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Botha, Martin John

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AN ANALYSIS OF PARAMEDIC OUT-OF-HOSPITAL ENDOTRACHEAL INTUBATION SUCCESS IN JOHANNESBURG, SOUTH AFRICA

Martin John Botha

A research report submitted to the

Faculty of Health Sciences, University of the Witwatersrand,

in partial fulfilment of the requirements for the degree of

Master of Science in Medicine in Emergency Medicine.

Johannesburg, 2011

DECLARATION

I, Martin John Botha, declare that this research report is my own work. It is being submitted for the degree of Master of Science in Medicine (Emergency Medicine) in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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DEDICATION

This work is dedicated to my loving wife Dawn
for her patience and support. I am indebted to and grateful for her abiding love during the seemingly endless drudgery of my research efforts.

I further dedicate this effort to The Lord God Almighty,
without whom I am nothing.

PUBLICATIONS ARISING FROM THIS STUDY

No publications have yet arisen from this study. It is the intention of the author to submit a paper to a peer-reviewed journal upon successful completion of this degree.

ABSTRACT

Study objective: The aim of this study was to describe and analyse the success of endotracheal tube (ETT) placement when performed by paramedics in the out-of-hospital setting in Johannesburg, South Africa.

Design: A prospective, observational study design with a consecutive convenience sample was used to analyse the prevalence of unrecognised mal-positioned ETTs by ALS paramedics.

Setting: The ETT position was evaluated by the receiving medical practitioner in patients arriving at eight different urban, public and private, Johannesburg emergency departments (EDs) after being intubated by paramedics from multiple, both public and private – emergency medical services (EMS) agencies out-of-hospital. The study is set in a developing context where EMS systems vary considerably in terms of clinical governance, paramedic experience and qualification, and resources.

Patients: All patients who arrived at Johannesburg EDs who had been intubated by paramedics out-of-hospital regardless of indication, aetiology or age, were included in the convenience sample.

Methods: The main outcome measure was the unrecognized misplaced intubation rate which was recorded via routine methods by the receiving medical practitioner

immediately upon arrival of the intubated patient at the ED. Findings were compared with international values. The use of endotracheal intubation confirmatory devices, both by paramedics and ED medical practitioners, was also reported.

Main results: Of the 100 patients who were intubated out-of-hospital, 2 (2%; 95 CI 0.4% – 7.7%, $p < 0.0001$) arrived with unrecognised oesophageal ETT misplacements, and the ETT cuff was found to be in the pharynx, above the vocal cords in 1% of the sample. Thus, unrecognised mal-positioned intubations were detected in a total of 3 of 100 cases (3%; 95 CI 0.8% – 9.2%, $p < 0.0001$). Right main bronchus positioning occurred in 9 (9%) of cases.

Paramedics reported the use of auscultation of the chest and stomach in 98% of the sample to confirm ETT placement, direct laryngoscopy in 22%, end-tidal carbon dioxide detection ($ETCO_2$) in 19%, and pulse oximetry in 12% of patients. None of the misplaced ETTs had $ETCO_2$ verification used out-of-hospital. ETT confirmation strategies by ED medical practitioners included auscultation of the chest and stomach in 97% of cases, direct laryngoscopy in 33%, and use of capnography to detect $ETCO_2$ in only 4% of out-of-hospital intubated patients.

Conclusions: This, the first known study to evaluate endotracheal intubation placement by EMS personnel in South Africa, found an overall 3% rate of misplaced ETTs (2 oesophageal and 1 hypopharyngeal), similar to several previous investigations, and much less than earlier studies. The findings of this study have important implications for South African EMS policy and practice.

Based on the findings of this study, it seems reasonable to recommend that in a resource-limited, developing country where expensive $ETCO_2$ is not readily available, the out-of-hospital ETT position should, at very least, be confirmed via auscultation, direct laryngoscopy and subjective clinical methods. Despite showing a statistically significant reduction in ETT misplacement rates when compared to international studies in similar settings, the results of this Johannesburg study are alarming and cause for concern, since any misplacement of an ETT in a critically ill or injured patient is calamitous with the potential for increased morbidity and mortality.

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NOMENCLATURE

Abbreviations

ALS	advanced life support
ECP	emergency care practitioner
ED	emergency department
EMS	emergency medical services
$ETCO_2$	end-tidal carbon dioxide
ETI	endotracheal intubation
ETT	endotracheal tube
GCS	Glasgow Coma Scale
HPCSA	Health Professions Council of South Africa
ILCOR	International Liaison Committee on Resuscitation
RSI	rapid sequence intubation
SA	South Africa

Definitions

Misplacement of the endotracheal tube (ETT) is defined as the:

1) distal tube position (ETT cuff) in the oesophagus, or

2) distal tip tube position (ETT cuff) above the vocal cords (hypopharyngeal placement).

The following situations are excluded from the definition of misplacement:

1) when direct laryngoscopy revealed the ETT between the vocal cords;

2) right-mainstem bronchus placement. (This has been reported in this study but was not considered misplacement.)

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Chapter 1

INTRODUCTION

This chapter frames the context and elucidates the rationale and background to the study, introducing the problem statement, aim and objectives, and justification for the research. It culminates in an overview of the chapter topics to follow in this report and will outline the overall structure adopted.

1.1 MOTIVATION AND RATIONALE FOR THIS RESEARCH

Paramedic out-of-hospital endotracheal intubation has been accepted emergency care practice for more than 25 years, introduced initially in an attempt to improve patient outcome by optimising airway protection and ventilation. Few studies, however, affirm or demonstrate improved outcome from out-of-hospital endotracheal intubation; moreover several studies describe worsened outcome, adverse events and errors associated with this practice.[1,2] The South African advanced life support (ALS) paramedic endotracheal intubation experience, despite being well established, has never been subject to audit or analysis. Unrecognised oesophageal misplacement is a potentially lethal complication that has to date not been studied in the South African context. In a 2005 study, Colwell, McVaney & Haukoos[1] assert that the true impact of an out-of-hospital intervention on patient outcomes can only be determined once it has been established whether, and in what settings, the intervention can be safely and correctly performed.

The background to this study is situated within the context of numerous reports in the literature of unrecognised misplaced endotracheal tubes (ETTs) when endotracheal intubation is performed by ALS paramedics out-of-hospital.[1-17] To the best of my knowledge, nothing has been published assessing or describing the success of out-of-hospital paramedic endotracheal intubation in South Africa (SA); neither has any study investigated the prevalence of misplaced ETTs on patient arrival at the hospital emergency department (ED) in SA. The published literature is, however, replete with audits of the safety and success of this practise within international emergency medical service (EMS) systems; it is this background that has framed the current research.[1,14-17]

1.2 STATEMENT OF THE PROBLEM

I hypothesized that misplacement rates of ETTs in this Johannesburg study would be significantly less than that reported in the literature. Since unrecognised oesophageal intubations have dire and potentially lethal consequences, the prevalence of this adverse event in the out-of-hospital environment remains to be described in the South African setting. Furthermore, the extent to which endotracheal intubation confirmatory devices – especially end-tidal carbon dioxide monitors – are employed in Johannesburg EMS and hospital EDs has not previously been audited or described despite being regarded as mandatory in the context of endotracheal intubation in any setting.

1.3 AIM AND OBJECTIVES

1.3.1 Study aim

This study aimed to describe and analyse unrecognised ETT misplacement when paramedics performed endotracheal intubation in the out-of-hospital setting; patients intubated by paramedics who subsequently presented to EDs in Johannesburg during the study period were assessed by the receiving medical practitioner for correct ETT placement.

1.3.2 Study objectives

The objectives of the study were as follows:

i) to determine the prevalence of unrecognised mal-positioned ETTs in patients arriving at eight different urban Johannesburg EDs, after being intubated by ALS paramedics out-of-hospital;

ii) to compare prevalence in Johannesburg with international ETT misplacement rates reported in the literature.

1.4 OUTLINE AND CHAPTER OVERVIEW

Chapter 1 provides relevant context to the study, and defines the scope and structure by introducing the problem statement, aim and objectives. The relevant literature to ground and justify the study is reviewed in chapter 2. In chapter 3 the chosen research methodology and design are clarified and substantiated. An analysis of the data and attempts to interpret the findings are depicted in chapter 4 while in chapter 5 the study findings are discussed. This research report culminates in chapter 6 where recommendations are also offered.

1.5 SUMMARY

The research problem has been contextualised and relevant background has been presented to illustrate and highlight the challenges and controversies surrounding out-of-hospital endotracheal intubation, and in particular the complication of unrecognised oesophageal intubation and mal-positioned ETTs. The problem statement has been advanced: patient safety should be paramount and therefore this potentially catastrophic complication must be audited to allow the regulators of the profession in SA to implement proper quality improvement processes. The aim and objectives of the study were stated and finally a synopsis of the remaining chapters was presented.

The next chapter provides a review of the relevant literature which situates the research problem, grounds the study and provides an argument for the aim of the investigation.

Chapter 2

LITERATURE REVIEW

The background to this study is situated within the context of numerous reports in the literature of unrecognised misplaced ETTs performed by ALS paramedics out-of-hospital. To the best of my knowledge, nothing has been published assessing or describing the success of out-of-hospital paramedic endotracheal intubation in SA. The published literature is however replete with audits of international EMS systems, where the safety and success of out-of-hospital endotracheal intubation practice is analysed, and this will form the framework of this research.[1-17]

Swift and effective airway management is an absolute and accepted priority in an emergency and is critical to a patient's outcome.[1] Placement of ETTs by paramedics in the out-of-hospital setting has long been considered the standard of care, with some studies demonstrating that this airway technique is safe[2-4] and may improve survival in a variety of clinical settings.[5,6] Emergency intubation in the out-of-hospital environment has been widely advocated by many as a life saving procedure in severe acute illness and injury associated with real or potential compromise to the patient's airway and ventilation.[1,2-7] In a Cochrane review[7] on the topic, investigators concluded that the efficacy of emergency intubation as currently practised has not been rigorously studied. Reviewers asserted that the skill level of the operator may be a key factor in determining efficacy of endotracheal intubation.

Table 2.1 Summary of published out-of-hospital ETT misplacement rates.

