate pressure to form an effective seal over the bridge of the nose, malar eminences, and the mandibular alveolar ridge.[1] In respiratory emergencies, effective MV is essential to ensure adequate patient oxygenation and ventilation until the patient's airway is secured by either a supraglottic airway device or an endotracheal tube.[2] Even though MV is considered a routine procedure, adequate BMV is sometimes challenging even in experienced hands. During in-hospital emergency situations, the initial caregivers at patient's bedside are caregivers with varied duration of experience, which include emergency medicine physicians and/or anesthesiologists. The technique of MV requires understanding facial contours, mask

design, and its effective application.[3] This requires sufficient experience as shown by difficulty in providing effective MV by novices, emergency room technicians, pre-hospital team personnel, nurses and operating room personnel other than anesthesiologists and emergency medicine physicianswho perform MV regularly.[3, 4]

Conventionally, the E-C clamp technique of mask holding is taught for MV for beginners where one hand is used to hold the mask over the victim's face in such a way that the little finger provides jaw thrust while the ring and middle fingers rest softly on the rim of the mandible forming an E shape while the thumb and the index finger form C shape attempting to secure the mask tightly around the victim's mouth and nose. This technique is described classically as E-C clamp technique of mask holding while the other hand is used to squeeze the bag (a self-inflating bag or a reservoir bag). There can be several factors contributing to inadequate BMV that can be classified as patient-related (such as beard, edentulous buccal cavity, thick neck, etc.), equipment-related (inappropriate size mask, non-cushioned rim of the masks, etc.), or operator-related factors (inexperience, improper technique). Overall, inadequate MV is contributed by either leak around the mask or an unrelieved airway obstruction or a combination of both. [5]

Several risk factors for difficult MV were identified so far. For example, age more than 55 yr., BMI > 26 kg/m2, lack of teeth, presence of beard, and history of snoring were reported to be independent risk factors for difficult MV, and the presence of two of these criteria should at least indicate a DMV[6]. *Kheterpal et al*., on a multicenter trial on 492.239 evaluated the association between difficult MV (grade 3-4) with difficult intubation, and they found it is an infrequent but not rare phenomenon (0.3%). This data also demonstrate that although many impossible mask ventilation patients may be difficult to intubate, most can be managed without a surgical airway, highlighting the importance of performing an effective MV [7]. An airway assessment attempting to predict difficult MV should be systematically realized. However, there are other patient independent factors that contribute to difficult MV, such as provider-and equipment-related factors. [8]

4) Although mask sealing against the face with 1-hand is the most preferred method during mask ventilation, 2-handed technique consistently and significantly resulted in larger tidal volume (Vt) than use of the one-hand technique. Switching from one handed MV to two-handed MV techniques improved expired tidal volume percentage from 31 % (95% CI 17-51%) with 1-handed technique to 85% (05%CI 78-91%) for two-handed technique [9],[10]. A prospective randomized study comparing three face mask ventilation techniques found no significant difference between two separate two-handed C- and V-E techniques. For this study, we will use 2-hand V-E technique demonstrated in Figure 2B as our control 2-hand mask ventilation technique and refer to it as 2VE. However, placement of both hands on the mask needs a second operator to squeeze the bag, which could be difficult in some scenarios. Mechanical ventilation can be applied by most modern anesthesia machines, allowing the operator to focus their attention on positioning the airway and the seal of the facemask. Knowing that physical characteristics of both patient and provider (sex, height, weight, hand size, and grip strength) determine the efficacy of

MV [6,8,11], past investigators have developed different devices striving to enhance this procedure, for the benefit of patient and user satisfaction.

Based on these principles, the mask ventilation grip device-(Figure 1)[12] was designed by an anesthesiologist (Gerald Rosen MD) after responding to many cardiopulmonary arrests and pre-arrest situations in the hospital setting and witnessing practitioners of all levels and professions, who were unable to create a sufficient mask-face seal and adequately mask-ventilated patients prior to intubation. The MVG is an add-on device which fits most standard ventilation masks. Its intent is to ensure proper technique enhancing the effectiveness of the 2-handed sealing technique by creating a tighter seal between the mask and the face, especially for providers with small hands or weaker grip strength or for patients predicted to be difficult for mask ventilation. [12]. The developer hypothesizes that it reduces the learning curve for lesser-trained individuals. Peck et al propose how the MVG device may improve mask ventilation on a difficult airway, helps and decreases the effort to maintain a good seal between face and mask during long periods of mask ventilation. [12]

Our goal is to investigate the efficiency of the newly designed ventilation grip. Specifically, we test the hypothesis that using the ventilation grip improves average tidal volumes achieved compared to the standard 2VE technique **, thereby establishing a more effective seal and reducing perceived fatigue after prolonged periods of providing 2VE in a manikin simulation setting**

