

The Esophageal Detector Device

Does It Work?

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Background: The esophageal detector device (EDD) is a diagnostic tool for confirmation of tracheal intubation. Capnography is the accepted standard for such confirmation. The purpose of this investigation was to determine whether results using the EDD and capnography agree.

Methods: Five hundred patients were divided into three separate studies. In study 1, with 300 consecutive patients, tracheal intubation was performed and tested with the EDD followed by capnography. In study 2, 100 patients had the esophagus intentionally intubated, and confirmation was tested similarly. The tube was then removed and the trachea intubated, and testing followed. Study 3 involved 100 patients and used a double-blind, randomized design. The tube was intentionally inserted into either the esophagus ($n = 51$) or trachea ($n = 49$), and testing followed.

Results: In study 1, the compressed EDD bulb reinflated 270 times and always agreed with capnography; in 20 of the 270 subjects (7%) bulb reinflation was delayed, taking from 5–30 s. In 30 instances, the bulb remained compressed, and there was no capnogram indicating esophageal intubation. In study 2, regardless of esophageal or tracheal intubation, agreement between EDD and capnogram was 100%. In study 3, the agreement between the two detecting instruments was 100%, but reinflation of the EDD bulb was delayed in 4% of tracheal intubations. In the 500 patients studied, results from the EDD and capnogram always agreed, but in 6% of all tracheal intubations, the EDD bulb inflated slowly. Of 181 esophageal intubations, the results from the EDD and capnogram always agreed, *i.e.*, there was no reinflation or capnogram. The sensitivity, specificity, and predictive value for the EDD in all of these studies was 100%.

Conclusions: The EDD is a valuable diagnostic technique for confirming tracheal intubation. Results using EDD agree with

results using capnography; in 6% of instances there is a slow reinflation; and where there is no capnography, such as on hospital wards, EDD may be a useful diagnostic tool. (Key words: Anesthetic techniques: tracheal intubation. Capnogram. Complications: esophageal intubations. Esophageal detector device. Measurement techniques: capnography.)

THE normal esophagus is fibromuscular, with no intrinsic structure to maintain its patency. In 1988, the esophageal detector device (EDD) was described; it consisted of a 60-ml catheter tube syringe fitted to one end of a catheter mount.¹ The principal underlying the use of the EDD is the following: The trachea is held open by C-shaped cartilages; hence, gas can be aspirated by the syringe if the endotracheal tube (ETT) is in the trachea. In contrast, the esophagus readily collapses when a negative pressure is applied to its lumen by the syringe. In 1989, Williams and Nunn described a modified device requiring only one hand,² rather than both hands, as was required to aspirate the original. The authors studied 100 patients in whom tubes were passed into the trachea and the esophagus. A second anesthesiologist, not present at intubation, used the EDD to identify trachea and esophagus. In no instance did the bulb reinflate when a tube was placed in the esophagus. However, in two instances, the tube was in the trachea and slow, not immediate, bulb reinflation occurred. Both the sensitivity and specificity of the EDD for detecting tracheal and esophageal intubations were 100%.

The rationale for conducting the present series of studies was to compare the accuracy and dependability of the EDD with the accepted high standard of the capnogram. Since capnography is not always available, nor are chemical tests such as the Easy Cap³‡ (Nellcor, Hayward, CA), a quick, easy-to-use, reliable alternative would be desirable. The American Society of Anesthesiologists 1993 *Standards for Basic Intraoperative Monitoring* states that, "when an [ETT] is inserted, its correct positioning in the trachea must be verified by . . . identification of [carbon dioxide] in the expired

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‡ Formerly called the Fenem carbon dioxide detector device.

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gas. End-tidal [carbon dioxide] analysis . . . is *strongly* encouraged.”§

This investigation was divided into phases: Study 1 was a comparison of the EDD with capnography. Study 2 involved a series of patients who had an intentional esophageal intubation followed by tracheal intubation and the use of the EDD-capnography sequence. Study 3 was a double-blind, randomized investigation of 100 patients, some of whom had an intentional esophageal intubation, while the rest had a tracheal intubation with the observers making the diagnosis using EDD capnography.

Methods

Informed consent was obtained from 500 patients, and the study was approved by the Internal Review Board of the University of Miami School of Medicine and the Veterans Administration Medical Center. The rubber bulb of a Tomac Ear/Ulcer Syringe (American Hospital Supply, Milwaukee, WI) was cut to fit tightly without leak over a plastic, 15-mm elbow fitting, which, in turn, fit tightly over the slip joint of the ETT (fig. 1). With a normally functioning EDD after tracheal intubation and inflation of the ETT cuff, when the rubber bulb of the EDD is compressed and the elbow tightly connected to the slip joint, the bulb when released will reinflate within 1 s. If this reinflation requires from 5–30 s, this is defined as “delayed reinflation.” This delayed reinflation is timed with a stop watch.

