A retrospective study on the practice and safety of airway management in Dutch emergency departments

RESEARCH PROTOCOL

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Subsidizing party	***None***

PROTOCOL SIGNATURE SHEET

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SUMMARY

Rationale:

Objective: To describe and evaluate the practice and safety of endotracheal intubation of patients in Dutch emergency departments (ED).

Study design: Retrospective cohort study.

Study population: Patients who underwent endotracheal intubation in the ED of one of the participating hospitals in the Netherlands

Intervention (if applicable): Not applicable.

Main study parameters: The practice of, indications for and incidence of complications of endotracheal intubation in the ED.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Due to the retrospective design, there is no active involvement of patients or randomisation, and only data relevant to the study will be collected. Data collection will be completely anonymized.

1. INTRODUCTION AND RATIONALE

Endotracheal intubation can be a lifesaving intervention for critically ill patients in the emergency department (ED). Endotracheal intubation is, however, a high-risk procedure with many potential complications, which seem to be even more prevalent when carried out in the ED compared to for example the operating theater(5). This is possibly due to multiple reasons such as a sicker population, non-elective setting, a higher variability among indications for intubation or competence of providers.

Internationally, large registries were established and multiple observational studies have been performed to gain more information about the methods, safety and complications of intubations in the ED. For example, a multicenter study in Australia and New Zealand set up the ANZEDAR (The Australian and New Zealand Emergency Department Airway Registry) and reported on the practice, indications, success rate and safety of 3710 intubations performed in emergency departments (1). The same was done with the NEAR (National Emergency Airway Registry) including ED's from the United States, Canada and Australia; in a prospective, multicenter international registry of intubations in emergency departments a total number of 17,583

intubations were registered and analyzed (3). These studies gave more insight into patient demographics, staff characteristics, pharmacologic agents used and complication rates. In the UK, a national audit project (NAP4) showed that there were relatively far more complications of airway management in the ED compared to the operating theater and that complications in the ED were more likely to result in harm or death than complications in the operating theater. Individual case review identified avoidable deaths and areas of care that need improvement (5,6).

While in recent years these studies have added to our knowledge of ED airway management, there is still a lack of high-quality studies and there is a strong argument for increased research. To date, no studies have been published of airway management in Dutch EDs. We therefore have no knowledge about any factors possibly influencing intubation outcomes and complications nor comparability with international data. Among these are factors that have been associated with preventable harm and death and insight into these factors could be used for improvement of the safety of airway management in Dutch EDs (6).

This study is therefore intended to provide a comprehensive review of the clinical practice and characteristics of endotracheal intubations within Dutch EDs. The results could potentially be used for comparative analysis against global datasets. Additionally, the insights gained from this study will shed light on existing gaps prevalent in the current registration processes of intubations in the Netherlands. Furthermore, these insights could act as a stepping stone for future investigations that can lead to a deeper understanding of the methodologies, safety protocols, and associated complications of endotracheal intubations within Dutch EDs.

2. OBJECTIVES

Primary outcome:

Describing characteristics of the practice of endotracheal intubation in Dutch EDs, including information about patient demographics, indications for endotracheal intubation, intubation performer characteristics, equipment and medication used and complications due to intubation.

3. STUDY DESIGN

This is a retrospective cohort study using electronic patient charts of patients who underwent endotracheal intubation in the emergency departments of the participating hospitals.

4. STUDY POPULATION

4.1 Population (base)

Patients undergoing endotracheal intubation in the emergency department of one of the participating hospitals.

4.2 Inclusion criteria

Patients who underwent endotracheal intubation between 01-01-2019 and 31-12-2023 in the participating ED's.

4.3 Exclusion criteria

Patients for which no information about the intubation can be found in the electronic patient chart will be excluded from the study.

4.4 Sample size calculation

Not applicable. Data of all patients eligible for the study will be included.

5. METHODS

5.1 Study parameters

- Intubator characteristics:
  - ∉ Specialty
    - Emergency medicine
    - Anesthesia
    - Intensive care medicine
    - Other
  - ∉ Seniority
    - Consultant
    - Resident

- Junior doctor

- Indication for intubation:
  - ∉ Trauma
  - ∉ Burns
  - ∉ Drowning
  - ∉ Overdose/ingestion
  - ∉ Respiratory failure
  - ∉ Cardiac arrest (active cardiac arrest)
  - ∉ Post-cardiac arrest
  - ∉ Stroke
  - ∉ Seizure
  - ∉ Altered mental status due to other cause (if altered mental status due to stroke, intoxication, seizure or post-cardiac arrest then score as the primary cause)
  - ∉ Sepsis
  - ∉ Cardiac failure
  - ∉ Airway obstruction
  - ∉ GI bleed
  - ∉ Anaphylaxis
  - ∉ Other

- Sedation agent used (Ketamine, etomidate, propofol, midazolam)

- Paralytic agent used (Rocuronium / Succinylcholine)

- Method of intubation
  - ∉ Direct laryngoscopy
  - ∉ Video (hyperangulated or direct)
  - ∉ Fiberoptic
  - ∉ Surgical airway
  - ∉ Use of airway adjuncts? If yes, which …

- Patient characteristics: age (years), gender (male/female), weight/obesity (BMI).

