Evaluation of Video Laryngoscopy in Patients with Head and Neck Pathology
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Mount Sinai	Protocol Title:	Evaluation of Video Laryngoscopy in Patients with Head and Neck Pathology
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MSSM Protocol Template HRP-503a

Instructions:

1. *Prepare a document with the following sections. Note that, depending on the nature of your research, certain sections below may not be applicable. Indicate N/A as appropriate, explaining where possible.*
2. *For any items described in the sponsor's protocol, grant application or other source documents submitted with the application, you may reference the title and page numbers of these documents rather than cutting and pasting into this document.* ***Do NOT refer to any derived documents, such as the Sample Consent document, or other internal documents required with the submission.***
3. *If you reference page numbers, attach those pages to this protocol.*
4. *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*

Brief Summary of Research (250-400 words):

Patients who undergo general anesthesia for surgical procedures frequently need to have a breathing tube placed ("tracheal intubation") for the duration of the procedure. Most often airway management is routine for an experienced anesthesiologist. Less often, airway management can be difficult and can result in patient harm. In order to reduce risk, anesthesiologists routinely evaluate patients' airways by obtaining a relevant history and doing a physical exam, which can aid in predicting which airways may be difficult to manage. The "gold standard" for management of the anticipated difficult airway is to perform an awake flexible bronchoscopic intubation after anesthetizing the airway with local anesthesia. This affords added safety because the airway remains patent and the patient breaths spontaneously until a tracheal tube is secured, at which point general anesthesia can be induced.

Recently, authors have advocated for alternative methods of management of the predicted difficult airway, most commonly by using a video laryngoscope to perform the awake intubation. A video laryngoscope provides an indirect view of the larynx using a camera at the tip of a rigid laryngoscope. It takes less training to gain and maintain proficiency compared to flexible bronchoscopy.

Previous studies that have shown successful awake intubation with video laryngoscopy in the predicted difficult airway have not included patients with head and neck pathology, including malignancies or a history of head and neck surgery or radiation. Video

laryngoscopy may be more prone to failure in this patient population, and randomizing this population to video laryngoscopy would pose too great a risk.

If results of previous studies are erroneously generalized, anesthesiologists' skills in flexible bronchoscopy will decline. We therefore propose to perform video laryngoscopy in patients with head and neck pathology who require awake bronchoscopic intubation for surgery after placement of the tracheal tube and induction of anesthesia. This will allow us to approximate what the laryngeal view would have been with video laryngoscopy. If there is a significant incidence of difficult video laryngoscopy in this patient population, it will reinforce that anesthesiologists need to continue to learn and maintain skills in bronchoscopic intubation.

Objectives:

Research Question: In patients with predicted difficult airways due to head and neck pathology (malignancy or a history of surgery or radiation therapy) who undergo awake bronchoscopic intubation, what proportion would have been possible to intubate with video laryngoscopy?

Hypothesis: A significant proportion of patients with head and neck pathology will have poor laryngeal views with post-induction video laryngoscopy by experienced anesthesiologists.

Primary objective: Determine the incidence of difficult (Cormack-Lehane grade >2) video laryngoscopic view of the larynx after awake flexible bronchoscopic intubation in patients with head and neck pathology

Secondary objectives:

a) grade the view (Cormack-Lehane) obtained by video laryngoscopy after awake flexible bronchoscopic intubation in patients with head and neck pathology

b) grade the view (Cormack-Lehane) obtained by video laryngoscopy after awake flexible bronchoscopic intubation in patients with head and neck masses

c) grade the view (Cormack-Lehane) obtained by video laryngoscopy after awake flexible bronchoscopic intubation in patients with a history of neck radiation

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1) Background

Awake flexible bronchoscopic intubation is considered the gold standard in the management of the anticipated difficult airway.[1] More recently, this has been called into question,[2] with alternative intubation techniques described in both asleep and awake patients. In particular, many have advocated the use of awake video laryngoscopy.[3,4] However, these studies did not include patients with head and neck pathology such as airway masses or previous neck radiation.

