TITLE: **The impact of suctioning on oxygenation during RSI in the Emergency Department – A Multi-centre Pilot Study**

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Introduction

Rapid Sequence Intubation (RSI) is a common procedure in Emergency Departments (ED). However, it is a high-risk procedure and has been associated with significant complications including hypoxia, hypotension, airway trauma, aspiration, and death (1-3). Specifically, hypoxic episodes during intubation can lead to poor outcomes such as dysrhythmias, haemodynamic compromise, hypoxic brain injury and cardiac arrest, and is therefore of primary concern during any intubation procedure (4,5). Aspiration is a serious adverse event and potential cause of hypoxia during RSI and can lead to poor patient outcomes downstream of the procedure. The reported incidence of aspiration during RSI in the ED ranges from 3 to 8% in the ED population (6,7). In order to achieve an optimal view of the glottis and prevent pulmonary aspiration of fluids in the oropharynx, , providers apply suction prior to and during laryngosopy, using a Yankauer or large bore suction catheter. (8).

There is currently significant variation in suctioning during laryngoscopy, with some providers using very little suction as needed to clear heavy fluids (judicious suctioning), while others utilise suction aggressively (lead with suction) and as a part of their routine laryngoscopy technique (9, 10, 11). Evidence suggests inline suction on already-intubated patients accelerates desaturation, but we are aware of no studies examining the impact suctioning has on the speed of desaturation during emergent endotracheal intubation (11,12).

This pilot study aims to compare the effects of intermittent, as-needed "judicious" suctioning versus aggressive "continuous" (lead with) suctioning on oxygenation during rapid sequence intubation in the emergency department.

Methods

Setting

In order to enrol patients into this pilot study and to gain experience from International centres this study will be performed at 4 sites: the Royal Prince Alfred (RPA) Hospital Emergency Department, Sydney, Australia, Mount Sinai Hospital, Manhattan, NY, Maimonides Medical Center, Brooklyn, NY and NYC H+H/Lincoln Medical Centre, Bronx, New York, USA. The RPA Hospital is a Level 1 Trauma Centre with approximately 85,000 presentations and 240 intubations per year. Lincoln Medical Centre is a Level 1 Trauma Hospital with approximately 175,000 presentations and 450 intubations per year. Mount Sinai Hospital is a tertiary referral center whose ED sees approximately 125, 000 patients per year with around 200 intubations. Maimonides Medical Center is a level 1 trauma center that treats about XXX and performs about XXX intubations per year.

Study Participants

All adult patients requiring emergent rapid sequence intubation (RSI) in the resuscitation bay will be included in the study. Patients that have a heavily soiled airway (i.e. secretions, vomitus, blood) as deemed by the physician requiring suction will be excluded.

Variables measured

The variables included in the study are shown on the Data collection sheet (Appendix 3) and will include the following:

- Patient details: Age, Gender, estimated weight
- Indication for RSI
- C-spine immobilisation and manual inline stabilisation
- Method of preoxygenation
- Method of apnoeic oxygenation, if performed
- Head up or supine position
- Oxygen saturation and ETO2 prior to starting preoxygenation and at induction (completion of preoxygenation)
- Oxygen saturation and ETO2 during procedure (at 10 second intervals starting with induction).
- Time of preoxygenation
- Induction medication and dose used
- Paralytic and dose used
- Induction time
- Endotracheal intubation time
- Method of intubation
- Number of attempts
- Cormack-Lehane grade of airway
- Use of cricoid or External laryngeal manipulation
- Continuous versus judicious suctioning

Intervention

The aim of this study is to investigate the effect of suctioning (a current technique used conventionally in RSI) on oxygenation levels during RSI. This being noted, there is no new intervention being applied to the patient.

In order to investigate this, the current standard of care of suctioning will be used either by judicious means (i.e. in and out suction as needed) or continuous means (i.e. throughout the procedure, including laryngoscopy and tube placement) according to conventional practice at the discretion of the treating physician. For all patients involved in the study, there will be no new intervention applied. The impact of the use of suctioning, again which is standard of care and applied by convention, will be determined by measuring oxygen saturation as a primary outcome. All aspects of RSI will be at the discretion of the treating clinician, which is the current standard, including induction/relaxant medication, positioning of the patient, preoxygenation method, method of intubation and post-intubation sedation. At all institutions RSI is performed in a similar manner utilising an airway checklist (Appendix 1 and 2). However, there are no 'Standard Operating Procedures' for RSI in any ED and therefore intubation technique will vary depending on clinician preference and the clinical circumstances.

Once the decision to perform RSI has been made by the treating team, the patient will be enrolled into either a judicious or continuous suction group at random. Ineither case, suctioning will be applied to the patient as determined necessary by the clinician. Rapid sequence intubation will then be performed in the standard means by the treating provider.

Outcomes

Primary Outcome

The primary outcome of this study is the oxygen saturation achieved (SpO_2) at the time of tube placement (via confirmation with first $ETCO_2$ waveform) achieved during the intubation period.

