RECOGNIZING OESOPHAGEAL INTUBATION: SUCCESSFUL USE OF THE OESOPHAGEAL DETECTOR DEVICE COMBINED WITH A DISPOSABLE END-TIDAL CARBON DIOXIDE DETECTOR

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ABSTRACT

Unrecognized oesophageal intubation leads to death or severe disability. Even careful, well trained anaesthetists may be unable to differentiate tracheal from oesophageal intubation by the commonly employed methods. End-tidal carbon dioxide measurement has been found to be a reliable test of tracheal intubation. The availability of a small disposable end-tidal carbon dioxide detector, the Easycap® makes this facility universally available. The oesophageal detector device is a small mechanical device used to recognize oesophageal intubation. By combining two reliable devices working on completely different principles the risk of false negative or false positive results are virtually eliminated. The potential defects of each device are covered by the other.

The purpose of this study was to evaluate the combined use of the oesophageal detector device and the Easycap® by a blinded observer to differentiate the endotracheal tube from an oesophageal tube in sixty patients. These two tests were found to be very reliable, easy, rapid and cheap - ideal for use in theatre, casualty departments and in the field. The advantages and disadvantages of these devices are discussed and the relevant literature is reviewed.

DECLARATION

I declare that this dissertation is my own, unaided work. It is being submitted for the degree of Master of Medicine in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination in any other University, nor has it been prepared under the aegis or with the assistance of any other body or organization or person outside the University of the Witwatersrand, Johannesburg.

This study, no 9012989W has been approved by the Post Graduate Committee of the University of the Witwatersrand.
Ethics Clearance No 28/4/92

Pieter Adriaan Bothma.

4th day of March 1994.

PREFACE

In South Africa (SA) there are hundreds of small, poorly equipped peripheral hospitals where the need for simple but reliable equipment is greater than anywhere else. The devastating result of unrecognized oesophageal intubation is encountered in anaesthesia as well as emergency medicine and it occurs in peripheral as well as sophisticated hospitals. Nobody, no matter how experienced, is immune from this dreaded complication.

The purpose of this study was to evaluate a combination of two new techniques to confirm correct endotracheal tube (ETT) placement.

The apparent reliability, ease and rapidity of using these devices described in the literature make them ideal for use in this critical situation. In addition minimal expense is required, which makes it affordable in every location where patients may be intubated.

I gratefully acknowledge the help received from Prof. D Moyes and Dr L Lourens with the planning and completion of this study as well as the writing up of the results. I would also like to thank Prof. J Lipman for his guidance and inspiration. Grateful thanks are extended to Mrs Elize Bothma for her technical assistance. Finally I wish to thank the anaesthetic and labour ward staff at Baragwanath Hospital for their help.

A summary of the study protocol, results and brief discussion of the literature has been submitted for publication in the South African Medical Journal.

DEDICATION

This work is dedicated to my wife and children for their loving support.

CONTENTS

LIST OF ILLUSTRATIONS

ABBREVIATIONS

ACD - anaesthetic contributory deaths.

ASA - American Society of Anesthesiologists.

CO_2 - carbon dioxide.

CPR - cardiopulmonary resuscitation.

ET CO_2 - end tidal carbon dioxide.

ETI - endotracheal intubation.

ETT - endotracheal tube.

Fig. - figure.

GP - General practitioner.

ICU - Intensive care unit.

kPa - kilopascal.

ml - millilitre.

mm - millimeter.

O_2 - oxygen.

ODD - oesophageal detector device.

PEEP - positive end expiratory pressure.

SA - South Africa.

Recognizing oesophageal intubation: successful use of the oesophageal detector device combined with a disposable end-tidal carbon dioxide detector

1 Introduction

Tracheal intubation is a common procedure in modern medical practice. Individuals of different background and levels of training are required to intubate patients in the operating theatre, casualty department, intensive care unit (ICU), hospital ward and at the accident site. In theatre it may be elective, under controlled conditions with technical and medical backup. In other siuations it may be a life saving procedure under less than ideal circumstances.

Anaesthetists are usually regarded as airway experts and therefore the anaesthetic experience with intubation will be emphasized. Reviews of anaesthesia-related mortality and morbidity have shown that undiagnosed oesophageal intubation is an important cause of death or permanent disability. Reviewing mortality studies throughout the world makes one aware of the magnitude of the problem.

1.1 United Kingdom

The Report on Confidential Enquiries into Maternal Deaths in England and Wales [1] found that four out of twenty-two deaths due to substandard care were as a result of undiagnosed oesophageal intubation. Substandard care was not only regarded as deficient clinical care but also a shortage of resources. This is probably a much bigger problem in a developing country like SA. Four deaths over three years due to oesophageal intubation may not be striking, but the magnitude of the tragedy becomes obvious when one considers that most caesarean section patients are young, often with small children and above all that these deaths were deemed to be avoidable.

All cases reported to the Medical Defence Union (MDU) in the United Kingdom (UK) from 1970 to 1977 were analyzed by Utting and associates. [2] It was found that one third, i.e. fifty out of 163 cases of death or cerebral damage were due to oesophageal intubation.

1.2 Australia

Holland analyzed all deaths possibly related to anaesthesia in Australia between 1960 and 1979. [3] Out of 109 deaths which could be said to be largely due to an anaesthetic mishap, four were due to oesophageal intubation.