Advantages cited for videolaryngoscopy include faster intubation time, less training required to gain and maintain skills, creation of space within the airway to suction secretions, view of the tracheal tube during intubation of the larynx (as opposed to blind "railroading" of the tube over the bronchoscope), lower cost, and easier maintenance of equipment. Disadvantages of videolaryngoscopy include possible increased risk of failure due to gag reflex unable to be attenuated with topical anesthesia, inability to use with very limited mouth opening, and inability to move around fixed lesions. While video laryngoscopy has a well-established role in management of the difficult airway, it does have recognized limitations and failures. There appears to be an increased risk of failure of video laryngoscopy in patients with airway masses, neck pathology, and neck radiation[5] plausibly because a flexible scope would be required to move around immobile tissues. Neither direct nor indirect video laryngoscopy can accomplish this necessary flexibility. Randomizing this patient population, for whom awake flexible bronchoscopic intubation is the gold standard, to other techniques would be unsafe, as multiple laryngoscopies can increase the difficulty of airway management. As these patients have been excluded from previous randomized studies, the results of these studies cannot be generalized to the head and neck pathology patient population. This study aims to assess the utility of video laryngoscopy in this patient population by performing a video laryngoscopy after the endotracheal tube is safely secured by awake bronchoscopy to get an estimate of what the laryngeal view would have been had awake video laryngoscopy been used for the intubation. While laryngoscopy conditions are not identical after an endotracheal tube is already in place and the patient is anesthetized, it is the most appropriate study design to ensure safety in this patient population.

If we find a significant number of difficult video laryngoscopies in this patient population, it will reinforce the need for anesthesiologists to maintain skills in flexible bronchoscopic intubation. Despite clear clinical indication and a good safety and success profile, experienced anesthesiologists may incorrectly forego awake bronchoscopic intubation. Qualitative analysis of cases in the United Kingdom's Royal College of Anaesthetists' 4th National Audit Project (NAP4) revealed elements of poor airway management in >75% of reports. Upper airway malignancy or disease processes of the head and neck were present in 40% of cases presented to NAP4. The report found

numerous cases where awake intubation was indicated but not used, possibly due to poor judgment, lack of skills, or lack of equipment.[6]

Bronchoscopy skills are challenging to attain and are prone to decay, potentially leading to practitioner discomfort with awake flexible bronchoscopy if not continually practiced.[7,8] This study aims to add to the current body of knowledge regarding the use of video laryngoscopy for the predicted difficult airway, specifically in the head and neck pathology patient population. Unlike previous publications, this study will provide a safe way to evaluate the use of video laryngoscopy in patients with head and neck malignancy and/ or previous head and neck surgery or radiation. Information from this study will help guide future strategies in difficult airway management. Our hypothesis is that the anatomy in this patient population does not lend itself to straightforward video laryngoscopy, and that flexible bronchoscopy continues to have a vital role in the management of these airways.

2) Setting of the Human Research

This study will be conducted at the Icahn School of Medicine at Mount Sinai at 1468 Madison Avenue in the 7th floor Annenberg Building operating rooms. Consent will be obtained in the preoperative holding area, and the study protocol will occur in the operating room in which the patient is assigned.

3) Resources Available to Conduct the Human Research

100 participants will be enrolled in this study. Between 3-10 awake intubations with a flexible bronchoscope are performed per week in patients with head and neck pathology coming to the Annenberg 7 operating rooms. Assuming conservatively that we can enroll 1-2 patients per week, we anticipate completing the study within two years after initiation.

Drs. Demaria, Levine, and Hyman are attending anesthesiologists with substantial experience in supervising and performing awake flexible bronchoscopic intubations and post-induction video laryngoscope intubations. We also each have previous experience with research involving ENT surgical patients in the same practice setting, and well-established professional relationships with our ENT surgical and nursing colleagues to help support the study.

Prior to initiating this study, all participating investigators and support staff will conduct a protocol initiation meeting to ensure adequate

knowledge of the study objectives, procedures, populations, and human subject protections. A log of meeting attendees will be maintained.

