The Self-inflating Bulb to Detect Esophageal Intubation during Emergency Airway Management

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Background: The negative-pressure test using a self-inflating bulb (SIB) during emergency intubation was studied to determine its reliability and predictive value in this setting.

Methods: The endotracheal tube (ETT) position was tested in 300 consecutive patients undergoing in-hospital emergency endotracheal intubation. Immediately after intubation and before ETT cuff inflation, the following protocol was strictly followed: (1) an SIB was compressed, connected to the ETT, and released. A 10-s period was allowed for the bulb to inflate; (2) the ETT cuff was inflated, and the ETT position was confirmed using colorimetric or infrared carbon dioxide detection, or both, combined with clinical evaluation.

Results: There were 19 esophageal intubations (6% incidence). The SIB correctly identified all patients with esophageal intubation (sensitivity, 100%) and correctly identified all but three ETTs placed in the trachea (specificity, 99%). The three tracheally placed tubes that were misidentified by the bulb syringe occurred during one case each of chronic obstructive pulmonary disease, copious secretions, and obesity; of note were three tracheally placed tubes that were misidentified by the carbon dioxide analyzers during cardiopulmonary resuscitation.

Conclusions: The SIB proved to be a sensitive and specific test for esophageal intubation in the emergency setting when used according to the protocol described, and it is complementary to carbon dioxide detection. The predictive value of the bulb syringe appears to be improved when a prolonged period for reinflation is allowed. It holds particular promise because of its low cost and portability. (Key words: Negative-pressure test; intubation; tracheal esophageal detector device.)

UNRECOGNIZED esophageal intubation can lead to progressive hypoxia, cardiac arrest, neurologic injury, and death. Unfortunately, clinical signs are insufficiently sensitive to detect esophageal intubation, and thus other techniques to confirm correct placement of an endotracheal tube (ETT) are necessary. Because detection of expired carbon dioxide using capnometry or capnography has proved highly reliable for confirming ETT position, this technique has evolved as the 'gold standard' in the operating room. In the emergency setting involving out-of-hospital, emergency department, and intensive care unit intubations, however, where esophageal intubation is perhaps more likely to occur, capnometry is not always available. Portable alternatives to capnometry include colorimetric end-tidal carbon dioxide detection and the negative-pressure test using a syringe or a self-inflating bulb (SIB). Although these methods have been reported sensitive and specific for elective procedures done in the operating room, fewer data are available comparing their use in the emergency or intensive care setting. We studied the SIB during emergency intubations to test its efficacy outside of the operating room.

Methods

With approval from our institutional review board, we prospectively enrolled 300 consecutive patients (219 male, 81 female; mean age, 49.7 yr) who were undergoing emergency endotracheal intubation at Harborview Medical Center between September 1, 1995 and March 31, 1996. All intubations were performed in the intensive care units (56%), the emergency trauma center (35%), or elsewhere (9%) by an anesthesiology attending physician or a resident. Most intubations were performed using direct laryngoscopy after administration of a hypnotic agent and a muscle relaxant, with

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cricoid pressure applied until correct placement of the ETT was verified. Immediately after intubation and before ETT cuff inflation, the following sequence was strictly followed by the respiratory care practitioner who was assisting with the intubation: (1) an SIB (TubeChek B; Ambu, Inc., Linthicum, MD) was compressed, connected to the ETT, and released. A 10-s period was allowed for the bulb to reinflate. (2) The ETT cuff was inflated. (3) An infrared carbon dioxide analyzer (StatCap; Nellcor, Pleasanton, CA) was connected to the ETT, and five manual breaths were delivered via a resuscitator bag. Esophageal intubation was diagnosed if there was no detection of carbon dioxide at the fifth manual breath, in conjunction with a consistent clinical examination. Repeated laryngoscopy with direct visualization of the ETT was performed if the tube position was in question. Immediate reintubation was performed when esophageal intubation was diagnosed. (4) If esophageal intubation was ruled out by the previous techniques and the patient’s arterial saturation remained >85%, a colorimetric carbon dioxide detector (Easy-Cap; Nellcor) was placed between the ETT and resuscitation bag and the presence of a color change was sought after the administration of five manual breaths. If a discrepancy arose between the infrared and colorimetric detector, the infrared was assumed to be correct.

Data sheets were provided in each intubation tray and were completed by the respiratory care practitioner who assisted in the intubation. Data collected included the patient’s age, sex, diagnosis, indication for intubation, number of intubation attempts, and route of intubation (nasal, oral, or tracheostomy). The results from the SIB, the carbon dioxide detectors, and the clinical examination were recorded along with the final decision regarding correct placement of the ETT and the need, if any, for reintubation. The final data analysis included only those patients in whom the SIB and carbon dioxide detection were used.