1.3 United States of America

Peri-operative cardiac arrests in a large university hospital were analyzed by Keenan and Boyan. [4] Twenty seven deaths were found to be caused by anaesthesia alone. Four of these were due to unrecognized oesophageal intubation. The ASA Closed Claims Study analyzed 1541 closed malpractice claims. Oesophageal intubation was found in ninety four of these, constituting 6% of the total. [5] Not all these cases died, but serious complications were seen in the majority of the survivors.

1.4 South Africa

The situation in South Africa may even be more serious, since a considerable percentage of anaesthetics are administered by practitioners with limited anaesthetic training. Critically ill or injured patients are frequently managed initially by junior staff in the casualty department, medical ward or ICU. These patients often need urgent endotracheal intubation (ETI) under suboptimal conditions without help of experienced colleagues or sophisticated equipment.

The earliest SA investigation into the cause of death under anaesthesia was published in 1936. [6] ETI was not mentioned as a cause of death under anaesthesia. This is not surprising, since ETI has only been practiced on a regular basis since Griffith and Johnson used curare in 1942 and more so after the discovery of suxamethonium in 1951. [7]

The CSIR Anaesthetic Deaths Research Unit analyzed 944 deaths from 1956 to 1962. ETI complications is mentioned but oesophageal intubation was not recognized as a cause of death. [8] In a later report they found inadequate ventilation the cause in 21% of deaths. [9] They did not specify oesophageal intubation at all. Sennet compared a fourteen months period in 1978/1979 to the 1974 - 1978 period. [10] Six out of seventeen deaths were due to airway or ventilation problems, but oesophageal intubation was not identified as an important problem.

The most recent SA mortality study is that of Harrison.[11] He analyzed the anaesthetic contributary deaths (ACD) at Groote Schuur Hospital for the period 1956 to 1987. He found ETI complications responsible for twenty six out of 145 ACD's (18%). The most prominent of these mishaps were failed intubation in eight, ETT obstruction in nine, severe bronchospasm in four, and disconnection or ETT dislodgement in five. No deaths due to oesophageal intubation were identified. His earlier publications studying periods overlapping with the above, also did not identify oesophageal intubation as a cause of death.[12,13]

The fact that oesophageal intubation was not identified as an important contributory cause to anaesthesia related deaths may indicate that SA forensic pathologists were not aware af the importance of this complication. Nevertheless, the experience of the rest of the world compels South Africans also to do their utmost to avoid unrecognized oesophageal intubation.

2 The ideal test

To rule out accidental oesophageal intubation, the ideal test should satisfy certain criteria: [14]

2.1 Specificity

The test needs to be specific. It should be negative when oesophageal intubation does not occur.

2.2 Sensitivity

The test should be highly sensitive, i.e. it must be positive whenever oesophageal intubation does occur.

2.3 High positive predictive value

The likelihood of oesophageal intubation should be high when the test is positive.

2.4 False positives

The test should have no false positives.

2.5 False negatives

It is not essential for the false negative rate to be zero as it is with the false positive rate. If the test falsely suggests oesophageal intubation, the anaesthetist will merely remove the ETT and repeat ETI. The false negative rate should however be low so as to avoid unnecessary removal of the ETT and reintubation, especially in the CPR situation where every second is crucial.

The same authors also indicate that the risk of missing an oesophageal intubation can be reduced by using more than one clinical sign or confirmatory test. [14]

The terms "false positive" or "false negative" or even "positive" and "negative" may be confusing. Is a tube found to be in the oesophagus a positive or negative finding? For this reason in further discussions of the ODD, "oesophageal sign" or "tracheal sign" will be used because they are self-explanatory.

2.6 Price, availability and simplicity

The ideal test should also be easy and rapid to do. The result should be clear and easy to interpret. The equipment should be small and light for ease of transport. It should also be cheap enough to make the equipment available at every site where patients may have to be intubated.

3 Popular tests to confirm ETI

In a review of the literature, Birmingham et al [15] emphasize that most of the commonly utilized methods of assessing ETT position have been documented to fail under certain circumstances. Solazzi and Ward emphasize that "even a conscientious, careful anesthesiologist may be unable to differentiate tracheal from esophageal intubation by the commonly employed methods". [16] Table 1 lists several diagnostic tests that are frequently claimed to be reliable indicators of tracheal intubation. References indicating failure of each test is also added. It can be concluded that no single test can exclude oesophageal intubation under all circumstances. Each person that is called upon to manage tracheal intubations should have a working knowledge of the strengths and weaknesses of each individual test.

TABLE I. Tests to confirm ETI and references of reported doubtful or unreliable results:

	Test	Reference
1.	Seeing ETT between vocal cords.	17, 26
2.	Characteristic feel of lung compliance with reservoir bag.	18
3.	Normal breath sounds on auscultation of the chest while compressing the bag.	15, 18, 19, 20, 21
4.	Visual and/or manual confirmation of bilateral chest expansion on inflation.	2, 18, 19, 21
5.	Lack of gas escaping around the tube.	19
6.	Absence of borborygmi on epigastric auscultation.	22
7.	Movement of the reservoir bag in time with the patient's respiratory effort.	19, 21
8.	Appearance of moisture from expired gases in transparent tracheal tubes.	23
9.	Absence of changes in blood pressure or heart rate.	24, 25
10.	Escape of gas from the lungs through the open end of the endotracheal tube when the sternum is abruptly depressed.	19
11.	Chest X-ray.	20
12.	Lack of distention of the stomach.	19
13.	Measurement of ET CO_2.	30, 52-58
14.	Palpation of cuff in suprasternal notch.	21

Visualization of the ETT passing between the vocal cord is often regarded as absolute evidence of tracheal intubation.[15] One well documented exception to this rule is seen with congenital laryngo-tracheo-oesophageal cleft.[17, 26] The tube may be seen passing between the vocal cords, but then the tip may be displaced over the inferior margin of the cleft into the oesophagus. Another possible exception is acquired tracheo-oesophageal fistula secondary to trauma, carcinoma or ischaemic necrosis. Nevertheless, seeing the ETT passing between the vocal cords still remain the most reliable evidence of correct placement of the ETT. Unfortunately, due to anatomical factors the cords are not invariably visible and therefore other reliable tests are also needed.