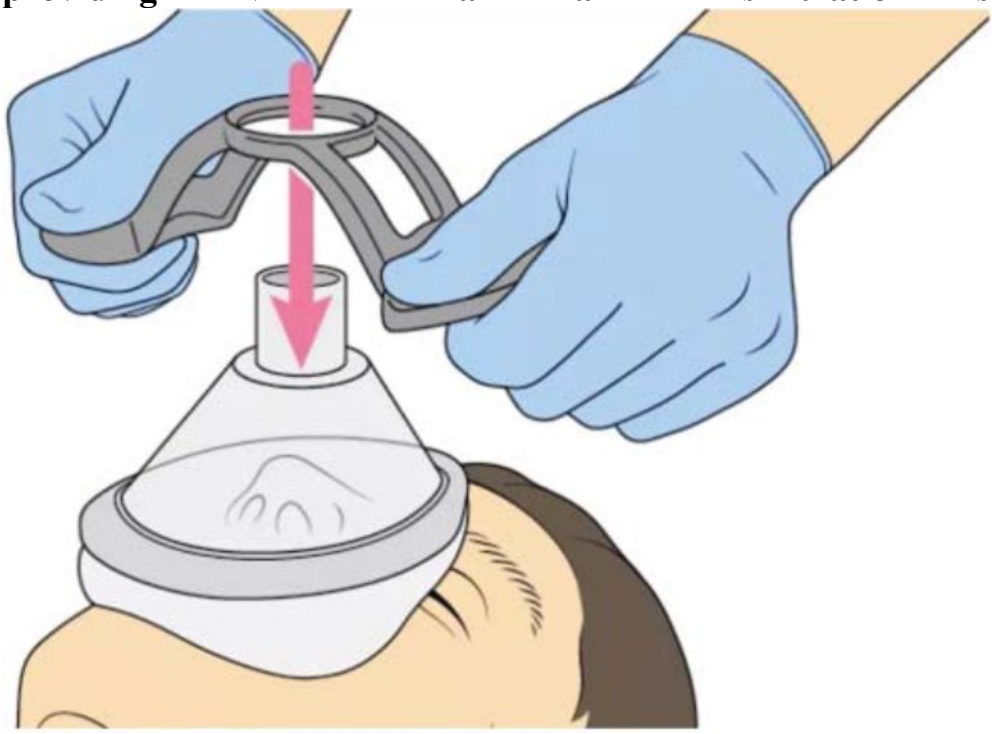

Figure 1. The Mask Ventilation Grip

5) **Inclusion and Exclusion Criteria***

Participants will be recruited via email. Novices (participants without any significant MV experience in a clinical setting) will be primarily recruited via contacting various University of Miami Miller School of Medicine clerkship directors who frequently utilize the CPS to train medical students. Whereas experts (participants with 2 or more years of clinical experience providing MV) will be primarily recruited via email distributed throughout the Department of Anesthesiology at the University of Miami Hospital and consisted of senior residents and attending physicians.

We propose a simulation based repeated-measures (mixed) cohort study that will include medical students, less-expereinced resident physicians and anesthesia attending physicians/anesthesia senior resident physicians with at least 2 or more years of experience. The study will be performed at the Center for Patient Safety at the University of Miami Miller School of Medicine campus..

Inclusion criteria:

- Current medical students, PGY1 residents or residents from other specialities with no prior experience in hand mask ventilation techniques
- Anesthesiology residents and attendings with at least 2 or more years of clinical experience

Exclusion criteria:

- Refusal to participate in the study.
- Medical students with prior experience in hand mask ventilation techniques (i.e. experiences in previous careers such as nursing or EMT professions)
- Any physical inability to adequately perform ventilation

6) **Procedures Involved***

After IRB approval and written informed consents, participating individuals will be categorized to novice or expert groups depending on previously described criteria/years of clinical experience. From these groups, they will be randomized via blindly selecting pieces of paper marked MVG or 2VE. There will be two boxes, one for novices with 16 pieces of paper (8 marked MVG/8 marked 2VE), and one for experts with 16 pieces of paper (8 marked MVG/8 marked 2VE.) Whichever option is selected (MVG or 2VE), the participant will begin with this technique and then switch to the alternative.

