

A RETROSPECTIVE DESCRIPTIVE ANALYSIS OF PREHOSPITAL ADVANCED AIRWAY MANAGEMENT IN A SOUTH AFRICAN PRIVATE EMERGENCY MEDICAL SERVICE

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List of abbreviations

ACLS	Advanced Cardiac Life Support
AES	Adverse Events
CPR	Cardiopulmonary Resuscitation
CO ₂	Carbon Dioxide
DFI	Drug-facilitated Intubation
ECP	Emergency Care Practitioner
EMS	Emergency Medical Services
ETI	Endotracheal Intubation
FPS	First Pass Success
GCS	Glasgow Coma Scale
HEMS	Helicopter Emergency Medical Services
HPCSA	Health Professions Council of South Africa
HR	Heart Rate
ILCOR	International Liaison Committee on Resuscitation
MAP	Mean Arterial Pressure
MILS	Manual Inline Stabilization
OOHCA	Out-of-hospital Cardiac Arrest
OS	Overall Success
PHAAM	Prehospital Advanced Airway Management
PHETI	Prehospital Endotracheal Intubation
PRF	Patient Report Form
RAF	Road Accident Fund
RSI	Rapid Sequence Intubation
SBP	Systolic Blood Pressure
SPO ₂	Pulse Oxygen Saturation
WCA	Workers Compensation Assistance

Declaration

I, Farzana Araie, hereby declare that the research detailed in this dissertation is my own work, except where indicated in the acknowledgments and that neither the whole work nor any part of it has been is being or is to be submitted for another degree in this or any other University.

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Abstract

Introduction: Emergency medical systems have evolved from mostly providing patient transport to healthcare facilities to the provision of emergency care interventions on scene or en route to a healthcare facility. Endotracheal intubation is one of these interventions but despite being performed in the prehospital setting for nearly two decades, the practice of prehospital ETI has not yet been examined on a national level.

Methods: This is a retrospective chart review of prehospital ETI performed by non-physician prehospital providers of a ground-based emergency medical service that operates on a national level over a 12 month period.

Results: Of the 806 cases recorded in the study period, 683 met the criteria for analysis. Male patients accounted for 67% of the cases. The majority of patients (56%) intubated were trauma patients while the remaining 44% were intubated for medical reasons. The first pass success rate was 74% and the overall success rate was 98%. Rapid sequence intubation was the method used to intubate 34% of patients. Approximately 29% received drug facilitated intubation and 27% of patients were intubated whilst being treated for cardiac arrest. Approximately 65% of patients had documented risk factors for difficult intubation. Clinical adverse events were recorded in 14% of cases.

Discussion: The first pass success and overall success rates compare favourably with those reported in similar contexts. Adverse events were thought to be under-reported.

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LITERATURE REVIEW

INTRODUCTION

Effective airway management is a key component of anaesthesia, critical care and emergency medicine. It is the first priority in the Airway-Breathing-Circulation tenet that underpins these disciplines. This is as true for the prehospital environment as it is for the theatre environment, critical care units and emergency centres^{1,2}.

In the pre-hospital environment, the majority of patients can be managed using basic non-invasive airway manoeuvres. The most physiologically compromised, severely ill or injured patients often require some form of invasive, advanced airway management strategy early in the course of their care to facilitate oxygenation, ventilation, and provide protection from aspiration of gastric contents or other body fluids. Very often, this is provided through Endotracheal Intubation (ETI), which is considered to be gold standard in the establishment of a definitive airway³.

ETI can be performed in a number of ways using a variety of pharmacological agents, techniques, equipment and numerous airway devices and adjuncts. These are all employed in order to achieve the same endpoint: the passage of an endotracheal tube into a patient's trachea. This variation in practise introduces a degree of complexity to this intervention.

Globally, much heterogeneity exists in the performance or conduct of prehospital ETI with respect to geographic and environmental factors, EMS system design, EMS practitioner training, experience and skill level, procedural protocols and algorithms, patient characteristics, and clinical governance.

There is also a distinct lack of standardisation with respect to data collection methods when evaluating the literature relevant to this topic. Despite the many studies that have been done internationally on Prehospital Advanced Airway Management (PHAAM), these inconsistencies affect the quality of conclusions drawn about such data and makes comparisons between data sets very difficult. This manifests as ongoing uncertainty within the medical community on the best method of PHAAM and its relationship to patient outcomes.

