

A comparison of direct laryngoscopy and video
laryngoscopy using the C-Mac in pediatric nasal
intubations.

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Study Title: A comparison of direct laryngoscopy and video laryngoscopy using the C-Mac in pediatric nasal intubations.

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Background, Rationale and Context

Nasal intubation is frequently used for dental procedures to promote an unimpeded view of the oral cavity. Following the induction of general anesthesia, the patient is given a dose of muscle relaxant. At this point, a vasoconstrictive agent such as oxymetazoline is commonly introduced into both nares to reduce the incidence of nasal bleeding.^{6,7} After this step, an appropriately sized nasal RAE (Ring, Adair and Elwyn) endotracheal tube, an endotracheal tube designed specifically for intubations secured by way of the nasal passage, is introduced into the nare that is associated with the least resistance. The nasal tube is then placed through the nasal passage and into the posterior pharynx, then advanced into the airway. A nasal RAE endotracheal tube is longer than a standard oral endotracheal tube (ETT) and it is shaped so that end of the tube which attaches to the ventilator exits upward toward the forehead. This unique shape ensures that the tube will not interfere with surgical exposure of the oral cavity and mandible.

The nasal RAE ETT can be placed in the trachea using either direct laryngoscopy or video laryngoscopy. In the case of direct laryngoscopy, following placement of the nasal RAE into the nasal passage, a laryngoscope is introduced into the oral cavity. The nasal RAE tube is advanced slowly until it is visualized in the oropharynx via the laryngoscope. Simultaneously, the practitioner attempts to visualize the glottic opening. The practitioner will then attempt to guide the distal end of the Nasal RAE ETT into the glottis. Sometimes this is possible without an adjuvant, but frequently a pair of specially shaped forceps, known as Magill forceps, is required to guide the distal tip of the Nasal RAE into the glottis due to the curvature of these ETT.^{1,2} Magill forceps are introduced into the mouth and are used to grasp the distal end of the Nasal RAE and direct it into the glottis.

Video laryngoscopy is a more modern approach to direct laryngoscopy in which a camera is present on the blade of the laryngoscope. This is different in some ways from direct laryngoscopy because the location of the camera on the blade allows for visualization of the glottic opening and other oropharyngeal structures without requiring a direct line of site. This can potentially facilitate intubation in more challenging airways because there no longer is a need for direct line of site to place the ETT into the glottis. At this time there are a number of different devices available from different manufacturers including the C-Mac (Karl Storz, Germany), the Glidescope (Verathon), and the Mcgrath (Covidien).^{3,5}

In a recent study looking at nasal intubation in children using the Glidescope, investigators found a fairly equivalent rate of successful intubation with DL and VL using a Glidescope. They found similar time to intubate and similar incidences of having to use the standard Magill forceps (90% in DL vs 87.5% in VL) in order to place the Nasal RAE tube. They also failed to intubate nasally with the Glidescope in 2 individual cases.^{1,4}

In another study looking at nasotracheal intubation in adults with a known difficult airway, the researchers examined the impact of modifying the shape of the Magill forceps to improve the success rate of intubation. They compared 3 different video laryngoscopic systems including the Glidescope, Airtraq, and C-Mac. They found that modifying the shape of the Magill forceps did improve the rate of intubation. However, there is no comment on whether or not the use of VL with any of these 3 systems reduced the rate of needing Magill's forceps overall.²

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Contrary to what some of these studies suggest, it has been our experience that nasal intubations using the C-Mac frequently do not require the use of Magill forceps at nearly the same rate as DL additionally they may overall be easier. As a result, this technique may improve the over all time and ease of intubation because of not having to use the Magill forceps to advance the Nasal RAE into the larynx. The use of Magill forceps can be awkward for the clinician, with poor visualization due to obstruction of the view by this tool in the airway, and small working space within the posterior oropharynx. For these reasons, the possibility of not having to use Magill forceps because we are using a C-Mac as the only tool to intubate is a potentially inviting one. Overall there may be other positive effects to having a closer and more magnified view of the glottis as well.