Year	STUDY	Overall ETT misplacement rate	Unrecognised Oesophageal inubations	Hypo-pharyngeal misplacement	Right Mainstem Bronchus	Setting
1984	Stewart[2]	0.4% (3/779)	0.4% (3/779)		0.4% (3/779)	Mainly cardiac arrest; EP confirm
1988	Pointer[3]	1.3% (5/383)				
1994	Jenkins[8]	5.1% (2/39)				
1996	Bozeman[9]	1% (1/100)				
1998	Sayre[5]	2.9% (3/103)				EMT-B trained to intubate
2000	Gausche[10]		2%		18%	Paediatrics only; paramedic self-reported data
2001	Katz[11]	25% (27/108)	16.7% (18/108)	8.3% (9/108)		EP confirm,* Non-academic with little out-of-hospital training/interest†
2003	Jemmett[12]	12% (13/109)				
2004	Jones[13]	5.8% (12/208)				Single EMS agency with close medical oversight
2005	Silvestri[14]	9% overall incidenc 0%‡ - with $ETCO_2$ 23.3% - no $ETCO_2$	22% (13/60)	1.7%(1/60)		
2005	Colwell[1]	1% (3/278)	0.7% (2/278)		9%	EP confirm
2006	Wang[15]	3.1% (61/1953)				Anonymous self-reporting by EMS§
2006	Wirtz[16]	9% (12/132)	8.3% (11/132)	0.8% (1/132)	15% (20/132)	EP confirm; large EMS
2007	Silvestri[17]		12% (6/70)			All cardiac arrest patients, $ETCO_2$ used in ED, not prehospital.

EP = emergency physician ETT =endotracheal tube RM = right mainstem
EMT-B = emergency medical technician – basic ED = emergency department

* Each tube was immediately evaluated upon arrival at the ED for $ETCO_2$ if it was not regarded as obviously misplaced (ie, epigastric sounds or vomitus via the ETT). Direct laryngoscopy was used to evaluate 63% of the ETTs.
† The frequency of field use of $ETCO_2$ detection was not documented during the study.
‡ 0% unrecognised misplacement rate in patients with continuous $ETCO_2$ monitoring; 23.3% in the group where no continuous $ETCO_2$ monitoring was employed.
§ Prospective multicentre effort involving 45 EMS services; data limited by moderate return rate.

Published literature has, however, illustrated diverse experience with out-of-hospital endotracheal intubation. Recently there has been increased attention and doubt cast on the value of out-of-hospital endotracheal intubation, in terms of the safety and benefit of out-of-hospital intubation in certain categories of patients.[7, 18,19] Table 2.1 provides an overview of published studies reporting on out-of-hospital ETT misplacement rates. Two studies have highlighted unacceptable rates of misplaced ETTs, ranging from 5.8% to 25% in a single EMS agency with close medical oversight using in-hospital emergency physician verification rather than field verification of proper placement by paramedics themselves.[11,13] Katz & Falk found a 25% rate of misplaced ETTs when performed by paramedics in an urban EMS system, two-thirds of which were located in the oesophagus.[11] This was attributed to the failure to use carbon dioxide detection to confirm tube placement. The extent to which South African paramedics use this device has not been previously studied.

A number of other studies have evaluated out-of-hospital endotracheal intubation.[7,10,20-22] Gausche, Lewis & Stratton, et al found a 2% oesophageal intubation rate, 14% dislodgement rate, and 18% right mainstem bronchus rate in out-of-hospital paediatric intubations.[10] Colwel, et al reported a right mainstem bronchus intubation rate of 9%[1] while more recently, Wang, Kupas & Paris, et al reported an endotracheal intubation success rate very similar to Colwell: 86.8% vs. 87.0% when they evaluated 45 EMS systems.[21]

These discrepancies in the literature should be cause for concern and careful consideration. Unrecognised misplacement of an ETT is a potentially lethal

adverse event, the clinical impact of which demands continued assessment of the success and complication rates of endotracheal intubation, to inform evidence-based protocols for urban EMS systems. Methods for determining success rates have included paramedic-initiated reporting and ride-along observers; some studies have included emergency physician evaluations for determining final position of the ETT in out-of-hospital intubations.[1]

One previous study has shown a 25% unrecognised oesophageal intubation rate. This alarmingly high rate of misplacement was attributed, *inter alia*, to non-uniform educational or retraining requirements and varying intubation experience amongst paramedics involved in that study.[11] The authors suggest that the high rate of misplaced tubes found was reflective of only a small number of the agencies and/or paramedics.[11] Colwell, et al reported that 1% of patients intubated by paramedics were found to have misplaced ETTs, with only 0.7% of the total ETTs being unrecognised in the oesophagus, in a hospital-based EMS system which is organised and directed by academic emergency physicians with a strong out-of-hospital care training and interest.[1] They concede, however, that their results may not be generalisable to systems not managed by emergency physicians with a keen interest in out-of-hospital care.

Unrecognised oesophageal intubation is a dire and deadly complication of attempted tracheal intubation – if the intubated patient is not breathing spontaneously, this could directly result in death of the patient. Immediate confirmation of correct placement of the tracheal tube (preferably via end-tidal carbon dioxide detection) is therefore mandatory and the first priority both in the

field and upon arrival at the ED. The availability of devices to monitor tube position after initial placement is however not standard in the South African out-of-hospital or ED milieu. The International Liaison Committee on Resuscitation (ILCOR) points out that evaluation of exhaled carbon dioxide is only one option of several independent methods for confirming tracheal tube placement.[22] The ILCOR guidelines state that accidental dislodgment of a tracheal tube can occur at any time but may be more likely during resuscitation and during transport.[22] It is thus overwhelmingly clear that correct placement of the ETT is best confirmed with various devices which are not routinely available in the South African out-of-hospital setting.

In the South African out-of-hospital environment, it is accepted practise for paramedics to confirm ETT placement via several methods. These include visualisation of the ETT cuff passing into the trachea on direct laryngoscopy, auscultation (listening to the abdomen and both sides of the chest), pulse oximetry (in the non-cardiac arrest patient), visualisation of chest rise while the patient is being ventilated, and misting of the ETT on exhalation. Oesophageal detector devices or end-tidal carbon dioxide detectors are ostensibly seldom used in the South African EMS. The oesophageal detector device – one of the objective methods to confirm proper ETT placement – is a bulb-like device which rapidly returns to its inflated conformation after being squeezed and then released.[22] It works by applying a negative pressure to the proximal ETT connector and will refill quickly if the ETT is placed in the air-filled trachea, but not if it is in the oesophagus, as the flaccid oesophageal walls collapse with negative pressure and occlude the lumen.

Data from Wang, Sweeney & O'Connor[23] in a large retrospective review of both out-of-hospital paramedic and ED patient records, suggest that 90.5% of patients were successfully intubated with two unrecognised field oesophageal intubations. This represents a rate of less than 0.4% (out of a total of 592 endotracheal intubations) in a setting where neither oesophageal detector devices nor colorimetric end-tidal carbon dioxide detectors were used to verify tube location in these cases.[23] In one case intubation was accomplished just prior to patient arrival at the ED, and only auscultation was used by the paramedics to verify placement; in the ED esophageal intubation was identified by re-auscultation and the lack of waveform on end-tidal capnography. In the other case field endotracheal intubation verification was accomplished by auscultation only; in the ED esophageal intubation was identified by direct laryngoscopy. Neither esophageal detector devices nor colorimetric end-tidal carbon dioxide detector devices were used to verify tube location in these cases.

Other studies cite unrecognised oesophageal intubation rates ranging from 0.4% to as high as 16.7%.[24-26] These varying results suggest that this complication may not be as prevalent as claimed by certain authors.[26] However, since unrecognised oesophageal intubation is potentially fatal, any occurrence of this complication should be worrisome. Wang, et al concede that their findings are limited to the extent that the study relied on a single out-of-hospital system with self-reporting by the paramedic and not on independent observation to assess and report the described endotracheal intubation complications.[23] The authors acknowledge that it is difficult to conclusively extrapolate their results to apply to other EMS systems and they state that further studies drawing on larger sample sizes from multiple

out-of-hospital systems and a cross-section of emergency departments (EDs) must be performed in order to develop more definitive conclusions.

Wirtz, Ortiz & Newman, et al affirm that while endotracheal intubation by out-of-hospital providers in the EMS is a well established practice, oesophageal placement is a catastrophic complication.[16] They examined the incidence of unrecognised out-of-hospital ETT misplacement in two EDs receiving patients from a large municipal out-of-hospital system. A prospective observational study with a consecutive sample was employed where all patients arriving with an ETT were assessed by the emergency physician immediately to determine proper placement. Of the 132 patients intubated in the out-of-hospital environment, 12 (9%) were misplaced – 11 tubes were found in the oesophagus and 1 in the hypopharynx. The study concluded that the rate of oesophageal misplacement of ETTs in the out-of-hospital environment in that particular urban setting, and the poor clinical course of patients with unrecognised misplacement, is consistent with previous reports. The authors went further to question the *de facto* benefit of out-of-hospital airway management which does not clearly supersede the potential risks.[16]

They further point out that self-reporting bias and imperfect reference standards have called into question the accuracy of previously reported data. Recent studies have used ED medical practitioner confirmation of tracheal placement on arrival of EMS, often using direct laryngoscopy and/or end-tidal capnometry as reference standards. These reports have shown disparate results, suggesting that misplacement rates may differ substantially in different settings.[14,16] Data also

showed that with the addition of out-of-hospital end-tidal carbon dioxide monitoring, the misplacement rate dropped dramatically.[14,16] Studies from mixed settings (urban/suburban and suburban/rural) showed misplacement rates of 5.8% and 9% suggesting that previous reports may have been an aberration.[12,13]

Akin to other EMS systems worldwide, SA implemented ALS out-of-hospital endotracheal intubation in the mid 1980s. Despite this time-honoured ostensible standard of ALS care, the failure to audit, analyse and study this accepted clinical practice in the last 20 years in SA has meant that, *inter alia*, the incidence of properly placed out-of-hospital ETTs is unknown. The virtual absence of medical direction or any meaningful form of clinical governance in the EMS in SA furthermore justifies and mandates this analysis.

While this issue has previously been studied elsewhere in the world, self-reporting methods are often employed to identify errors. Moreover, paramedics were aware of the assessment of their endotracheal intubation, introducing further bias and casting doubt on the accuracy of the reported data, i.e. the Hawthorne effect. Studies have identified equivocal results that are widely disparate and dependant on, *inter alia*, the setting (urban versus rural), paramedic experience and frequency of performing endotracheal intubation, clinical supervision and equipment to accurately confirm tube placement.

It was hypothesized in this current research project that the rate of unrecognised oesophageal misplacement of ETTs by paramedics in the out-of-hospital environment in the Johannesburg urban setting is considerably lower than that

reported elsewhere in the world. This perception could be attributed to the belief that there is more extensive experience and frequency of intubation attempts undertaken by Johannesburg ALS paramedics. This research served to audit, analyse and evaluate an aspect of South African endotracheal intubation practise, the results of which hopefully may encourage further studies to begin to assess whether this intervention has any impact on patient outcome in the South African urban context.[1] I analysed Johannesburg EMS practice, using prospective observational data, to accurately estimate unrecognised endotracheal intubation misplacement rates from multiple EMS agencies transporting intubated patients to several EDs. Paramedics in this study were all registered by the Health Professions Council of SA, with the same scope of practice, but with varying experience and resources, employed in different EMS agencies.

