

Study Protocol

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The Taiwan ED Airway Quality Surveillance Registry (TEAR): A Prospective Multicenter Observational Study

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Participating Sites

Emergency departments of Linkou Chang Gung Memorial Hospital, Keelung Chang Gung Memorial Hospital, Taoyuan Chang Gung Memorial Hospital, and New Taipei Municipal Tucheng Hospital

The Taiwan Emergency Department Airway Quality Surveillance Registry (TEAR): Protocol for a Multicenter Prospective Observational Study

Abstract

Introduction

Emergency tracheal intubation is a core procedure in emergency medicine and remains associated with substantial risk of peri-intubation complications, including severe hypoxemia, hypotension, and cardiac arrest. Multicenter registries such as the National Emergency Airway Registry (NEAR), the Australia and New Zealand Emergency Department Airway Registry (ANZEDAR), the Japanese Emergency Airway Network (JEAN), the Korean Emergency Airway Management Registry (KEAMR), the BARCO study, and the INTUBE study have established the value of structured airway surveillance. Taiwan does not currently have a comparable multicenter emergency department airway registry.¹⁻⁶

Methods and analysis

The Taiwan Emergency Department Airway Quality Surveillance Registry (TEAR) is a multicenter, prospective, observational registry designed to capture consecutive emergency department tracheal intubations across participating hospitals in Taiwan. The registry will collect demographic, clinical, physiologic, procedural, pharmacologic, and laboratory variables together with peri-intubation outcomes. Core process indicators include first-pass success, while major safety outcomes include severe hypoxemia, severe hypotension, and peri-intubation cardiac arrest. Data will be analyzed descriptively and with multivariable regression models to identify clinical and laboratory predictors of adverse events.

Ethics and dissemination

The registry has received Institutional Review Board approval. A waiver of written informed consent was granted because the study is strictly observational, based on routinely generated clinical data, does not affect clinical management, and poses no more than minimal risk. Study findings and site-level quality indicators will be regularly fed back to participating institutions.

Strengths and limitations of this study

1. TEAR is the first structured multicenter emergency department airway quality registry in Taiwan.
2. The registry incorporates laboratory variables not routinely included in prior airway registries.
3. The design supports ongoing quality surveillance through regular site-level feedback.
4. As an observational study, causal inference regarding airway interventions will be limited.
5. Data completeness will depend on consistent reporting and data capture across participating sites.

Introduction

Background

Emergency tracheal intubation is a core procedure in emergency medicine and is frequently performed in patients with critical illness. The procedure is associated with important peri-intubation complications, including

hypoxemia, hypotension, and cardiac arrest. First-pass success has consistently been associated with lower complication rates and is widely regarded as a key quality indicator in emergency airway management.^{1,7}

Several multicenter registries, including NEAR in North America, ANZEDAR in Australia and New Zealand, JEAN in Japan, KEAMR in Korea, the BARCO study in Brazil, and the international INTUBE study, have shown the feasibility and value of structured surveillance of emergency airway management. These studies have provided standardized data on practice patterns, first-pass success, and peri-intubation adverse events. Taiwan does not currently have a comparable multicenter emergency department airway registry.¹⁻⁶

This gap is important because peri-intubation adverse events remain common, are associated with worse outcomes, and may be reduced through improved surveillance and risk stratification.

Rationale

TEAR was developed to establish a multicenter platform for prospective surveillance of emergency airway management in Taiwan. In addition to procedural and physiologic variables commonly included in airway registries, TEAR will systematically collect laboratory variables obtained during routine care, including lactate, acid-base parameters, electrolytes, hemoglobin, platelet count, and coagulation measures. These variables may improve risk stratification and may clarify the contribution of physiologic instability to peri-intubation adverse events. Recent studies suggest that physiologic derangements such as hypoxemia, shock, and metabolic acidosis are important contributors to peri-intubation deterioration. TEAR is intended not only to describe practice and outcomes, but also to provide a platform for physiologically informed risk stratification and future quality improvement.⁷⁻¹¹

Objectives

Primary objective

To determine the incidence of major adverse peri-intubation events among adults undergoing tracheal intubation in participating Taiwanese emergency departments.

Secondary objectives

1. To describe airway management practices, including device selection, medication strategy, patient positioning, oxygenation methods, and operator level.
2. To monitor site-level airway quality indicators, including first-pass success and major adverse event rates.
3. To identify clinical and laboratory predictors of major adverse peri-intubation events.
4. To measure additional clinically relevant outcomes, including difficult intubation, esophageal intubation, aspiration, emergency front-of-neck airway, arrhythmia, trauma, pneumothorax, and in-hospital mortality.
5. To establish a multicenter airway surveillance platform that can support future quality improvement and implementation studies.

Methods and analysis

Study design

TEAR is a prospective, multicenter, observational cohort study. The registry will collect standardized data on emergency department airway management practices and peri-intubation outcomes across participating hospitals.

Study setting

Participating sites include the emergency departments of Linkou Chang Gung Memorial Hospital, Keelung Chang Gung Memorial Hospital, Taoyuan Chang Gung Memorial Hospital, and New Taipei Municipal Tucheng Hospital.

Eligibility criteria

Inclusion criteria

- Adults aged 18 years or older.
- Undergoing tracheal intubation in the emergency department during the study period.

Exclusion criteria

- Tracheal intubation performed before arrival at the emergency department.
- Tracheal intubation performed outside the emergency department, including the operating room, inpatient ward, or intensive care unit.

Additional analytic consideration

Patients with cardiac arrest preceding intubation, including those intubated during ongoing cardiopulmonary resuscitation, will be captured in the registry. Depending on the specific analysis question, these cases may be excluded from selected outcome analyses.