Objectives

The objective of this study is to compare the need for the use of standard Magill forceps when performing a nasal intubation with either conventional DL or VL with a C-Mac and overall ease of intubation. Secondly we will also examine the time to intubate (TTI) for both methods as well.

An additional objective will be to assess if there are any other significant clinical differences between these two approaches to placement i.e. increased rates of overall failure, clinical morbidity such as laryngeal or pharyngeal injury.

Methods and Measures

Design

Once the patient is recruited in the pre-admission clinic (PAC), 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 DL or VL with a C-Mac. In a minority of cases where a suitable patient has not gone through the PAC we will attempt to recruit them prior to going to the operating room after the pre-anesthetic evaluation.

We will record age, height, weight, gender, ASA status.

The patient will be pre-medicated at the discretion of the attending anesthesiologist. The patient will then be randomized to either DL or VL with a C-Mac. The patient will be brought to the operating room. Once in the OR the patient will have routine monitors placed. The patient will undergo an inhalational induction with sevoflurane. Once anesthesia has been induced, an IV will be placed. The patient will be relaxed with 0.8 mg/kg of rocuronium IV. The patient will then be hand-ventilated with 100% oxygen and sevoflurane for 3 minutes to allow for adequate relaxation and an end tidal oxygen concentration of at least 80%. During this time, the patient will receive oxymetolazine in both nares to reduce the risk of bleeding with a nasal tube. Prior to intubation, we will also attempt to insert an appropriately sized flexible nasal trumpet to assess which nares provides the least resistance to passage of an ETT. After 3 minutes have elapsed since the administration of rocuronium, an appropriately sized cuffed nasal RAE ETT that has been warmed using a warm blanket, and then lubricated with a water soluble lubricant will be inserted into the nares. Once the ETT is passed into the posterior oropharynx, depending on which randomized group the patient has been assigned (VL or DL), an attending pediatric anesthesiologist or a pediatric Certified Registered Nurse Anesthetist (CRNA) who has experience performing nasal intubations with both DL and with the C-Mac will attempt to intubate the patient with or without Magill forceps as needed.

We will record the time to intubation (TTI) from the time the laryngoscope or C-Mac is placed in the mouth to the first appearance of end tidal carbon dioxide (ETCO₂). We will record the presence or absence of nasal bleeding and its level of severity using a 4 point scale (0 No bleeding, 1-Trace, 2-Moderate, 3-copious) as well as the grade of laryngeal view. We will record the number of attempts. If the blade is removed from the mouth this will be considered the end of one attempt, and once the blade is reinserted this will be the beginning of another attempt. We will also record any general narrative comments from practitioners about the ease or difficulty of intubation in both the DL and VL group. In addition to the narrative comments we will have the laryngoscopist grade the degree of difficulty on a 100mm VAS scale after the intubation (0 easiest -100 most difficult). The laryngoscopist will be blinded to TTI until VAS score and other airway data are recorded. Intubation will be considered a failure at 5 minutes. At this point it will be at the discretion of the anesthesiologist of record to decide how to proceed, either with an oral tube or different technique for nasal intubation. TTI will be considered 5 minutes for the purposes of analysis and device comparison. We will record the lowest SpO₂ during intubation.

The patient will be extubated according to normal clinical practices and will be taken to the post anesthesia care unit (PACU).

Patients will be observed in the PACU and any significant events such as unintended admission, excessive hoarseness, persistent nasal bleeding, or pharyngeal injury will be recorded.

The study will be performed at Wake Forest Baptist Medical Center a tertiary academic medical center.

C-Mac Product Information

The C-Mac Video laryngoscope is produced by Karl Storz products. Product specifications can be found at:

https://www.karlstorz.com/cps/rde/xber/karlstorz_assets/ASSETS/3436753.pdf

<http://www.airwayworld.com/wp-content/uploads/2013/08/1.-C-MAC-VIDEO-LARYNGOSCOPES.pdf>

<http://www.airwayworld.com/wp-content/uploads/2013/08/Neonate-Pediatrics.pdf>



Subjects selection criteria

Pediatric patients between the ages of 3 and 14 scheduled for comprehensive dental treatment in which a nasal tube would be an appropriate method to secure of the airway.