Chapter 3

MATERIALS AND METHODS

3.1 ETHICS

This research was approved by the Human Research Ethics Committee of the Faculty of Health Sciences of the University of the Witwatersrand (protocol approval number M090543 – see Appendix 2). The right to privacy, confidentiality, and anonymity of research participants and data collectors was guaranteed. Confidential and personal information about the intubated patient or the intubating paramedic was not recorded on the original questionnaires, which were securely stored by the researcher.

Informed consent was not considered necessary in the study, akin to similar studies performed internationally where waivers of informed consent were granted.[1] This is because the primary focus was on out-of-hospital provider performance, where quality assurance and monitoring of out-of-hospital airway management is the goal. Furthermore, no personal identifying information about the intubated patient was recorded, and neither was any personal identifying information about the intubating paramedic documented. The observational, descriptive study – where the placement of an ETT was immediately assessed by the participating on-duty medical practitioner upon arrival at the ED – is part of routine clinical practice in a patient who has already been intubated out-of-hospital, who subsequently presents to an ED.[27] The only difference in this

research is that the clinical practice was specifically documented for the purposes of the study.

It is acknowledged that patients have a right to privacy and this ought not to be infringed without informed consent. Identifying information, including patients' names, initials, or hospital numbers, was not recorded.

3.2 STUDY DESIGN

A prospective, observational study design with a consecutive convenience sample was used to analyse the prevalence of unrecognised mal-positioned ETTs by ALS paramedics.[28]

3.3 STUDY SETTING AND POPULATION

The study was set in eight hospital EDs in Johannesburg, SA: Charlotte Maxeke Johannesburg Academic Hospital, Helen Joseph Hospital, Netcare Milpark Hospital, Netcare Garden City Clinic, Chris Hani Baragwanath Hospital, Life Flora Clinic, Netcare Olivedale Clinic, and Netcare Sunninghill Hospital. Paramedics from all EMS systems represented in Johannesburg deliver their patients to all of these facilities and do not service any one particular hospital involved in the study.

Johannesburg has a population of about 3.75-million people,[29] in a country of 47.9-million.[30] The City of Johannesburg Metropolitan Municipality is served by the municipal emergency management services, and at least two large private EMS providers, all of which provide a paramedic ALS service. The City of Johannesburg

EMS responds to approximately 611 calls per day, with 2 785 priority one[**] calls per month, with an average ALS paramedic staff of three per shift cycle[31]. Paramedic training is nationally standardised for all ALS providers and formally regulated by the Health Professions Council of SA.

The following inclusion and exclusion criteria defined the study population. The analysis included all patients who presented to eight EDs in Johannesburg, who had been intubated by paramedics out-of-hospital. Endotracheal intubation performed by medical practitioners out-of-hospital was not considered. Patients intubated by paramedics out-of-hospital who were unsuccessfully resuscitated, declared dead, and subsequently transferred to a mortuary were not included in the study. The rate of either successful or mal-positioned endotracheal intubations in this group was thus not taken into account.

3.4 STUDY PROTOCOL

All consecutive patients arriving at the selected EDs who had been intubated by an ALS paramedic out-of-hospital were investigated during the first eight months of 2010. The rate of correct ETT position was recorded by the medical practitioner receiving the patient at the relevant ED, who immediately assessed – as per standard clinical practice – whether or not the ETT was correctly placed in the trachea upon receiving the patient. At the very least, the chest and abdomen of all intubated patients was auscultated by the receiving medical practitioner immediately upon arrival of the endotracheal intubated patient. Any further assessment techniques used by the medical practitioner to confirm placement

[**] Priority one calls are those urgent emergency calls that require immediate response and clinical intervention, failing which the patient may demise or suffer serious irreversible morbidity.

were also reported, especially in all cases where tube misplacement was considered. No intervention or change in patient care was involved. Information about the paramedic's intubation experience was not requested in this study. Several other variables were also recorded by the receiving medical practitioner on a questionnaire (Appendix 1) to describe and analyse the situation. All data was anonymous and devoid of any identifying patient details.

Misplacement was defined as:

1) distal tube position (ETT cuff) in the oesophagus;

2) distal tip tube position (ETT cuff) above the vocal cords (hypopharyngeal placement).

The following situations were not defined as misplacement:

1) when direct laryngoscopy revealed the ETT between the vocal cords;

2) right-mainstem placement was documented by either chest radiography or by auscultation and was reported but not considered misplacement.

3.4.1 Data collection

Data collection via observation requires a formalised, prospective design, where the occurrence of events is recorded.[32] Observers – the ED medical practitioners – were orientated to use a standardised survey questionnaire with specifically defined objective criteria on a pre-designed data form.[32] All of the fifty ED medical practitioners oriented agreed to participate. A standardised data form, as used by Wirtz, et al,[16] included the method used by the medical practitioner to determine tube placement, whether oral or nasal route of out-of-hospital intubation, location of the tube, and whether the patient survived to admission.

ED medical practitioners completed the data forms once the out-of-hospital intubated patient arrived at the ED and the ETT was checked for misplacement. Each participant was previously introduced to the aims and methods of the study and trained in the use of study forms and the documentation of confirmation methods. These forms were placed within sealed envelopes and stored securely in dedicated data boxes in the EDs, under the control of the ED medical practitioner. I personally liaised with each participating ED medical practitioner every three weeks to collect data sheets. Furthermore, I regularly contacted the ED Heads of Department, medical practitioners and nursing staff via regular phone calls and personal visits to the ED, to follow up and encourage compliance with data capture. Data from all the participating centres was combined, and only entered into a database at the conclusion of the study. I managed the database personally. Data was collected from January to August 2010.

3.4.2 Outcome Measures

The study was designed to determine the prevalence of unrecognised mal-positioned endotracheal intubation in patients arriving at eight different urban Johannesburg EDs, after being intubated by paramedics out-of-hospital, and to compare the prevalence in Johannesburg with international values (specifically the 25% prevalence reported by Katz & Falk in a similar setting[11]). This comparator was chosen because, at the time, it was undeveloped and shared many similarities with the Johannesburg study.

Unrecognised misplacement rates were reported using descriptive statistics. Other variables that were analysed included:

- oxygen saturation and Glasgow Coma Scale (GCS)[††] values of the intubated patient upon arrival in the ED,
- the mechanism of injury, i.e. whether the patient was involved in trauma, and whether the aetiology included head injury,
- whether there was any airway trauma evident upon direct laryngoscopy by the ED medical practitioner,
- the methods employed by both the intubating paramedic and the receiving ED medical practitioner to confirm ETT placement,
- the drug doses of morphine and midazolam administered by paramedics out-of-hospital to facilitate endotracheal intubation.

3.4.3 Sample Size Estimation

A sample of 100 intubations overall would suffice to estimate the proportion of unrecognised mal-positioned intubations to an accuracy of within 10% with 95% confidence, conservatively assuming a prevalence of 50% less than international reported data. This sample size had power in excess of 90% to detect a 50% lowering compared to internationally published data, specifically the findings from the often-quoted Katz & Falk study in Florida, USA.[11] It is acknowledged that this represents outlier results but the systems share many commonalities.

3.4.4 Data Analysis

It was hypothesized that misplacement rates in the proposed study would be significantly less than 25% as reported in one mixed setting.[11] Historical controls

[††] A scale for measuring level of consciousness, the score out of 15 determined by 3 factors: eye opening, verbal and motor responsiveness.

derived from published literature were used to compare data generated in this study. The proportion of unrecognised mal-positioned intubations was expressed as a percentage and a 95% confidence interval was determined, by applying the Wilson score with continuity correction method, for small proportions. The comparison of the proportion of unrecognised mal-positioned intubations in Johannesburg with values reported elsewhere in the world employed the normal approximation of the binomial test.

3.4.5 Significance level

A p-value < 0.05 was considered to be significant for all statistical tests. Exact p-values were used unless they were very small in which case p<0.0001 was used.

3.5 SOFTWARE

All data was entered and stored in a Microsoft Excel® (Microsoft Office 2007, Microsoft Corporation) spreadsheet. All analysis was conducted using StatSoft, Inc. (2010) STATISTICA® (data analysis software system), version 9.1. www.statsoft.com.

3.6 METHODOLOGICAL LIMITATIONS OF THIS STUDY

The study is limited to the extent that data collection by the receiving medical practitioners at the various EDs was assumed to be complete and accurate. Inter-rater reliability of the receiving medical practitioners was assumed since the assessment of the endotracheal tube position upon arrival of the patient in the ED represents standard and routine emergency medical practise. This assumption however was untested and may be a source of bias and error in the study.

It is further assumed that all patients arriving at the EDs who had been intubated out-of-hospital were indeed reflected in the study. It is acknowledged that despite my attempts to cross-check patient records with numbers of data forms, the difficulty in tracking eligible patients for inclusion in the study to some degree may limit validity of the results.

Furthermore, patients in cardiac arrest out-of-hospital are generally not transported to the ED in line with current accepted ALS practise in SA. This convenience sampling may confound the external validity of the results as these patients who were declared dead on the scene were not assessed for proper endotracheal placement. Autopsy data would have been useful to include those patients transported directly to the mortuary, but this information was not available.

Any patient who may have suffered cardiac arrest en route would still have been taken to the ED for continued resuscitation and not re-routed to the mortuary. These out-of-hospital intubations would therefore still be reflected in the study results.

The validity of some of the results in this study is furthermore likely to be affected to some extent by reporting and recall bias, since the clinical data gleaned from paramedics is reliant on memory, and the forms completed by the medical practitioners are often completed after the emergency has been resolved.

Chapter 4

RESULTS

During the study period, data from 100 patients were recorded. A sample size of 100 intubations was sufficiently powered to estimate the proportion of unrecognised mal-positioned intubations to an accuracy of within 10% with 95% confidence, conservatively assuming a prevalence of 50% less than the worst available published data, i.e. 25% reported by Katz & Falk[11].

This study revealed that the proportion of unrecognised mal-positioned intubations (specifically where the distal ETT cuff position was found to be in the oesophagus by the receiving ED medical practitioner) performed by paramedics out-of-hospital amounted to 2% of the sample, with a 95% confidence interval (CI) 0.4% – 7.7% (applying the Wilson score with continuity correction method, for small proportions), $p < 0.0001$. The normal approximation of the binomial test was employed to compare the proportion of unrecognised mal-positioned intubations in Johannesburg with values reported by Katz & Falk in a similar setting.[11] The Johannesburg results were significantly powered to detect a 50% lower rate compared to this internationally published data.

In addition, the ETT cuff was found to be in the hypopharynx, above the vocal cords in 1% of the sample. Thus, in a total of 3 of 100 cases ($n = 3$) unrecognised mal-positioned intubations were found (3%; 95 CI 0.008–0.092, $p < 0.0001$). Two were oesophageal misplacements, and one was misplaced in the hypopharynx.

