Comparative study of the reliability of ultrasound to confirm the position of endotracheal tube with cuff inflated with saline versus air

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Abstract

Aim: To compare the reliability of transtracheal ultrasound to confirm the endotracheal tube position with saline versus air inflated cuff. **Methods:** This was a prospective randomized cadaveric study. Four techniques were randomized: endotracheal tube in the trachea with air or saline inflated cuff, and endotracheal tube in the esophagus with air or saline inflated cuff. The investigator used the Mcgrath to randomly place the endotracheal tube in the trachea or in the esophagus with saline or air inflated cuff. During the first series of measurements, nine residents performed transtracheal ultrasound with linear transducer placed transversely at the suprasternal notch. They were recorded with a cut off fixed to 30 seconds, and a questionnaire was completed by the residents after each transtracheal ultrasound in order to report where the endotracheal tube is positioned according to them. The second series followed the same protocol and included three residents who had participated in the first series. The primary outcome was the success rate in determining the position of the endotracheal tube. **Results:** In the first series, the success rate was 46.5%. In the second series, the success rate was 72.9%. There was no significant difference between cuff inflated with saline and air ($p = 1.00$). The overall mean time required was 20.6 s (95% CI 13.0–28.2 s). Based on an empirical data set, transtracheal ultrasound had a sensitivity of 62.2%, specificity of 100%, positive predictive value of 100%, and negative predictive value of 26.08%. **Conclusion:** This investigation shows that regardless of the contents of the endotracheal tube cuff, the use of transtracheal ultrasound to confirm the position of endotracheal tube reports disappointing results.

Introduction

After performing an intubation, the position of the endotracheal tube (ETT) is always verified. Esophageal intubation may have disastrous consequences and increases morbimortality[1,2]. Capnography is considered the standard of care for the primary evaluation of the ETT position[3,4]. However, capnography is time consuming, with about 48 seconds and 6 insufflations required to confirm the ETT position, with an increased risk of stomach ventilation and associated complications such as inhalation if the ETT is incorrectly placed[5,6].

Ultrasonography is a generally accessible tool. It is easy to perform and widely available. In addition, it is painless, relatively cheap, easily reproducible, and has good safety records. We can use ultrasonography before anesthesia induction and diagnose several conditions that affect airway management or identify the cricothyroid membrane prior to the management of a difficult airway[7,8]. Several studies of ultrasonography as a tool to evaluate the ETT position have yielded promising results[9–12]. In the meta-analysis published by Chou *et al.*, the sensitivity of the method was 93% and the specificity reached 97%[1]. Transtracheal ultrasound (TTUS) has the advantage of

being fast (3 à 30 seconds) and safe, confirming the ETT position without the need for ventilation or circulation[13].

However, TTUS is not used in routine practice to confirm the correct position of the ETT. First, the published studies had a small sample and were heterogeneous in their methodology. Differences exist in the method of interpretation (comet tail, shadow, double tract sign, etc.), in the transducer and where to place it. The TTUS is performed either in the dynamic mode (in real-time during intubation) or the static mode (after intubation). This methodological heterogeneity associated with the absence of a large-scale study explains the uncertainty about the usefulness of TTUS to reliably locate the ETT. Second, the air within the trachea remains a challenge for the interpretation of ultrasound (US) images[14,15]. The air around the tube attenuates ultrasonic waves and makes imaging difficult. The optimum US technique has not as yet been established. Inflating the ETT cuff with saline overcomes this difficulty and facilitates visualization of the cuff. Inflating the ETT cuff with saline should produce an anechoic sphere that would be easy to visualize[16]. Few available studies with small samples have reported promising results[17,18].

The aim of the study was to compare the reliability of US as a tool to verify the ETT position when the cuff is inflated with saline or air. The secondary objectives were to assess the visibility of the ETT, the diagnostic certainty of the ETT position, the average time required to perform the technique, and to perform an analysis of the learning curve.

Methods

This was a prospective randomized study which compared the reliability of US to confirm the ETT position when the cuff was inflated with saline versus air in a cadaver model. The study was conducted at the Nancy anatomy laboratory after obtaining the approval of the Nancy CHRU ethics committee (N°239).

The participating subjects were nine residents (volunteers) who had either obtained or were in the process of obtaining their TUSAR diploma (Ultra-Sonic Techniques in Anesthesia – Resuscitation) at Nancy's university. They were skilled at US but novice to upper airway ultrasonography examinations to verify the ETT placement. Eight thawed cadavers were used in the study. The exclusion criteria were age under 18 years and major airway abnormalities (malformations, extensive ENT cancer, radiotherapy).