Because the test is designed to detect esophageal intubation, we defined failure of the SIB to reinflate within 10 s as a positive result. False-positive results were thus defined as those in which the test indicated esophageal intubation when the ETT was confirmed to be in the trachea by other means, and false-negative results occurred when the test indicated tracheal intubation when the ETT was in fact in the esophagus. Standard formulas were used to calculate the sensitivity (true positives/[true positives + false negatives]), specificity (true negatives/[true negatives + false positives]), positive predictive value (true positives/[false positives + true positives]), and the negative predictive value (true negatives/[false negatives + true negatives]). The “rule of three” was used to estimate the sensitivity limits of our data. Based on the binomial distribution, the “rule of three” states that if none of n patients shows the event in question, we can say with 95% confidence that the chance of this event is at most 3/n. For our data, n is the number of esophageal intubations, and the event in question is a false-negative result with the SIB.

Results

Three hundred consecutive patients underwent 321 attempts at emergent tracheal intubation. Table I shows the indications for intubation, which included acute respiratory failure (145 [48%]) and airway protection or the need to facilitate pulmonary hygiene (123 [41%]). The remaining patients were intubated for various emergency diagnostic procedures or during cardiopulmonary resuscitation. Forty-two patients (14%) had known obstructive lung disease (chronic obstructive pulmonary disease or asthma); 31 (10%) had acute pulmonary edema, and 104 (35%) had copious pulmonary

Table 1. Summary Demographic Data

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>47 ± 19.86</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>219 (73%)</td>
</tr>
<tr>
<td>Female</td>
<td>81 (27%)</td>
</tr>
<tr>
<td>Indications for intubation</td>
<td></td>
</tr>
<tr>
<td>Acute respiratory failure</td>
<td>145 (48%)</td>
</tr>
<tr>
<td>COPD or asthma</td>
<td>42 (14%)</td>
</tr>
<tr>
<td>Acute pulmonary edema</td>
<td>31 (10%)</td>
</tr>
<tr>
<td>ARDS</td>
<td>9 (3%)</td>
</tr>
<tr>
<td>Other</td>
<td>63 (21%)</td>
</tr>
<tr>
<td>Airway protection</td>
<td>123 (41%)</td>
</tr>
<tr>
<td>Procedures</td>
<td>29 (11%)</td>
</tr>
<tr>
<td>CPR</td>
<td>3 (1%)</td>
</tr>
<tr>
<td>Route of intubation</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>285 (95%)</td>
</tr>
<tr>
<td>Nasal</td>
<td>13 (4%)</td>
</tr>
<tr>
<td>Tracheostomy</td>
<td>2 (0.1%)</td>
</tr>
<tr>
<td>Difficult intubations</td>
<td>10 (3%)</td>
</tr>
<tr>
<td>Failed intubations</td>
<td>2 (1%)</td>
</tr>
<tr>
<td>Esophageal intubations</td>
<td>19 (6%)</td>
</tr>
</tbody>
</table>

COPD = chronic obstructive pulmonary disease; ARDS = acute respiratory distress syndrome.

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Table 2. Predictive Value of the Self-inflating Bulb in Detection of Esophageal Intubation

<table>
<thead>
<tr>
<th>Variable</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Esophageal intubations</td>
<td>19</td>
</tr>
<tr>
<td>False negative results* (sensitivity)</td>
<td>0 (100%)</td>
</tr>
<tr>
<td>Tracheal intubations</td>
<td>297</td>
</tr>
<tr>
<td>False positive results† (specificity)</td>
<td>3 (99%)</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>0.86</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>1.0</td>
</tr>
</tbody>
</table>

* Bulb reinfates with tube in esophagus.
† Bulb fails to reinflate with tube in trachea.

secrections. Nine patients (3%) met criteria for the adult respiratory distress syndrome at the time of intubation.14

Three hundred sixteen tubes were available for testing. The SIB was not available for use during three intubation attempts because of misplacement of the device, but it was used during all other intubations. Surgical airways were required for failed intubation in two patients (0.6% incidence). During five intubation attempts, a tube was neither placed nor tested. There were 19 confirmed esophageal intubations (6% incidence). Difficult intubation, defined as three or more attempts at laryngoscopy, occurred in 10 patients (5% incidence).

Table 2 shows the predictive value of the SIB to detect esophageal intubation. The device was 100% sensitive in detecting esophageal intubation, with confidence limits defined by the “rule of three” between 84 - 100%. The specificity of the SIB in confirming correct ET position also was high (99%), and its positive predictive value was 0.86. The three false-positive results obtained with the SIB occurred during one case each of chronic obstructive pulmonary disease, copious secretions, and obesity (defined by body habitus and weight > 110 kg). Of note, there were three “false-positive” test results with both carbon dioxide analyzers, which occurred during cardiopulmonary resuscitation. The SIB reinfated quickly in all these cases.

Discussion

Esophageal intubation occurs relatively frequently in the emergency setting, with incidences ranging from 1 - 20%.7,15,16 This complication is of particular importance if it is unrecognized. Because of the inaccuracy of clinical signs to detect esophageal intubation, capnography and capnometry have been adopted as the standard of care in the operating room.12,17,18 Capnography and capnometry are not widely available outside the operating theater, however, and alternative techniques have been developed for the emergency setting.

