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Self-Assembled Modified Macintosh Video laryngoscope versus McGrath MAC® Video laryngoscope: Which is Better?

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Background

Endotracheal intubation, the gold standard in definitive airway management, is a procedure for inserting an endotracheal tube (ET tube) with the help of a laryngoscope. A study showed that 94% of intubation done by skilled operators would be successful in 1 to 2 attempts. In contrast, non-skilled operators had only 82% first-attempt success rate with 13.2% requiring 3 or more attempts, and 10.3% taking over 10 minutes.[1, 2] One of the biggest upgrades in the recent decade to improve this success rate is the addition of video camera to a laryngoscope, reintroducing the device as a Video laryngoscope (VL). McGrath MAC ® laryngoscope is one of the most widely used commercial video laryngoscopes that utilize a modified Macintosh blade, with a video camera and a light source attached at the end of the blade. The image is displayed in the *liquid-crystal display* (LCD) monitor mounted on the handle of the blade. [3,4]

VL has been shown to improve visualization of the larynx.[5,6,7,8] However, several studies showed that intubation time with McGrath MAC ® is the same or even longer compared to conventional macintosh blades.[7-10] Insertion of ET tube through the vocal cords is also more difficult even though it is clearly visualized because the ET tube is in contact with the anterior tracheal wall, and therefore a stylet is needed to bend the tip of the ETT to an angle > 35º.[3,10,11] McGrath's blades are also less effective than the wider sized Macintosh blades to displace the tongue and expanding the area for visualization of the larynx and ET tube insertion[10]

Despite the advantages of video laryngoscope, the expensive price becomes a problem, especially in developing countries.[6,12] As an alternative, we modified a classic Macintosh laryngoscope by attaching a flexible fiber optic-like camera to its blade. We compared the intubation time, success first attempt rate, laryngeal visualization, complications, and user satisfaction between this self-assembled video laryngoscope and McGrath MAC ®.

Research Methods

This is an experimental single-blinded randomized clinical trial conducted in the operating room for elective surgery at the dr. Cipto Mangunkusumo Hospital, a tertiary national referral hospital in Jakarta, Indonesia from June to August 2020. The sample size of 62 patients was calculated using numerical hypothesis testing formula for two unpaired populations with an

additional 10% of presumed sample dropout. Ethical clearance was obtained from Universitas Indonesia Ethical Board Committee.

All adult patients (18-65 years old), ASA I-II, with Body Mass Index (BMI) of 18 – 30 kg/m^2 scheduled for elective surgical procedures under general anaesthesia were included. All subjects provided written consent. We exclude patients with a difficult airway, pregnancy, cardiac condition, and neuromuscular disease.

The self-assembled modified Macintosh video laryngoscope (SAM-VL) used in this study was constructed from a portable video camera with a Wi-fi connection (Wi-fi Endoscope Video Camera model YPC99) attached to a no. 4 Macintosh Laryngoscope blade (Riester no.7040). The video signal is transmitted to an Android-based mobile phone (Android version 7.0). The portable 2 megapixels video camera is 8 mm in diameter with 8 LED lights for adjustable lighting level and 3 meters cable length. Video resolution output is 640x480 pixels (VGA) and 1280x720 pixels (HD). The camera has a 70º visual angle with a focal length of 4– 6cm and is water-resistant. The camera was taped to the Macintosh blade at a distance of 5 cm from the distal end of the blade, using transparent waterproof Leukofix ® tape. After installation, the camera was oriented on a flat plane to set the desired image. The video images are then viewed on the mobile phone screen using the Y-camera app (downloadable for free in Google Play Store for Android). The total cost for this camera device assembly was Rp260.000 (roughly 20 USD), excluding the Android phone. After intubation, the camera is removed from the Macintosh blade and the camera tip that enters the patient's oral cavity is flushed with running water and washed with soap for at least two minutes, using a soft bristle brush to remove any soil if needed. After drying, the camera is wiped with a 70% alcohol swab before the next procedure.