If the bulb does not reinflate within 30 s, a diagnosis of esophageal intubation is made. In such a case, the ETT is removed, lungs oxygenated, trachea intubated, and EDD reattached. The EDD bulb creates negative pressure, and the esophageal walls occlude the bevel of the ETT and its Murphy eye. This device must be airtight and is tested before induction. The negative pressure generated is approximately -40 cm H₂O.

Following each testing of the EDD and attaching the Y piece, lungs (or stomach) are inflated and the capnogram is displayed using a SARA CAP (PPG Biomedical Systems, Lenexa, KS). This may require three or four breaths, during which 10–20 s elapse if a side-stream technique is used.

For all three studies, data collected included: results from the initial and secondary tracheal intubations

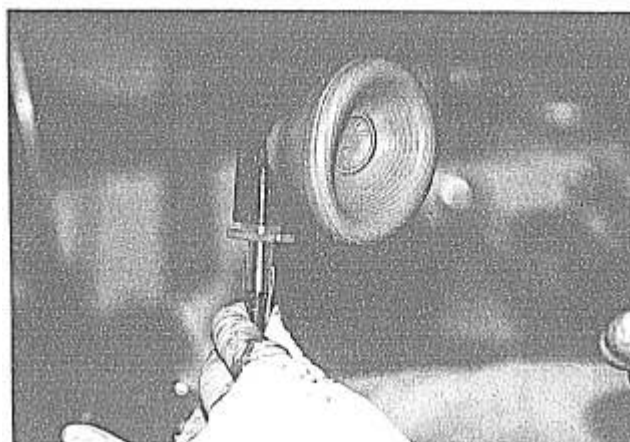


Fig. 1. Esophageal detector device consisting of an inflatable bulb connected to a common, plastic 15-mm fitting. If the compressed bulb is attached to an endotracheal tube placed in the esophagus, subatmospheric pressure will be created, precluding the bulb from reinflating.

(presence or absence of EDD bulb inflation and capnogram) and unintentional and intentional esophageal intubations (absence of EDD bulb inflation and capnogram; table 1). In all patients, anesthesia was induced with thiopental, and succinylcholine was given for paralysis. After intubation, all patients received isoflurane: nitrous oxide/oxygen in a 3/2-L ratio.

Study group 1 consisted of 300 consecutive patients. After what was thought to be tracheal intubation followed by ETT cuff inflation, the compressed EDD was attached to the slip joint of the ETT, and the EDD response was followed by capnography.

In group 2, 100 patients were studied. After ventilation of the lungs with oxygen, the esophagus was intentionally intubated. The EDD and capnography responses were obtained, the ETT was removed, patients' lungs were reoxygenated, and the trachea was intubated, followed by EDD capnography.

The third study involved 100 patients studied in a double-blind, randomized fashion. One author (MIG) instructed the resident who was administering anesthesia to insert the ETT into either the esophagus ($n = 51$) or the trachea ($n = 49$) according to a random number code. Two investigators, previously out of the room, were called into the operating theater to use the EDD-capnogram sequence and to determine whether results using the EDD agreed with results using capnography. If esophageal intubation had occurred, the ETT was withdrawn, the lungs were oxygenated, and

§ Standards for basic intraoperative monitoring, Directory of Members. Park Ridge, American Society of Anesthesiologists, 1993, p 710.

the trachea was intubated, followed by EDD capnography.

Statistical analysis comparing results using the EDD and capnography within the three groups of patients was performed. Definitions included: positive, the bulb remains collapsed; negative, the bulb reinflates; false-positive (FP)—bulb collapsed, tube in trachea; false-negative (FN)—bulb reinflates, tube in esophagus; true-positive (TP)—bulb collapsed, tube in esophagus; and true-negative (TN)—bulb reinflates within 30 s, tube in trachea. We also calculated sensitivity [$TP/(TP + FN) \times 100$], specificity [$TN/(TN + FP) \times 100$], and positive predictive value [$TP/(TP + FP) \times 100$].

Results

In study group 1 ($n = 300$), after confirmation (or lack of confirmation) of ETT placement, the EDD and capnogram results (presence of a rectangular waveform) agreed and indicated that the tube was in the trachea in 270 patients and in the esophagus (unintentional) in 30 patients (table 1). In each of 30 instances in which the compressed bulb of the EDD did not reinflate, there was no capnogram (flat trace). In 20 of 270 tracheal intubations, there was a capnogram, but the EDD bulb reinflated in a delayed fashion, within 30 s.

