Protocol Study

Comparison of 3 direct laryngoscopes: Inscope DL blade size 3.5 and DL blade 3.5 Sun-Med GreenLine®/D™ to DL blade 3 SunMed GreenLine®/D™ for tracheal intubation in patients undergoing lumbar spine surgery, a prospective randomized study

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Study Proposal

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STUDY OBJECTIVES

Hypothesis

The use of Macintosh blade sized #3.5 (vs Macintosh size #3) would reduce the time required to achieve successful tracheal intubation and improve the glottic view.

Study objective

The purpose of this research study is to compare 3 different laryngoscope blades (sizes: 3.5, 3.5 and 3) and see if the blades size 3.5 will reduce the time required to achieve successful tracheal intubation and improve the physician's view of the glottis compared to the standard direct laryngoscope using the blade size 3, in patients undergoing lumbar surgery. The Sun-Med GreenLine®/D™ Macintosh Blade laryngoscope (size 3 and size 3.5) are already used at Cedars-Sinai Medical Center, but the Inscope Direct Laryngoscope (size 3.5) will be used at Cedars-Sinai Medical Center for the first time, as part of this research.

Primary end point: time to achieve successful tracheal intubation.

Secondary end points: glottic view at intubation, number of intubation attempts and effectiveness of the integrated suction in the Inscope Direct Laryngoscope.

BACKGROUND AND SIGNIFICANCE

Laryngoscopy is a common medical procedure used during elective and emergency intubations. The procedure is performed with either a direct or video laryngoscope with the device selected dependent on tool availability, provider (i.e. anesthesiologist, emergency physician, ENT physician, paramedic, etc.) preference, patient characteristics, and intubation difficulty. The direct laryngoscope technique involves a line-of-sight view from the patient's mouth to vocal cords along the blade of the scope. The direct laryngoscopy technique is the oldest technique associated with intubation. However, despite continuous improvements to direct laryngoscope size and shape since its inception in the late 19th century,[1] no improvement yet addresses one major problem with airway visualization: the provider will experience a difficult intubation if liquids (i.e. gastric content, blood, mucus, etc.) obstruct the view.[2]

The Sun-Med GreenLine®/D™ Macintosh is a line of disposable direct Macintosh laryngoscopes. It features a stainless-steel blade and polycarbonate light-pipe to direct light into the airway. The handle, with integrated batteries and LED light, and blade are separately packaged prior to use. The GreenLine®/D™ Macintosh line is available in the standard sizes (0, 1, 2, 3, 4) and a new

size built to improve blade sizing for many adults 3.5 when a Mac 3 is too short, but a Mac 4 is too large. The GreenLine®/D™ Macintosh does not feature integrated suction.

The Inscope Direct Laryngoscope (developed by Inscope Medical Solutions) is a new disposable direct laryngoscope with two integrated and controllable (flow on/off) suction pathways. By integrating controllable suction with two independent pathways into the laryngoscope, the provider is able to select the primary (blade tip) suction pathway to clear secretions ahead of the laryngoscope and the secondary (at blade mid-length, below blade) to prevent and clear fluids that may re-accumulate during the procedure. Integrating the suction into the device prevents the common current practice of "juggling" the current suction catheter and endotracheal (breathing) tube in one hand while holding the patient's airway open with the other hand. While the incidence of aspiration of fluids into the lungs as a result of poor airway fluid management is low, the outcomes associated with this complication are very poor. [3-5]

The Inscope Direct Laryngoscope has been developed as a Macintosh 3.5 sized blade to meet the size requirements of the majority of patients. This assumption is backed up by a trend among disposable direct laryngoscope manufacturers toward the 3.5 blade size, with at least 5 creating a 3.5 blade, including Teleflex, Sun-Med, Flexicare, Mercury Medical, and Curaplex.

