Taiwan "Aerosol Box" versus UMMC "Intubation Box" : Clinical Evaluation Of The "Intubation Box" For Ease Of Intubation

INVESTIGATOR :
DR. SHAIRIL RAHAYU BINTI RUSLAN

CO-INVESTIGATOR :
ASSOC. PROF. DR. INA ISMIARTI BINTI SHARIFFUDDIN
ASSOC. PROF. DR. CHAW SOOK HUI
ASSOC. PROF. DR. LOH PUI SAN
DR. NOORJAHAN HANEEM BINTI MD HASHIM
DR. MOHD FITRY BIN ZAINAL ABIDIN
DR. NURAZREEN BINTI HUSSAIN
DR. MOHD AFIQ SYAHMI BIN RAMLI

DEPARTMENT OF ANAESTHESIOLOGY
UNIVERSITY MALAYA MEDICAL CENTRE

1st MAY – 31st DECEMBER 2020
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Background:

Intubation is classified as an aerosol-generating procedure (AGP). Intubation in a confirmed COVID-19 patient with a high viral load poses a high risk of exposure to health care workers (HCW). To reduce this risk, the HCW and their assistants are advised to don full personnel protective equipment (PPE) with a powered air purifying respiratory (PAPR) during intubation. In view of this concern, this procedure is highly recommended to be done in a negative pressure room to control the spread of aerosolizing particles in the room. A first-pass success in intubation is also crucial to minimize the risk of infection to health care workers involved.

Introduction :

An Aerosol Box (from here on known as Box A) was recently designed by Dr. Lai Hsien Yung from Taiwan which adds extra protection to the intubator and the surrounding environment (Everington, 2020). The Aerosol Box is a transparent box made of acrylic or transparent polycarbonate sheet, designed with an opening on one side allowing it to fit over the patient's chest and neck, while the opposing side has two holes through which the intubator can insert their hands through (Figure 1). It was shown that this barrier enclosure during intubation protects the laryngoscopist. Canelli et al simulated a patient with a cough during intubation with and without the Aerosol Box. With the box, they showed that the simulated cough resulted in contamination of only the inner surface of the box, the laryngoscopist's gloves and gowned forearms. Examination of the laryngoscopist and the room with ultraviolet light after the simulated cough also showed no macroscopic contamination outside the box. . In contrast, intubation without the box demonstrated that the laryngoscopist's gown, gloves, face mask, eye shield, hair, neck, ears, and shoes were all contaminated.

Feedbacks from our colleagues stated that intubation with Box A is slightly difficult and may cause delay in intubation. Canelli et al also concluded this observation. We, therefore, innovated the design of Box A to facilitate the laryngoscopist, as shown in Figure 2 ("Intubation Box", from here on known as Box B). We find that Box B has better ergonomics, and this will increase the rate of success of intubation.

Objectives :

We aim to compare the relative intubating efficacies of these two boxes. This study assesses the time to successful intubation as the primary outcome. Our secondary outcomes will be the quality of the laryngoscopy view (objectively defined as "percentage of glottic opening" / POGO) and ease of intubation.

Methodology:

This is a prospective randomized cross over trial to compare the time for intubation using these two devices by our anaesthetists. The planned duration from planning to recruitment to completion of study will be from 1st May 2020 to 31st December 2020. We will recruit eligible anaesthetists after obtaining written informed consent. The anaesthetist should have more than 5 years of experience with intubation as well as experience with intubating patients using videolaryngoscope for more than 20 times.

The anaesthetist will be randomised to intubate the manikin in either Box A or Box B first. The primary endpoint which is the time to successful intubation (defined as the interval from insertion of the laryngoscope blade into the mouth to inflation of the tracheal tube cuff) will be recorded. Other endpoints are the numbers of intubation attempts (each attempt defined as complete removal of video laryngoscope from mouth and reinsertion) will be recorded. Failed insertion is defined as the entire intubation procedure taking more than 120 seconds or more than 3 insertion attempts.

The participants will evaluate their intubation experience using both boxes with a questionnaire based on the ISO9421-11 standard, that is effectiveness, efficiency and satisfaction.

Sample size:

The primary endpoint of the study is time to successful tracheal intubation. Sample size is based on a calculation of 10.0 s as the clinically relevant difference in intubation time, with a prospective power analysis at 80% power and 0.05 level of significance. It shows that a sample of 28 laryngoscopists would be required. This will be a cross over study, hence we will recruit 30 laryngoscopists to also account for dropouts and protocol breaches. In view that the time to successful intubations data are not normally distributed, we will use the Mann Whitney U test to analyse intubation times. Categorical data such as number of intubation attempts will be evaluated for differences among the groups using the chi-square test. All statistical analyses

will be performed using IBM SPSS statistics 23 database. A value of $p < 0.05$ is considered significant.

