

Title:

Comparison of placement of double-lumen endobronchial tube using Glide Scope with 2 different stylet configurations vs standard Macintosh laryngoscopy.

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V. 03April2015

NCT02495259

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Site: Emory University Hospital (EUH) and Emory University Hospital – Midtown (EUHM)

IRB: Emory University School of Medicine

Purpose of Study

To evaluate the technique of placement of the double-lumen endobronchial tube (DLT) using an included stylet that has been radically bent (ZU-bend) as compared to a commercial GlideRite stylet with the GlideScope and direct laryngoscopy using Macintosh laryngoscope.

Introduction

Placement of the DLT is viewed as more challenging partly due to bulkiness and a lack of flexibility that the DLT has compared to single lumen endotracheal tubes, as well as a larger and more fragile occlusion balloon that is more prone to rupture. Securing an airway using traditional laryngoscopy as well as video-assisted indirect laryngoscopy each has its unique advantages and disadvantages.

In a recent study comparing laryngoscopy with Macintosh blade and GlideScope the former was concluded to be superior with respect to intubation success (1), while an earlier study indicated GlideScope to be equivalent to direct laryngoscopy (4). A follow-up editorial pointed out that in Russel's study there was no inclusion of the GlideRite stylet designed specifically for use with GlideScope and DLT, possibly explaining difficulties with GlideScope-assisted intubations (2, 3).

In a small anecdotal sample, the use of a radically curved DLT stylet, the ZU-bend, and GlideScope appeared to be useful in placement of the DLTs by multiple anesthetists under supervision of one anesthesiologist (Zhukov, presented at Thoracic Anesthesia Symposium 2015).

Therefore, we propose to merge the study protocol similar to Russel et. al. (1) with inclusion of both the suggestions from Bussier's editorial , as well as the experience with radically bent DLT stylet (ZU-bend) to evaluate each method with respect to intubation ease and to compare the complication rate with each technique.

Investigational Devices

The intubation modalities (GlideScope, Macintosh laryngoscope, GlideRite stylet and DLT intubating stylet) have all been approved for clinical use and have been used routinely at our institution for DLT placement.

Macintosh blade is one of the most commonly used direct laryngoscopy blades for both single and double-lumen endotracheal intubations. It allows the practitioner to visualize larynx for subsequent intubation.

The **GlideScope** is a video laryngoscope that provides a real-time view of the airway and tube-placement during intubation in place of the direct laryngoscope.

The **GlideRite Rigid stylet** is specifically designed to work with the GlideScope video laryngoscope to facilitate intubation. It provides necessary rigidity and curvature to an otherwise flexible endotracheal tube to permit easier manipulation of it for tracheal intubation.

ZU-bend is a specific shaping technique of the intubating stylet that is more closely related to GlideScope blade curvature. There is a commonplace practice of shaping a flexible stylet for intubation to suit a particular combination of patient and equipment variables. The degree of shaping is somewhat specific to each provider, and is a normal procedure for using the intubating stylet. Bending of the stylet prior to intubation constitutes a routine preparation step for the majority of intubations. The steps for shaping of the stylet are provided in the appendix A.

Objectives

The current research does not provide clear support for one method or another in DLT placement techniques. Additionally, our research has shown that the ZU-bend stylet may be useful with the GlideScope. This randomized controlled study will compare the efficacy of three different methods of DLT placement.

The primary outcome measures will be the mean time it takes to place a DLT with each modality. Secondary outcome measures include success rate of first endobronchial intubation attempt; assessment of difficulty by the provider and complication incidence.

The end points of evaluation of each technique were selected based on Russel's protocol with our modification as summarized in Table 1:

Table 1.

Metric:	Defined as:
First intubation attempt success	DLT placed during initial laryngoscopy, within 120s
Duration of laryngoscopy	Time from laryngoscope at pt's lips through 1 st EtCO ₂ detection
Blood on device	Yes/No
SpO ₂ <96% during intubation	Yes/no
Voice changes	Evaluated in PACU - subjective answer by patient
Lip trauma	Evaluated immediately post-intubation
Dental trauma	--/--
Sore throat	Analog pain scale 0-10, subjective answer in PACU
DLT cuff rupture	Loss of air pressure during procedure requiring >1 reinflation
Ease of device placement	Multi-question form to be filled by anesthetist after intubation
Overall ease of intubation	Subjective score 0-10; where 0 – worst, 10-best
Laryngoscope insertion	--/--
Glottic view	--/--
DLT delivery	--/-- placement of DLT mouth → into glottis proximity
DLT placement	--/-- ease of placing DLT through glottic opening

Study design and methods

This is a prospective, randomized, three-armed trial to investigate the efficacy of a radically curved DLT stylet to facilitate GlideScope-assisted tracheal intubation (Group 1) as compared to the commercial standard of GlideScope with GlideRite stylet (Group 2) and a direct laryngoscopy with Macintosh blade and a regular DLT stylet (Group 3).

This study will not impart additional risks on the patient in excess of those routinely cited for placement of the double-lumen endobronchial tube. All of the modern intubation modalities will be available at the intubation time, arguably decreasing the risk of an ultimately failed securing of patient's airway.

Following informed consent, each subject will be identified via a unique alpha-numeric code and randomized to either of 3 initial DLT placement technique groups. In all cases, the other 2 intervention modalities will be available in the event of failed 1st attempt intubation and will be used at practitioner's discretion. Patient's medical history and detailed airway exam will be recorded on the study form, including Mallampatti score, thyromental distance, ability to prognathize the mandible, any limitation in neck flexion/extension, any evidence of poor dentition or pre-existing dental damage, patient's height, weight and BMI.

