Bedside Ultrasound of the Neck Confirms Endotracheal Tube Position in Emergency Intubations

Ultraschall während der Notfallintubation bestätigt korrekte Tubuslokalisation

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Abstract
Purpose: In controlled environments such as the operating room, bedside ultrasound (BUS) of the neck has shown high accuracy for distinguishing endotracheal (ETI) from esophageal intubations. We sought to determine the accuracy of BUS for endotracheal tube (ETT) position in the emergency department (ED) setting.

Materials and Methods: We assessed the utility of BUS in a single-center observational study in an ED setting. BUS was performed either simultaneously with ED intubation (S/ED), within < 3 minutes of ED intubation (A/ED), or in < 3 minutes of patient’s ED arrival after pre-hospital intubation (A/EMS). Trained ED providers performed BUS; intubators were blinded to ultrasound findings. We used Cormack and Lehane categories (CL) to classify intubation attempts as “easy” (CL-I/II), “moderate” (CL-III) and “difficult” (CL-IV). Additional data included the diagnostic accuracy of the sonographer and intubator compared to the clinical outcome, anatomy identified by sonography and time to diagnosis.

Results: During a 10-month period, 89 subjects with 115 intubation attempts were included in the study, and 86 patients/101 attempts with complete data were used in the study (63-easy, 19-moderate, 19-difficult). The sonographers achieved 100% accuracy with respect to determining the correct ETT position utilizing an anterior neck approach, while the intubators’ accuracy in assessing correct tube location was 97% compared to the clinical outcome. A blinded review of sonography findings confirmed all BUS anatomical findings. A sonographically empty esophagus was 100% specific for esophageal intubation, and a “double trachea sign” was 100% sensitive and 91% specific for esophageal intubation. The sonographic time to diagnosis was significantly faster than the intubator time to diagnosis (“easy” p < 0.001; n = 47; “moderate” p < 0.001; n = 15; “difficult” p < 0.001; n = 19).

Zusammenfassung
Ziel: Kann Ultraschall des Halses im Rahmen einer Notfallintubation verlässlich die Tubuslokalisation bestimmen?


Ergebnisse: Während der 10-monatigen Studiendauer wurden 89 Patienten mit 115 Intubationen in der Studie aufgenommen, 86 Patienten/101 Intubationen mit komplettem Datensatz wurden zur statistischen Auswertung herangezogen. Sonografie des Halses zur Bestimmung der Lokalisation des Trachealtubus war 100% akurat, die Intubatoren erreichten eine Genauigkeit von 97% im Vergleich zum klinischen Verlauf. Ein sonografisch leerer Ösophagus war 100% spezifisch für eine tracheale Intubation, der sonografische Befund der „Doppeltrachea“ war 100% sensitiv, 91% spezifisch für Ösophagusintubation. Sonografische Diagnose war unabhängig vom Schwierigkeitsgrad der Intubation schneller (CL-I/II p < 0.001; n = 47; CL-III p < 0.001; n = 15; CL-IV p < 0.001; n = 19); Wilcoxon-Test; A/EMS-Fälle ausgeschlossen).

Schlussfolgerungen: Bei Notfallintubationen zeigte die Halssonografie eine sehr hohe Genauigkeit und schnelle Diagnosestellung zur Bestimmung der anatomischen Lage des Trachealtubus.
Introduction