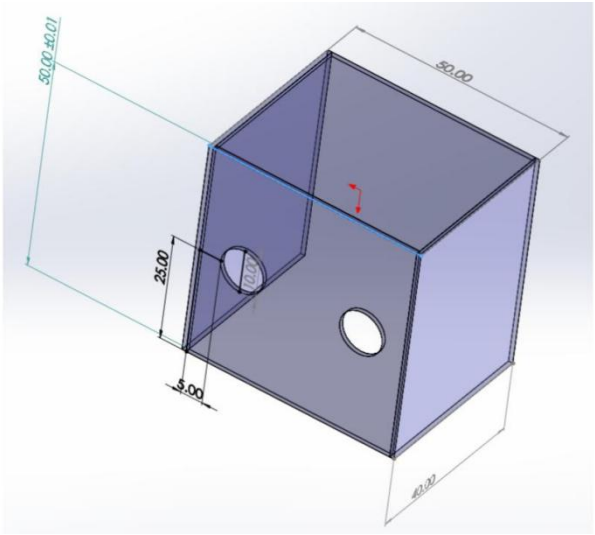
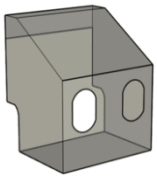
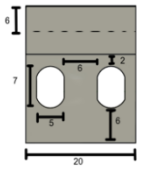


Figure 1 (Box A). Dimensions are 50 cm by 50 cm (height x width), with a thickness of 40 cm. (Source : https://sites.google.com/view/aerosolbox/design)





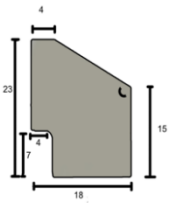
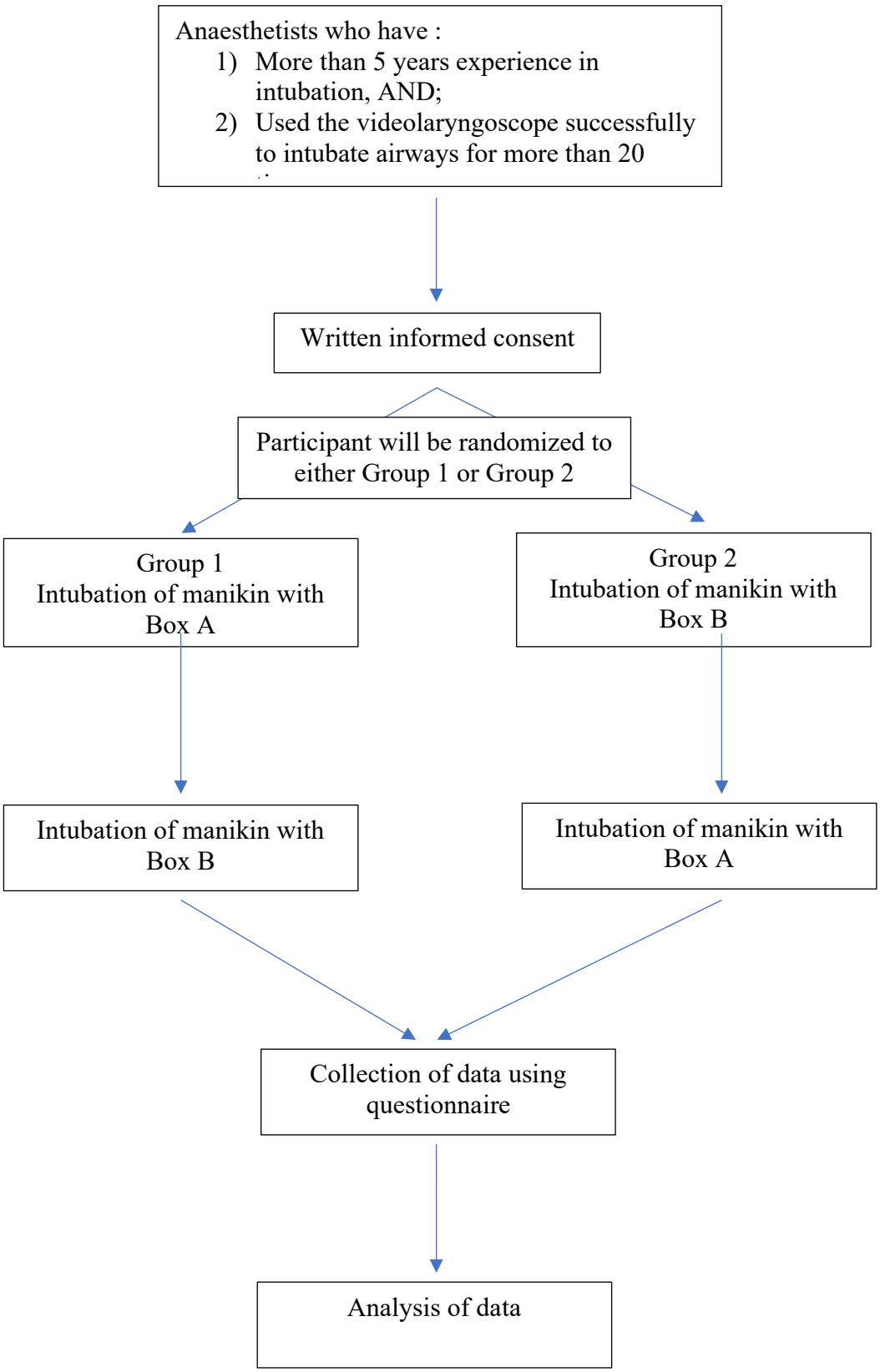


