

The Effectiveness of Out-of-Hospital Use of Continuous End-Tidal Carbon Dioxide Monitoring on the Rate of Unrecognized Misplaced Intubation Within a Regional Emergency Medical Services System

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Study objective: We evaluate the association between out-of-hospital use of continuous end-tidal carbon dioxide (ETCO₂) monitoring and unrecognized misplaced intubations within a regional emergency medical services (EMS) system.

Methods: This was a prospective, observational study, conducted during a 10-month period, on all patients arriving at a regional Level I trauma center emergency department who underwent out-of-hospital endotracheal intubation. The regional EMS system that serves the trauma service area is composed of multiple countywide systems containing numerous EMS agencies. Some of the EMS agencies had independently implemented continuous ETCO₂ monitoring before the start of the study. The main outcome measure was the unrecognized misplaced intubation rate with and without use of continuous ETCO₂ monitoring.

Results: Two hundred forty-eight patients received out-of-hospital airway management, of whom 153 received intubation. Of the 153 patients, 93 (61%) had continuous ETCO₂ monitoring, and 60 (39%) did not. Forty-nine (32%) were medical patients, 104 (68%) were trauma patients, and 51 (33%) were in cardiac arrest. The overall incidence of unrecognized misplaced intubations was 9%. The rate of unrecognized misplaced intubations in the group for whom continuous ETCO₂ monitoring was used was zero, and the rate in the group for whom continuous ETCO₂ monitoring was not used was 23.3% (95% confidence interval 13.4% to 36.0%).

Conclusion: No unrecognized misplaced intubations were found in patients for whom paramedics used continuous ETCO₂ monitoring. Failure to use continuous ETCO₂ monitoring was associated with a 23% unrecognized misplaced intubation rate. [Ann Emerg Med. 2005;45:497-503.]

0196-0644/\$-see front matter

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doi:10.1016/j.annemergmed.2004.09.014

INTRODUCTION

Background

Endotracheal intubation is considered standard of care in the United States for management of out-of-hospital respiratory failure. Emergency medical services (EMS) personnel in the United States perform this procedure routinely under difficult and uncontrolled conditions not encountered when endotracheal intubation is performed in a hospital setting. The most serious complication associated with endotracheal intubation in

the out-of-hospital setting is unrecognized misplaced intubation. Unrecognized misplaced intubation has been documented as an issue in EMS since 1984, with early studies showing a unrecognized misplaced intubation rate of 0.4% to 8%.¹⁻⁸ A previous study from 1997, conducted at the same regional Level I trauma center emergency department (ED) as our study, reported an unrecognized misplaced intubation incidence of 25%.⁹ Most recently, unrecognized misplaced intubation rates of 7% and 10% have been reported.¹⁰⁻¹² Although these

Editor's Capsule Summary

What is already known on this topic

Although endotracheal intubation by paramedics is widely used, failures in the procedure (during insertion or maintenance phases) are common and often unrecognized.

What question this study addressed

The authors introduced—but did not mandate—use of a continuous end-tidal carbon dioxide (ETCO₂) device after intubation. The frequency of device use and unrecognized endotracheal intubation failures noted on emergency department (ED) arrival were then recorded.

What this study adds to our knowledge

Of the 153 patients with a recorded intubation attempt, ETCO₂ monitoring was not used in 39% (60 patients). All of the unrecognized intubation misplacement events occurred in those cases where continuous ETCO₂ monitoring was not performed (14/60).

How this might change clinical practice

Continuous ETCO₂ measurement can be a part of out-of-hospital intubation quality improvement efforts, although its effect on outcome remains uncertain. Emergency medical services providers often fail to use such adjuncts despite known performance lapses.

Future research we'd like to see

Studies of isolated small segments of out-of-hospital airway management will never answer the question, "Should we be invasively managing airways in the field at all?" The next step should be a large randomized controlled trial that demonstrates that best practices endotracheal intubation in the field actually changes outcome (in cardiac arrest, the Ontario Prehospital Advanced Life Support [OPALS] study has shown it does not). Only then should we worry about what permutations of endotracheal intubation will provide this benefit most efficiently.

descriptive studies of out-of-hospital systems documented the rate of unrecognized misplaced intubation, none were designed to evaluate the association between a specific intervention and the rate of unrecognized misplaced intubation.