The aims of this literature review are to:

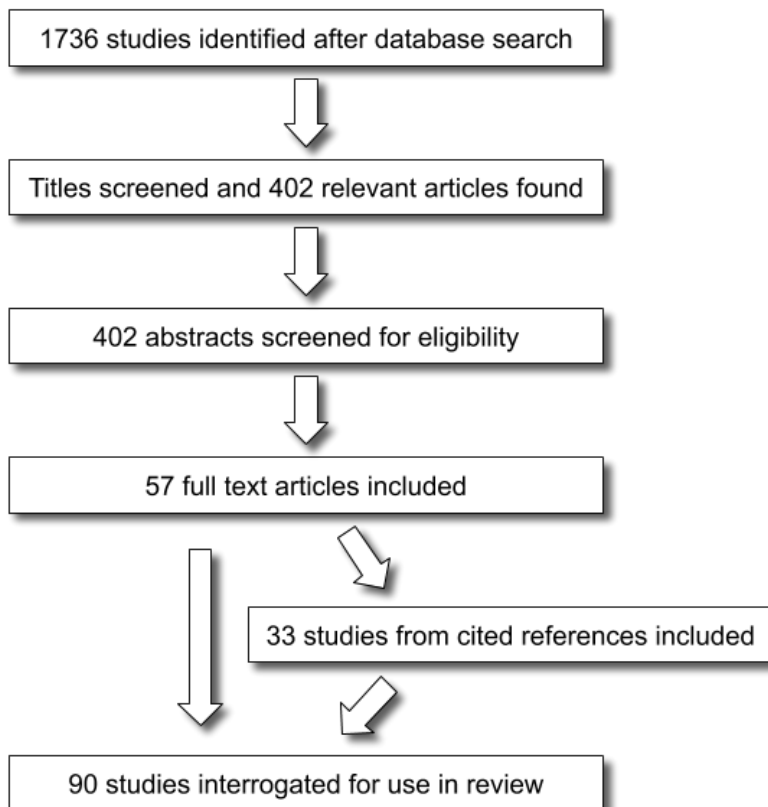
1. Provide clarity on the nomenclature and definitions used in this paper and in the more recent literature.
2. Briefly describe the different contexts in which PHAAM is practiced.
3. Discuss the major controversies and conflicts as reflected in the literature from both a global and a local perspective.
4. Elucidate the relevance of this topic to the discipline of Anaesthesia.
5. Highlight some of the emerging trends and developments in this field.

SEARCH STRATEGY

A literature search was conducted on the 22nd of December 2019 on PubMed using the following search terms:

1. "Airway Management/complications"[Mesh] AND ("Emergency Medical Services"[Mesh]) AND ("South Africa"[Mesh])
2. ("Airway Management"[Mesh] OR "Intubation, Intratracheal"[Mesh] OR "Rapid Sequence Induction and Intubation"[Mesh]) AND ("Emergency Medical Services"[Mesh]) AND ("South Africa"[Mesh]) = 0
3. ("Airway Management"[Mesh] OR "Intubation, Intratracheal"[Mesh] OR "Rapid Sequence Induction and Intubation"[Mesh]) AND ("Emergency Medical Services"[Mesh]) = 3686
 - a. filter to 10 years and English Humans = 1736

Titles were first screened for relevance. Hereafter, the abstracts were interrogated for eligibility as it relates to the aims of the literature review. Articles were then reviewed in full text. The reference lists of included articles were then interrogated for additional articles of interest. Figure 1 below outlines the literature review process and results. This process was based on the PRISMA outline⁴.



DEFINITIONS

In 2009, an international group of airway experts developed a template for the collection of airway management data using a modified nominal group technique (mNGT), which is a qualitative, systematic consensus process⁵. This template was refined and updated in 2018⁶. The most recent template consists of 32 operational variables and 6 system variables and is an attempt to standardise documentation related to airway research. The core variables are related to patient vital signs, co-morbidities and demographic data as well as indications for intubation. The system variables are fixed and describe factors relating to the type of EMS system involved as well as pharmaceutical agents, airway devices and medical equipment used in the airway management intervention. The objective of standardisation and uniformity of definitions is to allow for more homogenous reporting of study findings and accurate capturing of airway management episodes which will improve the quality of research in this field and allow comparisons to be made across EMS systems globally and for the development of evidence-based guidelines⁷. This new way of reporting airway data marks the first but very crucial step towards the goal of producing high-quality research in this field that will address many of the long-standing questions whose answers have remained elusive for far too long.

