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A comparison of positional stability: the EZ-blocker versus Left Sided Double Lumen Tube in adult patients for thoracic surgery

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Study Title: A comparison of positional stability: the EZ-blocker versus Left Sided Double Lumen Tube in adult patients for thoracic surgery.

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Background, Rationale and Context

One lung ventilation (OLV) is commonly used in thoracic surgery to improve surgical exposure and improve operative conditions. At this time, there are two approaches to OLV in routine use in adult thoracic surgery. One approach is to use of a double lumen tube (DLT). The other approach is to use a bronchial blocker (BB). Currently there are several different types of bronchial BBs on the market.

The EZ-Blocker is a bronchial blocker with a 7-Fr shaft with two separate occlusive balloons "Y" configuration designed to rest on the carina. Once secured in place, the operator can choose to inflate one of the two occlusive balloons to isolate either mainstem bronchus (1).

Studies have been performed comparing BBs to DLTs looking at time and ease of placement, differences in quality of lung isolation, and incidence of sore throat, hoarseness, and other morbidity associated with placement [2-4]. A recent meta-analysis published by Clayton-Smith et al found that BBs are associated with fewer airway injuries when compared to DLTs (5). They found the quality of isolation to be equivalent between BBs and DLTs. While quality of isolation over all may be comparable, it has been demonstrated in several studies that positional stability of bronchial blockers such as the Arndt or Cohen, is frequently inferior to that of a DLT (2,4).

At this time, there are a small number of trials looking at the use of the EZ-blocker in adult patients. In one study published in 2013 the EZ-blocker was compared to the Cohen Flex-Tip blocker. In this study they found that time to place the EZ-blocker was in fact shorter and that overall the number of repositioning required was less with the EZ-blocker (6). In 2013, a study was published by Mourisse et al which compared DLT to the EZ-blocker (7). In this study they found initial malposition of both devices to be fairly equivalent, and time to placement was longer with the EZ-blocker. They also found more tracheal and bronchial injuries in the DLT group, but importantly they found that positional stability was equivalent. In both of these studies however they did not design their studies to effectively differentiate between right and left sided procedures when quantifying the need for BB repositioning. Because the take off of the right upper lobe bronchus is sometimes adjacent to, or even proximal to the carina, it can impede effective isolation with a BB. Therefore, claims of positional stability may rely heavily on the laterality of the procedure, with right sided isolation being significantly more labile than left sided especially with respect to isolation using a BB.

In conclusion then, we feel that the potential morbidity of a DLT in terms of the potential for airway injury when compared to a BB suggests that further exploration of the possibility of equivalent positional

stability between these devices is necessary. We feel it is necessary to delineates the impact of laterality on the effectiveness of one technique for isolation versus the other.

In addition to this if there is a difference in stability in cases where right sided isolation via the EZ-blocker fails in the setting of multiple repositions or out and out failure we would like to examine the preoperative CT data to determine if there are anatomic measurement which could potentially inform the appropriateness or inappropriateness of choosing a DLT over an EZ-blocker.

Objectives

The objective of this study is to evaluate the positional stability and quality of lung isolation provided by the EZ-blocker compared to a DLT for both right and left sided thoracic surgery.

An additional objective will be to assess time to placement of both devices and other significant clinical differences between these two approaches to placement of the BB including airway injury and post-operatives sore throat, post-operative hoarseness, Additionally we would like to examine the preoperative high resolution CT imaging data to determine if there are anatomic landmarks that may potentially inform the appropriateness or inappropriateness of choosing an EZ-blocker or left sided DLT.

Methods and Measures

Design

Once the patient is recruited preoperatively in the PAC or within the hospital as an inpatient, this information will be relayed to the study investigators. On the day of surgery, the patient will then be randomized using a random number generator and opaque envelope method for group allocation to either extra-luminal placement of an EZ blocker bronchial blocker or left side double lumen tube. We will recruit at least 80 patients with right sided procedures: 40 EZ-Blocker and 40 left sided DLT. We will also recruit at least 80 patients with left sided procedures: 40 EZ-Blocker and 40 left sided DLT.

We will record age, height, weight, gender, ASA status, type of surgery, side of surgery, duration of one lung ventilation, duration of surgery, and duration of anesthesia.

An IV will be placed in the patient prior to going to the OR. Once in the OR the patient will have routine monitors placed. The patient will be pre-oxygenated with 100% O2 for 2 minutes and induced.. The patient will then be hand ventilated with 100% oxygen for 3 minutes to ensure relaxation. Patients will undergo direct laryngoscopy and according to group assignment will have either an extraluminal EZ-blocker placed or an appropriately sized left sided double lumen placed under the supervision of an attending experienced in thoracic anesthesia and one lung ventilation.
We will confirm endotracheal placement of the ETT or left sided DLT via ausculation and ETCO2. The ETT or DLT will be secured at an appropriated depth. The fiberscope will then be advanced into the lumen of the ETT or DLT to further adjust and confirm placement of the EZ-blocker or DLT. Time for initial bronchial blocker placement or DLT placement will be recorded from the point of the DL to removal of the fiberscope after visualization of the BB with the cuff inflated in the correct position or the DLT with the bronchial cuff inflated.