In this study, we will compare the Inscope Direct Laryngoscope (blade size 3.5) with the currently used standard single-use Sun-Med Greenline/D Macintosh laryngoscopes DL-blade mac size and Sun-Med Greenline/D-blade size 3.5
All Direct Laryngoscopes are considered a Class I exempt device by the FDA. Because the risks associated with laryngoscopes are well known and documented, they are considered a non-significant risk device for studies involving humans.

STUDY DESIGN

This randomized, prospective study will analyze the efficacy of three different airway intubating devices. The three different devices are as follows:

1. DL-blade mac size 3 (Sun-Med GreenLine®/D™ Macintosh)
2. Inscope DL–blade size 3.5
3. DL-blade mac size 3.5 (Sun-Med Greenline®/D™ Macintosh)

The Investigator will record the patient's BMI, Mallampatti classification,[6,7] size of mouth opening, thyro-mental distance, presence or absence of teeth, any unusual physical exam findings, time to successful intubation, number of unsuccessful attempts and the obtained glottic view. The necessity of rescue using a bougie, Mac #4, fiberoptic bronchoscope, LMA or videolaryngoscope. Also the end Tidal CO2 return, as well as the airway grade obtained by the anesthesiologist during intubation using the Cormack-Lehane classification[8,9] and POGO score [10] in order to objectively assess and compare the two intubation techniques. Any other unusual events will be documented. All variables for all devices will be compared, evaluated and analyzed.

STUDY METHODS:

I **Recruitment and Pre-operative period:**

a) Study investigators will contact anesthesiologists to ask for any potential subjects who scheduled for surgery that day. As part of standard of care, the anesthesiologist will review and examine subject information and evaluate the subject's airway upon patient arrival to pre-op. If the attending anesthesiologist finds the subject match all inclusion criteria, they will introduce the patient to the study and provide the consent documents and patient letter. If the patient expresses interest, the attending anesthesiologist will contact the study team. A consenting investigator will then approach the patient to review the study and address any questions or concerns. If the patient would like to participate, consent will be obtained.

   Only patients after the first case of the day will be approached for participation, giving second and third case patients time to review the study materials while they wait for their procedure. Patients are evaluated by the anesthesiologist upon arrival at pre-op.

   Subjects will be approached prior to entering the pre-op stage and prior to having IV lines placed. Investigators will explain the study protocol including the potential benefits and potential risks. Patients will be told that they have the right to choose or refuse the study without any loss and any penalty because their participation in this study is voluntary.

b) Only patients who have provided their written consent will be able to participate and undergo screening procedures for this study.
c) Screening procedures will make sure patients meet all inclusion criteria. If patient meets all inclusion criteria, they will be accepted into the study.

Written informed consent will be collected from all subjects who meet the inclusion criteria and they will be randomly assigned to one of the 3 study groups according to a computer generated randomization number table.

The anesthesiologist conducting the intubation will be one of the preselected attending anesthesiologists who have extensive experience using all these intubation techniques. The subjects can discuss the study further with the investigators and ask many questions as they want and sign the consent form.

(A) Before the case begins, each anesthesiologist will be informed which group the patient has been assigned to. The name of the assigned intubation device will be placed in sealed envelope and given to the participating anesthesiologist after they obtained informed consent and completed the patient's airway evaluation.

(B) In order to help eliminate bias, the anesthesiologist's experience with each of the intubating devices in 10 or more patients will be verified.

Data of demographic information and physical exam performed (e.g., vital signs and airway evaluation) will be collected.

II Operative period:

(A) The randomly selected intubating device (blade) will be prepared and the endotracheal tube will be selected by the attending anesthesiologist.

(B) The patient will be transported to the operating room and attached to all ASA standard monitors in the usual and customary fashion.

(C) Standard monitoring devices: an automatic blood pressure cuff, three-lead electrocardiogram, capnograph, pulse oximeter, and an EEG bispectral (BIS) index monitor.

(D) Midazolam 2mg will be giving as pre-medication.

(E) The patient will be positioned on the OR table using a donut head pad to create an angle of approximately 30 degrees and bringing the chest up so the sternal notch is at the level of the external auditory meatus.