Importance

Identifying processes or interventions that could affect the rate of unrecognized misplaced intubation is a critical step toward eliminating this problem in EMS systems. End-tidal carbon dioxide (ETCO₂) monitoring has been recommended as a standard practice for reducing unrecognized misplaced

intubation in the out-of-hospital setting. ETCO₂ confirmation of tube placement and continuous monitoring of endotracheal tube position is an accepted standard of care by the American Society of Anesthesiologists¹³ and is recommended by the American Heart Association for secondary confirmation of endotracheal tube placement.¹⁴ As a result, use of ETCO₂ monitoring has gained acceptance in emergency medicine and EMS.

Goals of This Investigation

We studied the effectiveness of continuous ETCO₂ monitoring on the incidence of unrecognized misplaced intubation within a regional EMS system. We hypothesized that the use of continuous ETCO₂ monitoring would be associated with a lower rate of unrecognized misplaced intubation. Our primary outcome measure was the rate of unrecognized misplaced intubations.

MATERIALS AND METHODS

Study Design and Setting

A prospective observational study was conducted during a 10-month period (March to December 2002) on all patients arriving at a regional trauma center ED who underwent out-of-hospital endotracheal intubation. The study ED is a Level I trauma center, geographically located within a designated regional trauma service area. This ED treats pediatric and adult patients and receives patients from numerous EMS agencies operating within this multicounty regional EMS system. During the study period, there were 65,611 ED visits, with 21% arriving by EMS.

The study setting was a service area that is composed of an 11-county region. Operating within this 11-county regional system are approximately 50 advanced life support EMS agencies, 450 advanced life support units, and 2,500 paramedics. In addition, there are 10 helicopters from 9 air medical agencies that operate within this region. This regional EMS system serves a population of approximately 3 million people and provides single and 2-tiered responses. All patient transports are provided by advanced life support units. Each county operates its own independent EMS system, composed of a number of separate EMS agencies.

Each EMS agency is individually licensed by the state Department of Health, Bureau of EMS. The study ED receives patients from all the surrounding EMS agencies. Advanced life support vehicle equipment requirements are listed in the state Department of Health administrative code.¹⁵ These rules contain the minimum standard equipment requirements; however, local medical control may authorize the use of equipment that exceeds these minimum requirements. Capnography devices are not part of these minimum equipment requirements. EMS protocols are based on local, jurisdictional, medical control authority. Equipment and protocols are not standardized within the numerous EMS agencies, and there are no standardized statewide EMS protocols.

Table 1. Demographics.

Characteristic	With ETCO ₂ (n=93)	Without ETCO ₂ (n=60)	95% CI on Difference With Minus Without
Mean age, y±SD	41.4±26.4	46.2±26.6	-33.8 to 24.2
Male sex/total (%)	69/93 (74)	38/60 (63)	-4.5 to 26.3
Medical/trauma+medical (%)	25/93 (26.8)	24/60 (40)	-28.6 to 2.2
Cardiac arrest/total (%)	34/93 (37)	17/60 (28)	-7.3 to 23.0

Interventions

The key exposure in this study was the use of continuous ETCO₂ monitoring. Paramedics applied capnography after endotracheal intubation at their own discretion. Several agencies defined protocols requiring capnography use, but this requirement was not mandated for all EMS services in the study region.

This study was approved by the institutional review board representing the regional trauma center and surrounding EMS systems.

Selection of Participants

The study group included all patients transported from the multiple EMS systems to the trauma center ED who underwent out-of-hospital intubation. Patients pronounced dead in the out-of-hospital setting were excluded from the study. Patients who arrived with bag-valve-mask ventilation, cricothyrotomy, laryngeal mask airway, or Combitube (esophageal-tracheal twin-lumen airway device; Kendall-Sheridan Catheter Corporation, Argyle, NY) were also excluded. To confirm that no patients were missed, investigators verified all intubated patients with the respiratory therapy log daily. The respiratory therapy log captures all intubated patients.