Two series of measurements were performed. The first series was performed by nine residents spread over three sessions, i.e. three residents per session. The second series included only one session with three residents who had already participated in the first series. To limit the selection bias, the cadavers were different between the first and second series of measurements (Fig. 1).

An investigator presented a single ultrasound's view explaining the anatomical structures and four techniques to be used
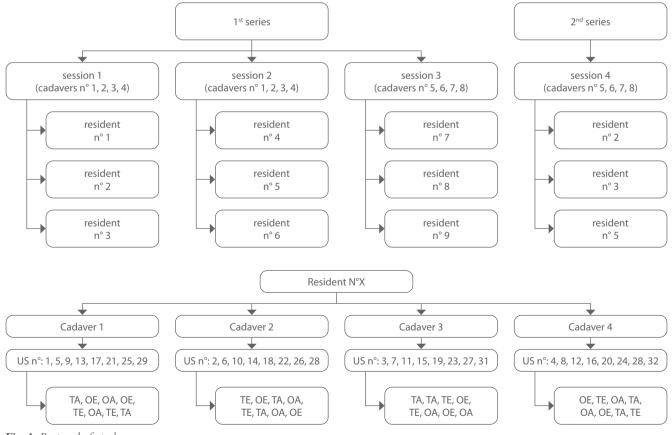

Fig. 1. *Protocol of study*

Tab. 1. *First series of measurements*

	N	%
Endotracheal tube position		
Trachea	147	51
Esophagus	141	49
Cuff		
Air	144	50
Saline	144	50
Primary outcome		
Failure	154	53.5
Success	134	46.5
Diagnostic certainty		
I don't know	34	11.8
Not sure	47	16.3
Pretty sure	72	25.0
Almost sure	82	28.5
Quite sure	53	18.4
Visibility		
I see nothing	39	13.5
Poor visibility	45	15.6
Average visibility	73	25.3
Good visibility	95	33.0
Very good visibility	36	12.5

in the study: the ETT placed in the trachea with the cuff inflated with air (TA), or saline (TS); and the ETT placed in the esophagus with the cuff inflated with air (EA) or saline (ES). The cadavers were intubated by the investigator using a 7.0 ETT. Each cadaver was subsequently intubated at the site and the cuff was inflated (10 cc) corresponding to randomization. The ETT position was confirmed using the McGrath. The volunteers were blinded to the ETT position. Then the volunteers performed one by one the TTUS on cadavers successively using logiq E (General Electric, Nancy, France) with a 6–13 MHZ linear transducer in the transverse view at the suprasternal notch. The time was recorded between the start of the scan and the confirmation of the ETT position. A cut-off value was fixed at 30 seconds. A three-item questionnaire was completed after each TTUS. The items included the diagnosis, visibility of the ETT, and diagnostic certainty. Success was defined as the correct location of the ETT. The ETT visibility and diagnostic certainty were measured using the Likert scale. The protocol was the same for the first and

second series of measurements. A total of 32 TTUS were done per resident (i.e. eight scans per cadaver) during each series. Each technique was randomized twice on the same cadaver who was its own control (Fig. 1). The learning curve was measured for a subgroup of three residents between the first and the second series of measurements.

Statistical analyses were performed using the Fisher exact tests, the Cochran-Armitage trend test for the qualitative variables, and the Kruskal Wallis test for the quantitative variables. Sensitivity, specificity and predictive values of transtracheal ultrasonography examination were calculated to compare our results with previous publications (based on an empirical data set). The learning curve with the "cumulative sum" or "Learning Curve – Cumulative Summation" (LC-CUSUM) method was generated with a subpopulation of three residents who participated in two series of measurements. Data were collected using Excel software, and statistical analyses were performed using SAS 9.4® software (SAS Institute Inc. 2013. SAS® 9.4 Statements: Reference. Cary, NC: SAS Institute Inc.)

Results

Overall, eight cadavers yielded a total of 384 TTUS performed by nine residents allocated over two series of measurements. For the first series of measurements, each resident performed 32 TTUS spread over four cadavers. The main characteristics of the TTUS are listed in Tab. 1. The success rate was 46.5%. The mean time to confirm the position of the ETT was 20.6 seconds (95% CI 13.0–28.2 seconds); the range was 3 to 30 seconds (cut-off).

Inflating the ETT cuff with saline or air did not change the reliability of the TTUS in confirming the location of the ETT ($p = 1.00$) (Tab. 2). The success rate was higher when the ETT was in the trachea (59.7% tracheal position versus 40.3% esophageal position, $p = 0.006$). The TTUS time was shorter when the diagnosis was a "success" ($p = 0.022$), visibility was good, and diagnostic certainty was high ($p <0.001$).

