The Australia and New Zealand Emergency Department Airway Registry

(ANZEDAR)

Hatem Alkhouri
Simon Craig
Toby Fogg
Elliot Long
John Mackenzie
Sally McCarthy
John Vassiliadis
Amanda Williams

Study Protocol

Version 1.2

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Introduction

Rapid Sequence Induction of anaesthesia and endotracheal intubation (RSI) is a core skill of specialist emergency physicians (EPs) in Australasia. RSI is high risk when performed outside of the operating theatre for multiple reasons. There is an expectation that doctors working in Australian and New Zealand Emergency Departments (EDs) should perform this relatively high risk procedure safely.

International registries have investigated airway management practices, and reported success rates and complications associated with RSI, techniques and outcomes. This project was the first multicentre study describing intubation in Australasian EDs [1-4]. The authors previously reported that Australasian ED doctors, predominantly emergency physicians or emergency medicine trainees, performed the majority of ED intubations using RSI as their preferred technique. First attempt success rate was high and was not different between different role delineations of EDs. Most importantly when studying factors associated with first pass success rate at intubation it was evident that video laryngoscopy, the use of bougie and doctors having performed >10 intubations are associated with higher first pass success. Complications were not infrequent, although are still comparable to other published series and this may reflect the cohort of patients who require ED intubation.

The findings of this project so far suggested ongoing vigilance in training and preparation. Monitoring and reporting of ED intubation practices will support improvements in safety of this high risk procedure.

This project is being led by Dr. Toby Fogg from the Royal North Shore Hospital ED in partnership with the NSW Emergency Care Institute (ECI) and Paediatric Research in Emergency Departments International Collaborative (PREDICT) , as a collaborative research venture with other EDs across Australasia. It is a surveillance study to acquire patient de-identified data on the practice of intubation in the ED in order to improve the quality of care associated with this procedure.

Objectives

Primary Objective

1. To monitor the safety of emergency airway management across participating sites, including first pass success rates, and the incidence of adverse events.

Secondary Objectives

1. To monitor the process of care involved with emergency airway management across

participating sites, focused on potential contributors to adverse events.

2. To use safety data to assess variation in practice, benchmark care and evaluate the impact of quality improvement interventions over time.

3. To provide baseline data informing the design and conduct of interventional studies.

It should be noted that this list is not exhaustive and other areas of interest may arise as data collection and surveillance continues.

Methods

This will be a prospective observational study of all intubations carried out within participating EDs.

Sample Size

All patients intubated in participating EDs. There are no specific exclusion criteria.

Data Collection

An electronic data collection form will be completed by the treating clinician / local clinical champion or research assistant at the discretion of the participating site in Research Electronic Data Capture (REDCap) as close to the time of intubation as possible. Any missing data will be established through interview with the staff involved and/or from the medical record.

"Clinical Champions", also known as Principal Investigators, will be required in all centres, with the responsibility of driving the project and ensuring data quality. Some episodes of intubation will be missed unless there is a checking process in place. Possible procedures include checking the resus patient registry books that are compiled by some departments or via review of the controlled drugs register, or equivalent, to identify patients who were administered thiopentone, propofol or ketamine for example. Each site will report the methods they use to ensure data accuracy, as this information will be described to discuss limitations and bias when reporting project outcomes. A data compliance rate of at least 90% should be achieved.

The Clinical Champion should have regular discussions with staff in order to ensure accuracy and completeness of data. This will also allow for case directed teaching to occur if required. Feedback sessions have been found to be beneficial. Data can be presented every 3-4 months to the clinicians and this will highlight some of the significance of the project and help to hardwire the practice of data collection.

Data Collection Forms

Local airway management data will be recorded online using a REDCap data system supported by the Agency for Clinical Innovation (ACI) consortium partner. REDCap is a secure web application for building and managing online surveys and databases, free to consortium partners, secure, browser-based, metadata-driven designed by Vanderbilt University. The licensing for REDCap for this study is via the ACI and database will besecurely stored on the NSW Health (e-health NSW) servers hosted with a 'nswhealth.gov.au' domain and adheres to the strict privacy and confidentiality policies of NSW Health". De-identified data will be extracted from REDCap for analysis in a variety of statistical programs including Excel, SAS and SPSS.