- **Inclusion Criteria**

Patients between the ages of 3 and 14 scheduled for comprehensive dental treatment, tooth extraction, or incision and drainage of tooth abscess under general anesthesia in which a nasal endotracheal tube is an appropriate method for securing the airway.
Normal appearing airway upon pre-operative assessment.

- **Exclusion Criteria**

Patient with a history of difficult airway/intubation
Patients suspected to have a difficult airway.
History of cleft palate and/or cleft palate repair
Pregnancy
Emergency status of surgery
Any patient with a contra-indication to nasal tube placement
Any patient with a potentially increased risk of nasal bleeding from nasal placement of the ETT i.e. patients on aspirin or other anticoagulants, patient's with hemophilia,

- **Sample Size**

Based on a published rate of approximately 90% of patients requiring Magill forceps to place a Nasal RAE ETT with DL and a rate of 50% based on pilot data in patients with a C-Mac VL system, we have performed a power calculation to determine the sample size needed. Based on a power of 80% and an alpha of 1% we have calculated a sample size of 35 patients in each group to be able to detect a significant difference in the rate of use of Magill forceps to place a nasal RAE ETT in this patient population. This is not a multi-site 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 or preoperatively in holding at the time of recruitment. One of the PAC investigators interview the patient's legal guardian (frequently their parents) and the patient for assent when appropriate. They will explain the study and attempt to recruit the patient if they are eligible. The study participant and their guardian will have their questions answered and if they agree to allow their child to participate will sign the consent form. Assent will be obtained from cognitively intact children over the age of 7.

In patients that have gone through and been recruited in the PAC, the patient will be identified in the holding area on the day of surgery and a study representative will make sure that the guardian or patient 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's guardian 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 attempted placement of a nasal RAE ETT via DL or VL with a C-Mac depending on which randomization group to which the patient has been randomized. After the procedure, the patient

will be observed in the PACU and discharged to home. A study representative will thank them for their participation and this will be the last interaction with the patient and patient’s guardian in 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	Patient intubated after induction of anesthesia. Data collected about nasal intubation including time to intubate and laryngeal view.	Patient will undergo dental procedure.	At the end of the dental procedure. The ETT will be removed and the patient will be taken to PACU	Patient will be observed and recovered post operatively in the PACU. Any significantly airway injuries or recurrent nasal bleeding will be noted.
Time required of Patient	0 min	20 min	5 min	10 min	Depends on surgical duration.	5 minutes	5-10 min

Outcome Measure(s)

We will record time to intubate and will assess the need for Magill forceps for intubation. We will also record grade of larynx view, presence of nasal bleeding, any and all comments from the practitioner related to intubation, and incidence of failed nasal intubation.

Analytical Plan

Results will be analyzed initially using descriptive statistics. Comparison between the two groups will be done using Fisher’s Test, and ANOVA procedures for continuous variables. Other inferential statistical analysis will be conducted as appropriate.

Human Subjects Protection

Subject Recruitment Methods

In most cases patients will be identified for participation in the Preoperative Assessment Clinic (PAC) prior to the day of surgery. Almost all pediatric patients scheduled for elective dental procedures pass through the PAC. In some cases though, patients do not go through the PAC and we will attempt to identify and recruit these patients in preoperative holding using the same inclusion and exclusion criteria. Patients will be recruited and consented by investigators with the participation and collaboration of the PAC attending present in the clinic. 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.

Informed Consent

Signed informed consent will be obtained from the parent or legal guardian of each subject. Informed consent will be obtained by investigators. This consent will be obtained in the PAC when ever possible, however we may obtain consent on the day of surgery in patients that have not gone through the PAC. Assent will also be obtained for children over the age of 7 who are cognitively able to provide assent. However, in many cases these patients present with a medical history of mental handicap or autism and will not be able to give assent.

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, stored 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] Riegler EV, et al. "Comparison of vasoconstrictors for functional endoscopic sinus surgery in children." *Laryngoscope* 1992; 102: 820-823.

Appendix

1. Data collection form
2. Consent form