Background
Over the last decades, clinician-performed bedside ultrasound (BUS) has seen a significant increase in popularity throughout the world. Improved portability and technology advancements initiated a steady growth of clinicians interested in using the technology in novel point-of-care clinical settings. One of the classic indications of BUS is procedure guidance, traditionally referring to visualization of the needle tip and target anatomy, but other indications such as sonographic placement confirmation of the endotracheal tube (ETT) have been investigated. Emergency endotracheal intubation (ETI) is a difficult procedure requiring successful execution of a complex psychomotor skill. It carries a much higher risk for complications than elective ETI performed in the operating room. The most important complication is inadvertent esophageal intubation, which occurs in about 4–10% of emergency ETIs and has a considerable morbidity and mortality rate [1–4]. Early detection of esophageal intubation is a primary focus of emergency airway management. Several direct and indirect methods for ETI placement confirmation are utilized, direct visualization of the ETT passing through the vocal cords being the gold standard. End-tidal CO2 capnography, although highly accurate, or fogging of the ETT provides only indirect evidence of correct ETI placement [5]. All verification techniques have weaknesses that lessen their reliability [6–10]. Therefore, utilization of multiple methods is recommended [5]. Newer tools like video laryngoscopy equipment are promising additions to difficult airway management strategies, but are also not completely fail-safe and are not readily available for every airway emergency, especially when intubation occurs during transport or outside the controlled setting of the operating room [11, 12].

Importance
Pilot studies conducted in controlled environments such as an operating room or ICU found that BUS detected endotracheal or esophageal tube placement with high accuracy when performed simultaneously with intubation. These studies focused on sonographic detection of a very brief and transient motion artifact within the trachea, only visible during tube insertion [13–22] (supplemental video 1). The sonographic sensitivity and specificity were reported with 100% and 97%–100%, respectively. However, these trials were performed in the operating room or on human cadavers [13–19]. To date, despite rapidly increasing use of point-of-care ultrasound in emergency department (ED) and critical care settings, only small studies and a case report evaluated the performance of BUS for emergent ETI in a select subgroup of patients [20–24], all using ultrasound for only a select subgroup of patients. No prior study evaluated BUS performance in a more realistic heterogeneous group of emergency airway patients that included sonography performed immediately post-intubation or patients arriving intubated in the ED, when the transient motion artifact of tube insertion subsided, or compared it with the clinical outcome. This would be relevant to prehospital intubations or transport situations requiring novel confirmation of ETT. Other studies have successfully evaluated lung sliding as an indirect sign for successful ETI, but this sonographic technique may not be feasible in patients undergoing CPR or chest procedures or who have chest trauma [25, 26].

Objective
Our main objective was to evaluate the accuracy of BUS in the uncontrolled setting to detect tracheal and esophageal intubation using anatomical landmarks including the empty esophagus compared to the initial intubator diagnosis. Additional outcome measures were 1) the time taken to confirm ETI location in an emergency setting 2) whether the identification of specific sonographic anatomical landmarks of the trachea and esophagus is a useful sonographic predictor of ETI location in all emergent airway settings and 3) if the difficulty of the intubation (as ranked by Cormack and Lehane classification) influenced the accuracy and efficiency of BUS.

Materials and methods

Study Design
We used a prospective, observational, single-blinded approach, enrolling a convenience sample of ED patients >18 years, who required emergency ETI in the pre-hospital setting or in the study ED, over a 10-month period. The study evaluated the accuracy and performance of neck BUS to determine the location of emergently placed ETT compared to intubator assessment and clinical outcome. The institutional review board of the Johns Hopkins Medical Institutions approved this study.

Setting
Urban academic teaching hospital, which is a tertiary referral center including trauma and burns. During the 12-month period including the 10-month enrollment period, the ED had a census of approximately 60,000 patient visits, received about 1300 ambulances and had about 10,100 inpatient admissions. About 7% of all admitted ED patients required intensive care.

Study Subjects

Inclusion criteria
Patients 18 years or older requiring emergency ETI for medical or trauma resuscitation while in the ED or during transfer to the study ED. Enrolled patients were categorized into 3 groups: 1) BUS of the neck performed simultaneously with ED intubation (S/ED), 2) BUS performed within three minutes after ED intubation (A/ED), and 3) BUS performed within 3 minutes of patient’s ED arrival post-EMS intubation (A/EMS).

Exclusion criteria
Age <18 years, non-emergent ETI, >3 minutes since ED-performed intubation or arrival of an EMS-intubated patient, non-blinding of intubator. We chose a 3-minute cut-off time, because we assumed that after that time the clinical condition of the pa-
tient could bias the sonographer towards either tracheal or esophageal intubation.

