Time to adapt: A prospective randomized study comparing intubation times with/without barrier box

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Objectives

Can an intubation barrier box be used during induction without any significant delay in time to intubate (TTI)?

Research question: Comparing time to intubate (TTI) with/without intubation barrier box in study group vs control group when used with video laryngoscopy (glidescope) during for anesthetic induction.

Setting of the Human Research

This study will take place in the operating room at the Robert Packer Hospital by the Anesthesiology Department and will involve only procedures that are part of routine care.

Background

The COVID-19 outbreak has presented unprecedented challenges and risks to health care personnel and pose unique challenges to airway management secondary to aerosol generation. The absolute risk increase is between 10% (cohort studies) and 15% (case-control studies) for transmission of SARS-CoV-1–associated infection to health care personnel performing intubation.[1] Recent changes to airway management of confirmed positive COVID-19 or persons under investigation (PUI) involve the use of full personal protective equipment (PPE) including N95 masks and the routine use of video laryngoscopy when accessible. Unrecognized asymptomatic and pre-symptomatic infections with SARS- CoV-2 virus might contribute to transmission. Clinicians have been compelled to improvise protective barrier enclosures for use during endotracheal intubation to minimize aerosol exposure to operating room personnel. We decided to evaluate time to intubate with an intubation barrier box to demonstrate safe use for routine anesthetic inductions during this pandemic era.

Funding:

NONE

Study Design:

Prospective randomized controlled trial

Recruitment methods:

Source of participants: Patients undergoing elective surgery at Robert Packer hospital

Patient will be recruited in pre-operative clinic after surgery date has been finalized. Patients will be invited to take part and provided a letter of invitation. The researcher will answer any questions and verbal consent will be obtained.

Total participants:

The study plans to enroll approximately 72 subjects to two groups with 36 subjects in each group. This sample size is based on the estimated time difference of 10 seconds between intubation times with and without the box.

Inclusion criteria;

Males and females above 18 years of age who are undergoing elective surgery at Robert Packer Hospital who are tested COVID negative.

Exclusion criteria:

Children, pregnant women, and prisoners, ASA 4 ,ASA5, patients with severe cardiopulmonary compromise, BMI >35 , known or anticipated difficult airway, patients with positive COVID status or person under investigation.

Statistics:

Comparing time to intubate (TTI) between study and control group using a t-test to compare means.

Study end points:

Primary end point:

Calculating time to intubate (TTI) which is defined as time duration from loss of twitch to confirmation of end tidal CO 2.

Secondary end point:

1)Time duration from induction with propofol to confirmation of endotracheal tube

2) Need for bag mask ventilation and duration of ventilation

3)Episode of hypoxia as evidenced of Spo2 < 90 %

4)Subjective assessment of intubation by provider: easy /moderate /difficult

Study Timelines:

Individual subjects participation is limited to time spent in operating room

Duration for enrolling all participants: 2 months

Estimated date to complete study: 4 months

Procedures involved in Human research:

After obtaining a verbal informed consent, patients will be randomized into study group - IB (intubation barrier box used) and control group -C (no intubation barrier box used).

Subjects will be randomized by block randomization. Randomization will be done by a random number generated computer program by someone not involved in the research. The randomization schedule will be placed in sealed envelopes to be concealed from the researcher until time of verbal consent.

After placement of intravenous line in pre- operative area, anxiolytics may be given as per the discretion of anesthesiologist caring for the patient. After arrival to OR, patient will be placed on standard ASA monitors. An intubation barrier box designed by our bio –medical team will be placed at the head end of operating table in the study group (IB) and patient will be comfortably positioned with their head on a pillow inside the intubation box.

Patients in control group - No intubation box.

Routine procedures for all patients:

Patients head will be positioned in optimal position. Head- end of the operating table elevated to 20 degrees to improve pulmonary reserve. A twitch monitor is placed pre induction.

Pre oxygenation will be achieved by providing supplemental oxygen through mask with either 3 minutes of tidal volume breaths/ 8 vital capacity breaths .

Standard induction technique for both groups. All patients will be induced with standard induction doses of lidocaine 1- 1.5 mg/kg, fentanyl 1-2 mcg/kg and propofol 1-2 mg/kg followed with saline flush. After loss of consciousness is confirmed, patients will be given Succinyl choline 1.5 mg /kg total body weight (TBW) for paralysis. Apneic oxygenation will be continued after induction. Ventilation will not be performed during this time unless desaturation with spo2 less than 90 % is observed .Loss of Train of four (TOF)will be checked to confirm paralysis, and the provider will proceed with intubation.

A video laryngoscope (glidescope) with style will be used for intubation of all patients. Time to intubate (TTI) will be calculated by an independent provider not directly involved in research study. If intubation is unsuccessful by primary provider , further attempts by any other provider will be documented separately. If difficulty

to intubate is deemed secondary to intubation box, it will be removed immediately. Intubation procedure will be performed by provider with more than 3 years of experience and has performed at-least 3 intubations with intubation barrier box with patients.

Timing of all events will be performed by independent provider.

Other data points calculated.

Induction time – loss of spontaneous ventilation to placement of ETT.

Episode of hypoxia defined by spo2 < 90 %

Time duration of bag –mask ventilation if needed.

Source record: Electronic medical record

Long- term data collection: None

Withdrawal of participants:

Unanticipated difficult intubation as described by> 3 attempts by experienced provider.

Patients in the study will be excluded secondary to any equipment malfunction

or unforeseen delays not related to patient care.

Risk to participants:

By design, there is a minimal risk to the participants in this study. The intubation barrier box could be a source of claustrophobia to the patient which will be mitigated by use of anxiolytics. The intubation box will be removed if it creates any difficulty in intubation.