4) Study Design

a) Recruitment Methods

Patients who are determined to require an awake flexible bronchoscopic intubation by the anesthesiologist caring for the patient on the day of surgery will be invited to participate in the study. After preoperative evaluation and explanation of the anesthetic plan and the awake flexible bronchoscopic intubation, the study will be explained in detail to the patient. All questions will be answered and if the patient agrees to participate, written informed consent will be obtained prior to entry into the operating room.

b) Inclusion and Exclusion Criteria

Inclusion criteria:

1. Age ≥ 18 years
2. Presence of oral, pharyngeal or laryngeal mass or history of surgery or radiation for head and neck cancer
3. Requiring awake flexible bronchoscopic intubation for surgery
4. Willing and able to provide informed consent

Exclusion criteria:

1. Emergency procedure
2. Presence of one or more loose teeth

c) Number of Subjects

100 subjects will be included in this study.

d) Study Timelines

Patients will be screened and consented on the day of surgery. The awake bronchoscopic intubation and asleep video laryngoscopy will be performed prior to the start of surgery. All patients will be seen in the hospital (or called at home postoperatively for ambulatory surgical patients) within 48 hours to assess for any delayed complications. As

patients only need to be followed for a maximum of 48 hours after discharge to be assessed for all primary and secondary endpoints, we estimate the study will be complete within 2 weeks of final patient enrollment.

e) Study Endpoints

Primary objective: Determine the incidence of difficult (Cormack-Lehane grade >2) video laryngoscopic view of the larynx after awake flexible bronchoscopic intubation in patients with head and neck pathology.

Secondary objectives:

a) grade the view (Cormack-Lehane) obtained by video laryngoscopy after awake flexible bronchoscopic intubation in patients with head and neck pathology

b) grade the view (Cormack-Lehane) obtained by video laryngoscopy after awake flexible bronchoscopic intubation in patients with head and neck masses

c) grade the view (Cormack-Lehane) obtained by video laryngoscopy after awake flexible bronchoscopic intubation in patients with a history of neck radiation

Subjects will be withdrawn from the study and video laryngoscopy will not be performed if the awake flexible bronchoscopy fails and the patient cannot be intubated, or if there is difficulty with the awake flexible bronchoscopy resulting in tissue trauma.

f) Procedures Involved in the Human Research

Patients who are undergoing non-emergency surgery who have a history of head and neck pathology (masses, previous surgery, and/or radiation) who as determined by the anesthesiologist caring for the patient must undergo awake flexible bronchoscopic intubation will be invited to participate in the study after preoperative evaluation prior to entry into the operating room. Once in the operating room, intravenous access will be obtained and American Society of Anesthesiologists' standard monitors (pulse oximeter, electrocardiogram tracing, blood pressure cuff) will be applied. The patient will receive glycopyrrolate 0.2mg-0.4mg and sedation as per the usual practice of the anesthesiologist. Airway topicalization with lidocaine and awake flexible bronchoscopic intubation will be performed. After the tracheal tube is secured and general anesthesia is

induced, the attending anesthesiologist will perform video laryngoscopy with the C-MAC D video laryngoscope and with the GlideScope AVL video layryngoscope and grade the view of the larynx obtained with each laryngoscope. Care will be taken to minimize tissue trauma and hemodynamic perturbations caused by video laryngoscopy. All patients will receive 10mg of intravenous dexamethasone to reduce airway edema.

All participants will be monitored by the anesthesia team throughout the surgical procedure and until handoff of care to the Post-Anesthesia Care Unit (PACU) nurse as per usual practice. All subjects will be evaluated for the appearance of any delayed complications within 48 hours of the end of the procedure. Relevant data will be collected from the patient, anesthesiologist, EPIC, and Compurecord.

All medications administered and procedures performed are identical to those performed if not enrolled in the study, with the only exception being the video laryngoscopy.