**Sonographers**
A total of 10 emergency medicine providers participated as sonographers. All used BUS regularly in at least three indications in their clinical practice, including for central venous catheter placement in the neck. All received a 1-hour standardized training on BUS of the neck including theoretical and hands-on components for the detection of endotracheal or esophageal intubation prior to study begin. This included sonographic identification of the thyroid, larynx, vocal cords, trachea, cervical empty esophagus, as well as the appearance of endotracheal and esophageal intubations during 5 proctored exams overseen by an experienced senior emergency sonologist.

**Intubators**
All ED providers with privileges for emergency airway management. This included attending physicians, residents and senior physician assistants, who were assigned to the critical care area of the ED during enrollment.

**Methods of Measurements**
One ED provider performed sonography and a separate ED provider performed intubation. The intubator and his clinical team caring for the patient were blinded to BUS results.

**Sonography**
BUS was performed in the 3 airway situations occurring in the ED: 1) simultaneously with ETI (S/ED) or 2) within < 3 minutes after ED intubation (A/ED) or 3) within < 3 minutes of arrival of a pre-hospital intubation (A/EMS). Sonographers used a transcutaneous ultrasound technique as described in a prior report and described in Fig. 1, visualizing both the esophagus and trachea [21].

**S/ED**
The sonographer performed BUS simultaneously with the team performing the intubation. The sonographer determined his time to diagnosis using a digital clock in the treatment area. If the sonographer visualized the ETT passing into the trachea or esophagus in real-time, the time to diagnosis was recorded as zero seconds.

**A/ED and A/EMS**
BUS was performed using the same equipment and ultrasound technique. Adherence to the time limit of three minutes was assured using documentation by nursing and EMS staff.

**Equipment**
A Sonosite M-Turbo ultrasound machine (Sonosite, Bothell, WA, USA) was utilized for the study. The transducer was a high-frequency linear probe (7 – 10 MHz) and placed over the anterior neck as shown in Fig. 1, below the area of cricoid pressure application, in transverse orientation.

**Intubation Attempts and Intubator Diagnosis:**
**S/ED and A/ED**
Providers performed all ED intubations using a curved or straight laryngoscope. No video laryngoscopy was in use during the study period. ETI was performed following standard of care, including pre-oxygenation and rapid-sequence induction if feasible. Difficult airway equipment such as a gum-elastic bougie and endoscope was used as deemed necessary by the intubator. An intubation attempt was counted when the ETF was inserted past the level of the cricoid. The intubator made the initial diagnosis of tube placement, which was timed by nursing staff using a digital clock and noted on the study sheet. The intubator’s time to diagnosis was measured from the passing of the tube into the pharynx to the final diagnosis of tube placement announced by the intubator. The times to diagnosis could range from zero seconds (if the tube was observed passing through the cords) to several seconds or minutes if the intubator had to utilize additional tools of ETT confirmation to form an opinion [5]. The intubator also reported the Cormack and Lehane grade laryngeal view for each intubation attempt. Laryngeal view grade one was assigned as “easy”, grade 2 as “moderate”; and grade 3 and 4 assigned as “difficult” [8].

**A/EMS**
EMS providers performed all intubations following standard of care per state EMS regulations. The number of attempts, Cormack and Lehane category and time to diagnosis were self-reported. The time from intubation to arrival in ED was obtained from EMS documentation. The time to diagnosis of pre-hospital intubation was not recorded.

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**Fig. 1** Left image shows probe placement for bedside ultrasound for endotracheal tube localization and normal sonographic anatomy. A high-frequency linear probe (7 – 10 MHz, Sonosite, Bothell, WA) was placed over the anterior neck, below the area of cricoid pressure application in transverse orientation. The middle image shows the typical anatomy, the right image with illustrations.

