ARTICLE IN PRESS

Journal of Critical Care (2013) **xx**, xxx–xxx

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Journal of Critical Care

Novel device (AirWave) to assess endotracheal tube migration: A pilot study☆,☆☆

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Keywords:
AirWave;
Endotracheal tube;
Migration;
Obstruction

Abstract

Introduction: Little is known about endotracheal tube (ETT) migration during routine care among critically ill patients. AirWave is a novel device that uses sonar waves to measure ETT migration and obstructions in real time. The aim of the present study is to assess the accuracy of the AirWave to evaluate ETT migration. In addition, we determined the degree of variation in ETT position and tested whether more pronounced migration occurs in specific clinical scenarios.

Methods: After institutional review board approval, we included mechanically ventilated patients from February 2012 to May 2012. A chest radiography (CXR) was obtained at baseline and 24 hours when clinically indicated. The ETT distance at the lips was recorded at baseline and every 4 hours. The AirWave system continuously recorded ETT position changes from baseline, and luminal obstructions.

Results: A total of 42 patients (age: 61 [SD ± 13] years, men: 52%) were recruited. A total of 19 patients had measurements of ETT migration at 24 hours by the 3 methodologies used in this study. The mean (SD) of the ETT migration at 24 hours was +0.04 (1.2), -0.42 (0.7) and +0.34 (1.81) cm when measured by portable CXR, ETT distance at the teeth and AirWave device, respectively. Bland-Altman analysis of tube migration at 24 hours comparing the AirWave with CXR readings showed a bias of 0.1 cm with 95% limit of agreement of −3.8 and +4.3 cm. Comparison of tube migration at 24 hours determined by AirWave with ETT distance at the lips revealed a bias of −0.4 with 95% limit of agreement −3.7 to +3 cm, similar to the values observed between CXR and ETT distance at the lips (bias of −0.3 cm, 95% limit of agreement of −3.4 to +2.8 cm). Factors associated with ETT migration at 24 hours were ETT size and initial measurement from ETT tip to carina by portable CXR. AirWave detected in eight patients some degree of ETT obstruction (30% ± 9.6%) that resolved with prompt ETT catheter suction.

☆ Conflicts of interest: The authors have no significant conflicts of interest with any companies or organization whose products or services may be discussed in this article.

☆☆ Funding disclosure: SonarMed INC. provided the AirWave equipments and an unrestricted educational grant in support of this study to Gustavo Cumbo Nacheli (#111128-PIP). Dr Tonelli is supported by a CTSA KL2 Grant [# RR024990] from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH), and NIH Roadmap for Medical Research.

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http://dx.doi.org/10.1016/j.jcrc.2012.10.015

Conclusions: The AirWave may provide useful information regarding ETT migration and obstruction in real time.

1. Introduction

Various methods are used to ascertain endotracheal tube (ETT) placement [1] such as direct laryngoscopic visualization of proper endotracheal intubation, abdominal auscultation, esophageal detector devices, ultrasonography, end tidal carbon dioxide detection, transthoracic impedance, and chest radiography (CXR) [2-6]. Upon successful confirmation of proper ETT placement, routine intensive care unit monitoring of the airway is usually performed by frequently measuring the ETT distance at the lips and obtaining a CXR to ensure that the ETT is positioned appropriately at approximately 5 cm above the carina when the patient's head is in a neutral position [7]. Placement that is too high can lead to inadvertent extubation. On the contrary, an ETT tip positioning too close to the carina may cause irritation or selective intubation of a main bronchus [7].

Unanticipated ETT migrations may go unnoticed during the usual care of critically ill patients [8]. Continuous ETT monitoring may reduce unintentional extubations or selective bronchial intubations that may lead to adverse outcomes [9-11]. However, non-radiographic techniques used to confirm proper ETT positioning are not accurate and no system has proven useful in providing real time information on ETT migration [12,13]. Thus, in practice, CXR continues to be the modality of choice to confirm ETT position [14-16]; nevertheless this approach increases exposure to radiation and only provides static information. In addition to the added costs, the quality of the CXR can be highly variable due to variations in film exposure, magnification, and rotation artifacts [7,17,18].