Outcomes

Primary outcome

The primary outcome is a composite of major adverse peri-intubation events occurring within 30 minutes after intubation, defined as any of the following: hypoxemia ($\text{SpO}_2 < 90\%$), hypotension (systolic blood pressure < 90 mmHg or mean arterial pressure < 65 mmHg; initiation of vasopressor therapy; increase in vasopressor dose by $\geq 25\%$; addition of another vasopressor agent; or rapid administration of fluid bolus ≥ 15 mL/kg), or cardiac arrest requiring cardiopulmonary resuscitation within 30 minutes after intubation.

Secondary outcomes

- First-pass success.
- Difficult intubation.
- Esophageal intubation.
- Cardiac arrhythmia.
- Aspiration.
- Pneumothorax or pneumomediastinum.
- Dental or airway trauma.
- Emergency front-of-neck airway.
- ICU admission and hospital outcome, including in-hospital mortality.

Data collection

Data will be abstracted from the electronic medical record and procedure documentation and entered into a standardized registry dataset using predefined variable definitions. Variables will include demographic

characteristics, comorbidities, pre-intubation physiology, laboratory data, airway difficulty assessments, procedural characteristics, operator characteristics, and peri-intubation outcomes.

Procedural variables will include the primary indication for intubation; anatomical and physiologic difficult airway features; degree of emergency; preoxygenation and apneic oxygenation strategies; intubation device, adjuncts, and maneuvers; glottic view; number of attempts; first-pass success; operator level; reasons for failed attempts; final successful device and intubator; and peri-intubation complications within 30 minutes.

Anatomically difficult airway features will include airway contamination, airway obstruction or edema, limited mouth opening, Mallampati class III-IV, reduced mandibular space, macroglossia, short or thick neck, reduced cervical spine mobility, facial or neck trauma, prior difficult laryngoscopy or intubation, prior head and neck surgery or radiation, neck mass or goiter, active upper airway infection, dentition-related difficulty, mask-seal difficulty, and pregnancy. Physiologically difficult airway features will include severe hypoxemia, hypotension or shock, severe metabolic acidosis or elevated lactate, severe asthma or chronic obstructive pulmonary disease with dynamic hyperinflation, right ventricular failure or pulmonary hypertension, raised intracranial pressure or traumatic brain injury, ongoing major hemorrhage or anemia, high aspiration risk, agitation limiting preparation, and cardiac arrest or ongoing cardiopulmonary resuscitation. Peri-intubation complications will include hypoxemia, hypotension, dysrhythmia, cardiac arrest, esophageal intubation, mainstem bronchial intubation, aspiration, airway or dental trauma, pneumothorax or pneumomediastinum, laryngospasm, medication error, and suspected malignant hyperthermia.

Laboratory variables obtained as part of routine clinical care will include pH, bicarbonate or base excess, lactate, electrolytes, hemoglobin, platelet count, INR, creatinine, and troponin when available. These variables are intended to characterize physiologic instability at the time of intubation and to support exploratory risk stratification analyses.

Enrollment workflow

In all participating emergency departments, airway management—including the choice of induction agent, neuromuscular blocker, technique, and device—is determined entirely by the treating physician according to routine clinical practice. Approximately one hour after the intubation episode, the intubator completes a brief standardized operator form documenting key intubation indicators, including indication and urgency, anatomical and physiologic difficult-airway features, oxygenation strategy, device and adjunct use, number of attempts, glottic view, and immediate complications. Additional data, including physiologic variables, laboratory values, timestamps, and peri-intubation outcomes, are abstracted from routine clinical documentation by the investigator or research assistant. The registry dataset is updated on a regular basis and reconciled with procedural records to improve completeness. Outcome adjudication is performed using predefined operational definitions.

Sample size determination

Primary estimation focuses on the incidence of major adverse events within 30 minutes after intubation. In emergency department-based studies, reported peri-intubation adverse event rates have ranged from approximately 11% to 32.3%, depending on case mix and outcome definitions, with rates of 11% in the JEAN multicenter registry, 26% in ANZEDAR, and 32.3% in the BARCO study.^{2,3,5}

Based on these data, we adopted a conservative anticipated MAE incidence of 25% for the primary precision-based sample size estimation.

With a two-sided 95% confidence interval and a margin of error of 3%, a minimum of 801 evaluable cases is required. Because this registry is conducted in a high-acuity emergency department setting, some enrolled cases are expected to have incomplete documentation of key procedural or physiologic variables, which may render them non-evaluable for specific analyses. Assuming that up to 30% of enrolled cases may not be fully

analyzable, we set an initial recruitment target of at least 1,200 cases to ensure that the primary analysis retains adequate precision.

To further improve the precision of the primary incidence estimate, strengthen multivariable modeling, and support prespecified subgroup analyses, including analyses of physiologically high-risk subgroups such as severe metabolic acidosis, the registry will continue consecutive enrollment toward an aspirational total sample size of 2,500-3,000 cases. This target is comparable to the scale of contemporary multicenter airway registries.

Statistical analysis

Continuous variables will be summarized as mean \pm standard deviation or median with interquartile range, as appropriate. Categorical variables will be summarized as counts and percentages. Group comparisons will use Student's t-test, Mann-Whitney U test, chi-square test, or Fisher's exact test, as appropriate.

Ethics and dissemination

The registry has received Institutional Review Board approval. A waiver of written informed consent was granted because the study is strictly observational, based on routinely generated clinical data, does not affect clinical management, and poses no more than minimal risk. Study findings and site-level quality indicators will be regularly fed back to participating institutions.

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