Abb. 1 Das linke Bild zeigt die Position des Ultraschallkopfes zur Untersuchung der Trachea. Ein hochfrequent Schallkopf (7 – 10 MHz, Sonosite, Bothell, WA) wurde auf dem vorderen Halsabschnitt unter dem Bereich des Kricoiddrucks in transversaler Orientierung aufgesetzt. Das mittlere Bild zeigt die typische Anatomie, das rechte Bild mit Illustration.
Clinical Diagnosis

S/ED, A/ED and A/EMS

Parallel to the intubation procedure or immediately upon arrival of the pre-hospital intubated patient, the clinical team evaluated the patient for a decision of endotracheal or esophageal intubation per usual standard of care, including capnography. The treating team utilized all information available at the bedside except the sonographic findings. If needed, a member of the clinical team (different from the intubator) performed a repeat direct laryngoscopy to confirm the initial intubator diagnosis. If the intubator and clinical diagnosis were in agreement, the result was acted on. If the intubator and clinical diagnosis were in disagreement, either a repeat direct laryngoscopy or re-intubation was performed at the discretion of the attending physician. The outcomes were recorded on study data sheets.

Data Collection and Processing

The intubators and sonographers recorded all data on data collection sheets immediately after the intubation. This included the diagnosis, time to diagnosis of tube location for the sonographer and intubator, Cormack and Lehane category, sonographic visualization of the trachea with or without tube movement, visualization of empty esophagus or esophagus with foreign body. Other data included patient demographics, vital signs, indications for intubation, utilization of induction agents, bougie or endoscopy use, or conversion to surgical airway and clinical outcome of ETI attempts. Representative video clips or still images were stored for documentation and blinded overread.

Data Analysis

Data was analyzed using SPSS (version 16.0, SPSS Inc. IL). The time to diagnosis of tube position data was summarized as median and interquartile range and comparisons between the clinical and ultrasound diagnosis were assessed using a Wilcoxon test. A formal sample size calculation could not be performed, as no pilot data was available. However, an estimate of the detectable difference in time to diagnosis was made. A sample size of 100 intubations, assuming the time to diagnosis was normally distributed, would be able to detect a true difference in the mean response of matched pairs of -0.33 or 0.33 (i.e. one third) standard deviations with probability (power) 0.9. The Type I error probability that this response difference is zero associated with this test of the null hypothesis is 0.05.

Results

Characteristics of Study Subjects

During the 10-month study period, 89 patients with a total of 115 intubation attempts/sonography scans were included in the study. The data represented about 50% of ED intubations during this time period. Of the 115 intubation attempts, 14 attempts were excluded because of either non-blinding of the intubator to the sonography results. Intubator diagnosis was 97.8% sensitive and 100% specific for both ETI and 9/10 esophageal intubations (EsI). Sonographers correctly identified all 91 endotracheal and all 10 esophageal intubations with complete data sets included in analysis. If the intubators and clinical diagnosis were in agreement, the result was acted on. If the intubator and clinical diagnosis were in disagreement, either a repeat direct laryngoscopy or re-intubation was performed at the discretion of the attending physician. The outcomes were recorded on study data sheets.

Two attempts were excluded because of incomplete data sets.

Three attempts were excluded because of incomplete data sets and two for unblinding of the intubator to the sonography results.

Two attempts were excluded because of incomplete data sets.

with a mean of 58 years. None of the patients required a surgical airway.

Sonographers

Ten physician-sonographers participated and performed BUS simultaneously with the intubation in 77/101 attempts (S/ED); in 4/101 attempts within <3 min of the ED intubation (A/ED) and in 20 attempts within <3 min of a pre-hospital intubated patient’s arrival in the ED (A/EMS). The majority of the BUS (81/101) were performed by 2 sonographers. While the observations by the 8 remaining sonographers were too few to allow meaningful comparison, there was unanimity in the results between the frequent and infrequent groups.

Accuracy of Sonographer Diagnosis

Clinical diagnosis confirmed 91 endotracheal intubations (ETI) and 10 esophageal intubations (EsI). Sonographers correctly identified all 91 endotracheal and all 10 esophageal intubations (100% sensitivity and 100% specificity for both esophageal and endotracheal intubations).