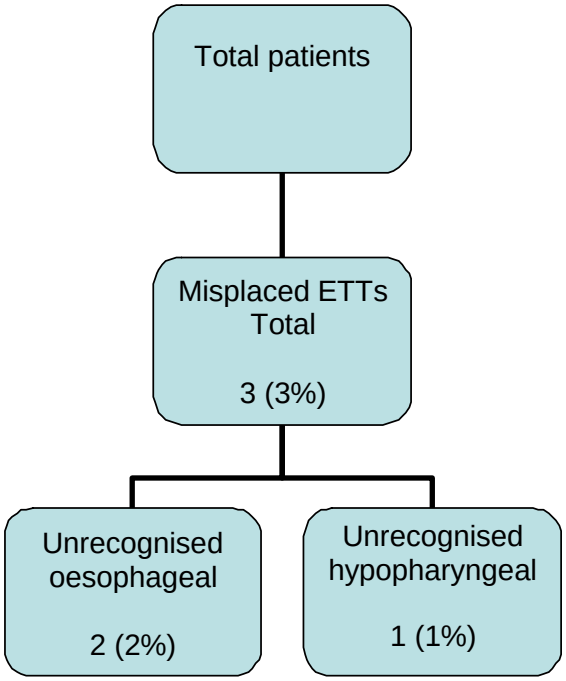


Figure 4.1 Synopsis of misplaced endotracheal tube study findings

Medical practitioners receiving these out-of-hospital intubated patients in the EDs further reported an additional 9% prevalence (n = 9) of right mainstem bronchus intubations. One of the right mainstem intubations was however only confirmed by the medical practitioner after chest radiography. The total number of adverse events – endotracheal tubes that were misplaced, including the right mainstem bronchus intubations – amounted to 12 out of 100 cases (12%; 95 CI 5.1–18.9, p = 0.0019). However, for the purposes of this study, only the proportion of unrecognised mal-positioned intubations (i.e. specifically where the distal ETT cuff position was found to be in the oesophagus or in the hypopharynx above the cords) was considered misplacement, and that figure was 3% (n = 3).

Table 4.1 Characteristics of the two unrecognised oesophageal intubations, and the single unrecognised hypopharyngeal intubation.

	Unrecognised oesophageal intubations		Unrecognised hypopharyngeal intubation
	Patient 1	**Patient 2**	**Patient 1**
Mechanism	trauma - head injury	non-trauma	non-trauma
Midazolam dose received (mg)	10	15	15
Morphine dose received (mg)	10	15	15
Age of patient (years)	64	65	35
Initial GCS on scene (/15)	15	9	10
SpO_2 upon arrival	80%	65%	89%
Confirmation technique used out-of-hospital	Auscultation	Auscultation	Auscultation
Confirmation technique used upon arrival at the ED	Auscultation	Auscultation + direct laryngoscopy	Direct laryngoscopy
Comment	-	-	Airway trauma evident upon arrival

GCS = Glasgow Coma Scale SpO_2 = Oxygen saturation measured via pulse oximetry

ED = emergency department

The two patients who had unrecognised oesophageal intubations upon arrival at the EDs were both intubated initially for a decreased level of consciousness via the oro-tracheal route. One of these patients presented with a severe head injury and the other was of non-trauma aetiology. End-tidal carbon dioxide detection was

not employed for either patient, out-of-hospital or in-hospital, and the initial SpO_2 recorded by the ED staff was 80% and 65% for these two oesophageal intubations respectively.

The mean age of all patients in the study sample was 37 years, the youngest patient enrolled in the study was 10 years old and the oldest 80 (median 35 years). Trauma was responsible for 70% of patients intubated out-of-hospital by paramedics, 84% of these (n = 59 of the 70 trauma patients) had sustained head injuries. All patients were intubated via the oro-tracheal route.

The indication for intubation was cited by the paramedic to be for: 1) a decreased level of consciousness in 70% of the sample, 2) airway protection in 14% of patients, 3) cardiac arrest in 3%, and 4) ventilation in 13% of patients intubated. The mean pulse oximetry oxygen saturation levels upon arrival of the intubated patient at the ED amounted to 92.5%, and a median of 95%. No oesophageal intubation was detected in the patients in cardiac arrest (3%) who were intubated out-of-hospital and subsequently transported to the ED.

Self-reporting of out-of-hospital confirmation of the ETT by paramedics revealed auscultation of the chest and stomach in almost every case (98%). Paramedics cited direct laryngoscopy as another method employed to confirm tube placement in 22% of intubated patients; 19% of patients in the sample had the ETT checked via end-tidal carbon dioxide detection, while paramedics reported using pulse oximetry to detect proper tube placement in 12% of patients. None of the misplaced ETTs had $ETCO_2$ verification used out-of-hospital.

Table 4.2 Summary of endotracheal tube confirmation methods used by the receiving medical practitioner in the emergency department.

	Percentage of patients assessed (%)
Auscultation of chest & over stomach	**97**
Direct laryngoscopy	**33**
Use of capnography	**4**

As illustrated in Table 4.2, ETT confirmation strategies by medical practitioners in the EDs included auscultation of the chest and stomach in 97% of cases, direct laryngoscopy in 33%, and use of a capnograph to detect $ETCO_2$ in only 4% of out-of-hospital intubated patients. Medical practitioners also reported airway trauma being evident after direct visualisation of the cords in 3 of the 33 patients assessed via laryngoscopy.

Two of the right mainstem bronchus paramedic intubation attempts utilised carbon dioxide detection to confirm tube placement, however neither of the two unrecognised oesophageal mal-positioned ETTs nor the single hypopharyngeal misplacement was checked via carbon dioxide detection modalities.

In terms of the pharmacological agents used to facilitate intubation, the mean dose of midazolam administered was 9.9 mg and morphine 8.9 mg, with no correlation apparent between the GCS and the dosages of either drug.

Chapter 5

DISCUSSION

Endotracheal intubation is widely and routinely practised to achieve definitive airway control, and has become an inherent part of out-of-hospital emergency care. However, published literature has documented conflicting and diverse results in terms of success, safety and adverse events resulting from out-of-hospital endotracheal intubation. Stewart, et al in as early as 1984 found that field endotracheal intubation was safe and could be skilfully performed by paramedics, with only a 1% unrecognised oesophageal intubation rate.[2] Katz & Falk in 2001 however reported a 25% rate of misplaced ETTs, two-thirds of which were found in the oesophagus.[11] Given the controversial discrepancies in the literature and the potential devastating impact on patient outcomes, the success and complication rates must be continually reviewed and audited.

5.1 INTRODUCTION

This study analysed the prevalence of paramedic out-of-hospital endotracheal intubation success and the findings are fittingly situated within the contentious context of out-of-hospital intubation in South Africa and indeed across the world. The present research findings are relevant and significant to our local circumstances where the Health Professions Council of South Africa registered Emergency Care Practitioner scope of practice now includes rapid sequence intubation (RSI). Each Emergency Medical Services system ought to institute a robust clinical governance structure that includes audit, quality improvement, self-

regulation, reflection, tracking of data and performance. This mandate should be informed and reinforced by the findings of this study.

The purpose of this study was to analyse the out-of-hospital endotracheal intubation experience in terms of unrecognized misplacement rates in the large urban environment of Johannesburg, in a mixed setting of both public and private EMS and hospital EDs, where out-of-hospital $ETCO_2$ monitoring does not yet appear to be the norm. Unlike other attempts to determine rates and successes elsewhere, this study did not employ paramedic self-reporting or retrospective record review, and is set in EMS systems with very different models of medical direction. This prospective observational analysis relied on the receiving ED medical practitioner to assess tube placement.

5.2 BACKGROUND

The decision to insert an ETT in the emergency patient is based on whether: 1) there is a failure of airway maintenance or protection, 2) there is failure of ventilation or oxygenation, and 3) the clinical condition of the patient is expected to deteriorate.[5] Developed EMS systems worldwide utilise endotracheal intubation, normally under strong medical practitioner control, as a critical element within the paramedic's armamentarium.[1] The procedure ostensibly has become the prevailing standard of care in this out-of-hospital environment with several reports documenting high endotracheal intubation success.[1]

In a 1988 study, Pointer describes paramedic endotracheal intubation performance and found clinically significant complications in 8.9% of patients who

were successfully intubated.[3] Paramedics encountered adverse conditions in 32.9% of the sample, but there were no significant differences in intubation success rate between survivors and non-survivors. They reported five unsuccessful intubations due to oesophageal misplacement, and attributed this to frank disregard of protocols or inadequate assessment skills. Success and complication rates compared favourably with other studies.[6] They concluded that paramedics are indeed able to intubate the trachea with a high success rate in an environment with strong prospective, ongoing, and retrospective medical practitioner control.[6] However, this notion remains a tenuous one in the South African EMS milieu, where only very few EMS systems in reality incorporate an operational, functional supervising emergency medical practitioner, or any formally structured clinical governance. In the present study setting in Johannesburg, there is wide variation in clinical experience, clinical governance, medical control, and specific equipment resources amongst individual providers and EMS systems. Similarly, the EDs selected for data collection in this study also vary widely in terms of resources, systems, case load and patient profile.

5.3 SOUTH AFRICAN CONTEXT

In South Africa, during the time of the Johannesburg study, all HPCSA registered Advanced Life Support (ALS) paramedics were only allowed to administer midazolam and/or morphine to facilitate drug-assisted endotracheal intubation – a combination discouraged widely.[33,34] The Department of Emergency Medical Care and Rescue at the Durban University of Technology (DUT), in their Advanced Airway Management Guidelines 2007, acknowledge – in accord with published data – that this in-vogue South African EMS practise of deep sedation (15mg

morphine and 15mg midazolam) to facilitate endotracheal intubation may be detrimental to the patient.[33-35]

A series of 862 electronic patient report forms in the South African setting were reviewed by Grindell, et al and the average use of morphine in the endotracheal intubated patient was noted to increase in tandem with the GCS.[36] The study found that 152 patients (17.6%) received 5mg of Morphine, 85 patients (9.9%) received 10mg, and 63 patients (7.3%) received 15mg. The authors further posited that RSI agents may thus mitigate this potential risk associated with excessive midazolam and morphine. Akin to the results in the present Johannesburg study, dosages of these medications were found to be substantial, which further portends the possibility of clinical instability and adverse events.

RSI has only recently been formally endorsed by the Health Professions Council of South for registered Emergency Care Practitioners. These providers have a four-year professional degree and are registered in the independent practice category. The RSI technique, when performed by experienced, competent clinicians, may increase the likelihood of successful tracheal intubation and simultaneously decrease complications[35-37] when compared to other intubation methodologies. This suggests that the introduction of RSI to the scope of practice of the Emergency Care Practitioner in SA may result in better intubating conditions and less adverse events, including oesophageal intubation.[35] However, this aspect remains to be studied in the South African context.