On arrival in the ED, patients were immediately evaluated by a standardized process to determine the position of the endotracheal tube. Emergency physicians assessed endotracheal tube placement according to a standardized airway confirmation algorithm. A designated physician then completed a standardized form that included items such as verification of ETCO₂ monitoring by EMS personnel on arrival to the ED, verification of tube position, and method used to determine tube position. Each run report was also checked for documentation of the use of ETCO₂ in the field. The completeness of the forms was verified daily by a designated research nurse. If forms were incomplete, the research nurse contacted the responsible physician within 24 hours to ensure completeness. All information from the study questionnaires was then entered manually into an electronic database.

Primary Data Analysis

Unrecognized misplaced endotracheal intubation rates with and without use of out-of-hospital continuous ETCO₂ monitoring were compared using an exact statistical procedure (StatXact 5, Cytel Statistical Software, Cambridge, MA). This test uses the correct underlying binomial distribution, rather than a normal approximation, to calculate confidence intervals (CIs).

Exact 95% CIs for unrecognized misplaced intubation were calculated for the control (non-ETCO₂) and the treatment (ETCO₂) groups. We used exact CIs because of the limited sample size.

RESULTS

Characteristics of Study Subjects

During the study period, 248 patients who received airway management in the out-of-hospital setting arrived at the study ED. One hundred fifty-three patients arrived with an endotracheal tube in place and were eligible for the study. Ninety-five patients received other means of airway management and were excluded from the study (bag-valve-mask: 79, laryngeal mask airway: 8, Combitube: 6, cricothyrotomy: 2). Data from 153 consecutive patients who arrived with an endotracheal tube in place were analyzed (Table 1). One hundred seven (70%) patients were men, and the mean age was 43±26 years. Forty-nine (32%) were medical patients, and 104 (78%) were trauma patients. Fifty-one (33%) patients were in cardiac arrest on arrival to the ED. Of the 51 cardiac arrest patients, 28 were medical and 23 were trauma.

Main Results

Of the 153 patients who arrived with an endotracheal tube in place, continuous ETCO₂ monitoring was used after intubation for 93 (61%) patients, and for 60 (39%) patients, continuous ETCO₂ monitoring was not used after intubation. All unrecognized misplaced intubation occurred in the group for whom continuous ETCO₂ monitoring was not used after intubation. The odds of unrecognized misplaced intubation was higher in the non-ETCO₂ group (odds ratio 28.6; 95% CI 4.0 to 122.0). In the group in which continuous ETCO₂ monitoring was used, the unrecognized misplaced intubation rate was 0% (95% CI 0% to 4.0%).

Of the 14 patients with unrecognized misplaced intubation, 9 were trauma and 5 were medical. In 13 patients, placement was esophageal, and in 1 patient placement was hypopharyngeal (Figure). Five patients presented to the ED spontaneously breathing, and 9 patients were apneic. Two patients had initial colorimetric ETCO₂ confirmation on the scene but did not have continuous ETCO₂ monitoring en route to the hospital (Table 2).

Of the 13 esophageally intubated patients, 9 died, 2 were discharged severely neurologically impaired to a long-term care facility, and 2 were discharged neurologically intact (Table 2). There was 100% mortality for unrecognized misplaced

