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Direct Cricothyrotomy Versus Orotracheal Intubation in Austere Hemorrhagic Airway Scenarios: A Randomized Crossover Simulation Study

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LAY SUMMARY

In emergency care, quickly securing a patient's airway can be necessary to save their life. This can be difficult in trauma scenes, where there may be poor lighting, limited resources, and patients may be bleeding heavily. Blood in the airway can make placing a breathing tube (intubation) difficult or impossible because it may be difficult to see important parts of the airway clearly. This can slow down treatment.

Cricothyrotomy is another way to secure the airway. Instead of going through the upper airway, it creates a direct opening into the windpipe through the neck. This method is usually only used as a last resort, but newer techniques have made it faster and more reliable. In cases of heavy bleeding in the airway, cricothyrotomy may allow clinicians to secure the airway faster than attempting intubation first. However, there is not much research that directly compares these two approaches in realistic conditions.

This study will use a simulation model (manikin) to compare intubation and cricothyrotomy in a scenario where blood is in the airway, lighting is dim, and background noise is present. Practicing paramedics will perform both techniques (intubation and cricothyrotomy) in a random order. The main outcome will be the time required to achieve a secure airway after it becomes clear that ventilation is not possible. Researchers will also look at success rates, errors, and delays.

The goal of this study is to identify which approach is faster and more reliable in these conditions. Findings may inform training and decision-making in prehospital care, where rapid airway control can be life-saving.

BACKGROUND AND RATIONALE

Effective airway management is a cornerstone of emergency medical care, particularly in time-critical situations where failure to establish oxygenation can rapidly result in hypoxic brain injury or death.[1,2] This challenge is amplified in austere and prehospital environments, where clinicians must operate under conditions of limited lighting, environmental noise, restricted equipment, and variable patient positioning.[1] Among the most difficult airway scenarios is upper airway hemorrhage, in which blood, secretions, and disrupted anatomy obscure laryngeal landmarks, impair visualization, and significantly degrade the performance of standard airway techniques.[3–6]

Endotracheal intubation (ETI), performed using direct or video laryngoscopy, remains the default first-line approach to securing a definitive airway in most emergency systems.[7,8] Under optimal conditions, ETI can be performed efficiently and with high success rates. However, its effectiveness is highly dependent on visualization of the glottis. In the presence of blood or vomitus, visualization is impaired, leading to reduced first-pass success, prolonged attempts, and increased complication rates. Observational studies have demonstrated that airway contamination is associated with decreased intubation success and increased time to airway securement, often exceeding one to two minutes in difficult conditions.[5,6] These delays are clinically significant, as multiple intubation attempts are associated with higher rates of hypoxia, aspiration, and other adverse events.

Cricothyrotomy provides an alternative approach, bypassing the upper airway and establishing direct access to the trachea through the cricothyroid membrane. Traditionally reserved as a rescue technique in “can’t intubate, can’t ventilate” (CICV) scenarios, modern scalpel-based and bougie-assisted techniques have simplified the procedure and improved its speed and reliability.[7,9–14] Simulation and cadaveric studies suggest that surgical cricothyrotomy can be performed rapidly, often within less than one minute, and is less affected by upper airway contamination because it does not rely on visualization of the glottis. Prehospital and emergency medicine literature further support its effectiveness, with reported success rates ranging from moderate to high depending on training, technique, and context.[1,10,15–18] Systematic reviews have demonstrated higher success rates for surgical cricothyrotomy compared with needle-based techniques, reinforcing its role as the preferred method of emergency front-of-neck access.[19]

Despite these findings, the current evidence base has important limitations. Most studies evaluating airway management focus on broad trauma populations or generic difficult airway scenarios, rather than isolating the specific challenge of upper airway hemorrhage. Studies examining ETI in hemorrhagic contexts often focus on airway protection rather than procedural performance and do not provide direct comparisons to cricothyrotomy.[2,5,6,15] As a result, the relative performance of these two techniques in the setting of controlled upper airway hemorrhage remains poorly defined. Ethical and logistical constraints preclude randomized clinical trials in actively bleeding patients, limiting the available evidence to observational data and simulation-based studies.