End-tidal carbon dioxide (ET CO_2) measurement is at present perhaps the most reliable means under most circumstances of determining proper tube position and should be employed routinely whenever possible.[15] Due to the expense, capnographs are not freely available and are most commonly found in the operating theatre complex, occasionally in some ICU's and very rarely at other locations where patients may need urgent ETI. Morgan believes that capnography is the ideal diagnostic test to confirm ETI,[1] however it is important to realise that end-tidal CO_2 detection is not an absolute method of confirming ETT placement (see chapter 7.4 & 7.5).

The American Society of Anesthesiologists (ASA) Committee on Professional Liability analyzed twenty nine anaesthesia-related insurance claims in which oesophageal intubation was the cause of injury. In eighteen of these cases auscultation "confirmed" ETI, indicating the inaccuracy of this widely trusted test. [15]

It is clear that no single test or clinical sign is foolproof. Like in many other clinical situations, a combination of signs or tests is used to confirm tracheal placement of the ETT. The combination of two quick tests with the usual clinical signs may make assessment of the ETT position easy and reliable.

4 Equipment used in this study

4.1 End-tidal carbon dioxide detector

The Easycap^R (Nellcor) previously known as the FEF ET CO_2 detector ^{R} (Fenem) (Fig 1) is a small portable device which is inserted into the breathing system between the tracheal tube and catheter mount. The detector weighs less than 30g, has an internal volume of 38ml and it offers minimal resistance to flow. [27] The dome of the device is clear plastic with a visible coloured membrane, which is normally purple. This indicates less than 0.3 % CO_2 present. If more CO_2 is present, the membrane changes to yellow on exhalation and on each inspiration the colour returns to purple again. Around the outside of the dome a colour coding is provided as a reference. A: with ET CO_2 of up to 0,5% a greyish-purple colour is noted. B: between 0,5 and 2,0% a brownish colour is evident. C: More than 2% has a definite yellow tinge. [28]

The method of action depends on a chemical pH indicator (metacresol purple) [29] reacting with exhaled carbon dioxide (CO_2) to produce a colour change from purple to yellow.[27] The Easycap^R has been found to be as reliable as the capnograph for confirming correct placement of the ETT [30,31] and is a useful substitute when a capnograph is not available. It does not need electrical power and can easily be used in the field or at the roadside. The Easycap^R has been found both useful in adults [27] and in babies. [28,32,33] It has been used in the presence of nitrous oxide, halothane, ethrane and isoflurane. [34] Although designed for short term use it has been left in the anaesthetic circuit for several hours before the indicator faded. [35]

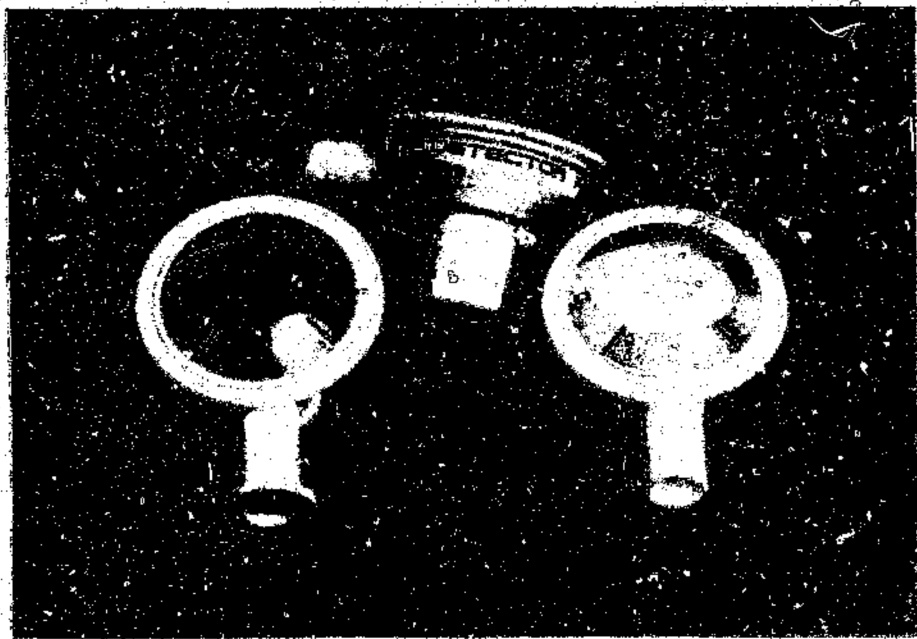


Fig. 1 The Easycap[R] end-tidal CO_2 detector.

4.2 Oesophageal detector device

Another cheap and apparently reliable apparatus is the oesophageal detector device (ODD) described by Wee. [38] The original device consists of a 60ml syringe with a catheter tip fitted to one end of a standard catheter-mount with a 15mm tracheal tube fitting at the distal end (Fig.2). The device must be completely airtight in order to function reliably. This can be tested simply by occluding the distal end with a finger and pulling back on the plunger. If resistance or negative pressure is felt and maintained it is suitable for use.