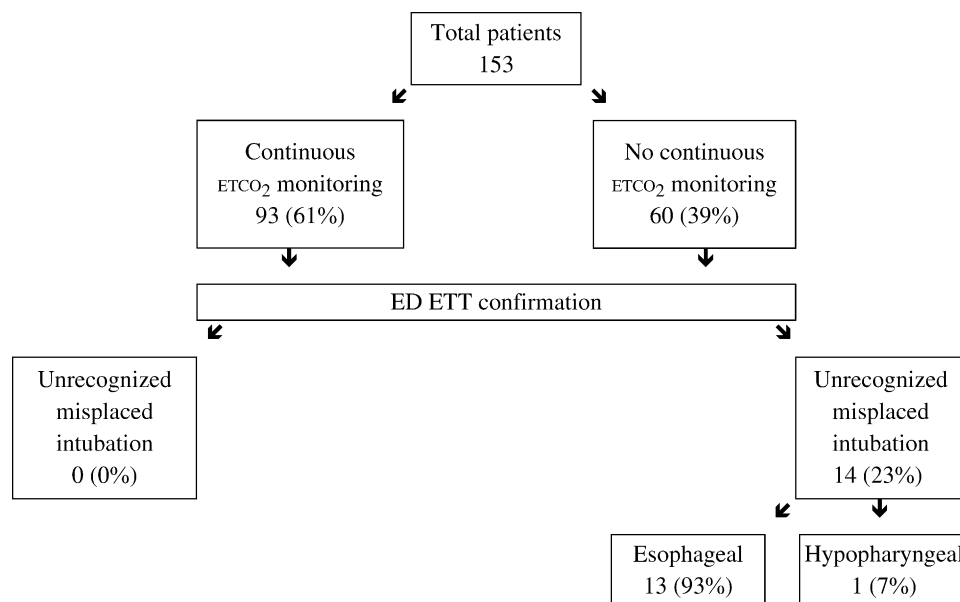


Figure. Out-of-hospital endotracheal tube placement and ETCO₂ use. ETT, Endotracheal tube.

intubation patients who presented to the ED apneic. All of the patients with unrecognized misplaced intubation who presented to the ED spontaneously breathing survived. However, spontaneous breathing on ED arrival did not predict final neurologic status. Of the 5 spontaneously breathing patients, 3 were medical and 2 were trauma patients. All 3 medical patients were discharged neurologically intact; 1 arrived at the ED spontaneously breathing around a nasally placed tube, 1 had an esophageal foreign body and was spontaneously breathing around a hypopharyngeal placed tube with an inflated cuff (the patient stabilized shortly after ED arrival and removal of the foreign body), and the third had chronic obstructive pulmonary disease and primary respiratory failure. Both trauma patients presented to the ED with a Glasgow Coma Scale score of 3 due to a multiple system trauma mechanism.

For the group for whom continuous ETCO₂ monitoring was used (n=93), 24 EMS agencies from 10 counties were involved in out-of-hospital airway management. For the group for whom continuous ETCO₂ monitoring was not used (n=60), 21 EMS agencies from 10 counties were involved. Because data collection did not include the individual paramedics involved in intubations, we were unable to determine the number of paramedics who intubated in each group. However, in reviewing the unrecognized misplaced intubation patients (n=14), we were able to determine that 14 paramedics from 7 EMS agencies performed the intubations.

LIMITATIONS

The limitations of our study include lack of randomization, not controlling for confounding variables, and paramedic self-reporting. The lack of randomization affects the ability to determine the independent effect of continuous ETCO₂ monitoring on misplaced intubations. However, given standards

used for capnography in the operating room and American Heart Association Guidelines 2000, we thought that withholding ETCO₂ monitoring from one group in a truly randomized design would present significant ethical concerns.

Because study investigators were not present in the field and patients were enrolled on ED arrival, we were unable to determine the recognized misplaced intubation rate or the specific factors resulting in unrecognized misplaced intubation in the field. There are numerous confounding variables that we did not control for in the study design, including patient-specific factors (eg, anatomic variations, difficulty of the case, patient movement) and paramedic-specific factors (eg, paramedic skill level, competency, judgment, experience, protocol compliance). We were therefore unable to determine whether frequency of intubation experience and the amount of training leads to a lower unrecognized misplaced intubation rate, whether patient population affected unrecognized misplaced intubation rate (systems with higher unrecognized misplaced intubation rates having the more difficult patients to intubate), whether procedures for stabilizing endotracheal tubes affected the unrecognized misplaced intubation rate (systems with lower unrecognized misplaced intubation rate had more effective procedures for securing endotracheal tubes during transport that resulted in less patient movement during transport), and the effect of ETCO₂ experience or training (systems with low unrecognized misplaced intubation rates had more field experience with the use of ETCO₂ monitoring).

We included data from a heterogeneous group of EMS services. Our data represent a diverse sample drawn from a 10-county region and more than 20 EMS agencies. It is possible that the EMS providers working for agencies that use protocols requiring continuous ETCO₂ monitoring received more airway management training and functioned with a heightened

Table 2. Characteristics of patients with unrecognized misplaced endotracheal tubes.