The AirWave is a novel, portable device that uses acoustic reflectometry to monitor the position and patency of ETT. Audible sound waves are emitted from a speaker into the ETT, while microphones detect the returning acoustic reflections (or echoes). Based on proprietary algorithms, the echo signals are analyzed and real time data on ETT position and obstruction are provided.

We conducted a pilot study to assess the usefulness of AirWave to determine real time ETT migration and obstruction among critically ill patients and compare the information provided by the AirWave with CXR and ETT distance at lips methodologies. An additional objective was to determine factors associated with ETT displacement.

2. Methods

This single center, prospective, cross-sectional study was approved by the Cleveland Clinic Foundation Institutional Review Board (#11-1235). Informed consent was obtained from the patient, whenever possible, or from the durable power of attorney or next of kin when appropriate.

2.1. AirWave

AirWave (SonarMed, Inc, Indianapolis, IN) is an Food and Drug Administration–approved system for use in humans as an adjunct device to airway management [19]. The AirWave system consists of an AirWave adapter connected to the proximal end of an ETT (Fig. 1). This adapter is then connected to a portable, battery operated monitor. The AirWave adapter is available in 3 sizes (small/medium/large). Each size is to be used for specific ETT internal diameters: small for ETT sizes 6.5 to 7.0 mm, medium for 7.5 to 8.0 mm, large for 8.5 and 9.0 mm. The AirWave was adjusted to the patient's fraction of inspired oxygen requirements ($F\text{IO}_2$), to either $F\text{IO}_2$ 21–60 % or 61% to 100%. Prior to connection to the patient, the device was calibrated ex-vivo with an identical ETT. Then the AirWave adapter was placed in line with the breathing circuit and a baseline ETT position was established by the system. A system upgrade allowed us to determine and record ETT migration at every minute in 24 patients.

2.2. Study population

We recruited consecutive patients from our medical intensive care population. We collected demographic data, acuity scores (on intensive care unit [ICU] admission), endotracheal tube size, oxygen requirements, and reason for intubation.

Inclusion Criteria: subjects were eligible for the study if they met all of the following criteria: (1) age >18 years old; (2) oral endotracheal intubation within 24 hours of recruitment; (3) expected duration of mechanical ventilation >24 hours; (4) ETT internal diameter sizes from 6.5 to 9.0 mm.

Exclusion criteria: subjects were excluded from participation if (1) ventilated through a tracheostomy, (2) unable to obtain consent, or (3) pregnancy.

2.3. Procedure

The standard plastic adaptor which connected the ETT to the mechanical ventilator tubing system was replaced by the AirWave adapter. The AirWave adapter was then connected to a handheld computer which displayed information for the investigators. There were no direct interventions on the patient at initial set-up or during follow-up based on determinations provided by the AirWave system. Airway