(F) The patient will be pre-oxygenated 100% oxygen for 3 to 5 min prior to induction of anesthesia using a facemask to achieve a baseline O2 saturation greater than 98%.

(G) A standardized induction technique (Standard of care induction) consisting of fentanyl 100 mcg IV, propofol 2 to 2.5 mg/kg IV, lidocaine 1 to 1.5 mg/kg IV, and succinylcholine 1 to 1.5 mg/kg IV. Supplemental bolus doses of propofol will be administered to increase the depth of anesthesia if necessary. If the anesthesiologists consider, additional doses

of anesthetics will be administered to keep a BIS value < 60. Maintenance of the anesthesia with propofol infusion, cisatracurium, and other medications (and dosages) selected by the attending anesthesiologist.

(H) The anesthesiologist will determine that the patient is adequately relaxed by verifying the patient has no twitches using a train-of-four nerve stimulator prior to laryngoscopy.

(I) The investigator will begin timing as the anesthesiologist attending introduces the intubating device into the patient's mouth, obtains glottic view, intubates and End Tidal CO_2 returns.

(J) The attending will let the study coordinator know the POGO (Percentage Of Glottic Opening) and the best glottic view grade obtained using the POGO grading system (0% to 100%), and the Cormack Lehane scoring system (1/2/3/4).

(K) If the intubation attempt is unsuccessful, time will be stopped when the anesthesiologist removes the intubating device from the mouth.

(L) Rescue with bougie, Mac #4, fiberoptic bronchoscope, LMA, videolaryngoscope or any device necessary used by the attending anesthesiologist will be recorded. Should the need for an adjunct airway device be necessary for ventilation, any device can be used in accordance with the American Society of Anesthesiologist (ASA) difficult airway algorithm in case of a difficult airway.

(M) If the anesthesiologist uses the suction, its time and frequency will be recorded.

(N) Vital signs (MAP, heart rate, end-tidal CO2 and SpO2) obtained at standardized intervals before, during and after tracheal intubation will be recorded.

III Post-operative period:

A postoperative follow-up assessment will be performed approximately 4 hours after surgery by a co-investigator blinded to the intubation device to evaluate:

1. The presence and severity of sore throat,
2. Any changes in voice (e.g., hoarseness),
3. Trauma to the lip,
4. Trauma to the tongue,
5. Trauma to the gum, or
6. Trauma to the teeth.

II. **Data Analysis:**

The total study size is estimated to be 120 patients. A sample size of 40 patients in each group is determined by power analysis based on:
The primary and secondary hypotheses, namely the mean time required to complete the intubation process, for each of 2 DL groups compared with the control (standard DL) group and with each other (i.e., Group 1 vs. Group 2, Group 1 vs. Group 3, Group 2 vs. Group 3). In a single factor ANOVA study, sample sizes of 40, 40, and 40 are obtained from the 3 groups whose means are to be compared. The total sample of 120 subjects achieves 88% power to detect a difference of at least 10 seconds using the Tukey-Kramer (Pairwise) multiple comparison test at a 0.05 significance level. The common standard deviation within a group is assumed to be 8.60.

The following items will be analyzed:

1. Demographic information (weight, height, BMI, age, gender)
2. Airway evaluation: Mallampati class, mouth opening, presence or absence of teeth, gaps, thyro-mental distance, neck range of motion (Patients will be asked to move their neck in extension, flexion, rotation, and lateral binding)
3. Vital signs (MAP, heart rate, end-tidal CO2 and SpO2) obtained at standardized intervals before, during and after tracheal intubation
4. Type and amount of drugs administered during induction
5. Assessment of the glottic view using the Cormack Lehane and POGO scoring systems at the time of tracheal intubation
6. Times from the passage of the blade between the teeth to obtain glottic view, to placement of the tracheal tube and the appearance of an end-tidal CO2 waveform
7. The number of intubation attempt(s) An intubation attempt was defined as the insertion of the laryngoscope blade in to the mouth of the patient, regardless of whether an attempt was made to insert a tracheal tube
8. The need to change to a different intubating device, and use of adjuvant airway device (eg, LMA, Bougie, fiberoptic bronchoscope, videolaryngoscope)
9. The use of suction and frequency
10. The presence and severity of trauma to the lip, tongue, gum, or teeth during intubation
11. The presence and severity of sore throat, any changes in voice, trauma to the lip, tongue, gum, or teeth in the recovery area
12. Blade Stained with Blood
13. Any complications