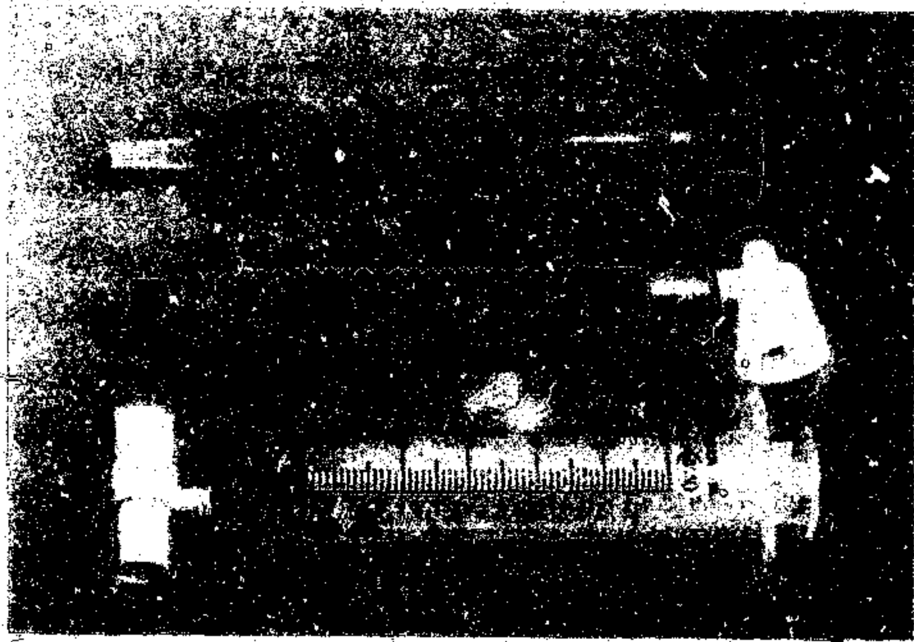


Fig.2 The oesophageal detector device. Fifty ml syringe (top) fitting in catheter mount (middle) constitutes Wee's original model. The Baragwanath model (bottom) has fewer potential leaks.

Unfortunately the original device was prone to air leaks occuring at several junctions. This was replaced by the Baragwanath modification which has only two junctions. (Fig.2.) It consits of a 60ml luer-lock syringe with a T-piece connector joining it to the ETT. Sidestream capnographs use a T-piece that is ideal and quite cheap. Certain paediatric T-piece circuits also have a similar metal or plastic connector that can be used, eg Portex[R], and most anaesthetic workshops have similar connections. This ODD is attached to the tube-connector to ensure an airtight seal. The opposite open end of the T-piece is closed with the index finger, giving the investigator an indication of the degree of suction or negative pressure created.

With the tracheal tube correctly placed, withdrawal of the plunger of the syringe will freely aspirate air from the patient's airways, because patency of the trachea is ensured by C-shaped cartilage rings. This is called a tracheal sign. No resistance will be felt apart from that inherent in the device. However, if the ETT is in the collapsable oesophagus, withdrawal of the plunger will cause the walls of the oesophagus to occlude the distal orifice of the tube, and cause a negative pressure or resistance when the plunger is pulled back. This is called an oesophageal sign. This immediately indicates that the tracheal tube is incorrectly placed and allows appropriate steps to be taken. [36] The ODD has been found to be equally accurate in the presence of a naso-gastric tube [37] and also in children older than two years of age. [38]

4.3 ODD Modifications

a The Baragwanath variation

Discussed in chapter 2.2.

b Nunn's modification

It comprises an Ellick's evacuator (a self-inflating rubber bulb) and is connected directly to the ETT with a tube connector. [39] An advantage is that the apparatus can be used with one hand. However at the stage that confirmation of ETT placement is performed the ETT is usually not secured to the patient and to prevent displacement most anaesthetists prefer to support it with one hand which makes Wee's or the Baragwanath version of the ODD quite easy to use in conjunction with the other hand.

The vacuum created with the Ellick's evacuator is 7.4 kPa or more below atmospheric [40] and is potentially harmful in patients with thin walled varices or even to the normal oesophageal mucous membrane. It is very important to note that the use of a smaller self inflating rubber bulb may make the apparatus unreliable. [40]

c Hayes and Morton's device

They chose a 5ml Plastipak[R] syringe with the nozzle of the syringe within the proximal portion of a corrugated tube connector. [38] They were concerned that the 60ml syringe in the original ODD may be subjecting the child to the risk of aspirating an excessive proportion of a small functional residual capacity (see Chapter 7.3).

The disadvantage of their version is that a smaller syringe with a smaller cross-sectional area of the plunger will generate a greater negative pressure which could be harmful to a small child. [41] In addition, this may partly explain the poor results obtained by them. [38]

5 Method of Investigation

Approval was obtained from the relevant authorities and Witwatersrand University Ethics Committee. Informed consent was obtained from all patients.

The study consisted of two sub-groups of patients.
Group A: Thirty ASA I/II patients with no known oesophageal abnormality needing ETI.
Group B: Thirty caesarean section patients with a history of severe heartburn.

The reason for including the last group of patients is to investigate the effect of an incompetent oesophageal-gastric sphincter on the reliability of the ODD. Previous studies only examined patients with normal oesophago-gastric structure and function.