Three of the initial nine residents performed a second series of measurements of 32 scans, each on four different cadavers. The success rate was significantly increased (72.9%) compared to the first series (53.1%) ($p = 0.004$). The mean time required for the procedure was unchanged (20.6 sec vs 21.4 seconds, $p = 0.504$) (Tab. 3).

Tab. 2. *Techniques*

	Failure N = 154 (53.5%)			Success N = 134 (46.5%)			p**
	N	%/mean	SD*	N	%/mean	SD*	
Endotracheal tube position							0.006
trachea	67	43.5		80	59.7		
esophagus	87	56.5		54	40.3		
Cuff							1.000
air	77	50.0		67	50.0		
saline	77	50.0		67	50.0		
Time	154	21.6	7.4	134	19.5	7.8	0.022

* Standard deviation
** Cochran-Armitage trend test for qualitative variables, Kruskal Wallis test for quantitative variables

Tab. 3. *Comparison of 1ˢᵗ and 2ⁿᵈ series of measurements*

	1ˢᵗ series N = 96 (50.0%)			2ⁿᵈ series N = 96 (50.0%)			p**
	N	%/mean	SD*	N	%/mean	SD*	
Primary outcome							0.004
failure	45	46.9		26	27.1		
success	51	53.1		70	72.9		
Time	96	21.4	8.0	96	20.6	8.6	0.504

* Standard deviation
** Cochran-Armitage trend test for qualitative variables, Kruskal Wallis test for quantitative variables
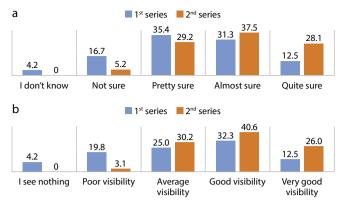
Fig. 2. *Comparison of diagnostic certainty (a) and visibility (b) between the 1st and 2nd series of measurements*

Tab. 4. *Sensitivity, specificity, VPP, VPN*

Reference	Test	Sensitivity	Specificity	VPP	VPN
Empirical	esophagus	38.5	66.7	89.6	12.6
Empirical	trachea	62.2	100	100	26.1

The improvement was significant for diagnostic certainty and visibility of the ETT between the two series (p <0.001) (Fig. 2).

Figure 3 presents an LC-CUSUM learning curve for the TA technique. The low number of TTUS and the randomization procedure do not enable us to draw conclusions. We can see that the technique seems to be learned after 15 trials, but more studies are needed to accurately calculate this number. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) were calculated for TTUS in the location of the ETT (Tab. 4).

Discussion

Confirming the correct ETT position is essential immediately after the patient's intubation. Many strategies for verifying the ETT position have been proposed[4]. Currently, capnography is the standard method: the sensitivity and specificity of which are 93% and 97%, respectively[19]. However, capnography is time-consuming (estimated at 48 seconds) and six insufflations are required to confirm the ETT position, with an increased risk of stomach distension and aspiration if the ETT is incorrectly placed[5,6].

US is a commonly used tool, and the use of TTUS to confirm the ETT placement seems to be an attractive option. First, US is portable, reproducible, relatively cheap, and widely available in the operating rooms, critical care areas, and even outside of the hospital. Second, TTUS can detect esophageal intubation even before ventilating the patient, which prevents expansion to the stomach and its associated complications. Third, the TTUS is a fast technique of confirming ETT position[13]. Multiple prior studies assessing the utility of TTUS to confirm the ETT placement have had variable success. Furthermore, most of these studies had small samples and followed different protocols: population studies (cadavers or living subjects), types of artifacts, dynamic or static method, transverse or longitudinal views, etc. The meta-analysis published by Chou *et al.* found TTUS to have an aggregate sensitivity of 93% (95% CI 0.86–0.96) and specificity of 97% (95% CI 0.95–0.98)[1]. Most of the participants in these studies were previously trained in TTUS. However, Hanlin *et al.* included participants who had no previous US training and performed the procedure using the static method after minimal education, recording the sensitivity and specificity of 66.7% (95% CI 38.6–87.0%) and 76.4% (95% CI 49.7–92.1%), respectively[20]. Ma *et al.* reported the sensitivity and specificity of static US at 51.4% (95% CI 34.0–68.6%) and 91.4% (95% CI 76.9–98.2%), respectively[21]. This methodological heterogeneity associated with small sample explains the lack of certainty as to the usefulness of the US technique for reliable location of the ETT.