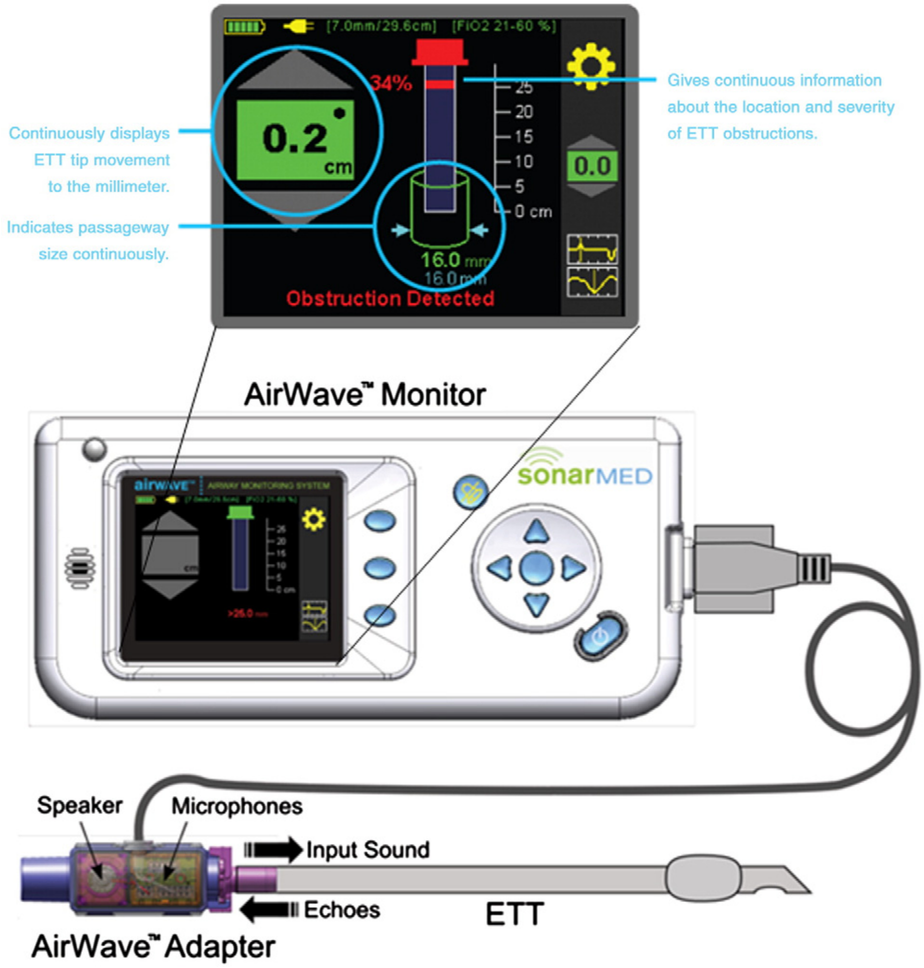

Fig. 1 The AirWave system consists of an adapter (speaker/microphone equipped), connected to the ETT, and to a hand held monitor. Reproduced with permission of SonarMed.

secretions were suctioned when needed per ICU protocol. To determine the accuracy of the device, we gathered information provided by the CXR (ETT-to-carina distance) and obtained readings on ETT distance at the lips. Negative values in the ETT migration at 24 hours meant that the ETT moved toward the vocal cords, while positive values denoted that the ETT moved toward the carina.

2.4. Chest radiography and ETT distance at the lips

An independent radiologist, blinded to the AirWave system data, measured the distance from the ETT tip to carina. These were obtained at time points 0 and 24 hours. CXR were obtained at discretion of the treating physician, consequently not all patients had CXR at 24 hours [20]. ETT distance at the lips was determined every 4 h by the respiratory therapies.

2.5. Statistical analysis

Results were expressed as mean ± SD. We compared ETT migration at 24 hours measured by the AirWave system, CXR and ETT distance at the lips by using Bland-Altman analysis. In this test, for each pair of variables the arithmetic mean of both methods (y-axis) is plotted against their difference (x-axis). Mean difference and upper and lower limits of agreement (±1.96 * SD) are reported. For each patient, we computed his/her averaged migration and the standard deviation of migrations. Then, the sample means and 95% confidence intervals for them (over all patients) are reported. Linear regression technique was used to assess the association of migration and different clinical predictors, and tests of significance of the predictors were conducted under the regression models. Statistical analysis was performed using the statistical software SAS 9.3 (SAS Institute Inc, Cary, NC, USA) and R 2.15.0 (R Development Core Team, http://www.r-project.org/).

3. Results

3.1. Demographic characteristics

During the study period, 42 patients were enrolled. Subjects had the AirWave system placed within 24 hours of endotracheal intubation. Need for endotracheal intubation and mechanical ventilation was largely due to septic shock (n = 12). Other frequent indications for intubation included inability to protect the airway (n = 7) and acute or chronic respiratory failure (n = 6). Demographic characteristics and other reasons for endotracheal intubation are shown in Table 1. Patients were intubated for 6.0 (±4) days and required an average F_{IO_2} of 0.48 (±0.16) (range, 0.3-1.0).

3.2. ETT migration at 24 hours

Migration at 24 hours as determined by (*a*) portable CXR (n = 28) was −0.06 (±1.3) cm with range of – 3.5 and + 3 cm, (*b*) ETT distance at the lips (n = 38) was −0.29 (±0.93) with a range of −2 to +3, and (*c*) the AirWave system (n = 27) was 0.39 (±1.5) with a range of −3 to +4 cm. Diverse reasons (Fig. 2) reduced the total number of patients in whom these three techniques can be compared.