Data to be collected:

Age
Gender
Body Mass Index (BMI)
Mallampati score
Head and neck pathology: a) Location of mass, if present b) History of surgical procedure c) History of radiation
Visual Analog Score (VAS) of ease of bronchoscopic intubation by anesthesiologist
C-MAC Video Laryngoscope Cormack-Lehane View (grade 1-4)
GlideScope AVL Video Laryngoscope Cormack-Lehane View (grade 1-4)

Occurrence of any complications

g) Specimen Banking

N/A

h) Data Management and Confidentiality

All researchers who will access the data have completed the institutional HIPAA certification. Extracted data will be de-identified before being given to the statistician for analysis. Any intermediary data files containing extracted PHI will be stored on secured hospital servers and destroyed after data analysis is complete. All study data at Mount Sinai stored electronically will follow MSMC policies. All PHI that is not stored on a limited access Mount Sinai IT maintained network drive will be encrypted and password protected. Statistical analysis will be carried out by a statistician employed by the Department of Anesthesiology. When the de-identified data set are released for analysis, a one-way hash ID will be generated for each record. Only Mount Sinai study investigators with access to the full data set will be able to match the hash ID to the original source

i) Provisions to Monitor the Data to Ensure the Safety of subjects

MSSM Principal Monitor (PI):
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Dr. Hyman and Dr. Demaria are board certified anesthesiologists with expertise in difficult airway management. All subjects will be monitored closely in the immediate perioperative period by the anesthesia team caring for the patient. Participants will also be seen postoperatively within 48 hours to assess for delayed complications, or called by telephone in the case of ambulatory procedures. Ambulatory participants will also receive instructions and a business card in order to have a point of contact to report a potential adverse event at any time during or after participation. They will also be specifically informed that they should receive emergency department care for any signs or symptoms of airway compromise. Any serious adverse event will be recorded by the research team in a non-anonymized fashion and reported directly to the Mount Sinai Institutional Review Board.

j) Withdrawal of Subjects

Subjects will be immediately withdrawn from the study if:

- Any difficulty resulting in airway injury occurs during the initial awake bronchoscopic intubation
- The awake bronchoscopic intubation is not able to be performed successfully

If withdrawn from the study, the anesthesiologist will not perform the planned laryngoscopy with the video laryngoscope.

5) Risks to Subjects

It is reasonably foreseeable that participants will have an increased risk of sore throat from the addition of video laryngoscopy.

Video laryngoscopy has the potential cause damage to oropharyngeal structures, including but not limited to: dentition, hard palate, soft palate, epiglottis, vocal cords, larynx, and soft tissue. These injuries are more likely to occur when struggling to obtain an adequate view of the larynx in order to intubate, which will not be the case for this study. Since the airway will be protected with an endotracheal tube during laryngoscopy, damage/ bleeding in the airway should not lead to issues with oxygenation or ventilation.

There is a risk of hemodynamic changes during laryngoscopy. The anesthesiologist will have the ability to treat tachycardia, bradycardia, hypertension, and hypotension with the appropriate pharmacologic agents.

There is a slight risk of unintentional extubation during laryngoscopy- if this is to happen the anesthesiologist should be able to reintubate the patient using either the flexible bronchoscope or video laryngoscope, but it is possible that reintubation would be difficult.

There is a slight risk of having to keep the patient intubated postoperatively due to continued bleeding or swelling from damage during video laryngoscopy. If this is to occur, the patient will be admitted to an acute care setting for further ventilation management and eventual extubation.

6) Provisions for Research Related Injury

Subjects will be monitored during surgery and during recovery from anesthesia. Upon discharge, subjects will be provided with a phone number to call should they have any concerns related to surgery, anesthesia, or the study. If necessary, subjects will be instructed to return to the hospital should any complication requiring medical attention occur, or to the nearest emergency department for any signs of airway compromise.

Subjects who are injured as a result of this study will be treated until the resolution of the adverse event and the cost billed to them and/or their insurance carrier. Patients will not be compensated for research related injury, with the exception of damage to dentition that occurs during the course of anesthetic care, which is routinely covered by the department of anesthesiology.

