Resuscitation 105 (2016) 36–40

Contents lists available at ScienceDirect

Resuscitation

journal homepage: www.elsevier.com/locate/resuscitation

Clinical paper

Automatic detection of oesophageal intubation based on ventilation pressure waveforms shows high sensitivity and specificity in patients with pulmonary disease

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ARTICLE INFO

Article history:
Received 28 January 2016
Received in revised form 9 May 2016
Accepted 15 May 2016

Keywords:
Oesophageal intubation
Emergency intubation
Pulmonary compliance
Automatic detection algorithm

ABSTRACT

Background: Unrecognised endotracheal tube misplacement in emergency intubations has a reported incidence of up to 17%. Current detection methods have many limitations restricting their reliability and availability in these circumstances.

There is therefore a clinical need for a device that is small enough to be practical in emergency situations and that can detect oesophageal intubation within seconds. In a first reported evaluation, we demonstrated an algorithm based on pressure waveform analysis, able to determine tube location with high reliability in healthy patients.

The aim of this study was to validate the specificity of the algorithm in patients with abnormal pulmonary compliance, and to demonstrate the reliability of a newly developed small device that incorporates the technology.

Materials and methods: Intubated patients with mild to moderate lung injury, admitted to intensive care were included in the study. The device was connected to the endotracheal tube, and three test ventilations were performed in each patient. All diagnostic data were recorded on PC for subsequent specificity/sensitivity analysis.

Results and discussion: A total of 105 ventilations in 35 patients with lung injury were analysed. With the threshold *D*-value of 0.1, the system showed a 100% sensitivity and specificity to diagnose tube location.

Conclusion: The algorithm retained its specificity in patients with decreased pulmonary compliance. We also demonstrated the feasibility to integrate sensors and diagnostic hardware in a small, portable handheld device for convenient use in emergency situations.

Introduction

Unrecognised misplacement of the endotracheal tube (ETT) during endotracheal intubation and ventilation, has a reported incidence of 2.9–16.7% and is a frequent cause of morbidity and mortality in emergency intubations.[1–3] In optimal conditions, such as in the operation room during elective surgery, correct positioning of the tube is simple in most cases, and correct tube position can be ensured by using techniques aiming to improve tube placement (such as direct visualisation of the vocal cords) and by techniques to check the position of the tube after placement (such as observation of chest expansion, chest auscultation, capnography, spirometry or more advanced methods such as ultrasound[4] or flexible bronchoscopy). Each of these methods has limitations and is often less reliable or even impractical in the emergency setting, and requires significant training for proper interpretation. Capnography with interpretation of the characteristic CO_2 waveform and the $EtCO_2$ value is currently the most reliable method to assess

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http://dx.doi.org/10.1016/j.resuscitation.2016.05.010

tracheal intubation, with a very high sensitivity and specificity both approaching 100%, although the specificity drops to 70–88% in patients with cardiac arrest.[5] Moreover, during cardiopulmonary resuscitation many of these methods require interruption of chest compressions.[6,7] In airborne emergency teams, weight constraints form an additional limitation.

During endotracheal intubation in an acute setting up to 17% of endotracheal tubes (ETTs) are positioned in the oesophagus, despite the performed checks,[3,8] leading to a high risk of brain damage and eventually death. Chest auscultation is the most commonly used method to confirm ETT placement, but as mentioned it usually requires interruption of chest compressions during CPR.[6,7] While quantitative waveform capnography is recommended as the standard for confirming correct ETT placement,[9] well-known limitations of capnography in cardiac arrest victims exist however, as the capnography signal may be falsely low as a result of low cardiac output, low pulmonary flow, airway obstruction, or epinephrine use.[10,11]

Consequently, in order to decrease the incidence of unrecognised oesophageal intubation, there is a need for a diagnostic device that is reliable, very easy to interpret, ultra-portable, economic and preferably integrable in existing devices, providing automatic immediate diagnosis after intubation from the first ventilation onwards. In addition such a device should involve minimal interruption of CPR, be independent of cardiac output, and practical in demanding out-of-hospital circumstances and suboptimal working conditions.

As shown and quantified in our previous research, the distinct difference in compliance and elastance between the trachea/lungs versus the oesophagus/stomach can be exploited to determine misplacement of the ETT. In a first study on two cohorts of 20 healthy patients enrolled for elective surgery, this method could discriminate between oesophageal and tracheal intubation with 100% sensitivity and 100% specificity,[12] after just one ventilation.

In the first reported evaluation,[12] our algorithm was assessed using pressure waveforms collected from patients with American Society of Anesthesiology (ASA) physical status I or II. This implies that the study population had healthy lungs with a normal compliance.