Figure 2 (Box B). Dimensions are 46 cm x 58 cm (height x width) with a thickness of 51cm. The upper portion of the box facing the intubator is made slanted at a 150 degree angle hence providing better ergonomics to the intubator. The curved design at one end of the box is to accommodate the obese/big build patient whose shoulder breadth may be wider than the box's width.

References :

1. Everington K. "Taiwanese doctor invents device to protect US doctors against coronavirus". *Taiwan News*, 23rd March 2020, https://www.taiwannews.com.tw/en/news/3902435
2. Canelli R., Connor C.W., Gonzalez M., et al. (2020) "Barrier enclosure during endotracheal intubation". New England Journal of Medicine. 3rd April 2020. DOI: 10.1056/NEJMc2007589.

FLOW CHART


Anaesthetists who have :
1) More than 5 years experience in intubation, AND;
2) Used the videolaryngoscope successfully to intubate airways for more than 20
Written informed consent
Participant will be randomized to either Group 1 or Group 2
Group 1
Intubation of manikin with Box A
Group 2
Intubation of manikin with Box B
Intubation of manikin with Box B
Intubation of manikin with Box A
Collection of data using questionnaire
Analysis of data

GANTT CHART OF RESEARCH ACTIVITIES
PROJECT TITLE : TAIWAN "AEROSOL BOX" VERSUS UMMC "INTUBATION BOX" :
CLINICAL EVALUATION OF THE "INTUBATION BOX" FOR EASE OF INTUBATION

	YEAR 2020																	
	Apr 1-15	Apr 16-30	May 1-15	May 16-31	June 1-15	June 16-30	Jul 1-15	Jul 16-31	Aug 1-15	Aug 16-31	Sept 1-15	Sept 16-30	Oct 1-15	Oct 16-31	Nov 1-15	Nov 16-30	Dec 1-15	Dec 16-30
ACTIVITIES																		
Submission for ethics committee approval																		
Preparation of resources required																		
Data collection																		
Data entry																		
Data analysis																		
Writing of report																		
Submission of completed paper to ISI journal																		

MILESTONES AND DATES CHART
PROJECT TITLE : TAIWAN "AEROSOL BOX" VERSUS UMMC "INTUBATION BOX" :
CLINICAL EVALUATION OF THE "INTUBATION BOX" FOR EASE OF INTUBATION

	YEAR 2020																	
	Apr 1-15	Apr 16-30	May 1-15	May 16-31	June 1-15	June 16-30	Jul 1-15	Jul 16-31	Aug 1-15	Aug 16-31	Sept 1-15	Sept 16-30	Oct 1-15	Oct 16-31	Nov 1-15	Nov 16-30	Dec 1-15	Dec 16-30
ACTIVITIES																		
Submission for ethics committee approval																		
Preparation of resources required																		
Data collection																		
Data entry																		
Data analysis																		
Writing of report																		
Submission of completed paper to ISI journal																		

Data collection sheet

Part 1: User profile

Name:

Professional category:

Anaesthesia experience:

Age:

Gender:

Part 2: Intubating conditions profile

For direct laryngoscopy:

Findings	Taiwan Box	UMMC Box
Time for successful intubation (seconds)		
Number of intubation attempts		
POGO grading (%)		
Cormack Lehane grade (1-4)		

For videolaryngoscopy:

Findings	Taiwan Box	UMMC Box
Time for successful intubation (seconds)		
Number of intubation attempts		
POGO grading (%)		
Cormack Lehane grade (1-4)		

Part 3: Usability profile

In this section, we would like to know the usability of this equipment (Taiwan Box vs UMMC Box) during intubation.