A total of 19 patients had measurements of ETT migration at 24 hours by the three methodologies used in this study. The mean (SD) of the ETT migration at 24 hours was +0.04 (1.2), −0.42 (0.7) and +0.34 (1.81) cm when measured by portable CXR, ETT distance at the teeth and AirWave device, respectively. By Bland-Altman analysis the comparison of migration at 24 hours by the AirWave system and portable CXR (n = 19 pairs) showed a bias of 0.3 cm (95% limit of agreement: −3.8 to +4.3 cm). The comparison of migration at 24 hours by ETT distance at the lips and the AirWave system (n = 26 pairs) revealed a bias of −0.5 cm (95 % limit of agreement: −4.3 to +3.2 cm). The bias (95 % limit of agreement) between ETT distance at the lips and portable CXR (n = 28 pairs) was 0.3 cm (−2.8 to +3.4 cm). Linear regression showed no association between the ETT migration at 24 hours by portable CXR and the AirWave system (R = 0.1, β 0.64, SE: 0.16, P = .7). Similarly no association was observed between ETT distance at the lips and either the AirWave system or portable CXR (P = .6 and P = .46, respectively) (Fig. 3).

Fifteen patients had significant ETT migration (defined as a migration more than 2 cm) at 24 hours by the AirWave system. These patients had ETT movements during repositioning in bed by nursing staff (n = 12), traveling outside the ICU (n = 1), getting a portable CT of the head (n = 1), or bronchoscopy (n = 1).

Table 1 Patient characteristics

	n (%) or Mean ± SD
N	42
Gender	
Male	22 (52.4%)
Female	20 (47.6%)
Ethnicity	
White	33 (78.6%)
Black	8 (19.0%)
Hispanic	1 (2.4%)
Mean age (y)	61 ± 13
BMI (kg/m^2)	30.6 ± 9
Reason for intubation	
Sepsis	12 (28.6%)
Mental status changes	7 (16.6%)
Acute on chronic respiratory failure	6 (14.2%)
Pneumonia	5 (11.9%)
Procedures (EGD, TIPS)	5 (11.9%)
Seizures	2 (4.8%)
Cardiac arrest	2 (4.8%)
Decompensated heart failure	1 (2.4%)
Foreign body aspiration	1 (2.4%)
TRALI	1 (2.4%)
Oxygen requirements in first 24 h (F_{IO_2} %)	48 ± 16
ETT size (internal mm)	
8.0	17 (40.5%)
7.5	21 (50.0%)
7.0	4 (9.5%)
APACHE II score on ICU admission	17.8 (±6.2)

APACHE, Acute Physiology and Chronic Health Evaluation; EGD, esophagogastroduodenoscopy; F_{IO_2}, fraction of inspired oxygen; TIPS: transjugular intrahepatic portosystemic shunt; TRALI, transfusion related acute lung injury.

3.3. Factors related with ETT migration at 24 hours

In univariate analysis (Table 2), ETT size was related with the degree of migration at 24 hours as determined by the AirWave system (R = 0.38, P = .048). Baseline distance from ETT to carina at baseline was the only variable measured associated with ETT migration at 24 hours by portable CXR (R = 0.48, P = .009). Five patients had their endotracheal tubes repositioned by more than 2 cm (one patient had the ETT advanced 3 cm). These changes were detected by the use of the AirWave.

3.4. Continuous AirWave assessment of ETT migration

In 22 patients, ETT migration from baseline was recorded by the AirWave every minute. The median (interquartile range) recording time was 9.4 hours (interquartile range: 4.3–17.7 hours). The averaged ETT migrations of patients had a mean (95% confidence interval) of 0.2 cm (−0.06, +0.56 cm) and the standard deviations of patients' ETT migration had a mean (95% confidence interval) 0.66 cm (0.53, 0.79 cm). The mean ETT migration (β = .00003, SE = 0.0002, P = .9) as well as its standard deviation (β = 0.0001, SE = .0001, P = .29) did not vary overtime. Interestingly, patient weight was significantly associated with the standard deviation of the patients' ETT migration (β = 0.008, SE = .002, P = .002). Regression analysis of other potential predictors (age, sex, height, F_{IO_2}, ETT size, and days on mechanical ventilation) and the dependent variables (averaged ETT migration or standard deviation of ETT migration) were nonsignificant (data not shown).