5.4 RISK VERSUS BENEFIT OF ENDOTRACHEAL INTUBATION

Airway management is a time-honoured priority during the resuscitation of severely sick or injured patients, offering early airway protection and controlled ventilation.[37-40] These outcomes are essential in the management of certain patients,[37-40] in particular, the patient with serious head injuries.[41-44] While there is evidence that out-of-hospital intubation can be performed safely when undertaken by properly trained practitioners,[41-44] the risks are also well recognised.[18,39,40,45-48] In addition to tube misplacement, as investigated in this study, other risks of ETI include, *inter alia*, protracted periods of hypoxia and hypercapnoea during the intubation attempt, hyperventilation leading to hypocapnoea and increased intrathoracic pressure which subsequently limits venous return and cardiac output; vomiting, vagal effects, laryngospasm and airway trauma are further complications.

Out-of-hospital endotracheal intubation as a means of airway management presents emergency teams with complex challenges – it is a skilled technique requiring considerable training and experience.[49] In comparison with in-hospital management, out-of-hospital airway management has been reported as more difficult.[50] Challenges to intubation in an out-of-hospital setting include non-fasted, awake or combative patients, blood, vomit and debris in the upper airway, difficult access to the patient and external conditions such as inadequate lighting, excessive noise, limited equipment and monitoring and lack of skilled help. Despite these factors, the same high standards for successful intubation demanded in the hospital environment must be applied to the out-of-hospital setting to ensure positive outcomes.

The potential benefit of out-of-hospital endotracheal intubation continues to attract much debate, despite the acceptance that intubation secures the airway and is a priority in the resuscitation of the trauma patient.[49,37-40] The skill of airway management has been shown to decline after initial training.[51] However, independent practice with feedback has been shown to be effective in maintaining performance[51] and performing a certain number of intubations over a certain period is said to maintain competency.[51,52] Standardised protocols have been found to improve intubation success.[53] Training in the use of end-tidal carbon dioxide ($ETCO_2$) detection and airway adjuncts such as the bougie and the use of external laryngeal manipulation to improve laryngoscopic view is recommended, as is a continual commitment to quality assurance and performance review.[51]

The rate of uncorrected misplaced tracheal tubes drops from 25% to 0% with the routine use of $ETCO_2$ monitors.[53] The British Paramedic Association's position paper notes that the paucity of aids to confirm correct placement does not in itself represent poor standards of clinical competence, but is indeed an indictment on clinical governance.[53] The use of $ETCO_2$ monitors is unfortunately not the norm in South Africa, despite this being generally recommended in the anaesthetic and ED environments. The present Johannesburg study found only 19% of patients intubated out-of-hospital had $ETCO_2$ measured, and 4% of ED medical practitioners reported using $ETCO_2$ to confirm tube placement. Furthermore, the routine use of the oesophageal detector device – again an item seldom encountered in paramedic kit – is strongly recommended[53] but did not feature whatsoever in the present study. Despite uncovering many adverse events, the

study from San Diego clearly showed that advanced monitoring including pulse oximetry and $ETCO_2$ should be mandatory when performing endotracheal intubation.[54,55]

Efforts to optimise out-of-hospital airway management must include *inter alia* regular intubation practise and continuing experience, consistent use of continuous waveform end-tidal capnography to verify ETT placement,[25,56] robust quality assurance and audit, and close medical oversight.[56, 57] Results of this current research show that 3% (3 of 100) of the study sample arrived with ETT misplacement during the study period: 2% (2 of 100) of these out-of-hospital endotracheal intubations arrived in hospital with oesophageal misplacement, and 1% (1 of 100) with hypopharyngeal misplacement. While these results reflect a substantial lowering of the prevalence compared to several other settings, any unrecognized misplacement is disconcerting and untenable due to the potentially catastrophic iatrogenic complication that this event represents. When compared to other studies with much larger prevalence data, the 2% rate of unrecognised oesophageal misplacement detected in the current study may suggest that little intervention or concern is warranted. However, since unrecognised oesophageal intubation may impinge on patient safety and be potentially fatal, any occurrence of this catastrophic complication is disconcerting and indeed untenable, and should trigger reflective audit and urgent remediation.[16]

5.5 INTEGRATION OF THE JOHANNESBURG STUDY

This present study was conducted in one of the largest EMS systems in South Africa, one that services close to 225 000 emergency calls per annum, of which

almost 35 000 are priority 1 calls. Receiving EDs in the Greater Johannesburg area were selected to include both public and private healthcare services, which enabled both the public and private out-of-hospital paramedic performance to be reflected in the data.

Unrecognised oesophageal intubation represents a serious adverse event that may lead to death or catastrophic brain injury. Colwell, et al have reported a 1% rate of misplacement of the ETT when a single large EMS agency was evaluated transferring patients to multiple EDs.[1] In this study setting, paramedics intubate on average just more than ten intubations per year in a hospital-based EMS system with strong academic specialist emergency physician input and rigorous reporting and review mechanisms in place.[1]

In an often quoted series of 108 patients, Katz & Falk found the ETT misplaced in 25% of cases in a setting where multiple EMS agencies transported patients to a single ED.[11] This Johannesburg study has analysed data from multiple EMS agencies delivering patients to multiple EDs.

Gausche, et al in a paediatric population found a 2% oesophageal intubation rate, and 18% right mainstem bronchus intubation rate.[10] This Johannesburg study showed a right mainstem bronchus intubation rate of 9%, however the difference may be attributed to the fact that the Gausche study assessed only paediatric patients, while the current study assessed mainly adults.

Jones, et al[13] in Indianapolis reported a 5.8% rate of unrecognised, misplaced out of-hospital intubations in 2004, in only the second study to evaluate the accuracy of out-of-hospital endotracheal intubation using emergency physicians as the verification criterion standard – the Katz study was the first[11]. In Indianapolis approximately 73% of the out-of-hospital intubations in the study were performed by paramedics from a single hospital-based ambulance service – the largest and oldest one in the United States – which receives its medical direction from an academic, university-based emergency physician. In contrast to this out-of-hospital model, the Orlando scenario described by Katz, et al was at that time bereft of strong, centralised, academic-based medical control, in accord with the Johannesburg setting.

The relative impact of the findings in the Johannesburg study, compared to the results found elsewhere, warrants further deliberation. In this current study the rate of ETT mal-positioning is substantially less than many international reports from developed settings with active and robust clinical governance, medical direction, and standardised protocols. Why then, the question may be posed, should the South African EMS community be concerned? While the results are not perfect, is it justified in a developing country, where resources in general are scant, to be aiming for a zero unrecognised oesophageal intubation rate?

The results of this Johannesburg study may support this argument, since the results reflect improvement in ETT misplacement rates despite a paucity of $ETCO_2$ detection devices and oesophageal detectors. It would thus be difficult to justify the considerable ostensibly superfluous expense of equipping every ALS provider,

and indeed every ED, with an $ETCO_2$ capnographic detector, if auscultation alone seems to correctly confirm ETT placement in the majority of patients. However, if the aim is a zero misplacement rate, then these goals must be pursued, and auscultation in tandem with direct laryngoscopy must be supplemented with further objective confirmation methods.

Moreover, there is now compelling evidence to suggest that all ALS providers, both in-hospital and out, should exploit the enhanced value of capnography in cardiac arrest patients, as it allows objective assessment of the quality and effectiveness of cardiopulmonary resuscitation, and provides insight into return of spontaneous circulation.[22,58,59] Continuous waveform capnography remains the most reliable method to confirm and monitor correct ETT placement, especially in patients at increased risk of ETT displacement during transport or transfer.[22,58]

Capnometry is a non-invasive monitoring technique which provides fast and reliable insight into ventilation and circulation, and particularly out-of-hospital has been widely posited as the gold standard to confirm correct tracheal tube placement.[22,58-60] Continuous capnography or capnometry monitoring may be beneficial by providing feedback on the effectiveness of chest compressions due to its correlation with cardiac output, and may inform the clinical evaluation of all critically ill patients, reflecting maintenance of adequate oxygenation, ventilation and perfusion. Changes in $ETCO_2$ partial pressure promptly reflect ventilatory and/or circulatory compromise and thus help in the timely recognition of patients at risk.[60]

Over and above $ETCO_2$ monitoring, clinical governance, medical direction and protocols are likely to address more than oesophageal intubation. This study reflects only those patients arriving at the ED, who were believed by the medics to have been successfully intubated. Although outside of the scope of this project, those cases where intubation attempts failed, and where complications, arose were not detected. A developed system is likely to monitor, identify and develop these aspects; it also may potentially provide cost effective improvements in patient care and ease the downstream burden of critically ill patients.

5.6 CONFIRMING ADVANCED AIRWAY PLACEMENT OUT-OF-HOSPITAL

Unrecognised oesophageal intubation is a dire complication of attempted tracheal intubation, and thus the passage of every single ETT mandates routine confirmation of correct placement to reduce this risk. An International Liaison Committee on Resuscitation (ILCOR) review found that no single confirmation technique is completely reliable to confirm tracheal tube placement, particularly in cardiac arrest patients.[22,58] However continuous wave-form capnography to detect exhaled carbon dioxide is currently regarded as the gold standard method to confirm and monitor ETT placement in the field, in the transport vehicle, on arrival at the hospital, and after any patient transfer to reduce the risk of unrecognized tube misplacement or displacement.[22,58,59] The oesophageal detector device is another adjunct that is sensitive for detection of misplaced tracheal tubes in the oesophagus, but may spuriously suggest oesophageal placement when the tube is indeed in the right place, prompting removal.[58,59] This reinforces the notion that multiple methods of ETT confirmation must always be employed. While continuous waveform capnography is recommended in addition to clinical assessment as the

most reliable method of confirming and monitoring correct placement of an ETT, it may be argued based on the results of the present study, that in developing settings where expensive resources are few, auscultation, direct laryngoscopy and subjective clinical assessment may be reasonable and justified.

