Comparison of Three Point-of-care Ultrasound Techniques to Confirm Endotracheal Tube Placement: a Randomized Clinical Trial

1. Materials and Methods

1.1 Trial design and setting

This study was a single-center, prospective, randomized, parallel-group clinical trial conducted in the ED of a tertiary care university hospital. The study period spanned from 1 June 2024 to 19 June 2025. The trial protocol was approved by the University Institutional Ethics Committee (Decision No: 09.2024.629) and was prospectively registered at ClinicalTrials.gov (NCT06656546). The study adhered to the Declaration of Helsinki and is reported in accordance with the CONSORT 2025 guidelines [1].

1.2. Study participants, inclusion, and exclusion criteria

Adults aged 18 years or older who required ETI in the ED at the treating physician's discretion and were managed with rapid sequence intubation were eligible for inclusion. Eligibility screening was performed for all weekday daytime presentations; conversely, nighttime presentations were screened and enrolled only when a study sonographer was on duty, with sonographer coverage spanning approximately 15 night shifts per 30-day period. Written informed consent was obtained from all participants or their legal proxies before enrollment. Exclusion criteria were as follows: pregnancy; prior neck or thoracic surgery potentially interfering with sonographic windows; known cervical spine disease or a history of surgery affecting diaphragmatic excursion; pre-existing or subsequently identified diaphragmatic paralysis or pneumothorax that could confound ultrasound assessments; and withdrawal of consent by the patient or a legal representative. For each patient, only the first intubation attempt was included in the analysis; if the initial attempt was unsuccessful, subsequent attempts were not re-enrolled or analyzed as separate events.

1.3 Interventions and procedures

Airway management was performed in accordance with routine clinical practice. The primary physician selected the induction and neuromuscular blocking agents and the endotracheal tube size based on clinical judgment, performed intubation, and initiated ventilation.

1.3.1 Roles during intubation

To minimize measurement and performance bias at the point of verification and timing, the following roles were assigned:

(1) Primary physician (intubator and reference assessor): Performed the endotracheal intubation and initiated ventilation. Subsequently, the primary physician evaluated quantitative end-tidal carbon dioxide ($EtCO_2$) by assessing five capnography waveforms and, in conjunction with auscultation findings, rendered the reference decision regarding tube location. The primary physician was blinded to ultrasound findings.

(2) Auscultation physician: Distinct from the intubator, auscultated the epigastrium and the four lung quadrants, and communicated findings to the primary physician.

(3) Sonographer (index test operator): Performed the assigned ultrasound verification concurrently while positioned to avoid interfering with clinical care. The sonographer wore sound-isolating headphones and was blinded to team discussions, auscultation findings, capnography values, and patient monitors, with access only to the ultrasound image.

(4) Timekeeper: Recorded all times with a stopwatch. Intubation duration was defined as the interval from the moment the laryngoscope was first picked up (hand contact) to ETT placement. Immediately after tube placement, timing for each confirmation modality was initiated and recorded separately. Specifically, the durations of ultrasound verification, auscultation, and quantitative $EtCO_2$ confirmation were measured from the time of tube placement.

1.3.2 Ultrasound techniques

Two experienced emergency physicians performed all ultrasound assessments. Each had eight years of ultrasound experience and documented competence in each technique. Following ETI, only one ultrasound technique, as assigned by randomization, was performed for each case. The sonographer classified the ETT location as tracheal or esophageal based on findings from the allocated technique. When the allocated technique was lung-sliding or diaphragm ultrasound, tracheal placements were additionally assessed for malposition to distinguish correct tracheal intubation from mainstem bronchial (endobronchial) intubation. The three sonographic techniques were defined as follows (Fig. 1):

Transtracheal ultrasound (TUS): A linear transducer was placed perpendicular to the trachea at the level of the cricoid cartilage. Visualization of the endotracheal tube moving within the trachea, posterior to the cricothyroid membrane, was interpreted as tracheal intubation. A second air-mucosa interface lateral to the trachea, producing a double-lumen appearance, was interpreted as esophageal intubation [2].

Lung-sliding ultrasound (LUS): After initiation of ventilation, lung-sliding was assessed bilaterally using a linear transducer positioned on the mid-clavicular line at the second to fifth intercostal spaces in a coronal orientation. Bilateral pleural sliding indicated tracheal intubation. The absence of bilateral lung sliding suggested esophageal intubation. Unilateral absence of lung sliding was interpreted as endobronchial intubation [3].