Anesthesiologists and intensive care unit staff will be available to maintain ventilation and airway management in the event of airway damage/ bleeding requiring prolonged intubation. ENT surgeons will be present in the operating room and immediately available in the unlikely case of need for an emergent surgical airway. ENT surgeons would also be available for evaluation and treatment of non-emergent oropharyngeal injuries.

7) Potential Benefits to Subjects

Participation in this study will not lead to any direct benefit to the patient.

8) Provisions to Protect the Privacy Interests of Subjects

The de-identified data will be stored on secure, password-protected servers maintained by Mount Sinai Information Technology (IT). Access to the data will only be available to Mount Sinai IT administrators, the primary investigator, and co-investigators. When the de-identified data set are

released for analysis, a one-way hash ID will be generated for each record. Only study investigators with access to the full data set will be able to match the hash ID to the original record. All investigators have completed HIPAA training regarding maintaining patient PHI confidentiality.

During the preoperative evaluation, subjects will be asked what number they prefer to be contacted at after discharge. They will also be asked whether it is ok for an investigator to leave a message. All messages will be of a general nature and will not contain personal health information. Moreover, post-operative evaluation by phone within the 48 hours following surgery is routine practice.

9) Economic Impact on Subjects

There are no costs to subjects for participating in this study. There will be no additional visits or tests related to study participation

10) Payment to Subjects

There is no payment to subjects

11) Consent Process

Eligible patients will be invited to participate in the study by an investigator after the preoperative evaluation in the preoperative holding area on Annenberg 7 on the day of surgery. A study investigator will describe the study in detail, answer questions, confirm understanding, and provide the consent form for review. The patient will be given privacy to review the consent form in detail and will then have another opportunity to ask questions prior to signing consent. The voluntary nature of this study will be emphasized, and patients who initially agreed to participate may choose to decline participation any time prior to anesthetic induction. Participants will be asked about the study to confirm understanding prior to providing written informed consent. Non-English speaking subjects will not be eligible for this study. SOP HRP-090 will be followed.

12) Process to Document Consent in Writing

Consent will be documented using the standard PPHS consent template

13) Vulnerable Populations

No vulnerable populations will be included in this study

14) Multi-Site Human Research (Coordinating Center)

N/A

15) Community-Based Participatory Research

N/A

16) Sharing of Results with Subjects

If the patient desires, the anesthesiologist will discuss any notable results from the laryngoscopy with the patient during the postoperative visit or phone call and all questions will be answered. Video laryngoscopic view will also be recorded in the patient's electronic anesthesia record.

17) External IRB Review History

This is a new IRB application

18) Control of Drugs, Biologics, or Devices

We will not use any new or different devices for this study. The flexible bronchoscope and the video laryngoscopes will be available through the Mount Sinai Anesthesiology department. All devices will be stored in the "anesthesia work room" located in close proximity to the operating rooms. The anesthesiology department will provide the personnel and resources to keep equipment clean and in good condition.

References:

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3. Kramer A, Muller D, Pfortner R, Mohr C, Groeben H. Fibreoptic vs videolaryngoscopic (C-MAC((R)) D-BLADE) nasal awake intubation under local anaesthesia. Anaesthesia 2015;70:400-6.
4. Rosenstock CV, Thogersen B, Afshari A, Christensen AL, Eriksen C, Gatke MR. Awake fiberoptic or awake video laryngoscopic tracheal intubation in patients with anticipated difficult airway management: a randomized clinical trial. Anesthesiology 2012;116:1210-6.

5. Aziz MF, Healy D, Kheterpal S, Fu RF, Dillman D, Brambrink AM. Routine clinical practice effectiveness of the Glidescope in difficult airway management: an analysis of 2,004 Glidescope intubations, complications, and failures from two institutions. Anesthesiology 2011;114:34-41.

6. Cook TM, Woodall N, Frerk C, Fourth National Audit P. Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: anaesthesia. British journal of anaesthesia 2011;106:617-31.

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8. Popat MT, Srivastava M, Russell R. Awake fibreoptic intubation skills in obstetric patients: a survey of anaesthetists in the Oxford region. International journal of obstetric anesthesia 2000;9:78-82.