The Emergency Medicine Society of South Africa states, via their rapid sequence intubation practice guideline, that out-of-hospital rapid sequence intubation can be a safe, appropriate and effective technique when performed in the out-of-hospital environment by either medical practitioners or appropriately trained and credentialed paramedical personnel.[61] A precarious evidence base fails to reinforce endotracheal intubation as an intervention without risk to patient safety (in both adults and children) when performed in the out-of-hospital environment. No guidelines validated in South Africa are available with respect to this practice. The Emergency Medicine Society of South Africa thus formally recommends several requirements to guide safe implementation of out-of-hospital rapid sequence intubation.[61] The availability of proper and sufficient equipment features prominently. This must include *inter alia* a variety of laryngoscope handles and blades, a bougie, rescue airway devices, surgical airway kits, some form of capnometry or capnography device. Appropriate monitoring equipment and protocols should furthermore be available and in place, in tandem with provisions for clinical governance and oversight of performance of endotracheal intubation.[61]

A clear and unambiguous pronouncement is made by the Emergency Medicine Society of South Africa regarding the confirmation and verification of correct placement of the ETT.[61] According to their practice guideline, ETT placement

should be confirmed by auscultation and an objective confirmatory device (ideally an exhaled carbon dioxide detector device or capnography).[61]

Misplacement of the ETT may reflect inadequate initial training or lack of experience on the part of the intubating provider, or it may have resulted from displacement of a correctly positioned tube when the patient was moved.[58] The risk of tube misplacement or displacement is high when the patient is moved, so despite seeing the ETT pass through the vocal cords and tube position being verified by chest expansion and auscultation during positive-pressure ventilation, additional confirmation via waveform capnography, exhaled CO_2 or oesophageal detector device is recommended.[58,59] The provider should use both clinical assessment and confirmation devices (continuous waveform capnography) to verify tube placement immediately after insertion and again when the patient is moved; however should waveform capnography not be available, use of an oesophageal detector device or non-waveform exhaled CO_2 monitor in addition to clinical assessment is reasonable.[58,59] However, in developing, resource-limited settings such as in the current Johannesburg study, it may be reasonable to recommend less expensive methods of ETT confirmation, including auscultation and direct laryngoscopy, in conjunction with subjective clinical assessment.

The literature is replete with controversy around the topic of out-of-hospital endotracheal intubation with many publications suggesting that that there may be overall harm associated with the procedure rather than benefit.[22-25] If the prevalence of patients with out-of-hospital misplacement of ETTs is likely to be statistically comparable to the best-projected potential benefit of out-of-hospital

endotracheal intubation, then a sober and serious re-evaluation of the value of this procedure seems warranted. It is in this context that the raw success rates of intubation need to be understood. This is especially relevant in the current urban study setting where transport times are in general short, and receiving hospital EDs are well resourced, suggesting a reasonable case for suspension of all out-of-hospital endotracheal intubation.[16] This aspect is beyond the scope of the present study.

It appears from several published reports however that a substantial reduction in unrecognized misplacement rate is possible where $ETCO_2$ detection is used.[10,12,14,16] Silvestri, et al, in a follow-up study to the original Katz, et al report, found that the miss rate decreased from 25% to 9% when a protocol mandating continuous $ETCO_2$ monitoring was instituted for all intubated patients.[14] Their rate of misplaced ETTs dropped to zero in the subset of patients with 100% protocol compliance.[14] A miss rate of 0.3% was furthermore reported when succinylcholine was used in tandem with $ETCO_2$ detection and a tube aspiration device (oesophageal detector).[24] Thus, it seems that a zero miss rate is indeed achievable in the out-of-hospital milieu. In the present Johannesburg study – although not demonstrating a zero miss rate – a substantial reduction in ETT misplacement was noted in a context largely without the benefit of $ETCO_2$, using predominantly auscultation to confirm proper ETT placement.

The overwhelming majority of patients (81%) enrolled in the Johannesburg study did not have their ETT position checked via $ETCO_2$ detection device. All three misplaced ETTs occurred without any SpO_2 or $ETCO_2$ detection. The real and

tangible possibility thus exists to significantly reduce misplacement rates of ETTs in this out-of-hospital setting, which is likely to have critical impact on mortality and morbidity given the apparently unfavourable risk-benefit ratios in the setting of unconfirmed tube placement.

Timmermann, et al[63] conducted an observational, prospective study in Germany amongst patients requiring transport by air and out-of-hospital tracheal intubation. In this setting it was the primary emergency physician who performed the intubation, not a paramedic as is the usual case in South Africa. Researchers evaluated the number of unrecognized oesophageal and endobronchial intubations. Tracheal tube placement was verified on scene by a study physician using a combination of direct visualization, end-tidal carbon dioxide detection, oesophageal detection device, and physical examination. Results from the five year study period (149 consecutive out-of-hospital tracheal intubations performed by primary emergency physicians) reflected right mainstem bronchus or oesophageal placement in 16 (10.7%) and 10 (6.7%) patients, respectively.[63] All oesophageal intubations were detected and corrected by the study physician at the scene, but 7 of these 10 patients died within the first 24 hours of treatment.[63]

These results attest to the fact that although rapid establishment of a patent airway in ill or injured patients is a priority for out-of-hospital rescue personnel, out-of-hospital tracheal intubation can be challenging for all providers, including primary emergency physicians.[63] Any unrecognized oesophageal intubation is a clinical disaster. Authors of the German study suggest that the incidence of unrecognized oesophageal intubation is frequent and is associated with a high mortality rate.[63]

They declare that oesophageal intubation can be detected with end-tidal carbon dioxide monitoring and an oesophageal detection device. Out-of-hospital care providers, whoever they may be, should receive continuing training in airway management, and should be provided additional confirmatory adjuncts to aid in the determination of tracheal tube placement[63] – an appreciably difficult task in the noisy, poorly illuminated, uncontrolled, transitional and mobile out-of-hospital environment.

5.7 CONFIRMING ADVANCED AIRWAY PLACEMENT IN THE ED

It is reasonable to assume that the same rigorous and deliberate ETT confirmation imperatives mandated for the out-of-hospital milieu should equally apply in the ED. The ILCOR review, which culminated in the 2010 Consensus on Science and Treatment Recommendations document, unequivocally affirms the use of capnography to confirm and continually monitor tracheal tube placement. Moreover, capnography is valuable to determine the real-time quality of cardiopulmonary resuscitation efforts.[58,59]

The routine practice of placing a tracheal tube – once considered the optimal method of managing the airway during cardiac arrest – is now contentious with evidence suggesting that without adequate training or ongoing skills maintenance, the incidence of failed intubations and complications (e.g., unrecognised oesophageal intubation or unrecognised dislodgment) is unacceptably high.[11,62,63] Waveform capnography is recommended to confirm and continuously monitor the position of a tracheal tube in victims of cardiac arrest and it should be used in addition to clinical assessment (auscultation and direct visualization are

suggested).[22,58,59] If waveform capnography is not available, a non-waveform carbon dioxide (CO_2) detector or oesophageal detector device in addition to clinical assessment can be used.[58]

Confirming advanced airway placement in all environments should include exhaled CO_2 detection and oesophageal detection devices.[22] Studies of waveform capnography to verify tracheal tube position in victims of cardiac arrest after intubation have demonstrated 100% sensitivity and 100% specificity in identifying correct ETT placement.[17,22,64] One of these studies included 246 intubations in cardiac arrest with nine oesophageal intubations,[17,64] and the other included 51 cardiac arrests with an overall oesophageal intubation rate of 23%; it is not specified how many of these occurred in the cardiac arrest group however. Three studies[65-67] on out-of-hospital cardiac arrest victims, with a cumulative total of 194 tracheal and 22 oesophageal tube placements, demonstrated an overall 64% sensitivity and 100% specificity in identifying correct tracheal tube placement when using the same model capnometer (no waveform capnography). Sensitivity, however, may have been adversely affected by prolonged resuscitation and transport times of many of the cardiac arrest victims included in the studies. Intubation was performed after arrival at hospital and time to intubation averaged more than 30 minutes.

Studies of colorimetric $ETCO_2$ detectors, syringe aspiration oesophageal detector device, self-inflating bulb oesophageal detector device[65-67] and non-waveform $ETCO_2$ capnometers showed that the accuracy of these devices is similar to the accuracy of clinical assessment (although not uniformly defined across all studies)

for confirming the tracheal position of a tracheal tube in victims of cardiac arrest. The oesophageal detector device – one of the objective methods to confirm proper ETT placement – is a bulb-like device which rapidly returns to its inflated conformation after being squeezed and then released. It works by applying a negative pressure to the proximal ETT connector and will refill quickly if the ETT is placed in the air-filled trachea. However, if the ETT is placed in the oesophagus – a non-patent potential space – the oesophageal detector device will not re-expand, or only do so slowly, after being squeezed and released.

Treatment recommendations in the ILCOR consensus document strongly advocate for waveform capnography to confirm and continuously monitor the position of a tracheal tube in victims of cardiac arrest, and it should be used in addition to clinical assessment – auscultation and direct visualization are suggested. If waveform capnography is not available, a non-waveform carbon dioxide detector or oesophageal detector device in addition to clinical assessment is an alternative.[22,58]

Confirming the location of the ETT is vital to avoid the potentially lethal possibility of unrecognised oesophageal intubation or hypopharyngeal placement.[68] According to Kovacs & Law,[68] observing the ETT inflatable cuff passing through the cords is the first objective method to confirm ETT position. In any setting, $ETCO_2$ detection to objectively confirm correct ETT placement represents the standard of care in emergency airway management, via either disposable CO_2 detectors or continuously reading capnographs.[68] The latter employ infrared spectrometry to measure and display CO_2 concentration on inspired and expired

gas, which may be reduced during profound shock states or cardiac arrest, leading to spurious readings.[68]

Correct ETT placement should be evidenced by at least two objective confirmation methods.[68] Subjective clinical signs to confirm proper ETT placement should also be sought, over and above visualisation of the ETT cuff passing just beyond the cords, and either $ETCO_2$ detection or use of the oesophageal detector. These subjective methods include chest and stomach auscultation, increasing oxygen saturation on pulse oximetry, compliance of the bag-valve-mask ventilator, and normalisation of heart rate and blood pressure parameters.[68]

A clinician expected to independently manage acute airway emergencies is mandated to be skilled and currently competent.[68] Airway management in the out-of-hospital setting should facilitate optimal oxygenation and ventilation via a range of techniques, which should be determined by local protocols. Whether out-of-hospital or not, the same principles and priorities apply. As Kovacs & Law[68] point out, clinician factors must be considered to allow effective airway management decisions. These factors include the knowledge base, psychomotor skills, equipment and the availability of trained assistants. Continuous training and practical experience must build on a strong educational foundation in order to maintain procedural skill proficiency. Exposure to insufficient numbers of patients who require endotracheal intubation, however, often presents a practical limitation to maintaining competence. Effective systems of continuous quality improvement in the context of a closely supervised, protocol-based practice should address these challenges. EMS systems with specific ETT verification protocols (which

include $ETCO_2$ monitoring), together with ongoing quality improvement programmes, demonstrate low rates of unrecognised oesophageal intubation.[9] Unacceptably high rates of oesophageal intubation are found when no such protocols are in place.[11] Kovacs & Law[68] assert that $ETCO_2$ verification of correct tube placement has evolved into the standard of care in the EMS arena. It is reasonable, at the very least, that the same standards should apply in all settings, including the in-hospital ED.