Randomization was done with tables and then presented in a closed envelope when the patient arrived at the operating room to determine the intervention group: (1) the Self-Assembled Modified Macintosh Video laryngoscope (SAM-VL) group or (2) the McGrath MAC ® video laryngoscope (McGrath) group. The laryngoscopist is the one who opened the envelope. A research assistant helped to prepare the laryngoscope according to the randomization results.

Anaesthesia monitoring was conducted following ASA standard and included ECG, non-invasive blood pressure, pulse oximeter, etCO_2, and temperature. Initial hemodynamic status

of the patient before induction including systolic, diastolic, mean arterial pressure, pulse, and peripheral oxygen saturation was noted.

Anaesthesia was co-induced intravenously with fentanyl 2 μg/kg, propofol 2 mg/kg, and rocuronium 0.6 mg/kg. Medications were titrated to effect. Subjects were given positive pressure mask ventilation with 80% oxygen for 3 minutes. Hemodynamic status was recorded three times: (1) pre-induction, (2) at 3 minutes after co-induction medications were given, and (3) after tracheal intubation in confirmed.

The intubation time "A" recording began when the tip of the laryngoscope blade passed through the incisors until the operator was able to achieve the best visualization of the glottis. The "B" intubation time recording began when the operator received visualization of the glottis and ended after the ET tube was confirmed to enter the trachea. Intubation time "B" consists of two components, insertion of the ETT into the vocal cords and connecting the breathing circuit so that the etCO2 wave appeared on the monitor. When inserting the ET tubes, all operators were assisted with a stylet. To minimize the delay in connecting the circuit, one assistant was present to help the operator.

Intubation was done using ET tube No.7.5 for men and No.7 for women with the help of a stylet. Subjects underwent laryngoscopy and intubation with either McGrath MAC ® video laryngoscope or SAM-VL according to randomization. During visualization of the glottis, the operator mentioned the POGO (Percentage of Glottic Opening) score visualized, with a scale ranging from 0–100%. Successful intubation was confirmed by capnography tracing. The SAM-VL can record both photo and video formats. McGrath MAC ® screen can only be used for visualization, but the image cannot be recorded. Thus, a smartphone video camera is used to record images from the McGrath MAC ® screen.

One attempt to intubate was noted if the ET tube was successfully placed into the trachea on the first attempt. If the laryngoscope blade was removed from the mouth and then reinserted, consequently the researcher noted the number of intubation attempts. If the intubation attempt was unsuccessful 3 times and/or the intubation time exceeds 120 seconds, the subject was dropped out.

If during the procedure an emergency or desaturation of ≤90% occurred, it would be managed following ALS algorithms and the subject was dropped out from the study. Any complication throughout the procedure was noted. This study also includes a survey to evaluate the operator's subjective experience using three questionnaires in Likert scale format. The items evaluated are ease in blade insertion, device maneuverability, glottis visualization, and overall satisfaction rating.

The results were calculated using the *Statistical Package for Social Scientists* (SPSS) 24. Analysis of the duration of intubation (numerical data) was done with an unpaired *t-test* for data with normal distribution, and Mann-Whitney if the distribution was not normal. The results were considered significant if the p-value was < 0.05.

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INFORMED CONSENT

I, ***dr. Raden Besthadi Sukmono, SpAn-KAR*** from the ***Department of Anesthesiology and Intensive Therapy FKUI / RSCM*** will conduct a study entitled ***Comparison of Endotracheal Intubation Time Using a Macintosh Laryngoscope Modified with the McGrath MAC ® Video Laryngoscope on Adult Population***

I will provide information to you about this research and invite you to be part of this research. You can participate in this research by signing this form. If you agree to participate in this research, you can back away from this research. You also have the right to receive the latest information from us about the treatments being tested, if any. If you refuse to participate or withdraw from this research, this decision will not affect the relationship between you with me and will have no impact on the applicable services in this hospital. If you do not understand each statement in this form, you can ask to me

1. **Research purposes**

   Comparing the insertion time of the airway tube into the airway using the modified Macintosh laryngoscope with McGrath video laryngoscope in the adult population.