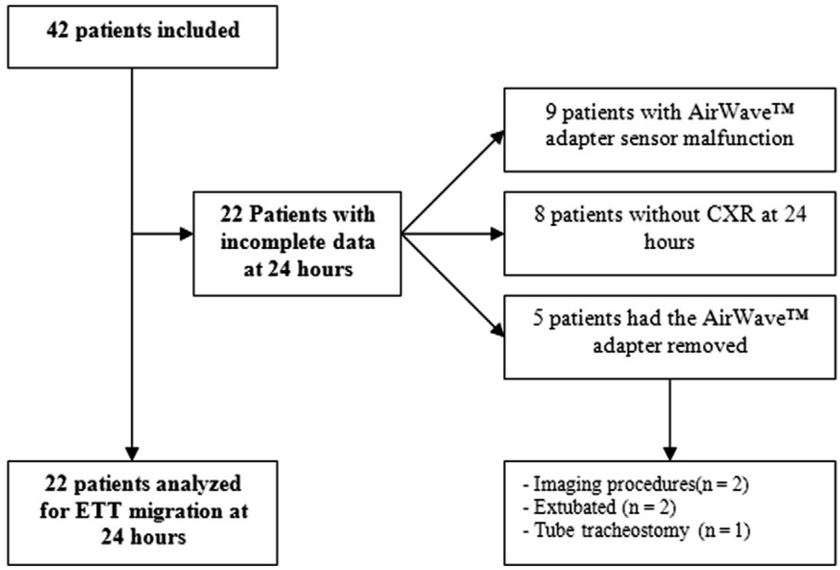

Fig. 2 Endotracheal tube migration at 24 hours.

3.5. ETT obstruction

Within the initial 24 hours, 8 patients experienced some degree of ETT luminal obstruction in the proximal one-third of the ETT as detected by the AirWave system (average obstruction 30 % [±9.6%]). In all these subjects, copious amounts of mucus secretions were removed, leading to resolution of the ETT obstruction.

3.6. Tracheal diameter

The AirWave displays the diameter of the passageway around the tip of the ETT (10 mm minimal diameter of the normal human trachea). Mainstem bronchial intubation would be indicated by diameters smaller than those expected for the normal human trachea. At baseline the diameter of the trachea (n = 42) by AirWave had a mean (SD) of 14.1 (1.3) mm, suggesting a tracheal location of the tip.

3.7. Complications associated with the use of AirWave

Throughout our study period, we observed that 9 of the sensors within of the AirWave adapter had malfunction during the first 24 hours. There were no adverse events associated with the use of the AirWave system. We did not observe disconnection from mechanical ventilation, ventilator circuitry malfunction, or oxygen desaturation events related to the device.

4. Discussion

The AirWave system proved to be a safe complementary method for the assessment of ETT migration and obstruction. This device appeared to be useful to detect ETT migration in real time however it had a wide limit of agreement when compared with CXR and ETT distance at the lips