When using for intubation with direct laryngoscopy:

Findings	Taiwan Box				UMMC Box			
On a scale of 0-10, how easy was it to use this box?	0 → 10 Very difficult — Very easy				0 → 10 Very difficult — Very easy			
Please choose your level of agreement with the statements below.	Degree of agreement:							
	1: Strongly disagree	2: Disagree	3: Agree	4: Strongly agree	1: Strongly disagree	2: Disagree	3: Agree	4: Strongly agree
It is comfortable for me to use								

this equipment								
My visual field is clear while using this equipment								
My hand movements were free while using this equipment								

When using for intubation with videolaryngoscopy :

Findings	**Taiwan Box**				**UMMC Box**			
On a scale of 0-10, how easy was it to use this box?	0 → 10 Very difficult Very easy				0 → 10 Very difficult Very easy			
Please choose your level of agreement with the statements below.	Degree of agreement:							
	1: Strongly disagree	2: Disagree	3: Agree	4: Strongly agree	1: Strongly disagree	2: Disagree	3: Agree	4: Strongly agree
It is comfortable for me to use this equipment								
My visual field is clear while using this equipment								
My hand movements were free while using this equipment								

Which box would you prefer to use?

_____

_____

_____

Do you have any suggestions on how we can improve this equipment?

_____

_____

_____

APPENDIX A

“PERCENTAGE OF GLOTTIC OPENING” VIEW (POGO)

The percentage of glottic opening (POGO) score for laryngeal grading. The POGO score represents the linear span from the anterior commissure to the interarytenoid notch. (source : “Laryngeal Exposure (Opening) Scores” https://www.e4ent.com/articles/laryngeal-exposure-opening-scores/)

APPENDIX B

CONSENT BY PARTICIPANT FOR CLINICAL RESEARCH

Version No.: 1.0
Version Date: 10/04/2020

I, …….
Identity Card No……..……
(Name of Participant)
of ……...
(Address)
hereby agree to take part in the clinical research (clinical study/questionnaire study/drug trial) specified below:

Title of Study: Taiwan Aerosol Box versus UMMC Intubation Box : Clinical Evaluation Of The "Intubation Box" For Ease Of Intubation

the nature and purpose of which has been explained to me by
Dr. ..……..……..……
(Name & Designation of Doctor)

and interpreted by ……..……..…..……
(Name & Designation of Interpreter)

…….. to the best of his/her ability in ……..…… language/dialect.

I have been told about the nature of the clinical research in terms of methodology, possible adverse effects and complications (as per participant information sheet). After knowing and understanding all the possible advantages and disadvantages of this clinical research, I voluntarily consent of my own free will to participate in the clinical research specified above.

I understand that I can withdraw from this clinical research at any time without assigning any reason whatsoever and in such a situation shall not be denied the benefits of usual treatment by the attending doctors.

Date: ……...…….. Signature or Thumbprint ……..……
(Participant)

IN THE PRESENCE OF

Name ……..…..……..…)
)
Identity Card No. ……..…..……) Signature

(*Witness for Signature of Participant)*
Designation ……..……)

I confirm that I have explained to the participant the nature and purpose of the above-mentioned clinical research.

Date …….. Signature ……
(Attending Doctor)

CONSENT BY PARTICIPANT FOR CLINICAL RESEARCH	R.N. Name Sex Age Unit		

CONSENT BY RESPONSIBLE RELATIVE FOR CLINICAL RESEARCH

Version No.: 1.0
Version Date: 10/04/2020

I, …….
Identity Card No……...……
(Name)
of ……
(Address)

hereby agree that my relative ……..
I.C. No……...……
(Name)
participate in the clinical research (clinical study/questionnaire study/drug trial) specified below:-
Title of Study: **Taiwan Aerosol Box versus UMMC Intubation Box : Clinical Evaluation Of The "Intubation Box" For Ease Of Intubation**
the nature and purpose of which has been explained to me by Dr...……..……..……
(Name & Designation of Doctor)

and interpreted by ……...……..…...……
(Name & Designation of Interpreter)

…… to the best of his/her ability in ……..…… language/dialect.

