

Sonomatic Confirmation Of Tracheal Intubation (SCOTI)

An acoustical implementation of the Esophageal Detector Device

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August 6, 1996

The Esophageal Detector Device (EDD) as described by Weeⁱ as a means to distinguish esophageal from tracheal intubation has been well established. Its efficacy has been demonstrated by Williams & Nunnⁱⁱ and further by Zaleski et alⁱⁱⁱ in an impressive clinical trial involving 500 patients. Its efficacy has also been confirmed by Salem et al^{iv} and its use in Sheridan Catheter Corporation's Combitube[®] has been tested by Wafai et al^v. It has been approved by the FDA.

The EDD works on the principal that due to the rigid structure of the trachea air can flow freely into an endotracheal tube placed there while air flow is impeded when the endotracheal tube is inserted into the esophagus because of its soft structure which allows it to collapse around the end of the tube. The suction used to detect this difference in impedance is generally supplied by a syringe or a collapsible rubber bulb. SCOTI, U.S. patent #5,331,967, works on the same principle but, instead of measuring the energy required to suck air into the tube once, does it about 600 times per second. This device has a speaker connected to the end of the endotracheal tube so that it propagates a sound wave down the tube. Each time the unit is used it self configures and selects the exact frequency which gives the greatest sensitivity between an open endotracheal tube and a closed one. Then it locks on this frequency and continuously determines the impedance to air movement at the end of the endotracheal tube just as the EDD does. To repeat a measurement with the EDD one has to manually recompress the rubber bulb while SCOTI automatically repeats its measurement as the cone of the speaker moves back and forth. The cone of the speaker acts as a kind of automatic rubber bulb which is electrically controlled and monitored. From a physics standpoint what this device is doing is exactly the same as the EDD, it just repeats the test about 600 times per second.

SCOTI continually monitors the acoustical impedance of the end of the tube and displays this with a number from "00" to "99". To assist the operator it also displays a red light indicating esophagus if the number is 15 or less and a green light indicating trachea if the number is 20 or greater. There is also an audible alarm which indicates the color of the light. This device is automatically configured each time it is used to adjust itself to the exact parameters of the actual endotracheal tube to be used. If, for any reason, it fails to configure adequately it turns itself off to prevent any chance of misinterpretation. Between the speaker and the endotracheal tube is a disposable bacterial filter and a 70 cm corrugated tube which allows for unencumbered movement of the endotracheal tube during intubation and protects against cross contamination between patients. This disposable circuit is provided assembled and has only one style and will be supplied by the manufacturer of SCOTI.

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Appendix C

The EDD and SCOTI can both be viewed as blocked tube detectors. Their operation can be tested in the lab by simply testing them with the end of the endotracheal tube left open and with the end of the endotracheal tube blocked with two fingers. It is highly advisable to check the placement of the endotracheal tube before forcing air into the endotracheal tube as is required to use any CO₂ monitoring device, such as capnography, or even to listen for breath sounds. Forcing air through an endotracheal tube which may indeed be in the esophagus heavily increases the chance of regurgitation and subsequent aspiration of gastric contents. This accepted method of using capnography as the primary means to verify tube placement actually does something that creates a new risk.

SCOTI's efficacy has been verified with three clinical trials:

- 1) Dr. Wilson Leon, Dr. James Riopelle and Dr. Heart Akerson wrote a paper "New Method for Endotracheal Intubation" 10/4/94 which describes a clinical trial done with 72 patients in the Hospital San Juan de DiÙs. These patients were all intubated first in the esophagus and then in the trachea and the readings recorded. The results indicated a confidence level greater than 98% for both the esophagus and the trachea. These findings were displayed in a scientific booth on SCOTI at the ASA convention in San Francisco in October, 1994.
- 2) Dr. D. Murray, Dr. Michael E. Ward and Dr. JW Sear of the Nuffield Department of Anaesthetics in Oxford, England wrote a report 11/10/94 of a clinical trial that was done at The John Radcliff Hospital with 90 patients. These patients were all intubated in the esophagus and also in the trachea with the results recorded. The results indicated a confidence level greater than 98% for both the esophagus and the trachea. This report was published in *Anaesthesia*^{vi}.
- 3) Dr. B. Martin and Dr. E. Wheatley wrote an abstract and a paper "Clinical Evaluation of the 'Sonar Confirmation Of Tracheal Intubation' Device" 9/28/95 which describes a clinical trial that was done at St. Bartholomew's Hospital in London, England with 125 patients. In this study 51 patients were intubated in the esophagus and also in the trachea with the results recorded. A further 74 patients were intubated in the trachea only. The results indicated a confidence level greater than 98% for both the esophagus and the trachea. This paper was presented by Martin at the 11th World Congress of Anaesthesiologists in Sydney, Australia in April, 1996 and the abstract is included in their publication of abstracts.