ev,The participants will then be guided to the OR simulator where the SimMan Essential patient stimulator (Laerdal Medical Wappingers Falls, NY) (manikin) will be placed supine on aa hospital bed. After this, mask holding technique with MVG device and without (2VE) will be demonstrated by investigators, who will then reviewparticipants' subsequent techniquesto ensure consistency throughout the experiment. The parameters for the anesthesia workstation/OR simulator will be checked and confirmed by one or more members of the research team for every participant before the baseline information of participants' demographics and level of experience is recorded. They will be instructed to maintain as tight a seal between the mask/manikin face as possible, that the "patient" only requires mask ventilation during the entire scenario, and that there is no need to perform

additional emergency maneuvers such as chest compressions. The ventilation mask will be connected to an air flow supply via the anesthesia machine ventilator.
Participants will then don their desired sized gloves and perform MVG or 2VE for 30 breaths (approximately 3 minutes) in accordance with the techniques demonstrated previously as an investigator in the room records tidal volumes achieved for each breath onto a data sheet and a separate camera in the OR simulator also simultaneously records the encounter. Tidal volumes will not be recorded until a proper seal is established so participants are aware of what a mask leak feels like. After providing mask ventilation with MVG or 2VE for 30 total breaths, participants are given a 5-minute rest period during which they were to complete the given NASA-TLX and SOFI instruments described above.

After completion of the surveys and the 5-minute rest period, participants were instructed to provide mask ventilation for another 30 machine-delivered breaths utilizing the alternative technique that they had not performed in the previous mask ventilation period. After this period of providing ventilation, participants were again asked to complete another set of NASLA-TLX and SOFI instruments in respect to the mask ventilation technique they had just used.

As the final component of the experiment, participants will have their dominant hand measured for hand span, palm circumference, and max grip force produced. Participants will be instructed to spread their fingers on their dominant hand as wide as possible, after which a measuring tape will be used to record the distance from the distal tip of the fifth digit to the distal tip of the first digit in centimeters. Subsequently, participants will be instructed to bring their fingers together, while keeping their first digit fully abducted. From this position, the measuring tape will be used to record the circumference of the widest portion of the palm in centimeters. After these measurements, investigators will demonstrate for the participants, how to grip the dynanometer while having the dorsum of their dominant hand resting against another table from a sitting position. Participants will be given 3 attempts to grip the device as forcefully as possible, from which the average force (kg) will be used as a final number.

All experimental runs will be conducted in the OR simulator at the Center for Patient Safety (CPS) Miller School of Medicine downtown campus of the University of Miami.The OR simulator consists of a SimMan Essential human patient simulator (Laerdal Medical Wappingers Falls, NY) an anesthesia workstation (Datex-Phmeda, GE Healthcare, Little Shalfont, UK,) and an ASL 5000 artificial lung (IngMar Medical, Active Servo Lung, Pittsburgh, PA.)

From the control room, an adjacent room with computers and one-way mirror view of the OR simulator, a CPS technician and another investigator operating the anesthesia workstation will input the following experimental parameters: pressurecontrolled ventilation (PCV) ventilator rate (Rate) of 10 breaths/min, peak inspiratory pressure (PIP) of 37 cm H2O, Trachea (artificial lung) resistance of 175 cm H2O/L/sec, compliance of 50

mL/cm H2O, and the right manikin lung resistance set to 100 cm H2O/L/sec while the contralateral lung is set to 0 cm H2O/L/sec. These parameters were designed to mimic the feeling of providing 2VE to difficult patients (obese patient, short neck, obstructive sleep apnea, etc...) while maintaining a tidal volume (TV) of approximately 500 mL $\pm$ 5 mLs.The height of the SimMan Essential Patients Stimulator (manikin) will be adjusted for each participant so that the top edge of the table is flush with the participants' iliac crests. An investigator with a timer will stand approximately 6 feet away from the participants with clear view of the monitors and participants' hands and give out instructions accordingly.

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Measurements

Baseline information including age, gender and years of experience will be recorded.

Primary outcome: **the difference in the average tidal volume achieved per breath** between the two techniques (MVG and 2VE) in the two groups (novice and expert) as recorded by the anesthesia ventilator over thetwo 30 breath mask ventilation periods.

Secondary outcomes: Hand fatigue and **difficulty perception**. All participants (both novice and expert groups) will be asked to rate the difficulty of each of the techniques (MVG and 2VE) and express their level of fatigue appreciated by filling out NASA-TLX and SOFI instruments after providing ventilation with each technique.

Exploratory outcome:
Hand fatigue and efficacy of MVG compared to 2VE in regards to participants' hand sizes/grip strength. All participants will have their hand span, palm circumference, and maximum grip force of their dominant hand recorded. This data will be analyzed alongside each participant's answers to the previously described NASA-TLX, SOFI instruments, and gross average tidal volume for each period of ventilation with both techniques.

7) **Statistical Analysis**

The required sample size for this study was calculated with an online power and sample size calculator for general linear multivariate models (GLIMMPSE v2.1.0) The parameters used for this study is in JavaScript Object Notation (i.e., JSON) file, which can be uploaded into GLIMMPSE website and reviewed (URL for GLIMMPSE program)
A data collection sheet will be used and completed for each included subject. Descriptive statistics will be used for demographic characteristics.