Each patient was anaesthetised by the anaesthetist on duty with routine monitoring: electrocardiography, non-invasive blood pressure measurement and pulse oximetry. The type of induction and maintenance were selected by the duty-anaesthetist as indicated by the clinical situation. After induction and ETI, the patient was stabilized. A second, similar, endotracheal tube was then inserted in the oesophagus with the relative position of each tube in the mouth allocated randomly. The patient was ventilated with 100% O_2 for four minutes, then disconnected from the breathing circuit and presented to the investigator (P.A.B.) with only the proximal end of each tube visible. The investigator, who was blinded for the position of both tubes, had to determine which tube was in the trachea and which in the oesophagus. The ODD was first connected to each tube, the plunger withdrawn and the one in which free air flow occurred was identified as the tracheal tube.

The next step was to ventilate each tube through the Easycap[R] to confirm the tracheal position by the change in colour. The pulse oximeter was observed by the anaesthetist to ensure adequate oxygen saturation during the test period which was not allowed to exceed thirty seconds. The time needed for confirmation was recorded. The patient was then reconnected to the ventilator and the oesophageal tube was removed by the anaesthetist.

6 Results

in all sixty patients of group A plus group B the oesophageal and the tracheal tube were easily and confidently identified with the ODD and confirmed by the Easycap[R]. (Table II.) This was always achieved in less than twenty seconds, with a mean of twelve seconds and a range of eight to nineteen seconds.

TABLE II RESULTS

	OESOPHAGEAL INTUBATION		TRACHEAL INTUBATION	
	CORRECT	INCORRECT	CORRECT	INCORRECT
GROUP A	30	0	30	0
GROUP B	30	0	30	0
TOTAL	60	0	60	0

7. Discussion

One hundred percent accuracy in sixty cases does not mean the ODD is foolproof, but 799 correctly diagnosed oesophageal and 3211 tracheal intubations have been recorded in patients older than one year.[36-38, 41-47] Only five false oesophageal reports could be found.[36, 48, 49] In four of these the tube had to be removed due to various technical problems.[36, 49] In the fifth case there is some controversy over the test result. These five cases will be discussed in chapter 7.1. Wafai et al investigated a variation in technique, using Nunn's modification of the ODD.[47] They used a 20ml instead of a 70ml bulb, but the results were unreliable. Users are advised to avoid the smaller bulb if they decide to employ Nunn's modification.

Results in babies under one year of age were also disappointing and will be discussed in chapter 7.3.

In a recently published study[46] 500 tracheal and 181 oesophageal intubations were correctly diagnosed in every case. The sensitivity, specificity and predictive value for this investigation with the ODD were all found to be one hundred per cent. According to the above criteria (chapter 2) the ODD could be called the ideal method to confirm ETI.

7.1 False oesophageal sign with the ODD

A false oesophageal sign could at most lead to the unnecessary replacement of a correctly placed ETT. Bearing in mind the well-known dictum "If in doubt, take it out", the five false negatives out of 3211 tracheal intubations is really negligible. Ideally this figure should be very low as well to avoid unnecessary replacement of the ETT in the CPR situation. Also when accomplishing a very difficult ETI, removing the ETT unnecessarily is extremely counter-productive. If one keeps publication bias in mind, the ratio of correctly diagnosed to incorrectly diagnosed ETI's is probably a lot better. A false oesophageal sign is remarkable and worth publishing, but hundreds or even thousands of correct diagnoses are not remarkable and probably not reported. The five false negatives will be analysed in detail.

<u>a Case reported by Wee</u>

In one case the observer was unsure of the test result and removed the ETT. [36] The first tube was found to be blocked by purulent secretions. Obstruction of the ODD by mucous, blood or gastric contents in the trachea will give the same resistance to air flow as with oesophageal intubation. As with oesophageal intubation an obstructed ETT needs to be replaced, and cannot be regarded as a failure of the ODD.

<u>b Case reported by Calder et al</u>

After fibre-optic bronchoscopic intubation of a patient, the ODD gave a false oesophageal sign. [48] They inserted the bronchoscope again and confirmed tracheal placement but found the bevel of the ETT lying against the posterior tracheal wall. The tube was rotated through 90^0 and the ODD then confirmed tracheal placement. These authors speculate that the use of unformed tubes predisposes to this complication. They believe that the mucous membrane covering the posterior tracheal wall may be sucked into the ETT if the bevel is lying against it, since the mucus membrane is unsupported by cartilage. They suggest that with preformed tubes the bevel will always point towards the side wall of the trachea and will then probably be less likely to cause false oesophageal signs with the ODD.

Wee [44] suggests that the bevel of the ETT may be more prone to occlusion by the tracheal mucosa in obese patients and when there is a degree of distortion of the trachea (see chapter 7.1 c). Endobronchial intubation may also lead to distortion of the ETT in the narrower right main bronchus. [44] He also proposes that vigorous aspiration may encourage adherence of the ETT bevel to the tracheal mucosa. Constant slow aspiration is probably adequate precaution and will also prevent damage to the tracheal (or oesophageal) mucous membrane. If resistance is felt, Wee's advice is to retract the tube by 1cm, to rotate it partially and then to repeat the test before removing the ETT. [44]

When utilizing the ODD, the use of a Murphy type ETT is invaluable to obviate the above complication in addition to the original goal of the Murphy eye, namely to allow ventilation when the bevel of the ETT is occluded. [25]

<u>c Cases reported by Baraka</u>

Two cases with gross distortion of the airway anatomy were reported. They probably needed replacement by arn oured tube or even by rigid bronchoscope. [49] A third case with severe asthma also had a false oesophageal sign. Baraka surmized that severe bronchoconstriction of the small airway would lead to slow re-inflation of Nunn's ODD.

