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Clinical paper

Tracheal rapid ultrasound saline test (T.R.U.S.T.) for confirming correct endotracheal tube depth in children☆

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ABSTRACT

Objective: We evaluated the accuracy of tracheal ultrasonography of a saline-inflated endotracheal tube (ETT) cuff for confirming correct ETT insertion depth.

Methods: We performed a prospective feasibility study of children undergoing endotracheal intubation for surgery. Tracheal ultrasonography at the suprasternal notch was performed during transient endobronchial intubation and inflation of the cuff with saline, and with the ETT at a correct endotracheal position. Ultrasound videos were recorded at both positions, which were confirmed by fiberoptic bronchoscopy. These videos were shown to two independent blinded reviewers, who determined the presence or absence of a saline-inflated cuff. The primary outcome was accuracy of tracheal ultrasonography for appropriate ETT insertion depth.

Results: Forty-two patients were enrolled. For correct endotracheal versus endobronchial positioning, pooled results from the reviewers revealed a sensitivity of 98.8% (95% CI = 90–100%), a specificity of 96.4% (95% CI = 87–100%), a PPV of 96.5% (95% CI = 87–100%), a NPV of 98.8% (95% CI = 89–100%), a positive likelihood ratio of 32 (95% CI = 6–185), and a negative likelihood ratio of 0.015 (95% CI = 0.004–0.2). Agreement between reviewers was high (kappa co-efficient = 0.93; 95% CI = 0.86 to 1). The mean duration of the ultrasound exam was 4.0 s (range 1.0–15.0 s).

Conclusions: Sonographic visualization of a saline-inflated ETT cuff at the suprasternal notch is an accurate and rapid method for confirming correct ETT insertion depth in children.

1. Introduction

Inadvertent endobronchial ETT placement occurs in up to 30% of pediatric emergency intubations [1]. Unrecognized endobronchial intubation increases the risk of hypoxia and barotrauma that can cause neurologic injury and death [2–4]. Critically ill pediatric patients are at particular risk from these complications, as children have higher oxygen consumption rates than adults and their indication for emergency intubation is often respiratory failure.

Chest x-ray is the most commonly used test to confirm ETT depth, but has numerous drawbacks. It may take approximately 20 min to generate a result [5,6], exposing patients with inadvertent endobronchial intubations to a dangerously long period with a misplaced ETT. It also requires lifting of the patient to place the x-ray film, which risks dislodging the ETT.

In the hands of appropriately trained providers, bedside ultrasonography of the anterior neck can accurately distinguish between tracheal or esophageal intubation [5,7–13], but has only been able to detect ETT tip depth in newborns [14,15]. Indirect ultrasound surrogates of correct ETT insertion depth (bilateral lung sliding and diaphragm movement) are inferior to chest radiography [6,16], and are not useful in cases of pneumothorax, subcutaneous emphysema, pleural scarring, pleural effusion, pulmonary malignancies, or endotracheal tube obstruction [6].

An ETT cuff located at the level of the suprasternal notch correlates to correct depth of ETT insertion [17]. While a cuff filled with air cannot be sonographically distinguished from the surrounding air-filled trachea, prior reports in adult patients [18] and cadavers [19] showed that ultrasonography at the suprasternal notch can visualize a saline-inflated ETT cuff. The use of saline in an ETT cuff is a well-established and safe practice [20–31], but no studies have explored the use of sonography on a saline-inflated ETT cuff to

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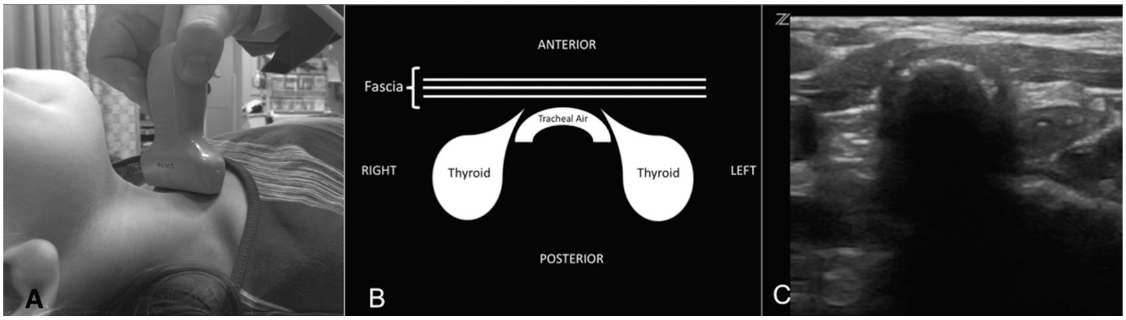

Fig. 1. Ultrasound technique. (A) Transducer position. The probe is held perpendicular to the anterior neck at the level of the suprasternal notch. The probe marker is towards the patient's right. (B) Diagram of airway structures as they appear on ultrasound imaging at this location. Tracheal air causes acoustic shadowing that eliminates visualization of deeper tissues. (C) Sonographic image corresponding to (B).

rule out endobronchial intubation, and no studies have included children.