Military and combat environments further highlight the importance of this knowledge gap. Tactical settings are frequently characterized by ongoing threats, low-light conditions, limited personnel, environmental contamination, and restricted access to advanced airway equipment. In these contexts, prolonged or repeated attempts at intubation may be impractical or unsafe, particularly in the presence of facial trauma or upper airway hemorrhage. Tactical Combat Casualty Care (TCCC) guidelines emphasize early recognition of failed airway management and advocate for rapid transition to surgical airway when ventilation is not achievable, identifying cricothyrotomy as the preferred definitive airway technique in such scenarios.[3,4] Analyses of battlefield care have demonstrated that delays in airway control contribute to preventable mortality and that cricothyrotomy is often performed as an early intervention rather than a late rescue maneuver. The procedural simplicity, reduced reliance on visualization, and compatibility with austere conditions make scalpel-based cricothyrotomy particularly well suited to these environments.[3,17,18]

Taken together, the existing literature suggests that ETI performance is vulnerable to degradation in hemorrhagic airway conditions, while cricothyrotomy may offer a more reliable pathway to definitive airway control by bypassing the contaminated upper airway. However, these conclusions are largely based on indirect comparisons rather than direct evidence. There remains a critical gap in the literature: no study has systematically compared time to definitive airway between ETI and cricothyrotomy in a controlled, hemorrhagic airway scenario.

Simulation-based models provide a feasible and ethically appropriate method to address this gap. These approaches allow controlled replication of airway hemorrhage while standardizing environmental conditions, operator experience, and procedural variables.[15,20,21] By directly

comparing ETI and cricothyrotomy under standardized hemorrhagic conditions using a randomized crossover design, this study aims to quantify differences in time to airway securement, success rates, and procedural performance.

Improved understanding of these differences has important implications for clinical decision-making. In time-critical airway emergencies—particularly in prehospital, austere, and military environments—early selection of the most effective airway technique may reduce delays, improve procedural success, and ultimately improve patient outcomes.

STUDY OBJECTIVES AND HYPOTHESIS

Primary Objective

To compare time from patient arrival to establishment of a definitive tracheal airway between direct cricothyrotomy and orotracheal intubation (VL) in an austere, hemorrhagic airway simulation.

Secondary Objectives

To compare rates of successful tracheal placement between techniques.

To compare rates of non-tracheal airway placement (esophageal or soft tissue).

To assess procedural failure rates and need for rescue techniques.

Hypotheses

Direct cricothyrotomy will result in a shorter time to definitive airway compared with orotracheal intubation in hemorrhagic airway conditions.

Orotracheal intubation will be associated with higher rates of delayed airway control and non-tracheal placement in the presence of simulated blood.

METHODS

Study Design

This is a prospective, randomized, crossover simulation study comparing time to definitive airway using two techniques: orotracheal intubation and direct cricothyrotomy.

Setting

The study will be conducted at the IWK Health Simulation Centre. Airway procedures will be performed using the Deluxe Difficult Airway Trainer (Laerdal Medical, Stavanger, Norway). To approximate a prehospital setting, the manikin will be positioned supine on the floor for all procedural attempts.

The airway trainer will be modified to simulate a contaminated, difficult airway. The tongue of the model will be inflated to partially obstruct the oropharynx, creating a difficult but still passable airway. In addition, the airway will be filled with dyed fluid to simulate the presence of blood within the upper airway. The degree of tongue inflation will be standardized across trials to ensure that the airway remains challenging but not impossible to manage.

Environmental conditions will be standardized for all study sessions. Ambient lighting will be maintained between 5 and 8 lux, measured at the level of the mannequin's neck using a calibrated lux meter. Background noise will be standardized at a fixed decibel level to simulate environmental noise commonly encountered in prehospital settings. The room configuration and equipment placement will remain identical for all participants. Lighting and sound levels will be measured and documented prior to each session to ensure consistency across study procedures. All attempts will be recorded using an overhead camera.

Participants and Recruitment

Target population.

Licensed paramedics currently practicing in Nova Scotia, Canada, including:

- Emergency Preparedness and Special Operations (EPSO) medics
- Critical Care Paramedics (CCPs)

Participants must have airway management within their scope of practice and prior formal training in both orotracheal intubation and direct cricothyrotomy.

Inclusion criteria.

Participants must:

- Be licensed and in good standing with the Nova Scotia College of Paramedics
- Be actively practicing in prehospital or transport environments
- Be credentialed in both orotracheal intubation and cricothyrotomy per service standards
- Have received formal training in bougie-assisted intubation

Exclusion criteria.

Participants will be excluded if they:

- Participated in pilot testing of this protocol
- Have physical limitations preventing safe airway procedure performance

Recruitment strategy.