Provisions to maintain confidentiality of the data:

Measures will be taken to protect patient confidentiality in accordance with HIPAA guidelines. Patient's names will not be used on the data collection sheet. Medical record numbers will be used on the data collection sheet. Once data collection has been completed, the MRN will be removed from the datasheet and the patients will be numbered consecutively. No patient names or medical record numbers will be published. Descriptive statistics will be used to summarize our objectives. Data will be stored as an electronic file on a password-protected computer and will only be available to primary and co-investigators.

Potential direct benefit to patients:

There are no direct benefits to patients, but they may be making a contribution to the scientific knowledge, and help create a model for correcting deficiencies, if present. Information demonstrated by the box will help provide additional safety to health care personnel.

Participant Compensation/Cost

There will be no payment or costs to subjects.

Vulnerable populations:

Children will be excluded from the study. Pregnant women and prisoners will not be specifically targeted for chart review.

Consent process:

Due to the prospective design of the study, a consent will be taken. Consent will be obtained verbal rather than written. A waiver of consent documentation is requested from the IRB because the research presents no more than minimal risk of harm to subjects, and the research involves no procedures for which written consent is normally required outside of the research context and is part of routine anesthesia patient care. The verbal consent will take place during pre- operative assessment prior to the surgery by a member of research team .

Sharing the results with the participants:

There are no plans to directly share data or results with the participants.

Sharing of individual participant data with other researchers

There is no plan to make individual participant data collected in this study available to other researchers. Data will be fully de-identified before sharing.

DATA SHEET

Pre-op

Age:

Sex:

ASA:

BMI:

Airway assessment:

METS / functional status:

Cardio –pulmonary status:

Previous known difficult airway record:

Medical history:

GERD, OSA, H/O MI, CHF, SEVERE COPD, HOME OXYGEN, RECENT COVID INFECTION

Surgical history:

H/O neck fusion

Labs:

BMP

ECHO

INTRAOP

Use of peri op anxiolytics

Induction medications

Apnea time

Time of intubation

Subjective difficulty in intubation

Need for bag - mask ventilation

Episode of hypoxia as defined by SpO 2 < 90 %

POST OP: Subjective patient experience

Peri- operative complications if any.

References:

1. Weissman DN, de Perio MA, Radonovich LJ Jr. COVID-19 and Risks Posed to Personnel During Endotracheal Intubation. JAMA. 2020 Apr 27. doi: 10.1001/jama.2020.6627.

2.Canelli R, Connor CW, Gonzalez M, Nozari A, Ortega R. Barrier Enclosure during Endotracheal Intubation. N Engl J Med. April 2020. doi:10.1056/nejmc2007589

3. Nouruzi-Sedeh P, Schumann M, Groeben H. Laryngoscopy via macintosh blade versus glidescope: Success rate and time for endotracheal intubation in untrained medical personnel. Anesthesiology. 2009;110(1):32-37. doi:10.1097/ALN.0b013e318190b6a7

4. Taiwanese doctor invents device to protect US... | Taiwan News. https://www.taiwannews.com.tw/en/news/3902435. Accessed April 26, 2020.

5. Naguib M, Samarkandi AH, El-Din ME, Abdullah K, Khaled M, Alharby SW. The dose of succinylcholine required for excellent endotracheal intubating conditions. Anesth Analg. 2006;102(1):151-155. doi:10.1213/01.ANE.0000181320.88283.BE

6.The GlideScope® Video Laryngoscope: randomized clinical trial in 200 patients D. A. Sun, C. B. Warriner, D. G. Parsons, R. Klein, H. S. Umedaly, M. Moult BJA: British Journal of Anaesthesia, Volume 94, Issue 3, March 2005, Pages 381–384, https://doi.org/10.1093/bja/aei041
Published:26 November 2004

Statistical analysis plan:

Sample size calculation

Sample size calculation was done by using the two means equation in the Power and Sample Size Calculation program (Dupont and Plummer, 1990). Based on a study by Teoh et. al., (2019), the mean of intubation time for Glidescope was 31.2 seconds and Airway Scope was 20.6 seconds. A clinically significant effect of 10 seconds would be of interest. The two-tailed hypothesis testing concluded that each group needed 36 subjects to achieve a power of 80%, with an error rate of 5%. A total of 90 subjects will be enrolled in this study with an estimated dropout rate set at 20%, 45 subjects will be enrolled in each group.

Suggested citation for Power and Sample Size Software:

Dupont WD, Plummer WD: 'Power and Sample Size Calculations: A Review and Computer Program', Controlled Clinical Trials 1990; 11:116-28.

Reference article;

Teoh WHL, Saxena S, Shah MK, Sia ATH. Comparison of three videolaryngoscopes: pentax Airway Scope, C-MAC, Glidescope vs the Macintosh laryngoscope for tracheal intubation, Anesthesia. 2010; 65: 1126-1132.

It is a standard practice to include a dropout rate of 20% for clinical trials so that the power of the study will not be affected by dropouts, missing data and other study deviations (https://online.stat.psu.edu/stat509/node/47/).

Randomization:

Sealed Envelope Ltd. 2019. Simple randomisation service. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/ [Accessed 6 May 2020].

Randomization will remain concealed from the researchers until the time of the verbal informed consent.

CONSORT flow diagram:

Participants will be tracked using a CONSORT flow diagram.

Primary end point:

Calculating time to intubate (TTI) which is defined as time duration from loss of twitch to confirmation of end tidal CO 2. Comparing time to intubate (TTI) between study and control group using a t-test to compare means.

Non-inferiority margin set at 15 seconds. Non- inferiority hypothesis (H_0: Mean TTI diff $\geq$15 s, H_A: Mean TTI diff < 15 s).