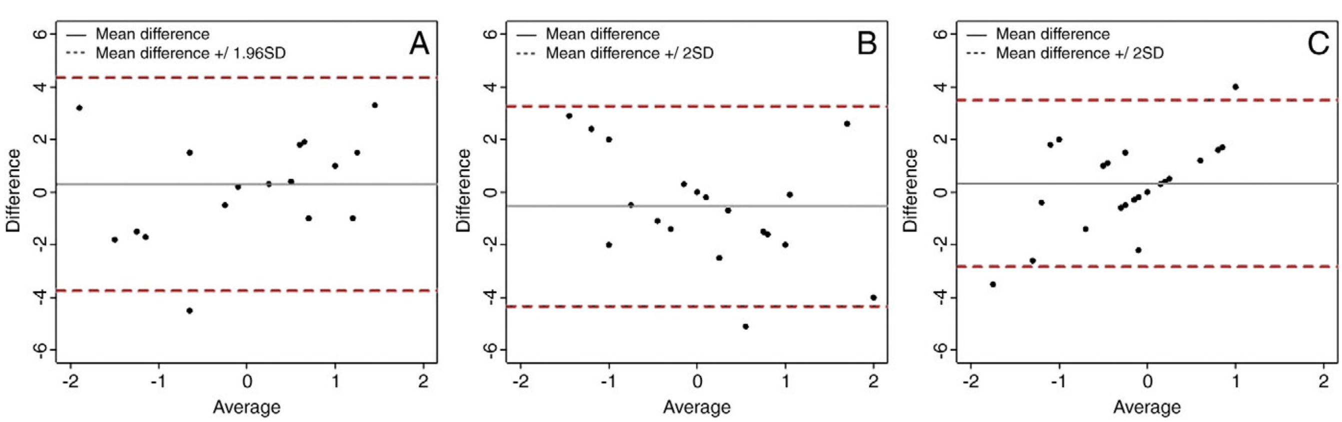

Fig. 3 Bland-Altman analysis of tube migration at 24 hours. A, Comparison between AirWave system and portable CXR. B, Comparison between ETT distance at the lips and AirWave system. C, ETT distance at the lips and portable CXR.

Table 2 Univariate analysis for prediction of 24 hours ETT migration by AirWave system or portable CXR

	AirWave system			Portable CXR		
	β	SE	*P*	β	SE	*P*
Age (y)	0.16	0.02	.46	−0.01	0.02	.6
Gender (male)	−0.39	0.6	.53	−0.33	0.51	.53
Race (black)	0.31	0.77	.69	0.03	0.65	.97
BMI (kg/m^2)	−0.01	0.038	.84	−0.03	0.03	.43
APACHE score	0.09	0.05	.06	0.05	0.04	.23
ETT size (mm)	1.87	0.9	.048	−0.26	0.91	.77
F_{IO_2} (%)	−0.01	0.02	.56	−0.02	0.01	.23
Baseline ETT distance at the lips (cm)	−0.17	0.14	.23	−0.06	0.13	.65
Baseline portable CXR distance to carina (cm)	−0.19	0.21	.36	0.41	0.14	.009
ETT obstruction at 24 h (yes)	0.97	0.64	.14	0.14	0.45	.77

measurements. Initial distance from the tip of the ETT to the carina, ETT size, and patient's weight were factors associated with ETT migration at 24 hours.

At the present time, there is no standard methodology for the real time assessment of ETT positioning. Contemporary practices in the intensive care unit regularly involve the use of three modalities for determining ETT position: CXR (which involves exposure of patients to ionizing radiation), ETT distance at the lips (an indirect and inaccurate method), and bronchoscopy (an invasive procedure) [1,21,22]. Bronchoscopy is probably the most accurate methodology; however it is expensive and not practical for serial measurements. Portable CXR suffers from difficulties related to patient positioning and source-to-image distance. These conditions can lead to significant variation in the measurements. Other less commonly used techniques involve the use of ultrasonography, thoracic impedance, and transilluminating devices. These three modalities are either not readily available in most centers or require special training.

In our study we observed that the bias between the methods was small but the limit of agreement was close to 4 cm in either direction. This held true for the comparison of the AirWave system with CXR or ETT distance at the lips. This is a similar variation when CXR was compared with ETT distance at the lips. It is not possible to determine from the data gathered in the present study whether the variations are due to imprecise determinations of the AirWave system or inaccuracies of the comparator, ie, CXR.

Endotracheal tube lumen obstruction or narrowing secondary to endoluminal secretions, tube kinking, or extrinsic compression (eg, patient biting) may go undetected for extended periods and/or result in adverse patient outcomes [10,23-25]. A promising feature of the AirWave system relies on real-time monitoring of ETT lumen patency. In addition to reporting the location and degree of obstructions within the ETT, the AirWave system also provides access to the airway sounds measured by the internal microphones by playing them over the hand-held computer's loudspeaker when selected. In 2 patients that had ETT obstructions detected by the AirWave, listening to the microphones prior to and after catheter suctioning of the ETT demonstrated marked improvement of breath sounds. To date, the most frequent method to assess such events is by monitoring the airway peak pressure in the mechanical ventilator and by scheduled ETT suctioning. Little is known whether frequent assessment of the peak airway pressure can reliably detect different degrees of ETT luminal obstruction. Frequent suctioning increases respiratory therapy support, and can lead to complications such as: airway trauma at the endobronchial mucosa, bleeding at suction sites, infection, hypoxemia, elevated intracranial pressure, cardiovascular instability, and atelectasis [26,27]. It is possible that use of the AirWave system may reduce ICU cost of care by reducing respiratory therapy time and potential complications.