Patient Age, y	Sex	Medical/Trauma	Out-of-Hospital ETCO ₂ Usage	Breathing Status	ETT Position	Outcome
70	F	M	–	S	H	D/C-NInt
61	M	M	–	S	E	D/C-NInt
ND	M	T	–	–	E	EXP
24	M	T	–	–	E	EXP
1	F	M	–	–	E	EXP
15	M	T	–*	S	E	D/C-NIm
46	F	M	–	–	E	EXP
72	F	M	–	S	E	D/C-NInt
35	M	T	–	–	E	EXP
30	M	T	–	S	E	D/C-NIm
36	M	T	–*	–	E	EXP
ND	F	T	–	–	E	EXP
ND	M	T	–	–	E	EXP
63	M	T	–	–	E	EXP

D/C-NIm, Discharged to a long-term care facility, neurologically impaired; D/C-NInt, discharged home, neurologically intact; E, esophageal; EXP, died; F, female; H, hypopharyngeal; M, male; ND, not documented; S, spontaneous respirations on arrival to the ED; –, not present.

*Patients had initial colorimetric ETCO₂ confirmation on the scene but did not have continuous ETCO₂ monitoring en route to the hospital.

awareness of endotracheal tube misplacement. Although some agencies may have had protocols that limited the number of endotracheal intubation attempts, others may have had unlimited attempts. Some of the agencies had alternative airway devices, whereas some did not. In addition, we could not control for the equipment that was carried by each of the EMS agencies. Some of the agencies carried capnography equipment, whereas others carried only colorimetric devices.

Finally, there is the limitation of self-reporting by paramedics on the use of out-of-hospital continuous ETCO₂ monitoring. Although we were able to prospectively evaluate which patients arrived at the ED with ETCO₂ monitoring in place (ED investigators recorded whether ETCO₂ monitoring was in place on arrival at the ED), we relied on self-reported paramedic data about continuous ETCO₂ monitoring before ED arrival.

DISCUSSION

Endotracheal intubation is an established standard of care for the management of respiratory failure in the out-of-hospital setting. Determining the safety and efficacy of this procedure has been problematic in EMS because of the lack of a consistent and objective database that eliminates the errors of EMS provider self-reporting. Studies performed using physician confirmation of endotracheal tube position on ED arrival have reported high rates of unrecognized misplaced intubations (7% to 25%).⁹⁻¹² These findings have raised awareness of unrecognized misplaced intubation as a significant issue in EMS airway intervention.¹⁴ Although these studies document the unrecognized misplaced intubation rate, none were designed to evaluate the association between specific interventions and the rate of unrecognized misplaced intubation.

Although early out-of-hospital studies (1984 to 2001) reported unrecognized misplaced intubation rates, their methodology did not include determination of the incidence of unrecognized misplaced intubation as a primary outcome

measure.¹⁻⁸ Several of these investigators used a physician confirmatory process, but this process was not applied to determine the incidence of unrecognized misplaced intubation, which may account for the initial low rates of unrecognized misplaced intubation reported compared with later studies examining unrecognized misplaced intubation rate as the primary outcome measure. Therefore, these studies reported unrecognized misplaced intubation as an incidental finding, with rates ranging from 0.4% to 5%. Katz and Falk⁹ were the first to combine determination of the incidence of unrecognized misplaced intubation rate in an out-of-hospital system as a primary outcome measure with a standardized, emergency physician confirmation process for all out-of-hospital-placed endotracheal tubes and reported a significantly higher unrecognized misplaced intubation rate (25%) than previous studies. Recent studies, from 2003, using a similar methodology also reported higher unrecognized misplaced intubation rates (7% and 10%, respectively).^{11,12}

We studied the relationship between out-of-hospital use of continuous ETCO₂ monitoring for endotracheal intubation on the rate of unrecognized misplaced intubation and found a positive association. The unrecognized misplaced intubation rate in the group for whom continuous ETCO₂ monitoring was used was 0%, whereas the rate in the group for whom continuous ETCO₂ monitoring was not used was 23%. Although we suspect that this is due to the device itself, it may also be due to indirect effects on airway management practices. We acknowledge that causality can be demonstrated only by a randomized trial. However, the observed unrecognized misplaced intubation risk difference is compelling. This study demonstrates that it is possible to attain a zero unrecognized misplaced intubation rate. Future efforts must identify the factors that may confound this observed effect and verify whether there is a direct causal relationship between unrecognized misplaced intubation and ETCO₂ use.