The rapid sequence intubation practice guideline for in-hospital emergency centres published by the Emergency Medicine Society of South Africa, in accord with the discussion above, affirms that the task of securing an airway ranks as one of the most important in emergency medicine. Any clinician managing an acutely unstable patient is mandated, as a priority, to obtain and maintain a patent, protected airway. The position of the tube must be confirmed to be within the trachea and not the oesophagus, by clinical examination – visualising the ETT passing between the vocal cords, listening for the absence of sounds over the stomach with a single ventilation, and listening for appropriate breath sounds in both lung fields. Although still useful, the difficulty in confidently distinguishing between correct and incorrect tube placement with auscultation alone is highlighted in the above guideline and elsewhere.[61,68] Additional means of excluding oesophageal intubation include confirmatory devices, ideally $ETCO_2$, to detect expired CO_2 by means of capnography or colorimetric CO_2 detector, and oesophageal detector device. Continuous oxygen saturation monitoring should be used routinely in the ED when a patient is being intubated.[61]

It is noteworthy and disconcerting that in the present Johannesburg study, only 4% of patients who arrived in the ED already intubated out-of-hospital, had their ETT position checked by the receiving medical practitioner via $ETCO_2$. Table 4.2 summarises the ETT confirmation methods utilised by the medical practitioners in this study. Other ETT confirmation strategies by medical practitioners in the EDs included auscultation of the chest and stomach in 97% of cases, and direct laryngoscopy in 33% of the sample. In 30% of cases, the medical practitioner used both auscultation and direct laryngoscopy to assess ETT placement. In 4% of patients assessed by the receiving medical practitioner, both auscultation and $ETCO_2$ was employed. Thus in 34% of cases, two methods of confirmation were used. No use of the oesophageal detector device was reported.

The above findings may appear to present an incongruous and paradoxical position. The ETT confirmation methods should perhaps be no different whether in the ED or out-of-hospital environment. Best-practice dictates that several methods should be employed to verify correct ETT placement, since auscultation alone is ostensibly unreliable.[68] The infrequent use of $ETCO_2$ detection and the absence of the oesophageal detector device in this study may be attributed to lack of resources in the EDs included in the study, and to ignorance of current best practice.

If it is assumed that auscultation alone is unreliable in the out-of-hospital or ED environment to accurately confirm correct ETT placement, and that this single, inexpensive method may lead to unrecognised oesophageal or hypopharyngeal ETT detection, then the validity of the findings in this present Johannesburg study

must be questioned. The study aim relied on the ED receiving medical practitioner to accurately evaluate the position of the ETT via whatever method they would routinely use. The ETT position was checked by the ED medical practitioner via auscultation of the chest and stomach in 97% of cases, and direct laryngoscopy in 33% of the sample, taking both into account in 30% of cases. It may be argued that in only 33% of cases, where the ED medical practitioner utilised two methods to assess proper ETT placement, can the veracity of the results be accepted.

However, it is important to note that the holistic, subjective clinical assessment of correct ETT position[68] over a period of time is furthermore a valuable indication of proper placement, a factor that mitigates the influence of this limitation. If a patient, who has been intubated out-of-hospital, arrives at the ED with good breath sounds upon bag ventilation and has good oxygen saturation on pulse oximetry, the likelihood of ETT misplacement is probably negligible.

5.8 LIMITATIONS OF THIS STUDY

There were several limitations to this study. It was assumed that all medical practitioners performing observational checks on the proper placement of the ETT in this study were competent and experienced in the emergency setting, and would document each patient entering the ED with a out-of-hospital placed ETT in situ. A further assumption was that the data collection by these medical practitioners will be standardised, valid and reliable based on the relevant specific training and experience accumulated by these providers in emergency medicine. Inter-rater reliability is unknown and a possible limitation. The paucity of $ETCO_2$ detection, direct laryngoscopy and multiple methods of ETT confirmation by the ED medical practitioner also limits the present study. It is assumed that the

medical practitioner correctly assessed the tube position via whatever means they chose to evaluate this. However, this casts doubt on the results of this study since an apparently unreliable benchmarking method, i.e. auscultation, was predominantly used by both the paramedic and the ED medical practitioner responsible for making a judgement regarding proper tube placement. I believe however that auscultation in this developing setting, when coupled with direct laryngoscopy and clinical subjective assessment, is indeed a valid a consistent marker for correct ETT placement, if that is all that is available.

In terms of further limitations, the attempt to ensure consecutive enrolment was imperfect, despite attempts to periodically cross-check charts to assess catchment rates. However this is unlikely to have significantly impacted study findings, because diligent efforts were made to communicate with staff the need to identify all out-of-hospital airway events, and oesophageal misplacements in particular. Thus any missed airway events seem less likely to have been a oesophageal misplacement.

Differences between hospitals was not taken into account, and neither was any data regarding the intubating paramedic described in this study, i.e. experience, available equipment, qualification, etc.. This may make the data difficult to generalise. Moreover, the study design could not detect those out-of-hospital intubated patients who were unsuccessfully resuscitated, declared dead and then removed to the mortuary, thus ignoring the rate of either successful or mal-positioned endotracheal intubations in this group.

Attributing misplacement of the ETT entirely to skill proficiency or experience of the paramedic should not be misconstrued as the intention of this study. It is acknowledged that the position of the ETT may well change as the patient is transferred from the scene, to the emergency vehicle, and ultimately to the ED.

This study did not evaluate the cause of improper tube placement, the consistency of the use of monitoring devices at the time of endotracheal intubation procedure, or whether tubes were misplaced initially or dislodged en route. This latter distinction however has little ultimate clinical consequence, and was not considered in this study. $ETCO_2$ detection may well be employed in this context to confirm proper ETT placement continuously over time while the intubated patient is in transit. A further significant limitation of the study was the lack of uniformity of direct laryngoscopy and $ETCO_2$ detection on all tube verifications by the ED medical practitioners receiving the patient.

5.9 STRENGTHS OF THIS STUDY

To the best of my knowledge, this is the first South African study to examine the prevalence of mal-positioned ETTs placed in the urban out-of-hospital milieu, despite endotracheal intubation being entrenched in out-of-hospital practise for the last 25 years in SA. Contrary to other similar studies, this prospective observational analysis did not rely on self-reporting by the paramedic, or retrospective chart review, and employed clearly pre-defined criteria for misplacement.

Furthermore, the Hawthorne effect (alteration in the behaviour of the studied population due to observation) is unlikely to have occurred as the study was implemented without any EMS notification and participating ED medical practitioners were specifically requested to keep the study motives furtive. Other studies have included formal EMS notification and feedback mechanisms to the out-of-hospital provider organizations after oesophageal misplacement events, resulting in significantly fewer out-of-hospital intubated patients arriving at their hospitals, and thus had the potential of reducing detection of oesophageal misplacements.

Chapter 6

CONCLUSIONS

The controversy surrounding the ability of paramedical personnel to perform orotracheal intubation revolves largely around the belief that this skill may be difficult to learn, that it carries significant risk, and requires frequent practice to maintain an acceptable and safe level of performance.[2]

It is fascinating to note that the above excerpt comes directly from a 1984 study reported by Stewart, et al.[2] Apparently there is nothing new under the sun…[69]

In light of the current controversies raging over the risk-benefit ratio of out-of-hospital airway management, it seems that if endotracheal intubation is indeed being performed in the out-of-hospital arena in South Africa, it should be compliant with current best-practice. Reducing risk and increasing patient safety should remain a primary concern, and includes confirming proper ETT placement and recognising inadvertent oesophageal intubation. Reducing risk involves clinical governance and systems thinking. However, in an environment sans any real medical direction, audit, research, supervision or meaningful clinical governance, it is incumbent on the professional regulator and all role-players to earnestly address these practical issues and develop a rigorous robust mechanism of clinical governance. In our country at present there are no formally established national standards and imperatives in this regard.

Paramedic training is purported to be nationally standardised for all ALS providers and formally regulated by the HPCSA. However, there is much variation in clinical experience, clinical governance, medical control, background and specific equipment resources amongst individual providers and EMS systems. This demands further study to propose recommendations and policy regarding quality assurance and quality improvement processes for out-of-hospital intubation in SA.

It was hypothesized that misplacement rates in the current study would be significantly less than 25% as reported by Katz & Falk in one mixed setting.[11] Although significantly lower than this figure, the rate of unrecognised oesophageal (2%) and hypopharyngeal (1%) misplacement of endotracheal tubes in the out-of-hospital environment in this Johannesburg urban setting is still alarming. The dearth of $ETCO_2$ detection devices is similarly disturbing. Most definitely, according to the international recommendations, more than one confirmation device including pulse oximetry and quantitative $ETCO_2$ monitoring should be mandatory for every out-of-hospital intubation performed. However, based on the findings in the present study, it is recommended that in a developing, resource-restricted environment, auscultation in tandem with direct laryngoscopy and clinical subjective confirmatory methods may well be appropriate and effective.

Systems should furthermore ensure the following: medical direction with concurrent and retrospective oversight supervision; resources for continuous monitoring and recording of heart rate and rhythm, oxygen saturation, and $ETCO_2$ (if available); appropriate training and equipment to confirm initial and verify ongoing tube placement; continuing quality assurance, quality control,

performance review, and when necessary, supplemental training; and ongoing research to clarify the role of out-of-hospital endotracheal intubation on improved patient outcome within EMS systems.[57]

Out-of-hospital care aims to improve survival in the emergency and specifically endotracheal intubation has been one of the interventions proposed to achieve this. However the current literature highlights shortcomings associated with the procedure and few studies affirm current practice, or demonstrate improved outcome.[70] Furthermore, adverse events and errors associated with out-of-hospital endotracheal intubation are frequently reported in the international literature.[70-72] This research report has presented an overview of significant research regarding out-of-hospital endotracheal intubation. It is accepted that ineffective ventilation and oxygenation is detrimental; similarly it is accepted that securing the airway via an endotracheal intubation is a beneficial and established intervention in this situation.[70] The trend that seems to emerge does not dispute the tracheal intubation per se, but rather how it is performed; the ostensible gold standard of advanced airway management remains endotracheal intubation and the patient, whether in-hospital or out, deserves the same level of competent care.[70]

Based on the results of this study, I recommend that the practice of out-of-hospital endotracheal intubation in SA must be supported by a system of clinical governance, review, audit, accountability, continuing competence assessments and proper confirmation resources. In particular, to reduce the risk of unrecognised oesophageal or hypopharyngeal tube placement in the out-of-hospital setting, the ETT position should be confirmed at the very least by

auscultation of the chest and stomach, direct laryngoscopy, and subjective clinical assessment methods.[71,72]

Furthermore, these same goals of patient safety and clinical quality assurance should be pursued in the hospital EDs. It is imperative that the skill is performed safely and in line with international best-practice, to protect the patient form harm and indeed the practitioner from liability.

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APPENDIX 1

DATA COLLECTION FORM

ANALYSIS OF PARAMEDIC OUT-OF-HOSPITAL ENDOTRACHEAL INTUBATION SUCCESS IN A SOUTH AFRICAN URBAN SETTING

Please ensure that the paramedic is not made aware of this study or this research project!