Data Management and Security

Principle Investigators at all participating EDs will need to provide their name and email address to Airwayregistry@health.nsw.gov.au in order to be registered on the REDCap system by the ACI research fellow. Once registered, an automatically generated email will then be sent by REDCap to the new users to reset their password. Registered users in

REDcap will be assigned to a dedicated Data Access Group (DAG) relevant to their department. A site specific log in will also be generated so that everyone at that department would use to access the form for data entry purposes.

There is no clinical risk associated with this study for participants as the study has no potential to interfere with the standard treatment. There is no risk to the rights, privacy or professional reputation of care providers, health professionals and/or institutions as the study solely concerns the impact of a single clinical management which is used ubiquitously, and has no intent to identify individual clinicians, nor to use the data as commentary on the institutions concerned.

Airway management data to be collected is solely to investigate the indication of intubation, clinical trajectories and patient outcomes. Fields with patient identifiers (MRN) will not be recorded. The name of the team leader or intubator will be only visible to the site investigator locally and will be used solely to collect missing data on disposition, patient vital signs and outcomes which were not available at the time of intubation. Once the record is submitted, all analyses will be carried out on the de-identified dataset and each episode will be allocated an ANZEDAR unique study number. The ability to re-identify patients from the data will then not exist.

Data Analysis

Dashboard Style Reports

REDCap has a built in module which allows Principle Investigators to easily view reports of their own DAG entries, inspect plots and monitor the practice of airway management locally. These reports are customized by selecting the fields/variables required for each report which could include:

1. Demographics, eg patient age, sex, indication for intubation
2. Time of day that intubations are occurring
3. Number of patients predicted to have difficult laryngoscopy
4. Degree of physiological derangement before RSI was commenced
5. Patient positioning for RSI
6. Use of pre RSI checklists
7. Drugs used for sedation and paralysis
8. Seniority and experience of intubator
9. Number of attempts required, what is first pass success rate
10. Devices/blades used and Cormack and Lehane grades of laryngeal view obtained
11. Use of airway adjuncts, laryngeal manipulation and cricoid pressure
12. Use of capnography
13. Incidence of airway manoeuvres and complications

14. The number of missing fields

The ANZEDAR team will generate a quarterly report to compare local performance of a single site to the rest of sites within the same role delineation level to enable benchmarking. This report will contain anonymous pooled data and site-specific information will not be revealed.

Study Questions

For publication purposes, all data will be entered into Microsoft Excel 2010 (Microsoft, Redmond, WA, USA) and analysed using SPSS PASW version 18.0 (SPSS, Inc., Chicago, IL, USA). Descriptive statistics will include median and inter- quartile range (IQR from the 25th to the 75th percentile). T-test or, as appropriate, exact tests will be used to compare groups of categorical data and to test for trends. Logistic regression analysis using the direct method will be used to calculate the odds of success of intubation on first attempt. For all analyses, actual *P*-values will be reported and all tests will be two-tailed. Statistically significant differences will be considered at the $P < 0.05$ level, and 95% confidence intervals (CI) will be presented where possible.

Definitions

- **Inclusion Criteria.** Every intubation in the E.D is to be included, not just RSIs.
- **Team Leader**. This is the person in overall charge of patient management i.e. the most senior clinician present. For example, if an ED Registrar is acting as team leader, but an ED Specialist is present, the Specialist is the team leader.
- **Indication for Intubation.** Only select one indication for intubation --- occasionally "other" may need to be used and this should be clarified below.
- **Difficult laryngoscopy.** Was laryngoscopy predicted to be difficult and if so, elaborate in the comments section on what basis? The question regarding a formal airway assessment refers to the use of any standardised tool, eg the LEON criteria.
- **Observations.** These are taken at the time that the decision to intubate is made and immediately after intubation is achieved. The former time point has been chosen as this will help identify the physiological status of the patients who are about to undergo an RSI, before attempts at physiological optimization occur.
- **Preoxygenation.** Indicate which device is the one used prior to intubation, eg if the non re-breather mask is taken off and a BVM used, indicate only BVM.
- **Apnoeic Oxygenation.** Indicates oxygen delivery technique (eg Nasal Prongs) once the patient is rendered apnoeic by the induction drugs. If the patient receives active bag-valve-mask ventilations from induction until attempts at laryngoscopy are made, BVM should be selected. Select both nasal cannula and BVM if both are used.
- **Patient Position.** Select the one that applies at the time of induction.
    - **Flat** – the patient is lying flat in the bed
    - **Pillow** – standard hospital pillow is used
    - **Trauma pad or occipital pad** – there is a small pad under the occiput

- **Shoulder pad** – a small pad is placed under the shoulder to compensate for a large occiput
- **Bed tilted head up** – the whole bed is tilted 20---30 degrees head up, i.e. reverse Trendelenburg
- **Elevated head of bed only** – the head end of the bed is elevated
- **Ramped–** Patient's head /neck / shoulders elevated on pillows.