The anesthesia field observed a similar decrease in unrecognized misplaced intubation when ETCO_2 was instituted as standard practice. The anesthesia community has accepted continuous ETCO_2 monitoring as a standard of care for the management of all general anesthesia care (intubated and nonintubated patients, inside and outside the operating room).¹³ This standard arose primarily from the concern for the unacceptably high rate of unrecognized misplaced intubation in the operating room. This standard was adopted independent of skill level or experience. Before the adoption of this standard, unrecognized misplaced intubation was an area of frequent medical malpractice claims.¹⁶⁻¹⁹

Historically, EMS providers have relied on the clinical subjective evaluation of tube position. Relying solely on clinical signs for verification of endotracheal tube position has subsequently been shown to be unreliable and inaccurate.²⁰⁻²⁴ The current guidelines, adopted by the American Heart Association in 2000, state that "emergency responders must confirm tracheal tube position by using nonphysical examination techniques. These include esophageal detector devices, qualitative end-tidal CO_2 indicators, and capnographic and capnometric devices."¹⁴ Additionally, the American College of Emergency Physicians in 2001 recommended that clinical evaluation of tube placement be performed in conjunction with secondary confirmation by carbon dioxide monitoring (capnography, capnometry, or colorimetric detector device), esophageal detector devices, or revisualization with direct laryngoscopy.²⁵ Moreover, other nationally recognized authors have further advocated the need for secondary device confirmation of tracheal tube placement.²⁶⁻³⁰

In summary, we studied the relationship between the use of continuous ETCO_2 monitoring and the unrecognized misplaced intubation rate in a regional EMS system. No unrecognized misplaced endotracheal tubes were observed in patients for whom paramedics used continuous ETCO_2 monitoring. Failure to use continuous ETCO_2 monitoring was associated with a 23% unrecognized misplaced intubation rate.

Author contributions: SS, GAR, and JT conceived the study and designed the trial. SS, GAR, JT, and JF developed the study protocol and data collection forms. SS, GAR, EC, and JF supervised the conduct of the trial and data collection. EC and AS ensured completeness of patient enrollment data forms. AS established and managed the database, including quality control. BK and SGR provided statistical consultation on the data analysis. SS and GAR chaired the data oversight committee. SS, GAR, and BK drafted the manuscript, and all authors contributed substantially to its revision. SS takes responsibility for the paper as a whole.

Funding and support: Dr. Krauss is a consultant for Oridion Medical, a capnography manufacturer.

Publication dates: Received for publication February 6, 2004. Revisions received June 8, 2004, and September 15, 2004. Accepted for publication September 16, 2004. Available online February 3, 2005.

Presented at the Society for Academic Emergency Medicine annual meeting, Boston, MA, May 2003.

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IMAGES IN EMERGENCY MEDICINE

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DIAGNOSIS:

Le Fort II fracture. The 3-dimensional reconstruction computed tomographic scan (Figure 2) showed a Le Fort II fracture, fracture on both sides through the orbital floor (Figure 2, arrow 2), and also through the bridge of the nasal bone (Figure 2, arrow 1). The separated part is triangular or pyramidal in shape, with mobility of the nose. There was also a fracture line on both sides through the maxilla into the nasal cavity, but the nasal septum was intact.

A Le Fort I fracture consists of a horizontal fracture of the alveolar process of the maxilla, through the nasal septum. A Le Fort III fracture consists of a horizontal fracture through the orbits with complete separation of the maxilla from the craniofacial skeleton.

In comparison to recent pictures of the patient, there was minimal dislocation of the fracture. An external fixture was not placed because of a very poor dental state, and the fracture was treated without any surgery.