Participants will be recruited from paramedics currently practicing within Nova Scotia. Recruitment will occur through multiple approaches to ensure broad awareness of the study among eligible clinicians. An invitation email will be distributed through the Nova Scotia College of Paramedics. This communication will include an initial recruitment email followed by a reminder email at one week and a final reminder at two weeks.

A recruitment flyer will also be shared with Clinical Development and Field Training paramedics present in Halifax during scheduled training sessions. Participants will have the opportunity to opt-in to a raffle prize draw for one $250 Amazon gift card.

Data Collection

Informed consent will be obtained from all participants prior to the start of study procedures. Participants will receive a REDCap link to a participant characteristics questionnaire:

- Demographics and provider characteristics: Basic demographics (age, sex), Provider type, Practice characteristics (years of practice, primary practice setting, average call volume), Training and exposure (formal cricothyrotomy training, military/tactical training), Handedness: right, left, ambidextrous
- Airway experience (lifetime and in the last 1, 3, and 12 months), self-assessed confidence with intubation and cricothyrotomy, likelihood to perform an early cricothyrotomy in hemorrhagic airway

Scenario structure.

At scenario start (T0), the participant will enter a simulated scenario as the first advanced airway provider on scene with:

- An unresponsive patient manikin supine on the floor
- No airway interventions already in progress
- Airway equipment available in a standardized layout
- Participants may assess, position, suction, ventilate, and manage the airway as they would in practice.
- Simulated blood will be present within the oral cavity to replicate upper airway hemorrhage. Mouth opening and anatomical difficulty will be standardized across participants.

- After an attempt is made at bag mask ventilation the randomization point is triggered as outlined below.

Randomization and crossover.

At a predefined “cannot ventilate” trigger point, the facilitator will announce, “No chest rise. Oxygen saturation falling. You cannot ventilate.” This moment will define T1 (Indication Time). Each participant will complete two simulated airway scenarios under standardized environmental conditions. Randomization will determine which procedure will be performed first. Participants will be randomized in a 1:1 ratio to one of two sequences:

- Sequence A: Intubation first, followed by cricothyrotomy
- Sequence B: Cricothyrotomy first, followed by intubation

Participants will serve as their own controls.

A standardized reset period of at least 20 minutes will occur between scenarios to minimize fatigue and carryover effects.

Participants will have a maximum of two attempts in cases of initial unsuccessful airway (tracheal placement).

Equipment standardization.

Equipment layout will be identical for all participants.

Cricothyrotomy kits and intubation equipment will remain sealed until the randomized command is delivered. Participants may not pre-open equipment specific to either technique prior to assignment. This ensures procedural timing reflects technique execution rather than pre-emptive preparation.

Scalpel–bougie cricothyrotomy procedure.

Participants will be oriented to a standardized scalpel–bougie cricothyrotomy technique (Appendix A) performed under simulated “cannot intubate, cannot oxygenate” conditions.

A trained assistant will be positioned at the head of the bed to maintain head positioning and provide equipment as required.

Timing definitions.

Four standardized time points will be recorded:

- T0 — Scene Entry: Participant crosses the threshold into the simulation space
- T1 — Indication Time: Delivery of “Cannot ventilate” command
- T2 — Procedure Initiation:

    - Laryngoscope pickup (intubation arm)
    - Scalpel pickup (cricothyrotomy arm)
- T3 — Definitive Airway Achieved: Confirmed tracheal placement verified by mannequin feedback

All times will be recorded using synchronized digital timing devices.

Post-simulation surveys.

After each procedure, participants will complete a survey about the subjective workload of the procedure, using the NASA-TLX[22]. Once both simulations have been completed, participants will answer comparison questions about the two procedures (preference, perceived speed, perceived reliability, threshold to perform cricothyrotomy).

OUTCOMES

Primary Outcome

- Time from Indication to Definitive Airway (T1 → T3)
  Defined as the interval between the "Cannot ventilate" command and confirmed tracheal access. This endpoint isolates procedural performance following standardized recognition of airway failure.