Intubators

36 different intubators performed the study intubations. Of the 101 intubation attempts included, 62% were classified as C-L (Cormack and Lehane) view “easy”, 19% as “moderate” and 19% as “difficult” by the intubator. A total of ten intubation attempts resulted in esophageal intubations; one was in a patient with an “easy” C-L view, and nine in patients with a “difficult” C-L view.

Accuracy of Intubator Diagnosis

The intubators diagnosed 89/91 of their endotracheal intubations and 9/10 esophageal intubation attempts correctly compared with the clinical outcome. Intubator diagnosis was 97.8% sensitive and 90% specific for ETI, and 90% sensitive and 98.9% specific for esophageal intubations.
Three Missed Intubator Diagnosis Cases

1) Missed esophageal intubation by intubator: EMS placed ETT with a 41-minute transport time to ED. On arrival in ED, both the sonographer and clinical team diagnosed esophageal placement and re-intubation confirmed tracheal placement (Fig. 2). 2 and 3) Missed tracheal intubation by intubator: 2 patients with severe lung disease and low O2 saturation were intubated in ED and sonography showed tracheal tube placement. The intubator diagnosed esophageal intubation. The clinical team reevaluated the patient and a repeat laryngoscopy and re-intubation over bougie revealed the tracheal tube location in both patients (Fig. 3).

Sonography Quality Assurance

Of the 101 attempts, 60 were documented in video format, the remaining 41 attempts documented as still images. During blinded read over by an experienced senior physician sonographer, no false-positive or false-negative cases were identified. All images were reviewed for frequency of visualization of the trachea and empty esophagus, and the presence or absence of the “double trachea sign”.

Accuracy of the Empty Esophagus and “Double Trachea Sign”

In our study, 11 patients had sonographic findings concurrent with the previously described paratracheal detection of the esophageal tube [22], which we called the “Double Trachea Sign” (Fig. 2). Of those, 10 were true esophageal intubations. One patient identified with ETI was found to have a calcified cystic thyroid mass that mimicked a “double trachea sign” (Fig. 4), but this finding was cystic, and within the thyroid, and an empty esophagus and the actual endotracheal tube within the true trachea were identified by the sonographer. Hence in this case, the sonographer still identified the ETT location correctly. A sonographically empty esophagus was located in 42/91 patients and was 100 % specific for endotracheal intubation, but only 46 % sensitive. A “double trachea sign” was 100 % sensitive and 91 % specific for esophageal intubation. The “double trachea sign” had a PPV of 91 % and NPV of 99 % for the correct identification of esophageal intubation. The positive predictive value for an empty esophagus detected for tracheal intubation was 100 % (Table 2).

Time to Diagnosis

For sonographers analyzing the pooled data, the median time to diagnosis of ETT location was 0 seconds (range 0 – 120). The median time per sonographer was also 0 seconds and identical.
but there were significant differences between the sonographers’ times, with one sonographer being significantly slower than the remainder of the group [median 120 seconds (range 60 – 120 seconds), p < 0.001]. This sonographer was the least experienced and his study subjects were undergoing CPR during sonography. For intubators analyzing the pooled data, the median time to diagnosis of ETT location was 30 seconds (range 0 – 300 seconds). The median time per intubator was also 30 seconds (range 0 – 180 seconds) and there were no significant differences between intubators (p=0.403). Again, pooling the data for all intubators/sonographers, the sonographic time to diagnosis was significantly faster than the intubator time to diagnosis ("easy" p < 0.001 (n = 47); "moderate" p = 0.001 (n = 15); "difficult" p < 0.001 (n = 19); Wilcoxon test; A/EMS cases were excluded).

Table 3 shows the time to diagnosis for intubator and sonographer. The data was positively skewed and is presented in median and interquartile range. The difference in the time to diagnosis for the intubator and sonographer was assessed using a Wilcoxon test.