This theory is disputed by Wee.[50] I had the personal opportunity to test the ODD after intubation in eight patients that needed urgent ETI for severe asthma. In all of them the ODD was unequivocal. However, with any new medical equipment or technique any adverse report must be regarded seriously and investigated carefully.

7.2 False Tracheal sign with the ODD

A false tracheal test could have disasterous results when oesophageal intubation is mistaken for tracheal intubation. It is remarkable that none such cases had been reported in patients older than one year when standard equipment was used. The exceptions are the group under one year of age [51] discussed in chapter 10 and a study with a 20ml instead of 75ml bulb. [40] Potential causes of a false tracheal sign with the ODD are all associated with gross structural abnormalities of the oesophageal-gastric area.

a Hiatus hernia or achalasia

A large hiatus hernia or achalasia involving the mid and lower thirds of the oesophagus, may allow the tip of the ETT to reach an airfilled cavity if inserted into the oesophagus. Aspiration with the syringe may allow free flow of air and confirm "tracheal" intubation if not combined with the Easycap® or similar device.

b Oesophageal diverticulum

Likewise a large oesophageal diverticulum could be misleading, but are usually in the pharyngeal area, associated with the inferior constrictor and unlikely to be at the level of the ETT tip if it is inserted in the oesophagus.

c Pregnancy

Marked inferior oesophageal sphincter incompetence as occasionally seen in pregnancy may theoretically allow air from the gastric bubble to escape into the oesophagus and allow free aspiration with the ODD. In our series of thirty cases, none were even slightly doubtful.

d Prior mask ventilation

The theory that prior mask ventilation may force gas into the oesophagus with false results [38] has been disproved in adults on many occasions. Williams and Nunn insufflated 50ml of air into the oesophagus before aspiration and had no erronous results. [43] Wee deliberately insufflated the oesophageal tube with two tidal volume compressions of the reservoir bag to simulate normal practice after ETI. [38] His results were not adversely influenced by this prior ventilation. In the Baragwanath-study half of group A received non-depolarizing muscle relaxants and were mask ventilated prior to intubation. The tracheal and oesophageal tubes were as easy to differentiate in these cases as in the others.

However Wee and Walker [38] suggested that the ODD should be used before any insufflation through the tube in children, particularly with the small volume aspiration recommended by them.

7.3 The use of the ODD in paediatrics

Some very disappointing results were published in the under one year age group by Hayes and Morton. [51] Their methodology was different and probably suspect. They used a modified ODD. A 5ml Plastipak® syringe was selected with the nozzle of the syringe within the proximal portion of a corrugated tube connector. [51] The greater negative pressure created by a 5ml syringe may in an infant or neonate collapse the softer trachea onto the ETT bevel in a similar fashion to the collapsable oesophagus.

Another group [41] however found the use of a 50ml syringe quite satisfactory. They aspirated 5ml only and could easily differentiate between oesophageal and tracheal tube placement. In a later study fifty oesophageal and fifty tracheal intubations were easily and rapidly diagnosed in one hundred children aged one to ten years. [38] Unfortunately, only two children in the age group one to two years were included, therefore no conclusions regarding the accuracy of the ODD in children under two years of age can be made. For this reason, another study in the under two years age group is being planned in the Baragwanath ICU in order to reach a conclusion.

7.4 False negative results with capnography

Low or absent ET CO_2 values are known to occur in patients with cardiac arrest. [52] With the less sensitive Easycap^R it is obvious that doubtful results may be obtained in cardiopulmonary resuscitation (CPR) situations. [30]

A big leak around an uncuffed ETT in the presence of positive end expiratory pressure (PEEP) can also lead to failure to detect ET CO_2. [53] Technical problems with the Capnograph has been described to cause false negative results and may not be immediately obvious under the stressful circumstances of a difficult ETI. [54] The simplicity of the Easycap^R is a big advantage in this respect.

False negative results are usually not immediately life-threatening, but may lead to the unnecessary changing of ETT. In the CPR situation however every second is important and therefore the use of the ODD combined with the Easycap^R becomes essential.

7.5 False positive results with capnography

The most common cause of CO_2 in the stomach is prior mask ventilation.[55] This usually disappears after a few ventilations.[56] Another source of CO_2 in the stomach that could lead to false positive results is prior ingestion of antacids or carbonated beverages[57,58]. In elective or semi-emergency anaesthesia the history is usually clear, but in the case of emergency intubation this possibility needs to be considered at all times. Using the ODD in conjunction with the Easycap[R] again improves the diagnostic accuracy consider bly.

7.6 Concerns about the Easycap^R

False positive and false negative results seen with capnography are prone to occur with the Easycap^R as well.

a Use in paediatrics

The deadspace of 38ml is excessive for use in spontaneously breathing babies. [28] A practical solution has been offered by Higgins. [32] He placed the device between the open tailed bag and the expiratory limb of the Jackson Rees modification of the Ayres T-piece circuit. The end-tidal CO_2 concentrations will be diluted by fresh gas flowing into the expiratory limb but he still found it accurate. The reliability of this mode of testing needs to be established in a bigger series, since it has been shown that small tidal volumes had a significant effect on the colour indicator at dilutions of 0,5% and 1 % ET CO_2. [59]