Patient intubated by ALS paramedics out-of-hospital: Trauma ☐ Non-trauma ☐ head injury ☐ Approx Time intubated

PATIENT PROFILE Indication for ETI | total amount of midazolam (mg) received prehosp ☐ | total amount of morphine (mg) received prehosp ☐ | patient age ☐ | GCS on arrival of paramedics E ☐ M ☐ V ☐

Initial S_pO_2 upon arrival at ED ☐ ORAL ROUTE ☐ NASAL ROUTE ☐

How did prehospital paramedic confirm tube placement? (according to paramedic)

I have personally assessed the endotracheal tube placed prehospital by the ALS paramedic **on arrival of this patient at** _____ hospital, on (date) ____/____/2009
and I confirm that at the **time of my initial assessment**_____, the endotracheal tube was: (please tick appropriate box)

1. Placed in the trachea, with the cuff beyond the vocal cords, confirmed by receiving ED medical practitioner ☐ Sign
2. Incorrectly placed, ETT cuff **in the pharynx above the cords**, confirmed by receiving ED medical practitioner ☐ Sign
3. Incorrectly placed, ETT cuff **in the oesophagus**, confirmed by receiving ED medical practitioner ☐ Sign
4. Right mainstem intubation, confirmed by receiving ED medical practitioner ☐ Sign

Method of ETI confirmation used by ED medical practitioner: direct laryngoscopy ☐ auscultation ☐ other, please specify: _____

Evidence of airway trauma from repetitive ETI attempts: YES ☐ NO ☐ If yes, please specify: _____

Please place completed document into box provided.

Should you have any queries, please do not hesitate to contact the researcher: Martin Botha on cell number 082 522 0033 or via email: mbotha@vodamail.co.za

THANK YOU FOR YOUR WILLINGNESS TO PARTICIPATE IN THIS STUDY!

APPENDIX 2

HUMAN RESEARCH ETHICS COMMITTEE CLEARANCE

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mr Martin J Botha

CLEARANCE CERTIFICATE	**M090543**
PROJECT	An Analsysis of Paramedic Out-of-Hospital Endotracheal Intubation Success in Johannesburg, South Africa
INVESTIGATORS	Mr Martin J Botha.
DEPARTMENT	Division of Emergency Medicine
DATE CONSIDERED	09.05.29
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 09.05.29 **CHAIRPERSON** .....
(Professor P E Cleaton Jones)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Prof EB Kramer

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES...
.....

APPENDIX 3

QUESTIONNAIRE INFORMATION

I am conducting a multi-centre prospective observational study to analyse the success of advanced life support paramedic out-of-hospital endotracheal intubation in Johannesburg, South Africa. As a medical practitioner working in a hospital emergency department, your contribution to this study is invaluable. I invite you to assist in this descriptive study by complendotracheal intubationng the brief survey questionnaire below whenever a patient arrives at your facility already intubated by the prehospital advanced life support paramedic. These questions will not take more that sixty seconds to answer.

This is an academic research project, and it is not sponsored by any company or institution. All individual responses will be kept *strictly confidential*; only the aggregate data of all the survey respondents will be reported. No personal identifying information about the intubating paramedic or the patient will be required or recorded.

Please complete the questionnaire as accurately, honestly and in as much detail as you can. Please be specific and include anything you think may be relevant. Your anonymity is assured, and any personal information is strictly confidential. I value your time and effort – thank you! Please ask me if you have any difficulty with any of the questions or you would like any explanation about anything.

I appreciate your willingness to participate in this study. Your contributions to this research will undoubtedly add value to the training of paramedics and the debate around the safety of out-of-hospital endotracheal intubation in the South African urban context. THANK YOU for your time and help in collecting and verifying the data!

Martin Botha

Cell 082 522 0033

Student: MSc Med (Emergency Medicine)

Faculty of Health Sciences, University of the Witwatersrand

INFORMATION AND CONSENT FORM

Dear Colleague

Good day! My name is Martin Botha – I'm currently a student in the MSc Med (Emergency Medicine) at the Division of Emergency Medicine, Faculty of Health Sciences, University of the Witwatersrand. I'm inviting you, as a practising emergency department medical practitioner, to participate in a research study by helping to collect authentic data. This research project is being conducted by me to partially fulfil the final requirements of the *MSc Med (Emergency Medicine)* degree.

Please would you consider helping me with my study? The aim of this research exercise is to analyse and describe the success rates of out-of-hospital endotracheal intubation by South African advanced life support (ALS) paramedics in the Johannesburg. Results of this research will be made available to you, should you want access to this.

You would be expected, should you agree to participate, to complete a survey questionnaire designed to evaluate whether the endotracheal tube placed by the prehospital advanced life support paramedic is indeed correctly placed with the cuff through the vocal cords, or elsewhere. The research will be conducted initially over a three month period and will require your attention whenever a patient arrives at your emergency department having already been intubated by the ALS paramedic out-of-hospital.

Please understand that your decision to participate in this research study is entirely voluntary – you are free to decline to join or withdraw your consent at any time, without consequence. You will need to sign a consent form at the outset, and will retain a signed copy. Participants' anonymity is guaranteed and any personal information collected during the course of this study will be kept strictly confidential. No personal identifying information about the intubating paramedic or the patient will be required, or mentioned.

Your contribution to this study will be most valuable in the audit of out-of-hospital endotracheal intubation safety in South Africa, and to benchmark this against international findings.

I, _____ (participant), fully understand:

- the research method and procedures to be followed;
- that my participation is entirely voluntary and that I may withdraw from the study at any time, without any consequence;
- that if I have any queries, I can direct these to the researcher.

I am aware that I will remain anonymous and strict confidentiality will be assured. By signing this consent form I offer my voluntary, informed, prospective consent and hereby agree to take part in the study.

Name: _____

Signature:_____ Date: _____

Witness: _____ Witness: _____

I, the researcher, confirm that I have explained the research process and methods to the participant, and that I will adhere to the generally accepted ethical norms of research.

Signature: _____ Date: _____

Name: **Martin J Botha**

082 522 0033

mbotha@vodamail.co.za

Supervisor:_____

Professor E Kramer

APPENDIX 4

REQUEST FOR PERMISSION TO CONDUCT RESEARCH AT HOSPITAL

The CEO / Manager

……....Hospital

REQUEST FOR PERMISSION TO CONDUCT OBSERVATIONAL RESEARCH IN HOSPITAL EMERGENCY DEPARTMENT

I am currently a student registered for the MSc Med (Emergency Medicine) programme at the Division of Emergency Medicine, Faculty of Health Sciences, at the University of the Witwatersrand. I am hereby requesting formal permission to conduct a prospective, descriptive, observational study in the Emergency Department of your Hospital to partially fulfil the academic requirements of my degree. This is an academic research project, and it is not sponsored by any company or institution.

The study aims to analyse the success of advanced life support paramedic out-of-hospital endotracheal intubation in Johannesburg. It is envisaged that the participating medical practitioner working in the hospital emergency department will complete a brief survey questionnaire whenever a patient arrives at the facility already intubated by the prehospital advanced life support paramedic. These questions will not take more that sixty seconds to answer. All individual responses will be kept *strictly confidential*; only the aggregate data of all the survey respondents will be reported. No personal identifying information about the intubating paramedic or the patient will be required or recorded.

BACKGROUND AND SUMMARY

Endotracheal intubation by South African advanced life support (ALS) paramedics has been a well established and accepted clinical practise for some 20 years, but never been subject to audit. Unrecognised oesophageal misplacement is a catastrophic complication that has to date not been studied in the South African context. This study aims to describe and analyse paramedic out-of-hospital endotracheal intubation success rates in the urban environment of Johannesburg, and will attempt to determine the prevalence of unrecognised mal-positioned endotracheal intubation in patients arriving at several different urban Johannesburg Emergency Departments, after being intubated by ALS paramedics out-of-hospital. Furthermore the study intends to compare prevalence in Johannesburg with international values reported in the literature. This research will serve to audit, analyse and evaluate an aspect of the South African endotracheal intubation practise and inform other studies to begin to assess whether this intervention does indeed improve outcome in the South African context.

The current literature highlights several shortcomings associated with out-of-hospital endotracheal intubation; in many studies the effectiveness and safety of paramedic out-of-hospital endotracheal intubation has been questioned, with errors and adverse events frequently been reported. This context validates and substantiates the need for this study – the staus quo of out-of-hospital endotracheal intubation South Africa must be described and analysed. Akin to other emergency medical services (EMS) systems worldwide, South Africa implemented ALS prehospital endotracheal intubation capability in the mid 1980s. Despite this time-honoured ostensible standard of ALS care, the failure to audit,

analyse and study this accepted clinical practise in the last 20 years in South Africa has meant that inter alia the incidence of properly placed prehospital endotracheal tubes is unknown. The virtual absence of medical direction or any meaningful form of clinical governance in the majority of EMS systems in South Africa furthermore justifies and mandates this analysis.

METHODOLOGY

A descriptive, prospective, observational study with a consecutive convenient sample is proposed to analyse the prevalence of unrecognised mal-positioned endotracheal tubes by ALS paramedics in patients delivered to several urban hospitals in Johannesburg. All patients arriving at a selected emergency department who have been intubated by an ALS paramedic out-of-hospital will be included in the sample, which constitutes a case series. The rate of success will be recorded by the medical practitioner receiving the patient at the relevant emergency department, who will immediately assess – as per standard clinical practise – whether or not the endotracheal tube is correctly placed in the trachea upon receiving the patient. The paramedic will not be aware of the study, to mitigate the Hawthorne effect. Several other variables will also be recorded by the receiving medical practitioner on a questionnaire to describe and analyse the situation. This data will be anonymous and devoid of any identifying patient details. It is hypothesized that the rate of unrecognized oesophageal misplacement of endotracheal tubes placed by paramedics in the prehospital environment in the Johannesburg urban setting is significantly lower than that reported elsewhere in the world. The results of this study will begin to suggest, in the South African urban

context, whether the benefit of prehospital airway management supersedes the potential risks or not.

REQUEST FOR PERMISSION

I am hereby formally requesting permission to conduct this study in the emergency department of your Hospital. I will approach selected medical practitioners in the emergency department, should your permission be granted, for their consent to participate in the study. Furthermore, should I receive authorisation to go ahead with this study from your institution, the study protocol and ethics application will be submitted to the University for approval. The study can only begin once all these requirements have been met. My proposed research is being supervised by Professor Efraim Kramer, head of the Division of Emergency Medicine in Faculty of Health Sciences, at the University of the Witwatersrand.

Your assistance in this regard would be sincerely appreciated, and would contribute significantly in the audit of out-of-hospital endotracheal intubation safety in South Africa, and to benchmark this against international findings. Please let me know if you require any further information or clarification.

Sincerely

Martin Botha
Student: MSc Med (Emergency Medicine) 8601618P
Email mbotha@vodamail.co.za
Cell 082 522 0033
Fax 086 623 1613