With all three clinical trials combined SCOTI was shown to have greater than 98% confidence levels for determining esophageal intubation in 213 patients and for determining tracheal intubation in 287 patients. This establishes, as with the EDD, that a blocked tube detector is an effective device for differentiating between esophageal and tracheal intubation. SCOTI has been tested extensively in the lab for its effectiveness as a blocked tube detector for endotracheal tubes ranging in sizes from 6.0 mm to 10.0 mm using tubes manufactured by Curity[®], Sheridan[®], Portex[®] and Mallinckrodt[®] with positive results for all brands. Because SCOTI is substantially equivalent to the EDD then all of the clinical trials for the EDD should also be relevant for SCOTI.

SCOTI, while basically an automatic version of the EDD, gives an added benefit of indicating tube position while the intubation is taking place where the EDD can only be used

Appendix C

to confirm tube placement after the intubation. In fact, while using SCOTI the operator never even fully inserts the endotracheal tube into the esophagus since as soon as it starts to enter the esophagus the alarm starts to beep and the light turns red signaling the operator to reposition the tube. While it may seem obvious to compare the times required to use and interpret the results for capnography, colorimetric CO₂ monitors, EDD and SCOTI this isn't really the relevant time. The important issue is the cycle time between intubation attempts when there has been an esophageal intubation. This would be the time from when the device indicated that there was an esophageal intubation until the patient had been intubated again and the device had given its results a second time. For capnography for instance, this would include the times needed to disconnect the airway circuit, reinsert the laryngoscope, reintubate, reconnect the airway circuit and interpret the results of the capnograph. This time could be substantial for a patient who isn't breathing. For SCOTI this time is reduced to less than a second since this device indicates tube position while the tube is being inserted and the laryngoscope would not even be withdrawn until the tube was correctly placed. In the event of a difficult intubation or with an inexperienced operator there could be several of these cycles before the patient was successfully intubated. If a test was done using all of these methods, SCOTI would always give its result first. In the case of emergency intubations time is even more critical and the experience levels are often lower. If there is a cardiac arrest then end-tidal CO₂ monitoring techniques do not work and time is even more critical.

ⁱ Wee MYK: The esophageal detector device: Assessment of a method to distinguish esophageal from tracheal intubation. *Anaesthesia* 43:27-29, 1988

ⁱⁱ Williams KN, Nunn JF: The oesophageal detector device: A prospective trial on 100 patients. *Anaesthesia* 44:412-414, 1989

ⁱⁱⁱ Zaleski L, Abello D, Gold MI: The Esophageal Detector Device: Does It Work?: *Anesthesiology* V79, No.2, Aug 1993

^{iv} Salem MR, Wafai Y, Joseph NJ, Baraka A, Anaesth FRC, Czinn EA: Efficacy of the Self-inflating Bulb in Detecting Esophageal Intubation: Does the Presence of a Nasogastric Tube or Cuff Deflation Make a Difference?: *Anesthesiology* V80, No 1, Jan 1994

^v Wafai Y, Salem MR, Baraka A, Joseph NJ, Czinn EA, Paulissian R: Effectiveness of the Self-Inflating Bulb for Verification of Proper Placement of the Esophageal Tracheal Combitube: *Anesth Analg* 1995;80:122-6

^{vi} Murray D, Ward ME, Sear JW: SCOTI — a new device for identification of tracheal intubation: *Anaesthesia* V50, 1062-1064, 1995