- Vital parameters before intubation (respiratory rate, saturation, systolic blood pressure (SBP), heart rate).

- Was a pre-intubation airway assessment performed? Yes / no / missing

- If yes, were there any signs of a difficult intubation?

- Performance and mode of pre-oxgenation; no pre-oxygenation / nasal canula / NRM / mask ventilation / NIV / missing

- Was capnography used during intubation? Yes / no / missing

- The occurrence of complications of endotracheal inubation. Complications will be identified in two ways. The first option is that a complication is explicitly stated in the electronic medical record. The second option is that there are significant changes in vital signs as described in more detail below. The following complications will be registered:
    - significant decrease of peripheral oxygen saturation (SpO2). Defined as a desaturation of >10% from baseline or as defined by the treating physician
    - significant decrease of blood pressure. Defined as a systolic pressure <90mmHg with a drop of >20% from baseline or as defined by the treating physician.
    - significant increase of blood pressure. Defined as a systolic pressure > 160mmHg with a rise of >20% from baseline, or as defined by the treating physician.
    - significant bradycardia. Defined as a heart rate < 40/min and a drop of > 20% from baseline, or as defined by the treating physician.
    - significant tachycardia. Defined as a heart rate > 160/min and a rise of > 20% from baseline, or as defined by the treating physician.
    - dental or airway trauma due to intubation attempt
    - oesophageal or mainstem bronchial intubation
    - vomiting or aspiration
    - laryngospasm
    - equipment failure
    - medication error
    - cardiac arrest
    - failed attempt / need for an emergency surgical airway
    - other, ….

  For inclusion, complications should have occurred within 10 min of intubation, even if recognised after this time.

- As it is expected that complications of intubations are recorded in the electronic chart, the absence of notions of complications could be interpreted as an uncomplicated intubation. However, other physicians always explicitly mention that no complication occurred. Therefore, in this study the occurrence of complications can be coded as:
    - Complications occurred (complication specified)
    - No statement about complications
    - Explicitly stated that no complications occurred

5.2 Data acquisition

To guarantee accurate and consistent data acquisition, a data acquisition system will be used as proposed in emergency medicine literature. (5,6) Data abstraction forms will be used, abstracters will be trained and interrater reliability will be measured using Cohen's kappa. Data abstraction will be blinded, which means that during data abstraction they will not be aware of the aim of the study.

5.2.1 Identification of subjects

We will collect data by searching the database via one or multiple ways, depending on the local registration infrastructure of the hospital. Options are searching for procedural code for endotracheal intubation, screening ICU admissions, screening resuscitation room logbooks, screening medication logbooks for intubation medication, searching ICD-10 code for cardiac arrest and other pathologies that could lead to intubation.

5.2.2 Abstraction forms

The abstraction form is attached as an appendix. All data will be abstracted via an electronic abstraction form. The data is completely anonymized and cannot be linked to individual patients. The abstraction forms will be pilot tested in the participating hospitals.

5.2.3 Quality of data acquisition

All abstractors are medical students, emergency medicine trainees or emergency medicine physicians. They will receive an abstractor manual and a standardized training program. During this training, abstractors will be instructed about definitions used in the abstraction form and how to interpret the medical charts. During the abstraction phase, abstractor meetings will be scheduled

to discuss coding rules and to resolve disputes. To assess interrater reliability, interrater variability will be measured using Cohen's Kappa. 10% of the charts will be reviewed by two abstractors, after which interrater agreement will be calculated. Interrater agreement will be assessed for the incidence of complications, method of intubations and sedation agent.

5.2.4 Missing data

All missing data will be reported in the results section.

6. STATISTICAL ANALYSIS

Continuous data are presented as mean and standard deviation or median with interquartile range (IQR), depending on normality of data (graphically and numerically assessed), whereas nominal data are presented as absolute numbers and percentages. The Chi-square test or Fisher exact test will be used for comparison of nominal variables and the independent t-test and Mann Whitney test will be used when appropriate for comparison of continuous variables across treatment groups.. For all tests a $p < .05$ will be used to indicate statistical significance. All tests are two-tailed. Statistical analysis will be performed using IBM SPSS Statistics Premium' V 22 for Windows (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, version 22.0. Armonk, NY: IBM Corp.).

7. ETHICAL CONSIDERATIONS

7.1 Regulation statement

The patients will not be asked for signed informed consent. The data collection will be retrospective and completely anonymized. Patients are not randomized. In addition, this research focuses on standardized care and no new or additional actions were carried out. We suspect to screen at least 500-1000 patients for inclusion and find it not feasible to ask every patient for consent retrospectively. This would cost a disproportionate amount of effort and possibly excludes a large number of patients due to not being able to reach the patient, especially since it is expected that a high proportion of the patients died due to the seriousness of the underlying disease. Also, to a lesser amount it may cause a selection bias because it could be more difficult to get consent in the case of complicated intubations. Data will be derived from electronic patient files, from 2019up to

now. Asking for informed consent from patients who had an intubation 3 years ago would not outweigh disadvantages for the patient.

8. ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

8.1 Handling and storage of data and documents

Study data files (SPSS, REDCap) will be stored electronically on a secured data source within the Medical Centre Leeuwarden, only accessible for the research team, during the study period. After this only the primary investigator will have excess. All files will be stored for 15 years.

9. REFERENCES

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