Secondary Outcomes

- Pragmatic Scene-to-Airway Time (T0 → T3): Reflects real-world operational performance from arrival to definitive airway.
- Procedure Initiation Time (T1 → T2): Measures cognitive-to-action latency.
- Successful tracheal placement (yes/no)
- Incorrect placement (esophageal or soft tissue)
- Failure to secure airway within predefined time limit (5 Minutes)
- Need for rescue airway technique
- Participant preference for technique
- NASA-TLX

DATA ANALYSIS PLAN

Data will be analyzed using generalized linear mixed models in R statistics software using the lme4() package. [23]These models will use random intercepts and main effects for both treatment

and time, with the formula in the form: $Y = B_0 + B_1(\text{Treatment}) + B_2(\text{Time}) + r0$. Though the hypothesis pertains to the effect of treatment, time is included to explore whether practice effects exist (i.e., if the second attempt sees improvements, regardless of condition). A potential threat to carryover designs are carryover effects (i.e., the effect of treatment at time 1 persists at time 2). In the current design, carryover effects are unlikely, but we will probe for carryover effects by creating a dummy-coded variable for carry-over effects as described in Lee et al. (2019)and including it in the model along with treatment and time as a sensitivity analysis.[24] Distributions of data will be assessed, using Gaussian distributions, positively skewed distributions (Poisson or Negative Binomial) with a log link, or binomial distributions with a logit link, as appropriate.

Sample Size Estimation

The target sample size was based primarily on recruitment feasibility. Based on the number of eligible participants available within the study setting and the anticipated recruitment period, we determined that enrolling a minimum of 30 participants was achievable. We would consider additional recruitment based on availability but would cap recruitment at 40.

We therefore conducted a sensitivity power analysis to determine the smallest standardized effect size that could be detected with this fixed sample size. Assuming 80% power and a two-sided alpha of 0.05, a crossover study with 30 participants would be able to detect a standardized effect size of approximately 0.73 or larger, corresponding to a between-condition difference of 0.73 standard deviations. Smaller effects may not be detected reliably; therefore, the study was designed to identify only moderate-to-large differences between conditions.

STAKEHOLDER ENGAGEMENT

This study addresses a high-acuity, low-frequency procedure performed in critical, time-sensitive scenarios. As such, stakeholder engagement has focused primarily on clinicians and operational leaders who are directly involved in airway management and prehospital care, where the findings are most likely to influence practice.

The research question was developed in response to identified uncertainty in clinical decision-making and procedural approach in austere airway scenarios. Early engagement included discussions with Canadian Armed Forces (CAF) medical personnel, including Major Barlow, to ensure the study reflects operational realities and challenges encountered in military and austere

environments. These discussions helped refine the study focus toward clinically relevant scenarios involving hemorrhagic airways and constrained conditions.

Engagement with civilian prehospital stakeholders was also integral to study development. The physician lead for Critical Care and Special Operations (CPSO) medics, Dr. Armstrong, conducted informal outreach to frontline paramedics to assess whether this question represented a meaningful knowledge gap. Feedback from this group confirmed that uncertainty regarding optimal airway strategy in these scenarios is both common and operationally significant, supporting the relevance and priority of the study.

Ongoing engagement will continue through collaboration with these stakeholders during study conduct and interpretation of results. Findings will be shared with participating clinical groups, paramedic educators, and military medical leadership to facilitate integration into training, protocols, and operational planning.

While direct patient engagement was not feasible given the technical and simulation-based nature of the study, future work evaluating clinical implementation and outcomes will incorporate broader patient and system-level stakeholder perspectives.

KNOWLEDGE TRANSLATION

All collected data will be analyzed and reported in aggregate to ensure participant confidentiality. The knowledge translation strategy is designed to reach key clinical, operational, and academic audiences, with an emphasis on prehospital and military environments where the findings are most applicable.

Results will be disseminated through peer-reviewed publication, with *Military Medicine* identified as the target journal given its relevance to austere care, operational medicine, and airway management in resource-constrained settings. Findings will also be presented at both military and civilian conferences, including Canadian Armed Forces medical forums and national prehospital and emergency medicine meetings. These venues will allow direct engagement with clinicians who are most likely to apply the results in practice.

Relevant audiences include prehospital providers (e.g., critical care and special operations paramedics), military medical personnel, anesthesiologists, and emergency physicians. Messaging will be tailored accordingly. For frontline clinicians, results will focus on practical implications such as timing, reliability, and decision-making thresholds for early transition to cricothyrotomy in hemorrhagic airway scenarios. For educators and system leaders, emphasis

will be placed on implications for airway algorithms, simulation training design, and procedural standardization.

At a systems level, findings may inform updates to airway management protocols, particularly in austere and transport environments where delays in airway control can significantly impact outcomes. By providing objective comparative data on two competing airway strategies, this study has the potential to influence training, clinical decision-making, and guideline development in high-risk airway management.

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