Because of the lower compliance of the lungs in many pathological conditions, and considering the physiological principle on which the algorithm is based, we anticipated that the algorithm might misdiagnose tracheal for oesophageal intubation, and consequently have a lower specificity in a patient population with decreased pulmonary compliance. Therefore, the aim of the study was to validate the specificity of the algorithm in patients with abnormal pulmonary compliance, admitted to an intensive care unit (ICU).

A secondary aim was to demonstrate the reliability of a newly developed small device that incorporates the technology and algorithm mentioned above. The hand-held device can be connected to an ETT and has integrated pressure sensors and electronics, enabling real-time analysis of the pressure waveforms and immediate alerts in the case of malpositioning of the endotracheal tube. For this research setting, the pressure waveforms are also transmitted through a Bluetooth connection to a laptop for data analysis and display of the waveform.

Methods

Study design and setting

The Ethics Committee of the University Medical Centre Groningen approved the study and waived the requirement for informed consent. A convenience sample of patients in the intensive care unit was included. Inclusion criteria were controlled mechanical ventilation and at least mild to moderate lung injury with alveolar consolidation on chest radiography. To quantify the severity of the pulmonary disease, a Murray score was calculated for each patient.[13] The Murray score is calculated based on alveolar consolidation on chest radiography, PaO_2/FiO_2 ratio, Positive End-Expiratory Pressure (PEEP) and lung compliance (Table 1). Exclusion criteria were: colonisation with multi-resistant bacteria, possible adverse effects on the patient (the decision was left to the treating physician of the ICU), pregnancy and age <18 years.

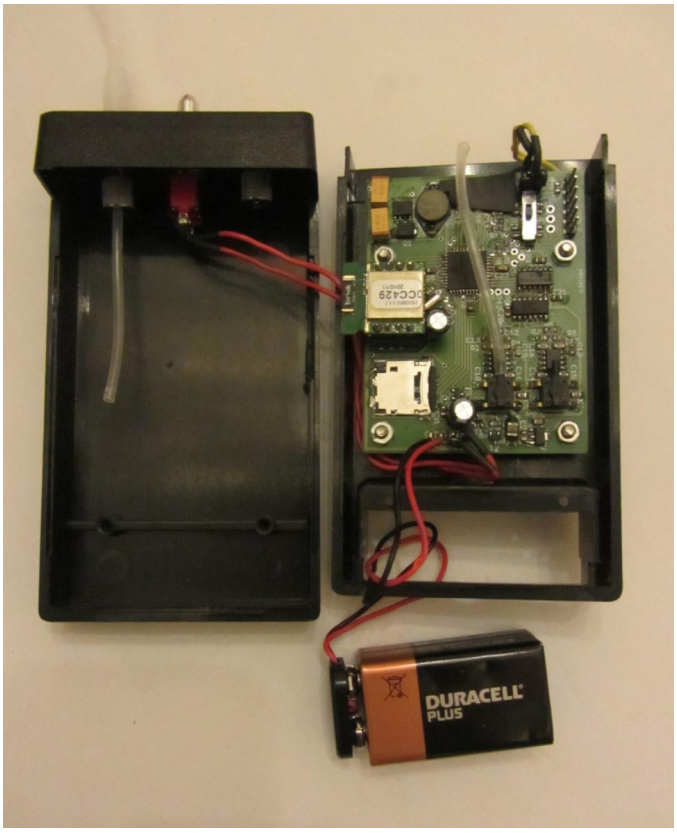

Fig. 1. Hand-held stand-alone diagnostic device.

Study protocol and data collection

In the current study, only tracheal pressure waveforms were recorded. To record the waveforms, a connecting piece was attached to the in-site tube, as described previously.[13] This connecting piece comprised one disposable thin air filled catheter (Vygon 71100.20 with an internal diameter of 1 mm) inserted through the tube lumen until 1 cm from the distal end, and a second catheter located at the proximal end of the tube. The catheters were connected with a luerlock to our custom-made battery-powered device containing two pressure transducers (Fig. 1). The device collected the pressure waveforms and determined tube location. Synchronously, the waveforms were sent to a laptop through a Bluetooth connection for subsequent real time and off-line data analysis.

After a patient was considered eligible for inclusion, haemodynamic stability and adequate oxygenation confirmed by pulse oximetry were assured before the measurement was performed. After assuring the patient had not been recruited for at least ten minutes, mechanical ventilation was stopped and the connecting piece was attached to the ETT and a self-inflating