Secondary Outcomes

The secondary outcomes measured include:

- Incidence of desaturation (SaO2 <90%) or >10 points from baseline during the intubation period
- Lowest O2 saturations at any point during the intubation period
- The ETO_2 at induction and at ETT confirmation.
- Time from preoxygenation to endotracheal intubation
- Complications during RSI: bradycardia, tachycardia, hypotension, hypertension, oesophageal intubation, aspiration, airway or dental trauma, equipment or medication error
- Number of intubation attempts

Data Collection

The data will be collected prospectively during the time of RSI by nursing and medical staff with the use of a data collection sheet (Appendix 3). Staff at RPA ED are familiar with the data collection sheets as prior studies in relation to RSI have been performed previously (Study number Re: X12- 0394). Similarly staff at Lincoln Medical centre and Mount Sinai perform routine data collection on all RSI's performed in the ED for quality improvement purposes. The staff at Maimonides and Mount Sinai will be trained in the procedure for collecting data with the use of the data collection sheets.

Patient risk

This study investigates the effect of providing suction during RSI on SpO_2 levels. This study will have no direct impact on patient care as it evaluates the use of a current accepted standard in the ED. This adds to clinical information and may lead to either no change or improved patient care. There are no risks to the patient as the patient will be receiving standard of care in both arms of the study. Patients will be critically ill requiring an emergency procedure and therefore, consent is not necessary for this study as per the criteria of the Common Rule for waiver of informed consent for emergency research.

Sample Size

A sample size calculation for this study is not possible as this is a pilot study and there is currently no reported data on the impact suctioning has on oxygen saturation during RSI in emergency department patients. For this reason we have decided to perform a convenience sample of 100 patients (50 in the judicious group and 50 in the continuous group). Data from this study will be used to provide statistics for a sample size and power calculation for a larger randomized control trial in the future.

Statistical Analysis

Descriptive statistics will be used for the cohorts. Means with 95% confidence intervals and medians with interquartile range will be used to describe the cohorts. Chi squared test will be used to compare the proportion of patients that experience desaturation between the cohorts. A simple student's t-test will be used to compare the mean oxygen saturations and end tidal oxygen levels measured between the cohorts.

Study Endpoints

The endpoint for this pilot study will be the enrollment of 50 patients in each group to a total of 100 patients.

References

1. Martin LD, et al. 3,423 emergency tracheal intubations at a university hospital: airway outcomes and complications. *Anesthesiology* 2011; 114: 42–8.
2. Bair AE, et al. The failed intubation attempt in the emergency department: analysis of prevalence, rescue techniques, and personnel. *J. Emerg. Med.* 2002; 23: 131–40.
3. Fogg et al. Prospective observational study of the practice of endotracheal intubation in the emergency department of a tertiary hospital in Sydney, Australia. E*mergency Medicine Australasia* (2012) 24, 617–624
4. Mort TC. The incidence and risk factors for cardiac arrest during emergency tracheal intubation: a justification for incorporating the ASA guidelines in the remote location. *J Clin Anesth*. 2004;16: 508-516.
5. Davis DP, et al. Rate of decline in oxygen saturation at various pulse oximetry values with prehospital rapid sequence intubation. *Prehosp Emerg Care*. 2008;12:46-51.
6. Driver BE, Klein LR, Schick AL, Prekker ME, Reardon RF, Miner JR. The occurrence of aspiration pneumonia after emergency endotracheal intubation. Am J Emerg Med. 2018 Feb;36(2):193-196. doi: 10.1016/j.ajem.2017.07.066. Epub 2017 Jul 19.
7. Thibodeau LG, Verdile VP, Bartfield JM. Incidence of aspiration after urgent intubation. Am J Emerg Med. 1997 Oct;15(6):562-5.
8. Scott Weingart. Podcast 196 – Having a Vomit SALAD with Dr. Jim DuCanto – Airway Management Techniques during Massive Regurgitation, Emesis, or Bleeding. *EMCrit Blog*. Published on April 3, 2017. Accessed on January 21st 2019. Available at [http://emcrit.org/emcrit/having-a-vomit-salad-with-ducanto/].
9. https://twitter.com/em_resus/status/963106111858663424?lang=en
10. https://twitter.com/TBayEDguy/status/919306089409150977
11. https://www.smacc.net.au/2017/04/leisurely-laryngoscopy-best-practice-technique-airway-success/
12. Caramez MP1, Schettino G, Suchodolski K, Nishida T, Harris RS, Malhotra A, Kacmarek RM. The impact of endotracheal suctioning on gas exchange and hemodynamics during lung-protective ventilation in acute respiratory distress syndrome. Respir Care. 2006 May;51(5):497-502.
13. Caramez MP1, Miyoshi E, Harris RS, Kacmarek RM, Malhotra A.Gas exchange impairment induced by open suctioning in acute respiratory distress syndrome: impact of permissive hypercapnia.Crit Care Med. 2008 Feb;36(2):560-4.