Definitions:
Intubation attempt: laryngoscope blade is inserted into the study participant. A failure will be recorded if the assigned laryngoscope is removed from the mouth to re-position twice.

Intubation Time: The time starts when the tip of laryngoscope blade passes the upper incisors and the time stops when the endotracheal tube is placed in the trachea, the cuff in inflate, and positive end-tidal CO2 detected.

Time to visualized vocal cords: The time starts when the tip of the video laryngoscope passes the upper incisors and the time stops when the provider has clearly visualized the vocal cords.

Ease of intubation: Immediately after the surgery, the performing anesthesiologist will be asked to judge the ease of intubation with each device on a scale from 1 to 4, where 1 = easy insertion without need of adjustment; 2 = need of one adjustment; 3 = two or more adjustments to obtain optimal visualization of the vocal cords, and 4 = impossible visualization and blind intubation or necessary use of an alternative airway device.

The provider will clear secretions as necessary to visualize and report the secretions encountered on a scale from 1 to 10, where 1 = no secretions and no visual obstruction 10=severe visual obstruction, unable to clear without removing device.

Postoperative evaluation: sore throat (0 = none and 10 = maximum discomfort), and whether they have postoperative dysphonia. Furthermore, the incidence of postoperative airway complications will be reported.

INCLUSION AND EXCLUSION CRITERIA

It is anticipated that approximately 120 patients age greater than 18 years scheduled to undergo lumbar spine surgery procedures will be enrolled in this study.

A. Inclusion Criteria

Subjects may be included in the study only if they meet all of the following criteria:

1) Patients scheduled to undergo lumbar spine surgery procedures under general anesthesia
2) Patients with a documented BMI of <35
3) Willingness and ability to sign an informed consent document
4) 18 – 80 years of age of either gender
5) ASA Class I– III adults

B. Exclusion Criteria

Subjects will be excluded from the study for any of the following reasons:

1) Patients who are deemed to be such a significant of an airway risk that they necessitate awake fiberoptic intubation or a difficult tracheal intubation is anticipated
2) Patients with history of difficult intubation
3) Patients with oxygen saturation less than 95% at room air
4) Patients with history facial abnormalities, oral-pharyngeal cancer or reconstructive surgery
5) Any pathologies of the mouth, pharynx or larynx, or the access to the airway is restricted
6) Patients with Immobilized cervical spine, or history of cervical abnormalities
7) Patients with a history of uncontrolled gastroesophageal reflux, hiatus hernia or diabetic gastroparesis
8) Any coagulation disorder
9) Pregnant patients
10) Emergency surgeries
11) Any other conditions or use of any medication which may interfere with the conduct of the Study

DATA HANDLING/RESOURCING: Physician Investigators will have access to the patients' medical records as part of this clinical study. All data will be recorded in forms provided by the Investigator(s). Collected data will be coded and used for research purposes only.

SUBJECT RECRUITMENT: Physician Investigators will interview and explain the details of the study to all potential subjects, who will subsequently be asked to sign an informed consent form to participate in this study.

Each participant will receive as compensation a $50 gift card provided by the company Inscope.