<table>
<thead>
<tr>
<th>Clinical</th>
<th>Ultrasound</th>
<th>p</th>
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<tbody>
<tr>
<td>time to diagnosis (all intubations)</td>
<td>30 sec (0 – 60 sec)</td>
<td>0 sec (0 – 0 sec)</td>
</tr>
<tr>
<td>easy</td>
<td>9.6 sec (0 – 60 sec)</td>
<td>0 sec (0 – 0 sec)</td>
</tr>
<tr>
<td>moderate</td>
<td>60 sec (12 – 62 sec)</td>
<td>0 sec (0 – 0 sec)</td>
</tr>
<tr>
<td>difficult</td>
<td>60 sec (30 – 60 sec)</td>
<td>0 sec (0 – 0 sec)</td>
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1 This patient was found to have a round calcified thyroid mass appearing on the initial scan as a “double trachea sign”, but found to have a cystic appearance (Fig. 4).

Discussion

In our study, BUS of the neck was feasible, fast and highly accurate for determining correct endotracheal tube location in emergency airway situations, using the novel approach of evaluating “all-comers” of both pre-hospital and ED intubations, and sonography using the novel approach of focusing on localizing the cervical esophagus anatomy as well as the trachea. We also found that the performance of BUS was independent from the degree of difficulty of the intubation, as measured by Cormack and Lehane grading. Overall, the sonography time to diagnosis also seemed independent from the Cormack and Lehane classification observation, making it a potential independent confirmation tool in difficult airway situations challenged by trauma, blood, and massive secretions. We found that evaluating the esophageal anatomy as a landmark for tube location was 100% specific for both peri- and post-intubation patients, and suggest that this may be an additional bedside tube location verification tool for patients post-
intubation, either from pre-hospital intubation or ICU patients with concern for tube displacement after transport, and since real-time visualization of the ETT motion sliding into the trachea is not available in these patients. The vast majority of the neck ultrasounds in this study (87%) were completed within less than 5 seconds. These results are similar to other sonography studies performed in the controlled setting of the operating room [19, 21, 22]. However, we observed that 3 of the 101 sonography evaluations took 120 seconds, and 6 sonography evaluations took 60 seconds. All those sonography scans were performed by the 2 most junior sonographers, and on study subjects undergoing ongoing CPR. These circumstances under which it can be challenging to find esophageal anatomy may have contributed to this long sonography time. However, the sonography time-to-diagnosis was still significantly shorter than the intubator time-to-diagnosis and ultrasound determined ETT locations rapidly, with 100% accuracy and independence from how difficult the airway management was. Larger multicenter trials will be necessary to validate this data and also should include data with video laryngoscopy, which might help with difficult airway management, but might also be susceptible to problems in airway management of patients with massive secretions, or blood from trauma. Future studies should also evaluate a combination of neck BUS and lung sliding ultrasound. Prior studies in controlled settings have shown lung sliding to be highly accurate as an indirect sign of ETT verification, but accuracy and feasibility might be unclear in patients undergoing CPR or chest procedures. Future research comparing the two modalities is necessary and should include patients peri- and immediately post-intubation as well as patients with a difficult airway situation and undergoing CPR, as these situations may be challenging for both the lung sliding technique and neck ultrasound.

Limitations

Our study had several limitations: First, because of staffing and scheduling limitations, this study included a convenience sample, allowing for potential bias in patient selection. However, during the study period, about 50% of attendings participated and 50% of in-ED intubations were captured. For logistical reasons, we did not include emergency intubations performed in the ICU or on the wards. Future studies would benefit from consecutive enrollment of this patient group. Second, the sonographer was not blinded to the intubation diagnosis or clinical events. However, in the vast majority of patients, the sonography diagnosis outperformed the intubator diagnosis. Future studies could attempt double blinding and also utilize a separate study coordinator for timing and data processing. Third, we were unable to control for intubator skill level and also did not assess for interobserver reliability in both sonographers and intubators. Lastly, the technique may be limited in patients with subcutaneous emphysema, pneumomediastinum, neck hematoma, a wide neck wound, or a large neck mass distorting anatomy. Larger follow-up studies might be necessary to eliminate this limitation. However, this might be difficult given the nature of the research topic.

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