I have been informed of the nature of this clinical research in terms of procedure, possible adverse effects and complications (as per patient information sheet). I understand the possible advantages and disadvantages of participating in this research. I voluntarily give my consent for my relative to participate in this research specified above.

I understand that I can withdraw my relative from this clinical research at any time without assigning any reason whatsoever and in such situation, my relative shall not be denied the benefits of usual treatment by the attending doctors. Should my relative regains his/her ability to consent, he/she will have the right to remain in this research or may choose to withdraw.

Date: …….. Relationship to Participant …… Signature or Thumbprint ……

IN THE PRESENCE OF

Name ……..…..)
)
Identity Card No. …….) Signature ……
) (*Witness*)
Designation ……)

I confirm that I have explained to the patient's relative the nature and purpose of the above-mentioned clinical research.

Date ……..
Signature ……
(Attending Doctor)

PARTICIPANT INFORMATION SHEET

Study Title: Taiwan "Aerosol Box" versus UMMC "Intubation Box" : Clinical Evaluation Of The "Intubation Box" For Ease Of Intubation

Version No: 1.0

Version Date: 10/04/2020

We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

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1. What is the purpose of this study?

The UMMC "Intubation Box" is an innovation to the open-source Aerosol Box design that was released recently as a protective device used to minimize aerosolization of contaminant from the patient's airway during airway manipulation and intubation. The UMMC "Intubation Box" is designed with better ergonomics and is more user-friendly which is aimed to increase the rate of successful intubation as well as reducing the time needed to intubate the airway.

2. Why is this study important?

We hope to gain evidence that the UMMC "Intubation Box" is indeed a superior design that allows for increased rates of successful intubation within a shorter duration of time.

3. What type of study is this?

This is a prospective randomized cross-over trial that involves the usage and analysis of a medical device.

4. What is the procedure that is being tested? (If applicable)

We will observe and record the time taken for successful intubation of airway manikin using both the Taiwan "Aerosol Box" and UMMC "Intubation Box".

5. Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine? (if applicable)

No.

6. Why have I been invited to participate in this study?

You are invite to participate as you would be an anaesthetist who have had experience in intubation for at least 5 years and experience with using videolaryngoscopy for more than at least 20 times.

7. Who should not participate in the study?

Anaesthetists with less than 5 years experience in intubating airways.

8. Can I refuse to take part in the study?

You have the right to refuse as well as the right to withdraw from the study at any time.

9. What will happen to me if I take part?

You will be given a set of questionnaires asking details regarding your demographics and experience in intubating airways, as well as a post-study survey assessing your findings and views after using the two different boxes.

10. How long will I be involved in this study?

You will spend about an hour with us for the practical aspect of data collection.

11. What are the possible disadvantages and risks?

As this study will only involve the participants intubating manikins, there are no obvious risks to be seen. No human or animals will be used directly to demonstrate the intubating conditions.

12. What are the possible benefits to me?

You will have experience intubating with two different boxes and participate in a continuous quality improvement session which aims to optimize intubating conditions for anaesthetists on a national level in view of the current COVID-19 pandemic.

13. Who will have access to my medical records and research data?

The result of the data obtained will be reported in a collective manner with no reference to a specific individual.

14. Will my records/data be kept confidential?

Your records/data will be kept confidential.

15. What will happen to any samples I give? (If applicable)

Not applicable.

16. What will happen if I don't want to carry on with the study?

The participation in this study is voluntary. If you prefer not to take part, your decision will be respected and it will not be questioned.

17. What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)

It would not affect the data that we collected from you and you would not be required to return for a repeat session.

18. What happens when the research study stops? (If applicable)

Not applicable.

19. What will happen to the results of the research study?

The results of the study will be used to make further improvements to the intubation box as well as collated and analyzed and submitted as a manuscript to an appropriate ISI journal for publication.

20. Will I receive compensation for participating in this study?

No compensation is available to you for participating in this study.

21. Who funds this study?

This study is self-funded.

22. Who should I contact if I have additional questions/problems during the course of the study?

Name of investigator 1 : DR SHAIRIL RAHAYU BINTI RUSLAN
Affiliation : DEPARTMENT OF ANAESTHESIOLOGY
Telephone number (Mobile number) : 012-3291074

Name of investigator 2 : DR. MOHD FITRY BIN ZAINAL ABIDIN
Affiliation : DEPARTMENT OF ANAESTHESIOLOGY
Telephone number (Mobile number) : 019-3354708

23. Who should I contact if I am unhappy with how the study is being conducted?

Medical Research Ethics Committee
University of Malaya Medical Centre
Telephone number: 03-7949 3209/2251