POTENTIAL RISKS: The risks of this study are the same risks that the patient will undergo being induced and intubated for general anesthesia for the procedure. By participating in the study, the patient takes on no added risk relative to a patient who is not participating in the study. There will be no deviation from the customary and standard practices of general anesthesia for this study. The attending anesthesiologist is able to remove their patient from the study at any time should they deem some aspect to be unsafe for patient care.
Independent of the randomization, in this study as in any standard intubation with direct laryngoscopy the subject during the intubation process has the risk of experience trauma to the lip, tongue, gum, or teeth, sore throat with any changes in voice.
Steps to be taken to minimize this research-related risk:

1. Anesthesiologist is always the only one who decides whether or not the subject is candidate to be part of the study after a complete clinical evaluation of the airway in the pre-operative holding area.
2. Anesthesiologist is the only one preforming the intubation and each anesthesiologist participating in this study are experienced.
3. In the case the anesthesiologist cannot perform the intubation procedure he/she is free to use any blade or airway intubating device they consider will be the best option for the subject.

MAINTAINANCE OF CONFIDENTIALITY: Patients' names will not be divulged and all data will be coded in the study records. Information gained during the course of the study will only be used by the investigators for the purpose of comparing the intubating devices. Copies of signed informed consent will be kept on file by the principal investigator, and no patient names or other identifying data will be used in any future publications. Any video or still images obtained of the patient's airway will not include any identifying features of the patient.

SPECIAL PRECAUTIONS: All the devices will be used by a board certified anesthesiologist who is, familiar with their use and trained to handle any untoward events.

PROCEDURES TO MAINTAIN CONFIDENTIALITY: All data will be coded and patient's name will not be disclosed in any of the study records according to standard HIPPA policy. All the information gained during the course of the study will be used by the investigator for the evaluation of the intubating devices. Copies of signed written consent form will be kept on file

by the investigators. No patient names (or other identifying data) will be used in any further publication. We hope the information gained from this clinical study will benefit other patients undergoing similar procedures in the future.

RISK/BENEFIT ASSESSMENT: Risks to subjects are the same as the anticipated risk of a general anesthetic in the absence of the study. The techniques used in the study are not different from commonly accepted standards of practice used for intubating morbidly obese patients. In view of the low risk associated with this study we feel that the potential clinical importance of this information clearly justifies the conduct of this research project.

REFERENCES

1. Hirsch NP, Smith GB, Hirsch PO (January 1986). "Alfred Kirstein. Pioneer of direct laryngoscopy". Anaesthesia 41 (1): 42–5.
2. Gleeson, S., Groom, P., & Mercer, S. (2015). Human factors in complex airway management. BJA Education BJA Educ, 16(6), 191-197.
3. Brimacombe JR, Berry A: The incidence of aspiration associated with the laryngeal mask airway: a meta-analysis of published literature. Journal of clinical anesthesia 1995, 7(4):297-305.
4. Gibbison B, Cook TM, Seller C: Case series: Protection from aspiration and failure of protection from aspiration with the i-gel airway. British journal of anaesthesia 2008, 100(3):415-417.
5. Khazin V, Ezri T, Yishai R, Sessler DI, Serour F, Szmuk P, Evron S: Gastroesophageal regurgitation during anesthesia and controlled ventilation with six airway devices. Journal of clinical anesthesia 2008, 20(7):508-513.
6. Mallampati SR, Gatt SP, Gugino LD, Desai SP, Waraksa B, Freiberger D, Liu PL: A clinical sign to predict difficult tracheal intubation: a prospective study. Canadian Anaesthetists' Society journal 1985, 32(4):429-434.
7. Samsoon GL, Young JR: Difficult tracheal intubation: a retrospective study. Anaesthesia 1987, 42(5):487-490.
8. CORMACK, R. S. and LEHANE, J. (1984), Difficult tracheal intubation in obstetrics. Anaesthesia, 39: 1105–1111
9. Yentis SM, Lee DJ: Evaluation of an improved scoring system for the grading of direct laryngoscopy. Anaesthesia 1998, 53(11):1041-1044.
10. Levitan, R. M., Ochroch, E. A., Rush, S., Shofer, F. S., & Hollander, J. E. (1998). Assessment of Airway Visualization: Validation of the Percentage of Glottic Opening (POGO) Scale. Academic Emergency Medicine, 5(9), 919-923.