T-paired test model will be used for comparison of the tidal volumes between two groups (MVG and 2VE groups)

Recruitment and consenting strategy

Recruit a sample of medical students, residents and attendings at the Miller School of Medicine of the University of Miami.

The study will be performed at the Center for Patient Safety (CPS). The CPS is an educational site for residents, medical students and attendings to undergo specialized simulation- based training. As these three groups attend their regularly scheduled training sessions, they will be approached by a member from the research team to assess their willingness to participate after their simulation session in the study. If willing, they will be advised that it will be only this one session and their participation is voluntary and that it is in no way connected to their academic, educational assessment and grades.
We will obtain written consent from all participants. No participant will receive any compensation for their participation. We will maintain documentation of participant flow in accordance with the Consolidate Standards for Reporting Trials Statement. Figure 2 [12]

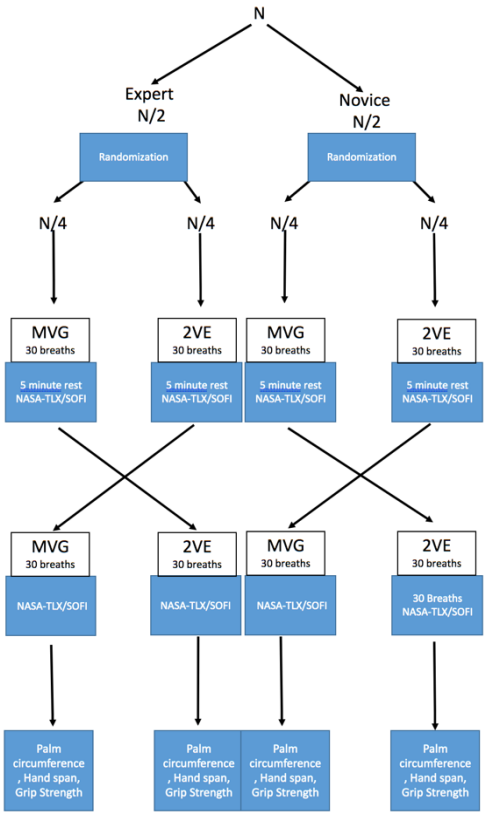

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) diagram of participant enrollment, allocation, and analysis[13].

8) **Risks to Subjects***

There is a minimal risk associated with this study. We propose a prospective cross-over single center cohort study that will include anesthesiology residents and

attendings. The study will be performed at the Center for Patient Safety, University of Miami Miller School of Medicine.
The only descriptors which will be collected include age, gender and years of experience, which will remain secured.

9) **Confidentiality**

The descriptors mentioned above will be collected on the approved data sheet., with each participant assigned an alphanumeric label. Study data will be accessed only by the PI and the team.
All data forms are going to be stored in the office of the Principal Investigator, Department of Anesthesiology, Jackson Memorial Hospital, 1611 NW 12th Avenue, SW 301, Miami FL 33136. Data transferred to an excel spreadsheet will be stored electronically in a secured encrypted file on the Principal investigator's Computer. The Investigator (or research staff) will record (e.g. write down, abstract) data collected in a manner that does not include any indirect or direct identifiers and the recorded data will not be linked to the individual's identity.

10) **Provisions to Protect the Privacy Interests of Subjects**

Access to the information is limited to members of the research team. Each member is already trained in maintenance of confidentiality as evident in their medical, CITI training as well as their past experience with studies.

11) **Consent Process**

Written informed consent will be obtained for each subject. The consent will be obtained in the Center for Patient Safety, University of Miami Miller School of Medicine. Only subjects who speak English will be enrolled due to limited funds for Spanish translation of ICF.
Subject's identity and age will be verified prior to obtaining informed consent, as well as their understanding of risks and benefits and possible alternatives available explained before any informed consent signature from those subjects willing to participate. The PI(s) with each study participant will:

- Ensure each subject is given full and adequate oral and written information about the nature, purpose, possible risk, and benefit of the study.
- Ensure each subject is notified that they are free to discontinue from the study at any time.
- Ensure that each subject is given the opportunity to ask questions and allowed time to consider the information provided.
- Ensure each subject provides signed and dated ICF before conducting any procedure specifically for the study.
- Ensure the original, signed ICF(s) is/are stored in the investigator's Study File.
- Ensure a copy of the signed and dated ICF is given to the subject for future reference of the study.

All potential subjects will be given ample time to review the consent form and discuss any questions and concerns with research personnel or study doctor and will be provided with

a copy of the signed ICF. Consent will be documented with a dated signature on the consent form from both the patient and the study personnel conducting the consent discussion. Study team will be following SOP: Informed Consent Process for Research.

12) **Process to Document Consent in Writing**
We will be following SOP: Written Documentation of Consent.

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