Other intravascular lines such as a radial arterial line and additional peripheral IV may be placed at the discretion of the attending anesthesiologist.

Once in the final position prior to prepping and draping the blocker or DLT in all groups will be checked to make sure it is still correctly placed with a FOB. The patient will be prepped and draped.

The surgeon will be blinded to technique and queried as to the quality of isolation upon entry into the chest and this will be recorded. This will be queried every 60 minutes for the duration of the procedure.

We will record any episodes of loss of isolation and details of repositioning including times and the issue of malposition i.e. the blocker or DLT slipped out or slipped in too far. We will record any episodes of ongoing desaturation which require deflation of the EZ-blocker cuff and/or ventilation of both lungs with a DLT.

We will record the point at which the surgeon the end of OLV. The patient will be extubated according to normal clinical practices and will be taken to the post anesthesia care unit. The Ez-blocker will be removed simultaneously with the ETT. In patients in the EZ-blocker group that remains intubated post procedure the EZ-blocker will be removed prior to going to the ICU. In the DLT group the DLT will be exchanged according to routine clinical practice to a single lumen ETT.

The patient will be contacted on post-operative days 1 and 2 to assessed for hoarseness and sore throat via a VAS scale from 0-100: 0=No sore throat and 100=the worst sore throat imaginable. We will also record any significant morbidity or mortality events such as prolonged mechanical ventilation or cardiac arrest or stroke that may occur within the first 2 post-operative days.

In patients where isolation is troublesome requiring multiple repositioning we will evaluate their preoperative CT scan to determine if there are any anatomical findings on CT which maybe predictive of failure. We will compare these to an equivalent number of control patients from this study population in which isolation was successful. We will attempt to match these patients for size and diagnosis.
The study will be performed at Wake Forest Baptist Medical Center a tertiary academic medical center.

Subjects selection criteria

Adult patients scheduled for thoracosopic surgery or thoracotomy requiring lung isolation in which both an EZ-blocker or double lumen tube would be considered an appropriate choice for lung isolation will be recruited.
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- **Inclusion Criteria**

  Patients greater than 18 years of age scheduled for thoracoscopic surgery or thoracotomy requiring lung isolation
  Patient presenting as an outpatient for elective thoracic surgery
  Inpatients scheduled for thoracic surgery.

- **Exclusion Criteria**

  History of difficult airway/intubation
  Patients suspected to have a difficult airway.
  Morbid obesity BMI >39
  Pregnancy
  Emergency status of surgery
  Thoracic surgery requiring a right sided double lumen tube

- **Sample Size**

  Assuming a power of 80% and a type 1 error of 5% and a rate of repositioning in the DLT group to be approximately 0.3 repositioning/hour from our experience and a projected rate of repositionings using an EZ-blocker of 0.5 with a standard deviation of 0.3 we estimate a sample size of 36 patients in each arm to demonstrate non-equivalence and so we anticipate enrolling 40 patients in each device in both the left and right sided arm bringing our total enrollment to 160 patients. This is not a multisite study.

Interventions and Interactions

Interventions and interactions for the patient should be fairly reasonable. The largest overall commitment of time from the patient will be in the PAC at the time of recruitment or in their room as an inpatient. One of the PAC attendings, or investigators, or study personnel will interview the patient explain the study and attempt to recruit the patient if they are eligible. The study participant will have their questions answered and will be consented.
On the day of surgery, the patient will be identified in the holding area and a study representative will make sure that he or she has not changed their mind about participation and will answer any questions the study subject may have thought of since the interview in PAC. If the patient is still in agreement to participate in the study they will be taken to the OR and care will proceed as it would otherwise with the induction of general anesthesia and placement of the EZ-blocker or DLT per the protocol depending on which group the patient has been randomized to. In some cases, in which the patient is an inpatient or does not go to the PAC a member of the study team may approach them to participate either the day before or on the day of surgery. After the surgery, a study representative will contact the patient to evaluate for any postoperative issues such as a sore throat or increase hoarseness on post-operative days 1 and 2. This will be the last interaction of the patient with the study.

	Patient identified in PAC.	Patient approached in PAC and questions answered about. Patient to sign consent for study participation here.	Confirmation and randomization on day of surgery	Bronchial Blocker placed intraluminally or extraluminally. Data collected about placement	Patient will undergo surgery. Intra-operative events related to blocker position will be recorded	At the end of surgery BB or DLT will be removed, and the patient will extubated, and patient taken to PACU or ICU	Patient interviewed on post-op days 1 and 2 to evaluate sore throat.
Time required of Patient	0 min	20 min	5 min	10 min	Depends on surgical duration.		5-10 min

Outcome Measure(s)

We will measure the number of DLT or BB replacements, time of placement, quality of isolation at 1-hour intervals during the operation, incidence of sore throat and/or hoarseness postoperatively.