EMERGENCY MEDICAL SERVICE SYSTEMS

Over the last few decades, prehospital care has evolved from providing mainly transportation for patients to health care facilities to the provision of urgent medical treatment and emergency care en route to a treatment facility. Aeromedical transport is available in addition to ground transport⁸.

Broadly speaking, EMS systems fall into one of two categories. The Anglo-American 'Load & Go' approach aims to minimise on-scene times and transport the patient to an appropriate health care facility as rapidly as possible. Paramedics, emergency nurses and emergency medical technicians usually form the backbone of this type of EMS system and have access to physician support and oversight. Countries that use this type of system generally have the infrastructure that allows timeous access to hospital facilities⁸.

The Franco-German EMS system is staffed by a higher proportion of emergency physicians and anaesthetists who are experienced in the provision of out-of-hospital anaesthesia and airway management. Because of this higher provider skill level and experience, a 'Stay & Stabilise' approach is utilised where certain critical interventions are performed either on scene or en route to a health care facility. Many countries, including South Africa, are now adopting a mix of these 2 strategies⁹.

In stark contrast to the controlled situation in most operating theatres, the prehospital environment is full of unique challenges for healthcare practitioners who deliver care in this unpredictable and often hazardous setting. Practitioners are required to simultaneously perform scene management, diagnostic patient assessment, clinical care duties and make decisions about patient extrication and transportation in an extremely dynamic workspace.

Both material and human resources are often limited and there is huge pressure to minimise on-scene times^{10,11}.

Clinical procedures are performed in less than ideal settings; often on the ground, uneven terrain or confined spaces under ambient lighting conditions. Adverse weather conditions, environmental hazards, multiple competing priorities and unfortunately in many parts of South Africa, the very real risk of interpersonal violence require the prehospital practitioner to develop a very high level of situational awareness¹².

They encounter patients who are usually unable to provide an adequate history, if any at all. Advanced airway management, when performed on these patients, must be undertaken with the assumption that they are not fasted and thus at high risk for aspiration. Trauma patients might have maxillo-facial injury with distorted airway anatomy which could pose significant challenges to the prehospital provider who is managing their airway. Patients who require spinal precautions to prevent potential neurologic injury provide additional difficulties with airway management¹².

These factors are challenging in any country, but South African practitioners often have to contend with even more concerns. South Africa is considered to be an upper middle income, developing and resource constrained country according to recent World bank data. An overwhelming majority of trauma related deaths occur in resource constrained countries and the majority of these occur in the pre-hospital environment¹³. This partly due to poor access to health care facilities and sub-optimal EMS provision due to economic constraints¹³.

South Africa experiences some of the highest volumes of trauma related deaths worldwide, mostly due to road traffic accidents and interpersonal violence. This is also expected to increase further with increasing urbanisation. In addition to trauma, communicable diseases particularly HIV/AIDS and tuberculosis and the increasing prevalence of non-communicable disease, South Africa's health care system is faced with a quadruple burden of disease¹⁴.

Prehospital EMS systems differ considerably between high income countries and low to middle income countries. These differences influence access to healthcare especially with respect to readily available access to health care facilities with adequate trauma, emergency management and interventional cardiology capabilities as well as training and expertise of EMS providers. EMS providers in South Africa (and other low to middle income countries), although arguably well skilled, face high workloads, difficult access to scenes and health facilities due to informal or incomplete road networks which cause unpredictable and often long travel times. They often arrive at overburdened Emergency Centres on handover, leading to prolonged waiting times for the patients they transport¹⁵.

For these reasons, amongst others, EMS in South Africa follows a predominantly Franco-German approach which allows for the provision of critical advanced interventions for certain patients, when certain indications exist and when performed by appropriately qualified personnel. Pre-hospital emergency endotracheal intubation has been within the scope of practice for paramedics since the early 2000's. In 2009, the Health Professions Council of South Africa (HPCSA), which is the national regulatory body for the medical profession, approved the Rapid Sequence Intubation approach for use by a certain cadre of pre-hospital providers; the Emergency Care Practitioner (ECP)¹⁶. More recently, in 2019, the HPCSA has

deemed that prehospital intubation remain within the scope of practice for ECPs only, and that patients may only be intubated using the Rapid Sequence Intubation technique.