With controlled ventilation for a short period the risk of rebreathing should be negligible. [28] Hundred percent sensitivity and 100% specifity was found in twenty-one tracheal intubations and thirty-three oesophageal intubations in newborn piglets weighing 2.1 to 3.1 Kg. The same group found 100% accuracy in all paediatric patients in a subsequent study except in those with cardiac arrest, where it was unreliable [33] as indicated earlier (chapter 7.4).

b Inactivation of indicator

The Easycap^R is not specific for CO_2. It is composed of a pH-sensitive indicator which reacts with all acidic solutions. Gastric contents contaminating the device gives an orange discolouration to the indicator, but it is a permanent change and the breath by breath variation is lost.[29] Drugs like atropine, adrenaline or lignocaine all have a pH of less than 5,93. When administered via the ETT during CPR they could easily inactivate the indicator with a permanent yellow colour.[29]

c Rebreathing ventilation system

When rebreathing is occurring eg. in a Bain or Mapleson D system, the usual breath by breath colour change will not be seen as inspired air contains more than 2% CO_2.[28]

d Effect of poor lighting and colour-blindness

Wee's concern that the Easycap[R] may be unreliable when lighting is poor or when the observer is colour-blind[60] has been challenged[61] and needs further investigation.

e The Easycap[R] is unreliable

Extremely negative conclusions were made by Sum Ping and associates.[62] Their main criticism is about the detector's limitations during CPR and after carbonated beverages or antacids, which has been discussed with regards to capnography in chapter 7.5.

Another criticism was the interpersonal variation among blinded observers during a colour matching process. A certain degree of interobserver variation is understandable because there is a gradual transition from the A to B to C colour and different observers may disagree at which point each division stops and the next begins.

The degree of variation reported seems excessive. [62] Numerous other investigators reported favourably on the Easycap® without any comment about observer variation. [27, 28, 30, 31, 33-35, 59, 63-66]

f. Cross-infection

In some operating-theatres breathing circuits are replaced routinely after each patient. In others each patient gets a heat and moisture exchanger combined with a bacterial filter. However, in the majority of theatres in SA the circuits are re-used if not wet or macroscopically soiled. The same conditions apply to mainstream capnographs or sidestream adaptors. It has been shown that there is no apparent contamination of tubing with patients' microflora even after fifteen to 360 minutes of anaesthesia. [67] In the very small probability of such an occurrence, there is little risk of such contamination being passed on to subsequent patients. [67] There is no reason to believe that the Easycap® could be more prone to cause nosocomial infections than the above equipment, since only six mechanical breaths are given through the Easycap®. Re-use of the Easycap® is therefore justified. The same applies to the ODD, but since it is small and easily sterilizable by gas or heat it should probably be sterilized after every case, or at the end of each day at least.

7.7 Cost

In our series two Easycap[R] units were used, one for forty two cases and the other for the remainder. The cost per use would be in the order of two rand per case, if used thirty times. In view of the serious consequences of undiagnosed oesophageal intubation the cost to each institution is acceptable even if each unit is used once only for doubtful cases. The ODD is constructed from material readily available in any hospital, and represents minimal cost.

8 Familiarity with the ODD and Easycap^R

The ODD and Easycap^R received extensive publicity in the medical literature in the period 1988 to 1991. Despite that, these devices are largely unknown and unused in South Africa. The reason for this is probably due to lack of interest from the medical equipment industry and the absence of the usual aggressive marketing. The ODD especially received little attention because it cannot be patented: it is readily assembled from equipment universally available in any hospital.

One cannot avoid wondering cynically whether the lack of bells and whistles and electronic gadgetry explains the fact that physicians have not become aware of these devices.