2. **Participation in research**

   Overall, this research will run for 3 months. If you decide to participate in this research, you will be asked to participate in the event when you will undergo surgery under general anesthesia. This research will involve you in one period, namely when going to undergo general anesthesia.

3. **Reasons of recruitment**

   You were chosen for this study because it meets the criteria for adults aged 18–65 years, with the condition of the body does not have severe disease or complication in anesthesia and has a mass index body 18.5–30 kg / m 2

4. **Research procedure**

   - One day before surgery, during the pre-anesthesia visit, you will be interviewed by the doctor to be asked and recorded. Basic data: Name, record number medical, place of birth date, age, weight, height, address, telephone number, medical history, history of drug use, history of allergies, diagnosis, surgery, and history of previous anesthesia.

- The night before the study, you were asked to fast 6 hours before the operation and were allowed to drink plain water 2 hours before surgery.
- On the day of the surgery, you will be received by the operating room officer at RSUPNCM.
- After entering the operating room, you will be sedated using the usual anesthesia technique practiced in the operating room. Then the type of assistive device to insert the breathing tube into the airway will be selected according to the options listed in the closed envelope. The patient will be supervised by trained personnel during anesthesia and surgery.
- The assessment and recording of your condition will be carried out at the beginning anesthesia by the research team. What will be assessed is the time it takes to enter the breath tube of each device used.

5. Risks, side effects, and their management

The device for inserting the airway into the airway is widely used and does not provide significant side effects but sometimes minor mucosa of the lips and mouth injuries can occur in some people. During the research, you are supervised by trained personnel. When an emergency condition happens, then you will be managed according to the basic life support algorithm.

6. Benefits

The time of breath tube insertion into the airway can be shorter

7. Compensation

You will not get any reward for participating in this research

8. Financing

Research funding will be fully borne by the researcher

9. Confidentiality

All data and original research files will be stored in the department's research cabinet which will be locked and only accessible for audit purposes. The patient's ID will be saved in the initial format. Presentation research results in scientific meetings/conferences and

publications in scientific journals will not include the name of subjects. However, representatives from sponsors, ethical committees, and national regulatory bodies will have access to research data for verification.

10. Obligations of research subjects

As research subjects, you are obliged to follow the research rules or guidelines as written above. If anything is not clear, you can ask the research team.

11. Right to refuse and resign

You do not have to participate in this research if you don't want to. You must understand that even if you agree to participate, you have the right to withdraw from this research. If you refuse to participate or withdraw from the study, the decision will not affect your relationship with me, and it will not have an impact on the standard of service that applies at this hospital. I will allow you at the end of this explanation to consider the decisions to be taken.

12. Additional Information

You are allowed to ask all the things that are not yet clear in this research. If at any time there are side effects or need further explanation, You can contact **R. Besthadi Sukmono, MD** in **the Department of Anesthesiology and Intensive Therapy FKUI / RSUPN Dr. Cipto Mangunkusumo, Jakarta**

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RESEARCH PARTICIPATION AGREEMENT SHEET

All these explanations have been presented to me and all my questions have been answered by ***doctor*.** I understand that if I need an explanation, I can ask the ***doctor***

Certificate of Approval (*Consent*)	
I have read all the descriptions about this research. I've been given the opportunity to asked and all my questions have been answered clearly. I am willing to participate in this research study voluntarily _____ Subject / guardian name _____ Signs hand participants study Date _____ day / month / year	I confirm that the participants have given the opportunity to ask about research, and all questions have been answered correctly. I confirm that consent has been granted voluntarily. _____ Name of researcher / approval requester _____ The signature of the researcher / approval request Date _____ day / month / year

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