Bedside ultrasonography of a saline-inflated ETT cuff would be an ideal intubation depth verification test as it involves no radiation, requires no patient repositioning, gives an instantaneous result, and can be repeated as frequently as needed. It could potentially improve patient safety during pediatric intubation by rapid and accurate detection of endobronchial intubation.

We sought to determine whether the use of a saline-inflated ETT cuff would allow rapid and accurate ultrasonographic confirmation of correct ETT insertion depth in pediatric patients undergoing general anesthesia.

2. Methods

2.1. Study design and setting

This was a prospective feasibility study enrolling a convenience sample of pediatric patients undergoing general anesthesia requiring endotracheal intubation in the operating room of our institution's ambulatory surgery center. Approval for the study was obtained from the Institutional Review Board of Maimonides Medical Center (study number 2013-02-19).

2.2. Selection of participants

Families of patients aged 3 months to 18 years who were scheduled for procedures involving endotracheal intubation and were ASA class 1 or 2 were approached in the pre-operative area of the ambulatory surgery center. Patients were excluded if they had developmental delay (due to inability to provide assent), an anticipated difficult intubation, a congenital airway anomaly, a nasogastric tube, or guardians that did not read or speak English. Informed consent was obtained from parents, and patient assent was obtained in children 7 years of age or older.

2.3. Study protocol

The anesthesiologist performed a validated pediatric intubation technique involving transient right mainstem endobronchial intubation [32–35], and the ETT cuff was inflated with saline in the right mainstem bronchus as well as in the trachea, with these positions confirmed by the gold standard of fiberoptic bronchoscopy. An investigator recorded ultrasound video clips with the transducer positioned on the anterior neck at the sternal notch prior to the intubation, at the time of endobronchial intubation, and when the ETT tip was positioned in the trachea.

Sonograms were performed by a pediatric emergency medicine ultrasonography fellow. Prior to the start of the study this fellow performed airway ultrasonography of intubated patients as part of his clinical practice, and after performing 10 of these sonographic examinations, the fellow developed proficiency in recognizing the sonographic appearance of a saline-inflated cuff at the distal portion of the ETT. We used an ultrasound system (z.one ultra sp; Zonare Medical Systems, Mountain View, CA) with a 5–10 MHz linear transducer. The transducer was placed in a transverse orientation perpendicular to the anterior neck at the level of the sternal notch (Fig. 1).

Patients were nasally or orally intubated by an anesthesiologist using standard polyvinyl chloride ETTs with a high-volume, low-pressure cuff (Hi-Lo ETT, Mallinckrodt, Dublin, Ireland). A fiberoptic bronchoscope was introduced through the ETT and advanced to just within the right mainstem bronchus. The ETT was introduced into the mainstem bronchus over the bronchoscope, which was then removed. The ETT cuff was inflated with saline, with a manometer used to ensure cuff pressure did not rise above 35 cm H_2O. The ETT was left in the endobronchial position for no longer than 6 s, and was then withdrawn until the sonographer noted the appearance of the saline-inflated cuff at the level of the sternal notch, and the time from the initiation of ETT withdrawal until cuff visualization was recorded. Fiberoptic bronchoscopy was then repeated to establish whether the ETT tip was in a correct endotracheal position, using markings on the bronchoscope to measure the distance from the carina to the tip of the ETT. A fiberoptic bronchoscope with an insertion diameter of 2.2 mm (Olympus LF-P, Center Valley, PA) was used with ETTs with inner diameters of 3.5–5.0 mm, while a scope with an insertion diameter of 4.0 mm (Olympus LF-2) was used with ETTs with inner diameters of 5.5–6.5 mm and a scope with an insertion diameter of 5.2 mm (Olympus LF-TP) was used with ETTs with inner diameters of 7.0–8.0 mm.

The sonographer recorded 6 s video clips at three time points: prior to intubation (unintubated control), during cuff inflation at the endobronchial position, and at the time of cuff visualization. To reduce bias on the part of the sonographer (who was not blinded to the ETT tip position), the video clips from all patients were pooled together and their order randomized using the random sequence generator at www.random.org, and then presented to two blinded reviewers, who independently rated each clip for the presence or absence of a saline-inflated cuff. These reviewers were both board certified emergency physicians who had completed a one year emergency ultrasound fellowship and who each had more than 5 years experience in bedside sonography. Prior to rating the video clips, these reviewers underwent a 30 min lecture on airway ultrasound in intubated patients.