Patient will then be taken to the operating room and anesthesia will be induced in the standard fashion per provider's discretion after denitrogenation of patient with 100% O₂ until EtO₂ value is greater or equal to 80%.

Laryngoscopy with the specified randomization modality will be performed by the anesthetist or fellow with timing of intubation recorded as described above. DLT size used will be recorded on the form as well.

The placement of DLT will be verified in a standard fashion using fiberoptic bronchoscopy, auscultation and capnometry. The anesthetist/fellow then will complete their experience questionnaire portion of evaluation. After the conclusion of the procedure, patient will be extubated using standard ASA guidelines and taken to the Post-Operative Admission Unit (PACU), where the final evaluation of patient will take place, assessing voice change and throat pain as described above. This will conclude our study period and patient care will be resumed.

Human Selection Criteria

We plan to enroll up to 130 subjects in order to achieve 120 evaluable subjects with 40 in each arm at Emory University Hospital (EUH) and Emory University Hospital Midtown (EUHM). We will include patients that are scheduled for a thoracic surgical intervention in which surgeon requests lung isolation, including but not limited to: VATS, open thoracic surgery for lung or esophageal disorder, thoracic duct intervention, sympathectomy procedure.

Inclusion Criteria

- Male and female patients requiring DLT placement for their surgery at EUH or EUHM
- Patients willing and able to provide written informed consent

Exclusion Criteria

- Patients in whom a previously difficult airway manipulation was recorded on an anesthetic record.
- Lung transplantation procedures, as underlying pulmonary disorder will confound SpO₂ metric.
- Any patient who is receiving anticoagulants in excess of a daily aspirin, patients with INR >1.4
- Patients in whom one lung ventilation or placement of DLT is contraindicated.
- Patients who require a rapid-sequence intubation.
- Patients undergoing emergency procedures.

Patients who meet eligibility based upon the above criteria will initially be screened by the study team in concert with the patient care team. The study design will be explained to the patient and their interest assessed. Sufficient time will be allotted for the patient to discuss the study in detail with a study investigator, read the informed consent, ask any questions, and sign the informed consent prior to performing the study protocol. This will permit final confirmation that the patients who are enrolled in the study do not have airway anatomy consistent with an expected difficult airway and therefore meeting exclusion criteria for this study.

Estimated time to completion of study: 24 months from enrollment of first subject.

Statistical Analysis

The protocol in Russel's paper and previously cited data within their paper indicated that statistical significance can be attained at 30 subjects in each arm for 2 intervention comparison.

In our evaluation with 3 treatment arms, increasing sample size to 40 patients should provide adequate statistical power. Categorical data will be analyzed using Fisher's exact test. Mann-Whitney and Student's t-test will be applied where appropriate for continuous variables.

Adverse Event Reporting

The study team will comply with Emory University IRB policies for reporting adverse events. In this study, events that are determined by the Principal Investigator to be related to the research will be recorded and reported. Additionally, all deaths, related or unrelated, will be reported to the IRB. All events that are unanticipated problems that are related or possibly related to the research and place the subject or others at greater risk of harm than anticipated will be immediately reported to the Emory IRB.

Data and Safety Monitoring Plan

The data will be continuously analyzed to ensure there is not a significant trend that warrants early termination of the study. The PI will conduct monitoring after the first 10 patients are enrolled and again halfway through the study at 60 patients to evaluate for any related adverse events and ensure continued patient safety. Any serious complications encountered by the anesthesiologist in the room will be relayed to the principal investigator or co-investigators.

All investigators will complete the required training for conducting research at Emory University. All investigators will be made aware of the adverse event reporting policy and will report these events to the principal investigator in a timely manner.

References

1. Russell T, Slinger P, Roscoe A, McRae K, Van Rensburg A. A randomised controlled trial comparing the GlideScope and the Macintosh laryngoscope for double-lumen endobronchial intubation. *Anaesthesia* 2013; 68: 1253–8
2. Bussieres JS, Martel F, Somma J, Morin S, Gagne N. A customized stylet for Glide-Scope(R) insertion of double lumen tubes. *Canadian Journal of Anesthesia* 2012; 59: 424–5.
3. Bussieres JS, Somma J, Rousseau A. Use of the GlideScope for double-lumen endobronchial intubation. *Anaesthesia* 2014, 69, 180–194
4. Hsu H, Chou S, Tseng K, Kuo Y, Chou C, Cheng K. Comparison of the GlideScope videolaryngoscope and the Macintosh laryngoscope for double lumen tube intubation. *Anaesthesia* 2012; 67: 411–5.

Appendix A:

The stylet is then shaped as follows:

- The inside lumen of the tube and the stylet are lubricated with food-grade silicone spray such as SilkoSpray® by Rüsch.
- If the tube and stylet are separated for lubrication, they are reassembled for the subsequent steps.
- The tip of the endobronchial tube, approximately at the proximal end of the bronchial balloon is placed over the tip of the GlideScope blade with the bronchial lumen facing the lesser curvature of the GlideScope blade
- Proceeding from distal to proximal, the tube and the stylet are shaped to the outline of the GlideScope blade; the resulting curvature resembles "U" shape rather than a "J" of GlideRite. (Fig. 1, 2)