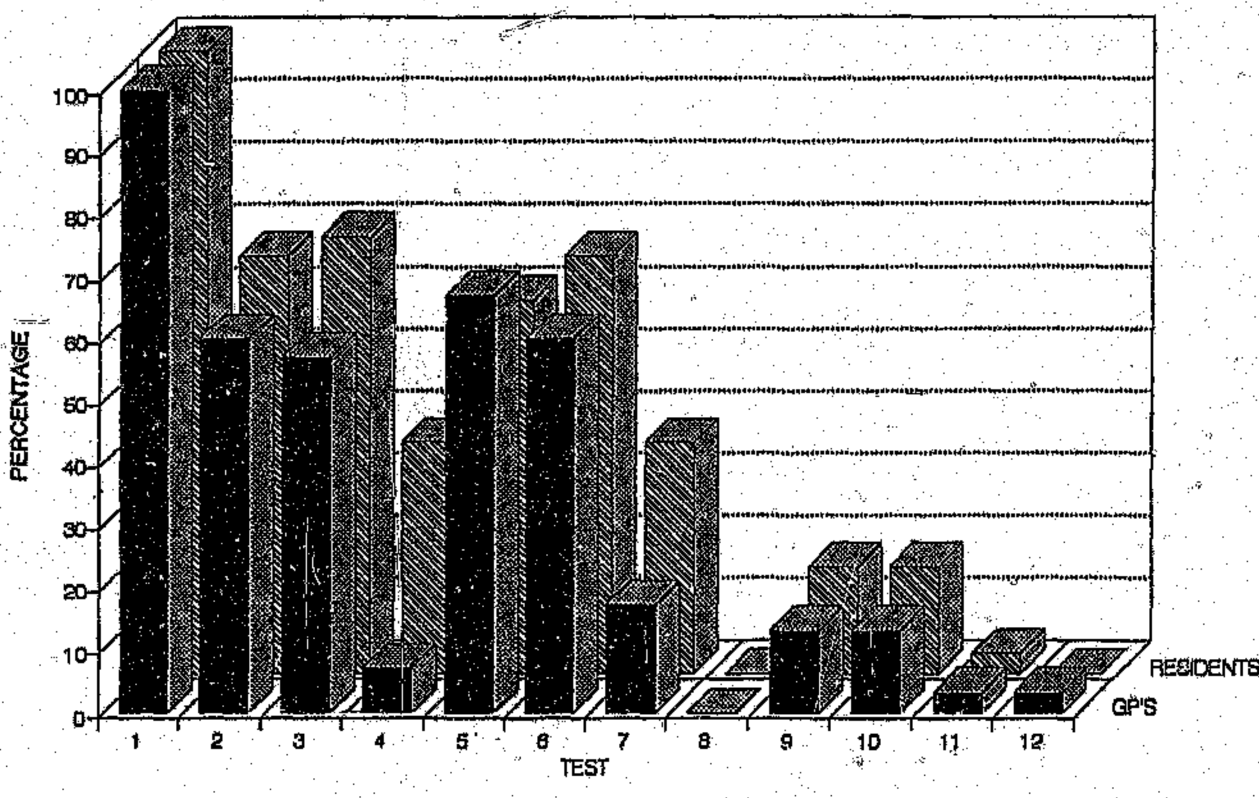
In 1992 a questionnaire was distributed amongst thirty anaesthesia residents varying from senior House Officers to senior Registrars to establish the tests employed by them to confirm ETT placement. A list of commonly used tests to confirm ETT placement was presented. Each respondent had to indicate whether they used it or not. (Table III). In order not to suggest the use of the ODD and Easycap^R in the survey, an open ended question was posed at the end of the questionaire: "Please mention other methods used to confirm ETT placement?" The same questionnaire was distributed amongst non-specialist practitioners involved with anaesthesia in peripheral hospitals. Completed questionnaires were received from thirty one of these general practitioners (GP). An analysis of the response is given in Table III. The methods used by the two groups were very similar, but it is remarkable that not even the anaesthesia residents used the ODD and the Easycap^R.

TABLE III

Response to questionnaire from GP's and residents

	TEST USED.	RES. %	GP's %
1	SEEING ETT BETWEEN CORDS	100	100
2	AUSCULTATION AT LUNG APICES	67	60
3	AUSCULTATION IN AXILLAE	70	57
4	AUSCULTATION IN EPIGASTRIUM	37	7
5	CONDENSATION OF MOISTURE IN ETT	60	67
6	COMPLIANCE ASSESSED WITH BAG	67	60
7	CAPNOGRAPHY	37	17
8	FIBREOPTIC BRONCHOSCOPY	0	0
9	PULSE OXIMETRY	17	13
10	AIR ESCAPING FROM ETT ON COMPRESSING CHEST	17	13
11	CHEST MOVEMENT	3	3
12	RECORDING TIDAL VOLUME	0	3

Fig. 3 Graph indicating percentage of general practitioners (GP's) and residents using different tests to confirm tracheal intubation.



9 Further research

Studies done so far include relatively small numbers. Bigger studies like the one by Zaleski et al [46] are essential. A lot of the information about the ODD is anecdotal, especially as far as adverse results are concerned. (See chapter 7.1). With any new equipment it is imperative that any untoward effect or doubtful result be reported in order for it to be investigated and be seen in perspective. As mentioned in chapter 7.2, no false tracheal sign has yet been described except with the use of non-standard equipment. [31,40] However, the theoretical possibilities do exist and these groups of patients need to be specifically investigated. The Baragwanath study indicates that the ODD could be used reliably in caesarean section patients with severe heartburn. However the size of the study was small and further studies with bigger groups are indicated, particularly because of the frequent difficulty with ETI in the pregnant patient at term. [1] Patients with other anatomical or physiological abnormalities of the trachea or oesophagus should also be investigated in bigger numbers.

The controversy between Wee and Baraka about the ODD in asthmatics has not been resolved yet. [49,50,68] An audit of all severe asthmatics who needs ETI may in a short period resolve the issue if all the Wits ICU's would be involved. Baragwanath ICU alone admits two to three asthmatics per month for ventilation.

The newborn to two year age group needs further evaluation to establish if the device could safely be used in this unique group. Such a study has been approved by the University of the Witwatersrand Ethical Committee and will commence before the end of 1993.

A study to evaluate the accuracy of the Easycap^R in poor lighting conditions and when used by colour-blind observers will resolve the issue discussed in chapter 7.6 d.

10 Conclusion

Some of the deficiencies of the clinical tests used to confirm ETI has been emphasized. The potential defects of the ODD and the Easycap[R] has been discussed at great length to emphasize that no single test can under all circumstances be relied upon to diagnose correct ETT placement.

We were impressed by the accuracy of the ODD and the Easycap[R] as described in the literature and confirmed in our own study. The ease of use, convenient size and rapidity of the two tests suggest that their use in combination should be strongly recommended in all situations where patients are intubated. They are also invaluable to confirm ETT position when patients have to be transported. Most anaesthetists, once familiarized with their use, would be advised to use these devices for most or at least the doubtful intubation. The combined use of the ODD and the Easycap[R] seems to be meeting all the requirements for the ideal test to confirm ETI. When used in conjunction with the traditional clinical tests in a disciplined fashion to confirm correct placement of every ETT, missed oesophageal intubations should become a rare complication.

I would like to conclude that the presence of a laryngoscope at any site in hospital or in emergency care facilities should also indicate the need for the Easycap[R] and the ODD.

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