2.4. Outcomes

The primary outcome was the diagnostic accuracy of ultrasonography of a saline-inflated ETT cuff in confirming correct ETT position and excluding endobronchial intubation.

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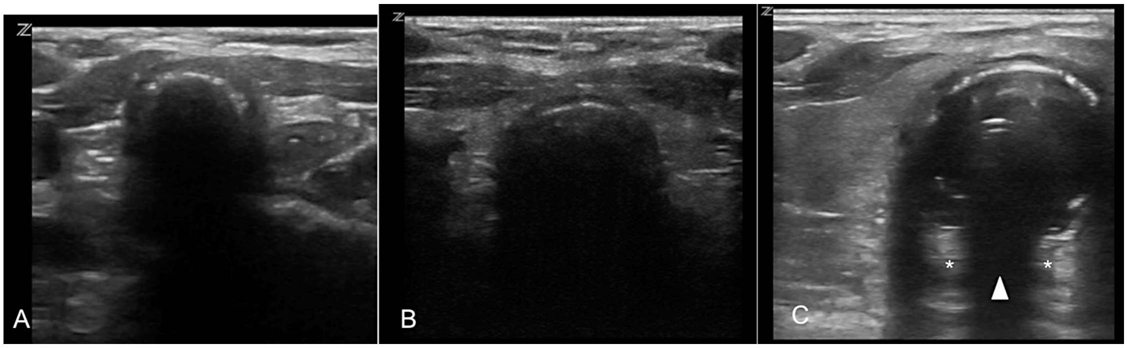

Fig. 2. Ultrasound appearance of the anterior neck of a 4 year old male at the level of the suprasternal notch during intubation involving an ETT with a saline-inflated cuff. (A) Image prior to intubation. (B) ETT tip is in the right mainstem bronchus. The saline-inflated cuff is not seen. (C) ETT tip is 3 cm above the carina. The saline-inflated cuff allows visualization of tissues deep to the cuff (indicated by *), except where acoustic shadowing occurs from air within the endotracheal tube itself (indicated by arrowhead).

Table 1
Summary of reviewer impressions from randomized ultrasound video clips.

	Reviewer 1 Video clip $n = 126$		Reviewer 2 Video clip $n = 126$	
	Cuff not seen	Cuff seen	Cuff not seen	Cuff seen
ETT tip position				
Unintubated	42	0	41	1
Endobronchial	41	1	40	2
Endotracheal	0	42	1	41

The secondary outcomes were the speed with which the ultrasound exam was performed, and the inter-rater reliability of the technique (which was measured using a kappa statistic).

2.5. Data analysis

Statistical analysis was performed using IBM SPSS 20 (IBM Inc., Kerhonkson, NY) and the online calculator at http://www.vassarstats.net/clin1.html. Data are presented as mean (with range) for continuous data and as percentages with 95% confidence intervals for frequencies. The results of the video reviews by the blinded reviewers were pooled together and sensitivity, specificity, predictive values and likelihood ratios were calculated by standard formulas and 2 × 2 tables. The impressions of the unblinded sonographer were not included in these calculations.

2.6. Sample size determination

A kappa coefficient of 0.55 was considered inadequate while a kappa equal to 0.80 was considered as the minimum level of acceptable agreement between blinded reviewers. With an alpha of 0.05, we calculated that we would need 20 patients to have a power of 80% to test for whether there was adequate agreement.

3. Results

42 patients were enrolled. The mean age was 6 years (range 9 months–18 years), and the median ETT inner diameter was 4.5 mm (range 3.5–8.0). 23 (55%) of the patients were male. As each patient generated 3 video clips (unintubated, right endobronchial intubation, and endotracheal intubation), there were a total of 126 ultrasound video clips.

The sonographer never visualized the saline-filled cuff when the ETT was not present or was in the right mainstem bronchus, and always visualized it at the level of the suprasternal notch upon withdrawal of the tube from the endobronchial position (Fig. 2). At the time of cuff visualization, the mean ETT tip position was 2.7 cm above the carina (range 1.5–4.5 cm). Mean time to cuff visualization was 4.0 s (range 1.0–15.0 s).

The impressions of each blinded reviewer for the presence or absence of a saline-inflated cuff in the randomized video clips are shown in Table 1. Agreement between reviewers on the presence or absence of a saline-inflated cuff was 96.8% (kappa co-efficient = 0.93; 95% CI = 0.86 to 1), and the test characteristics from the pooled results of both blinded reviewers are shown in Table 2. Using visualization of a saline-inflated cuff to rule in correct endotracheal position and to rule out endobronchial position, the blinded reviewers exhibited a sensitivity of 98.8% (95% CI = 90–100%), a specificity of 96.4% (95% CI = 87–100%), a positive predictive value of 96.5% (95% CI = 87–100%), a negative predictive value of 98.8% (95% CI = 89–100%), a positive likelihood ratio of 32 (95% CI = 6–185), and a negative likelihood ratio of 0.015 (95% CI = 0.004–0.2).