Table 1. Comparison of Esophageal Detector Device and Capnography

	Study 1 ($n = 300$)	Study 2 ($n = 100$)	Study 3 ($n = 100$)
Initial tracheal intubations	270	0	49
TN	250	0	46
TN delayed >5–30 s	20	0	3
Capnogram	270	0	49
Esophageal intubations	30	100	51
FN	0	0	0
TP	30	100	51
Capnogram	0	0	0
Secondary tracheal intubations (after esophageal intubation)	30	100	51
TN	30	95	50
TN delayed >5–30 s	0	5	1
Capnogram	30	100	51
Sensitivity (%)	100	100	100
Specificity (%)	100	100	100
Predictive value (%)	100	100	100

TN = true-negative (tube in trachea, bulb reinflates); TP = true-positive (tube in esophagus, bulb stays compressed); FP = false-positive (tube in trachea, bulb compressed); FN = false-negative (tube in esophagus, bulb reinflates).

There were no FPs or FNs.

This was considered a true-negative. A delayed EDD bulb reinflation sometimes started the process of reinflating at 5 s, achieving full bulb shape at 15–30 s. Therefore the sensitivity, specificity, and positive predictive value were 100%.

In study 2, in 100 patients in whom the ETT was intentionally placed in the esophagus and then the trachea intubated, followed by capnography, the results using the EDD and capnogram agreed in all cases (table 1). In all 100 instances, the first intubation into the esophagus was confirmed by both a failure of the compressed bulb of the EDD to reinflate and a flat capnogram. The next 100 intubations into the trachea were confirmed by 100 capnograms indicating presence of carbon dioxide, 95 immediate EDD reinflations, and 5 delayed EDD reinflations. These were true-negatives. The sensitivity, specificity, and positive predictive values within this group of 200 intubations were 100%.

In study 3, 100 patients were investigated by a double-blind, randomized method (table 1). In all instances, the observers independently knew when the trachea and the esophagus were intubated. Of the 49 initial tracheal intubations, three bulb inflations were delayed; and of the 51 secondary tracheal intubations, one was delayed. There were no false-negatives. Sensitivity, specificity, and predictive values in this group were 100%. In all 500 patients (681 total intubations: 500 tracheal and 181 esophageal intubations), capnography results always agreed with EDD results. However, there were 29 delayed (total of 6%) bulb reinflations. Total sensitivity, total specificity, and total positive predictive values were 100%. We knew without capnography that each of the 29 delayed bulb reinflations represented a tracheal intubation: the EDD always reinflated by 30 s.

Discussion

Our results suggest that the EDD is a useful diagnostic device for the anesthesiologist. The EDD results agreed with capnographic results, and not once in 181 esophageal intubations did the compressed EDD bulb reinflate (false-negative).

Capnography remains the most accurate and common sensor for confirming tracheal intubation.⁴ Other techniques include pulse oximetry combined with auscultation and chemical devices such as the FEF (FENEM, New York, NY) and Easy Cap,⁵ both of which are owned by Nellcor. Both have been criticized because, on occasion, carbon dioxide escapes from the stomach into

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the esophagus.^{5,6} There is no foolproof detector for esophageal intubation.^{4,6-9} Studies have been published concerning the use of the EDD, but none have correlated results using it with the capnogram for confirming tracheal intubation.

A limitation of this study is that we did not study the use of the EDD in patients with tracheal or esophageal disease. Though the amount of subatmospheric pressure generated by the compressed bulb of the EDD is low, there may be certain precautions, hazards, and limitations to its use. The bulb must be tested as described before each use.

The use of the EDD from patient to patient may constitute a means of spreading infectious disease; we strongly suggest that, after each use, the EDD be washed and gas-sterilized. We are concerned primarily by the 29 delayed bulb reinflations when the tube was in the trachea. We believe that reinflation of the EDD bulb within 30 s indicates tracheal intubation, unless the EDD is improperly used, *i.e.*, not a tight fit or a leak in the bulb. However, an individual inexperienced in the use of the EDD, especially following a difficult intubation, may judge incorrectly that the esophagus has been intubated and prematurely extubate the trachea. If the bulb shows no sign of reinflating after 30 s, the tube should be removed, the lungs oxygenated, and the trachea intubated. We do not know why a delayed reinflation of the EDD occurs. Perhaps a partially paralyzed or nonparalyzed diaphragm, during succinylcholine recovery, descends when the compressed EDD bulb is applied, thereby creating relatively more subatmospheric pressure in the trachea. Perhaps delayed reinflation occurs when the tube bevel is at the level of the carina or impinges on the wall of a mainstem bronchus.

The EDD does not require that the reservoir bag be squeezed and, therefore, may help to avoid gastric distension. It also gives an immediate response, unlike capnography. With chemical devices, instances of unreliability have been reported during periods of no cardiac output.¹⁰ We conclude that the EDD is a useful tool in the operating room. It also may be useful for accurately detecting esophageal intubations in hospital locations where there is no capnograph, such as on hospital wards, the emergency room, and in ambulances.

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