We studied the reliability and predictive value of a relatively new technique for confirming ET position during emergency intubation. We found that the negative-pressure test using an SIB is sensitive and specific for detecting esophageal tube placement in the emergency setting when the device is used as described in this study.

Ours is the largest series of emergency intubations to be evaluated with the negative-pressure test and contains the largest number of unintentional esophageal intubations. Previous series of emergency intubations that reported 100% sensitivity in detecting esophageal intubation using the negative-pressure test are of limited value in determining the utility of the test because only one19 and two20 esophageal intubations occurred during the study periods. The power of our study and others that have evaluated the negative-pressure test in the emergency setting remains limited by the infrequency of esophageal intubation19 - 21; based on our correct identification of all 19 esophageal intubations, the 95% confidence limits for the sensitivity of the SIB in detecting esophageal intubation are 84 - 100%. A considerably larger trial is required to determine a more precise mathematical sensitivity.

The SIB had a high specificity (99%) when the intratracheal position of the tube was present but gave misleading results (i.e., did not inflate) in three patients: one each with chronic obstructive pulmonary disease, copious secretions, and obesity. These circumstances were all reported previously to cause false-positive results using this technique.21 - 23 As noted before, the carbon dioxide detection devices gave misleading results (no carbon dioxide detected) in two patients undergoing cardiopulmonary resuscitation, a finding that has also been widely reported.19,21 The complementary nature of the negative-pressure test and carbon dioxide detection is illustrated by the observation that in all instances in which one technique was misleading, the alternative technique correctly identified the intratracheal position of the ET.

We developed a rigid protocol for this study that precluded randomization of the SIB with carbon dioxide detection. As has been suggested before, we believe that the negative-pressure test should be performed before initiation of manual ventilation to avoid inadvertent introduction of gas into the esophagus and stomach.
which may in turn lead to bulb reinflation and a false-negative test. Although Salem et al. suggested that the delivery of three small breaths through a tube placed in the esophagus did not affect the reliability of the SIB, a case of unrecognized esophageal intubation associated with a contradictory negative-pressure test performed after vigorous attempts at ventilation at our institution suggested that esophageal and gastric insufflation might lead to false-negative results with the SIB. We also compressed the SIB before connecting it to the ETT to avoid introduction of air into the esophagus, as described by Salem et al. Although compression of the bulb after connection to the ETT increases the specificity of the test in morbidly obese persons, this benefit occurs at a potential cost of decreased sensitivity. We performed the negative-pressure test with the ETT cuff deflated to allow entrainment of air from the upper airway passages when the tube is in the trachea and to prevent stenting of the tip of the ETT away from the wall of the esophagus with a possible false-negative result in the opposite situation. A previous report suggests that cuff deflation does not affect the sensitivity or specificity of the SIB. It is important to recognize that esophageal disease may affect the sensitivity of the SIB, although there are no reports in the literature that directly address this issue. We did not survey for the presence of esophageal disease in our patients.

We allowed 10s for bulb reinflation to occur and counted all reinflations within that time period as negative test results. We believe that this step is important to reduce false-positive results (absent or delayed reinflation of the SIB despite intratracheal position of the tube). In contrast to the findings of Czinn et al., who used a 4-s reinflation period and reported a test specificity of 86%, we found the SIB to be 99% specific. In most of our cases, the SIB reinflated immediately, and no adverse consequences were reported in those instances of delayed reinflation.

In concurrence with the opinion of Salem et al., we elected to use the SIB rather than the syringe aspiration technique described by Wee because of the former device’s simplicity and decreased interuser variability. A difference in efficacy between different negative-pressure tests has not been shown, however.

Portability, availability, ease of use, and cost are important considerations for acceptance of devices designed to detect esophageal intubation in the emergency setting. The SIB is portable and takes little space to store, is simple to use, has an unlimited shelf life, and can be used in areas of low light. The SIB also is relatively inexpensive, with the commercial device priced approximately $10.00 less than the colorimetric carbon dioxide detector.

In conclusion, we found that the negative-pressure test using a SIB is a sensitive and specific test to detect esophageal intubation in the emergency setting. This technique is not infallible but, importantly, its few failures are usually false-positive results, or incorrect indications that the endotracheal tube is in the esophagus when it is actually in the trachea. In addition, the SIB is complementary to carbon dioxide detection, and specific instances when a particular device might fail (and where the alternative device might be of use) can be predicted. As previously shown, obesity, chronic obstructive pulmonary disease, and copious pulmonary secretions can affect the SIB’s performance, while cardiopulmonary resuscitation and the presence of carbonated beverages or antacids in the stomach also may affect the reliability of exhaled carbon dioxide monitoring. At our institution, the SIB is used in combination with clinical examination to detect esophageal intubation in the emergency setting. Carbon dioxide detection with a colorimetric device is used as a backup when the SIB results do not correspond with those of clinical examination.

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References

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