4. Discussion

Bedside ultrasonography is widely available in critical care environments, and tracheal ultrasonography could serve as a powerful complementary test to detect incorrect depth of endotracheal tube insertion. It is rapid, requires no interruption of chest compressions or ventilation, is unaffected by hemodynamic status, and involves no radiation [8,11].

Table 2
Test characteristics of ultrasonography of a saline-inflated ETT cuff in excluding endobronchial intubation.

Test characteristic (95% C.I.)	Pooled result from blinded reviewers
Sensitivity	98.8% (90–100%)
Specificity	96.4% (87–100%)
Positive predictive value	96.5% (87–100%)
Negative predictive value	98.8% (89–100%)
Positive likelihood ratio	32 (6–185)
Negative likelihood ratio	0.015 (0.004–0.2)

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The data from this prospective study suggests that tracheal ultrasonography using a saline-filled ETT cuff can accurately and rapidly distinguish between correct endotracheal versus endobronchial ETT positions in children. We refer to this ultrasound technique as the Tracheal Rapid Ultrasound Saline Test (TRUST), adapting the name from the TRUE ultrasound exam of Chou et al. for diagnosing esophageal intubation [8]. This is the first study to evaluate this ultrasonographic method in ruling out endobronchial intubation, as previous studies of this method did not include endobronchial ETT positions [18,19]. It is also the first study of this method involving children.

A recent study using review of videos from the resuscitation bays of a major academic pediatric emergency department reported an inadvertent endobronchial intubation rate of 30% [1]. The current American Heart Association Guidelines for Pediatric Advanced Life Support require verification of ETT position in children by both clinical assessment and confirmatory devices, as no single confirmation technique is completely reliable [36]. Direct visualization of the ETT passing through the vocal cords confirms tracheal rather than esophageal position, but cannot confirm correct tube depth. Clinical assessment by auscultation and chest rise fails to detect up to 55% of endobronchial intubations [37]. Palpation of an ETT cuff at the sternal notch is subjective and non-recordable, and cannot distinguish tracheal from esophageal placement. Capnography can suggest a tracheal versus esophageal position but provides no information on ETT depth. Fiberoptic devices can be placed through the ETT to confirm both tracheal location and depth, but they are rarely found in emergency departments due to cost, specialized training requirements, and the period of apnea associated with the near-occlusive presence of the scope within the ETT. Chest radiography is commonly used but is time-consuming, requires interruption of chest compressions, and involves ionizing radiation. The TRUST maneuver may address many of the drawbacks of these other confirmatory techniques.

Our study has several limitations. The small sample size means our results will need validation in studies with larger numbers of participants. This study involved healthy participants in the controlled environment of the operating room, and as such we are limited in our ability to generalize our results to the resuscitation setting or to patients with abnormal airway anatomy. The use of only a single sonographer and only 2 blinded reviewers (all of whom were fellowship-trained in emergency ultrasonography) further limits the generalizability of our results, especially to physicians without such training. As of yet there are also no published studies addressing the amount of experience required for point-of-care sonographers to become competent in tracheal ultrasonography. More research in settings outside of the operating room is needed before this TRUST exam can be incorporated into routine use in resuscitation.

Along with the "too deep" (endobronchial) position, an ideal assessment of this technique would have included a "too high" position, in which the ETT tip was located close to or above the vocal cords. This would not have been ethical, however, as such a position is not part of the well-established transient endobronchial intubation technique that was employed, and would pose unacceptable risks of unintended extubation or vocal cord damage. We also could not ethically include esophageal intubations, but previous work in cadavers showed that even novice sonographers could accurately distinguish tracheal from esophageal intubations using a saline-inflated ETT cuff [19].

5. Conclusions

In a controlled setting and when performed and interpreted by trained sonographers, ultrasonography of a saline-inflated ETT cuff at the level of the suprasternal notch appears to be an accurate and rapid method to verify correct depth of ETT insertion in healthy pediatric patients.

Author contribution statement

All the authors were involved in the conception and design of the study. MOT and LEH obtained research funding. MOT supervised the conduct of the trial and data collection. MOT and EPS undertook recruitment of the patients. MOT analyzed the data. MOT drafted the manuscript, and all authors contributed substantially to its revision. MOT takes responsibility for the paper as a whole.

Conflicts of interest statement

The authors have no conflict of interests.

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