- **Pre RSI checklist** – was a cognitive aid used to ensure adequate pre RSI preparation?
- **Was there a plan for failure** – was there a plan to change something should the first attempt at intubation fail?
- **Timings.** Time of intubation is recorded as the time of ETT passage. If no drugs are administered (e.g. patient in cardiac arrest) these patients do not have a time of induction so the value for time between induction and intubation is "Not applicable".
- **Drugs.** If multiple doses of induction agent are given for repeated attempts at a prolonged intubation, state the first dose only. If a top up follows the first dose because it was inadequate, write down the total dose.
- **Attempts**. An attempt at intubation is defined as the passage of the laryngoscope blade into the mouth.
- **Prior experience.** This is somewhat arbitrary, as no clear definitions of novice or expert exist in the emergency literature. Clinicians will rarely know if they have performed 90 or 110 but they will likely perceive themselves to be an "expert ED intubator", i.e. mark the form as >100.
- **External Laryngeal Manipulation** = bimanual laryngoscopy.
- **Capnography.** Select the device used for immediate ETT position confirmation
- **Complications.** To be included, complications should occur within 10 minutes of completion of the RSI even if they are recognised after this time. For example, a reduction in the BP requiring a fluid bolus after 5 minutes is included as is a mainstem bronchial intubation identified when the CXR was reviewed after 20 minutes
- Complications are defined thus:

1. **Hypoxic**
   a. Desaturation 1: Sp02 < 93% IF Sp02 >92% at end of pre-oxygenation.
   b. Desaturation 2: Sp02 < 93% at end of pre-oxygenation AND then fell by >10 points.
   c. Sustained desaturation (> 60 seconds)
   d. Critical desaturation: < 70% at any time.

2. **Haemodynamic**
   a) Adult Bradycardia - HR < 40 bpm and 20% decrease from baseline.
   b) Paed Bradycardia- HR < 60 bpm requiring atropine/compressions
   c) Adult Tachycardia: HR >140 and 20% increase from baseline
   d) Paed Tachycardia: HR > 180 bpm
   e) Adult Hypotension - SBP < 90 mmHg (or MAP < 60 mmHg) and 20% decrease from baseline.
   f) Paed Hypotension- requiring fluid bolus/ vasopressor bolus or infusion
   g) Hypertension: SBP > 160 mmHg and 20% increase from baseline.

h) Cardiac arrest (asystole, bradycardia, or dysrhythmia with non-measurable MAP and/or CPR during or after intubation.

3. **Other respiratory**
   a) Aspiration (visualisation of newly regurgitated gastric contents below glottis or suction removal of contents via ETT).
   b) Regurgitation (gastric contents which required suction removal during laryngoscopy, in a previously clear airway).
   c) Laryngospasm
   d) Mainstem bronchial intubation
   e) Oesophageal intubation (even if promptly recognised).

4. **Other**
   a) Airway trauma by intubator
   a) Dental trauma due to intubation
   b) Equipment failure (state what in comments).
   c) Medication error
   d) Other

Project Timeline

Data collection will commence using the electronic form at current registered sites once ethics approvals and SSA are achieved. Once sites have their ethics approval, they will start data collection and continue until August 2022. All data entries will be pooled and analysed with regards to the primary objective.

Study Authorship and Database Access

Site Investigators will have their contribution acknowledged in any manuscripts arising from the project but will not be listed as authors unless they contribute to data analysis or writing a manuscript.

The database will be held securely at the ACI on password-protected servers owned by the Ministry of Health. A researcher may make a written application to the ACI to access the database in order to research a specific question and a committee comprising the investigators listed below will review their proposal. Authorship of subsequent papers will include the investigators listed in this research protocol.

Ethics Approval

RNSH HREC has granted ethics approval: (Study no. LNR/12/HAWKE/306)
Site-specific approval still needs to be obtained for each new ED in NSW.

Ethics approval has also been granted for sites in Victoria, Queensland and Tasmania, Western Australia and New Zealand.

Contact

Dr Toby Fogg
RNSH Emergency Department
Reserve Road
St Leonards
NSW
2065
toby.fogg@health.nsw.gov.au
+61 422 397159

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