Analytical Plan

Results will be analyzed initially using descriptive statistics. Comparison between groups will be done using chi square tests for proportions, and t-tests or ANOVA procedures for continuous variables. Other inferential statistical analysis will be conducted as appropriate.

Human Subjects Protection

Subject Recruitment Methods

Patients will be identified for participation in the Preoperative Assessment Clinic (PAC) prior to the day of surgery or via the OR schedule for patients who are not seen in the PAC. All patients scheduled for elective thoracic surgery pass through the PAC. PAC attendings will be educated by the investigators as to the specific inclusion and exclusion criteria. Patients will be recruited by investigators and/or the study coordinator with the participation and collaboration of PAC attending and other staff present in the clinic involved in this study. We will attempt to recruit qualified subjects in a non-biased manner. Privacy will be protected because subjects will be recruited in the process of a confidential preoperative evaluation in

PAC. If they choose not participate no research record will be created and as such there will be no contact information to destroy. In house patients will be approached to participate either the night before surgery or on the day of surgery.

Informed Consent

Signed informed consent will be obtained from each subject. Investigators, study coordinator, and PAC attendings involved in the study will obtain informed consent. Inpatients will be interviewed and recruited by either study investigators or other member of the study team.

Confidentiality and Privacy

Confidentiality will be protected by collecting only information needed to assess study outcomes, minimizing to the fullest extent possible the collection of any information that could directly identify subjects, and maintaining all study information in a secure manner. To help ensure subject privacy and confidentiality, only a unique study identifier will appear on the data collection form. Any collected patient identifying information corresponding to the unique study identifier will be maintained on a linkage file, store separately from the data. The linkage file will be kept secure, with access limited to designated study personnel. Following data collection subject identifying information will be destroyed 4 years after closure of the study via shredding, consistent with data validation and study design, producing an anonymous analytical data set. Data access will be limited to study staff. Data and records will be kept locked and secured, with any computer data password protected. No reference to any individual participant will appear in reports, presentations, or publications that may arise from the study.

Data and Safety Monitoring

The principal investigator will be responsible for the overall monitoring of the data and safety of study participants. The principal investigator will be assisted by other members of the study staff.

Reporting of Unanticipated Problems, Adverse Events or Deviations

Any unanticipated problems, serious and unexpected adverse events, deviations or protocol changes will be promptly reported by the principal investigator or designated member of the research team to the IRB and sponsor or appropriate government agency if appropriate.

References

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7. Mourisse et al. “Efficiency, Efficacy, and Safety of EZ-Blocker Compared with Left-Sided Double-Lumen Tube for One Lung Ventilation.” Anesthesiology 2013; 118: 550-561.
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9. Templeton TW et al. “Bending the Rules: A Novel Approach to Placement and Experience with the 5 French Arndt Endobronchial Blocker in Children Less than 2.” Pediatric Anesthesia 2016; 26: 512-520 .

Appendix

1. Data collection form

Appendix 1 Data Sheet

Data Form for EZ-bronchial Blocker vs. Double Lumen Study

Patient Sticker

ASA:
Weight: Height: BMI:
Gender:
Diagnosis:
Laterality: RIGHT LEFT

EZ-Blocker DOUBLE LUMEN

Induction Drug Doses:
Propofol_____ Fentanyl_____ Rocuronium(0.8mg/kg)_____
Etomidate_____

Ventilate/Wait 3 minutes at least.

Begin Blocker or Double Lumen with DL. START TIMING:

Time for placement of EZ-blocker or DLT:_____

Number of EZ-blocker or DLT Replacements During Procedure: _____

Quality of Isolation: 1- Excellent 2 – Fair 3 - Poor
Time 1 _____ Quality of Isolation T1 _____
Time 60 min Quality of Isolation 60 _____
Time 120 min Quality of Isolation 120_____
Time 180 min Quality of Isolation 180_____
Time 240 min Quality of Isolation 240_____
Time 300 min Quality of Isolation 300_____
(Excellent=complete collapse with perfect surgical exposure; Fair=total collapse but the lung has residual air; Poor=no collapse, or partial collapse with interference in surgical exposure)

Incision Time:_____ Closure Time:_____ Time of OLV_____

Sore Throat Post procedure:
VAS score from page 3

Day 1 _____
Day 2 _____
Additional Comments/Adverse Events/Other significant intra-operative events

Blocker or Double Lumen Replacement

Replacement Event:	Time	Brief Description of event including duration of replacement event
		Too Deep Too Proximal Other
		Too Deep Too Proximal Other
		Too Deep Too Proximal Other
		Too Deep Too Proximal Other
		Too Deep Too Proximal Other
		Too Deep Too Proximal Other
		Too Deep Too Proximal Other

Day 1

No Sore Throat Worst Sore Throat Imaginable

0 _____ 100

Day 2

No Sore Throat Worst Sore Throat Imaginable

0 _____ 100