Some studies have involved inflating the ETT cuff with fluid, with promising results[16–18]. The aim was to create a contrast between the fluid in the anechoic cuff and the hyperechoic artefacts formed by the air normally present in the trachea. However, a number of limitations
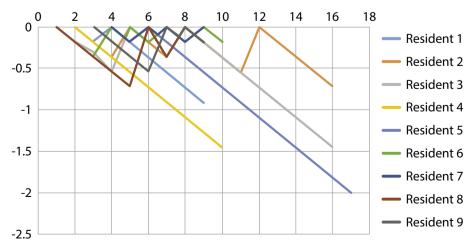

Fig. 3. *LC-CUSUM learning curve for the TA technique*

associated with these studies still need to be highlighted. Most of them were observational in design and had small sample sizes, so the statistical power might be inadequate. We performed one of the first studies comparing the suitability of TTUS to confirm the ETT position when the cuff is inflated with saline versus air, and the ETT in the trachea versus esophagus. In our study, we noted no significant differences between the cuff inflated with saline and the cuff inflated with air. The mean time to confirm the position of the ETT was 20.6 seconds (95% CI 13.0–28.2 seconds), which is consistent with the available data[22]. We observed moderate sensitivity, specificity, PPV and NPV for the confirmation of the correct positioning of the ETT. The sensitivity is reduced compared to the meta-analysis (93% versus 62.22% in our study) but similar to other studies. The success rate is higher when the ETT is placed in the trachea, which differs from the data reported in the literature.

The differences in results could be due to the population studied. However, we found that visualizing the anatomic structures of the airway with sonography was not difficult and was representative of the structures seen in living patients. Existing publications do not report a difference in echogenicity between living subjects and cadavers[23]. Other publications on TTUS performed on cadavers, such as Uya *et al.*, report excellent sensitivity (96% 95% CI 79–100%)[18].

In our study, the residents were novice to TTUS and had no prior training. Gottlieb *et al.* in their study compared experts versus novices and reported the superiority of experts with better sensitivity and shorter time (17 seconds versus 29 seconds for novices)[22]. Similar observations were reported by Stuntz *et al.*[24]. In the same way, our results report a significant improvement in the success rate during the second series of measurements. We used the static method even though it is considered less powerful in terms of data[21]. We chose the static method in order to simulate the real-life conditions and because no additional person is needed during the induction (unlike in the dynamic method). The static method allows an organization of the team in charge of airway protection with the possibility of reinforcement if a complication occurs. Furthermore, studies performed with the static method have produced excellent results[25,26]. Studies report that the ETT is better visualized in the esophagus resulting in the use of the indirect method[14]. TTUS confirmation of the ETT in the airway is categorized by applying either a "direct" or an "indirect" method. The direct method involves visualization of the ETT in the trachea (or lack of it). The indirect method refers to TTUS does attempt to visualize or not the ETT in the esophagus. Despite the data, we chose the direct method because it is possible to immediately conclude whether the intubation procedure has succeeded or failed. Unlike the indirect method which loss time if the esophagus is not visible. In fact, in more than 16% of cases,

the esophagus is behind the trachea and, therefore, not visible[14]. Finally, our results report better visibility of the ETT when it is in the trachea.

This study was limited by its application to cadavers. This introduces a potential bias as well as the risk that airway anatomy can become altered after repeated intubations. Another limitation was the learning curve. The LC-CUSUM curve relate the acquisition of the method but data collected in our study were insufficient to attain the H limit and to conclude on learning. Future studies are needed to assess the learning of the TTUS. The secondary outcomes were subjective and can introduce an evaluation bias. Nevertheless, the secondary outcomes were not compared with the literature, they report the difficulty experienced by the residents. This was a static study which may have adversely affect participant's ability to accurately determine the ETT location. Finally, it would have been interesting to record the US scans made by the participating residents in order to perform a review by experts. The strengths of our study include its methodological quality, and the large number of TTUS and cadavers studied by the residents with a similar level of expertise, which allowed to overcome multiple biases. Proficiency of the TTUS to confirm the position of the EET can be helpful for the specialties of anesthesia, in intensive care units and in emergency department in airway management. The US method is quick and safe (no insufflation), but not very efficient.

Conclusion

In this study, regardless of the contents of the ETT cuff, TTUS performed to confirm the position of ETT brought disappointing results. Further studies are needed to try to find a factor which would induce better sensitivity and specificity.

Conflict of interest

The authors have no conflicts of interest to declare that are relevant to the content of this article.

Ethics approval

The methodology for this study was approved by the Research Ethics committee of the University of Nancy (Ethics approval number: 239).

Consent to participate

Informed consent was obtained from all individual participants included in the study. The participants have consented to the submission of their data to the journal.

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