Due to the AirWave system's need for a short period of relative quiet within the airway to acquire its acoustic measurements, the use of concurrent nebulized solutions through the ETT appeared to impair the monitoring capability of AirWave (system reported "excessive noise") during this treatment. This problem resolved soon after the nebulization treatment finished. In cases during normal ventilation when "excessive noise" was displayed in the hand-held computer, the use of an "inspiratory pause" resolved the issue by allowing a quiet period during which the AirWave could acquire measurements.

Up to 10% (3%-16%) of mechanically intubated patients may experience an unplanned extubation during their ICU stay [28]. Although there is variability with the ETT migration as measured by CXR, we believe that the AirWave may assist in the detection of critical ETT migration, potentially allowing early detection of selective endobronchial intubation or accidental extubations.

Factors associated with ETT migration at 24 hours included distance from the tip of the ETT to the carina and ETT size. The first association is probably the results of repositioning after reviewing the CXR after intubation. ETT close to the carina are withdrawn and those closer to the glottis are advanced. The second association is likely related to the fact that tubes of different size were placed at similar distance at the lips but needed different degrees of repositioning. We did not find an association between ETT migration by CXR or AirWave and age, sex, body mass index (BMI), F_{IO_2} on mechanical ventilation, Acute Physiology and Chronic Health Evaluation II score on ICU admission, partial ETT obstruction and baseline ETT distance at the lips.

Interestingly, we were able to measure and record ETT migration every minute using the AirWave device. We observed that the average tube migration during a median of 9 h of recording time is small, with a standard deviation less than 1 cm. This standard deviation was significantly associated with the patients' weight.

Limitations of our study include the inability to assess ETT migration at 24 hours in a number of patients because CXR were not routinely performed in all subjects, and the AirWave adapter sensor life was less than 24 hours among 9 patients. Our study protocol limited interference of routine medical ICU care, and therefore routine CXR were not mandated. The current practice in our medical ICU is to reduce radiation exposure, so CXR are not routinely performed at 24 hours or after endotracheal tube repositioning [14]. We hypothesize that patient with larger BMI may be more prone to ETT migration, although further studies are necessary to establish this relationship. A trend toward association was noted, although future studies among this population are encouraged to elucidate a possible "BMI effect" on ETT migration accurately. This device was not tested in patients requiring BILEVEL or high frequency oscillatory ventilation, as these alternative modes of mechanical ventilation were not required by any of our 42 consecutively recruited patients. We observed that the most frequent event resulting in malfunction of the AirWave adapter sensors was "ETT in-line catheter suctioning". Another limitation is that although AirWave system measurements were done at the same time of CXR, we cannot exclude some degree ETT displacement during the acquisition of CXR that may affect the comparison among techniques. In fact, Conrardy et al showed that with neck flexion and extension, the ETT can move as much as 3.1 and 5.2 cm from a neutral position, respectively [29]. In spite of these limitations our pilot study provides data on a novel technology designed to monitor ETT migration and luminal narrowing which are relevant ICU problems. Technological improvements are underway in order to improve sensor life and performance. Future research is warranted to assess whether AirWave provides similar information than repeated bronchoscopic measurements. Additionally, we envision further trials to ascertain AirWave usefulness to reduce rates of unplanned extubations, selective main bronchus intubation, in-line suctioning associated complications, and financial impact among mechanically ventilated patients.

5. Conclusion

The AirWave proved to be a safe and potentially promising alternative to aid in the diagnosis of ETT position and obstruction in real time.

Acknowledgment

We appreciate the invaluable help of Cleveland Clinic respiratory therapists in this project.

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