Diaphragm ultrasound (DUS): A curvilinear transducer was positioned on the mid-axillary line at approximately the seventh to ninth intercostal spaces in a coronal orientation. Bilateral diaphragmatic movement over the liver and spleen during ventilation indicated tracheal intubation. The absence of bilateral movement suggested esophageal intubation. Unilateral movement was interpreted as endobronchial intubation [4].

Before study initiation, each sonographer performed five examinations using each technique. The ultrasound videos were recorded, and a second sonographer independently reviewed the recordings and classified the tube location. Agreement between the initial classification and the independent video-based classification was used to quantify interrater agreement, which was 0.967 (95% CI 0.828–0.999).

To maintain independence and blindness, the second assessor's video-based assessment was methodologically necessary. In cases of oesophageal intubation, immediate removal of the tube was clinically mandated, which precluded a second independent assessment of the same tube in situ. Conversely, when the tube remained in place, tracheal positioning would have been readily apparent from the ongoing clinical course, jeopardising the feasibility of a blinded, real-time bedside reassessment. Accordingly, the second assessor determined the tube's position using standardised ultrasound video recordings rather than a concurrent bedside assessment. For the same reasons, these clinical and methodological limitations also prevented the application of multiple ultrasound verification techniques in the same patient.

1.4. Outcomes

The primary outcome was endotracheal tube location, coded as tracheal or esophageal. Secondary outcomes were intubation duration, the time required for each confirmation method (auscultation, $EtCO_2$, and the assigned ultrasound technique), and sonographer confidence. Sonographers' confidence was measured on a 5-point Likert scale (1 = not confident; 5 = very confident) [5].

1.5. Sample size

Esophageal intubation occurs in approximately 8% of emergency intubations in the emergency department [6]. Budhram et al. evaluated the diagnostic accuracy of ultrasonography for detecting esophageal intubation [4]. Using the sensitivity and specificity reported in that study as reference parameters, the minimum required sample size was calculated as 180 using G*Power, assuming 80%

power and a two-sided alpha of 0.05 [7]. To account for an anticipated 10% data loss, we planned to enroll 200 patients.

1.6. Randomization, allocation, and masking

After enrollment, participants were randomized in a 1:1:1 ratio using a computer-generated permuted-block sequence with variable block sizes (6, 9, and 12). Allocation was concealed using sequentially numbered, opaque, sealed envelopes. Group assignment was revealed only after enrollment and consent, at which point the sonographer was informed of the assigned ultrasound technique. The sonographer performed the allocated ultrasound assessment while blinded to all non-ultrasound confirmation data, including team discussions. Conversely, clinicians responsible for non-ultrasound confirmation (auscultation and capnography-based reference assessment) were blinded to the ultrasound findings throughout the verification process. A non-blinded investigator managed randomization and envelope processes however had no role in ultrasound interpretation or adjudication of the reference outcome.

1.7. Statistical analysis

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY). Data distribution was assessed using histograms. Categorical variables were reported as counts and percentages, and continuous variables as medians with interquartile ranges (IQR). There were no missing data for the primary outcome.

The reference standard was the primary physician's final decision based on capnography and auscultation. Endobronchial intubation was determined by bilateral auscultation, with chest radiography obtained when clinically indicated. The diagnostic performance of the index tests (ultrasound) was evaluated against the reference standard. It was reported as sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and diagnostic odds ratio, with 95% confidence intervals. Diagnostic odds ratios were calculated using a Haldane–Anscombe correction (adding 0.5 to each cell) when zero cells were present.

References

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Figure and Table Legends

Fig. 1: Representative images of the three sonographic techniques used for post-intubation confirmation. (A) Transtracheal ultrasound (TUS) demonstrating tracheal ETT location (red arrow). (B) "Double-tract/double-lumen" appearance consistent with esophageal intubation, with the trachea indicated by the red arrow and the esophagus by the yellow arrow. (C) Lung sliding assessment, with the pleural line indicated by the green arrow. (D) Diaphragm ultrasound during positive-pressure ventilation, showing diaphragmatic excursion on M-mode. (E) Diaphragm ultrasound during positive-pressure ventilation, showing absent diaphragmatic excursion on M-mode.

Fig. 2: Patient Flow Diagram

Fig. 3: Fagan nomogram illustrating the impact of pooled ultrasound findings on the post test probability of esophageal intubation.

Fig. S1: A pre-existing nasoduodenal feeding tube generated an additional air–mucosa interface within the esophagus (Red arrow), creating a double-tract–like appearance that can mimic esophageal intubation under protocol-mandated blinding.

Table 1. Baseline demographic and clinical characteristics of the study population according to ultrasound techniques

Table 2: Diagnostic performance of US techniques for confirming ETT position