CONTROVERSIES IN PHAAM

Prehospital ETI is generally reserved for those patients presumed to have the most significant physiological derangements as a result of life-threatening injury or illness eg. severe hypoxaemia, hypercarbia and acidosis. These features are usually present in most hypo-perfusion states such as cardio-respiratory arrest or hypovolaemic shock. From first principles, the provision of a definitive airway as early as feasibly possible in the care of these patients appears to be logical and intuitive¹⁷.

However, particularly over the last decade, this intervention has been the subject of much scrutiny and a growing body of literature in the international sphere has raised concerns regarding the value of pre-hospital ETI, especially with respect to the safety and efficacy of this procedure¹⁸. Many of these landmark studies are not within the scope of this literature review but are worth a brief discussion as they created the context in which subsequent studies attempting to address these issues were undertaken, thus shaping the discourse of prehospital airway management as we now know it.

In 2002, the San Diego Paramedic Rapid sequence Intubation trial¹⁹ caused much concern within the emergency medical services world when the study found that amongst severely head injured patients, the cohort that received intubation as opposed to BVM ventilation had worse outcomes than the BVM group. Reasons that may have led to this include more severely injured patients in the intubated group and longer on-scene times. Causes for these poorer outcomes were also due to secondary brain injury caused by hypotension and hypocarbia as a result of the intubation procedure itself, and inadequate post-intubation care. Two years later the first author of this study confirmed his findings when conducting a retrospective database review examining the same issue²⁰. In 2003, Katz and Falk²¹ found that a concerning 25% of patients in their prehospital intubation group had missed or unrecognised oesophageal intubation. The studies that found adverse outcomes for the recipients of prehospital intubation, prompted the EMS world to closely question their practices and critically examine the interventions to which patients were being exposed. The next decade generated volumes of literature on the purported advantages and disadvantages of providing PHAAM to patients.

However, despite the volume of new literature, many questions still remain unanswered because of the variability in provider, process and practise, and this heterogeneity limits the external validity of many of these studies. Study samples often contain a mixture of both trauma and medical patients, which are dissimilar groups despite having indications for the same procedure. In fact, a Cochrane review in 2008 by Lecky et al.²² was unable to tease out all of these many interwoven threads and concluded that the ability of the provider was a key factor in determining patient outcome but also concluded that large-scale well-conducted trials were ethically imperative to perform in order to justify the cost of EMS training and expenditure. Many studies on this topic focus on a single centre or a particular patient sub-

group and the majority are of a retrospective nature^{23–29}. Admittedly the prehospital environment does not easily lend itself to the performance of randomised controlled clinical trials, partly due to an inability to obtain informed consent from patients³⁰. Despite this, well conducted cohort studies and audits of databases and large airway registries have yielded useful data that has begun to bridge key patient safety gaps and strengthen the performance of certain EMS systems worldwide³¹.

The EMS community, on a global level, has started to examine long term outcomes more closely, develop evidenced-based protocols and begun to operate their systems under more close medical oversight with more stringent quality assurance measures. Much of the research generated in recent years focuses on out-of-hospital cardiac arrest with a small number dedicated to trauma patients. This research therefore has limited application in the South African context. Unfortunately, in South Africa, there was, and still is, a relative paucity of data on PHAAM, with the few studies that were done on this topic being limited to specific patient groups eg. Traumatic Brain Injury³², student intubation³³, limited geographical areas or single centre studies³⁴, or helicopter-based services only^{35–37}.

MEASURES OF ETI SUCCESS

A common variable that is reported in the literature on PHAAM is first pass success, which refers to the placement of the endotracheal tube within the patient's trachea on the first attempt at intubation⁶. While this is a useful measure of the efficacy of the intervention, it is a very incomplete measure of the success of the intervention as it does not provide any information about potential deleterious effects of medications that may have been used to facilitate intubation (eg. hypotension and tachycardia) nor does it provide any information about other physiological derangements that may have been present such as hypoxia. FPS rates also provide no information regarding patient outcomes.

A retrospective analysis³⁸ done in 2017 of prehospital RSI performed by a ground-based non-physician EMS service in an urban area sought to identify peri-intubation physiologic alterations and found that the majority of adverse physiologic events occurred on the first intubation attempt. These included severe desaturation and significant hypertension in response to intubation. Continuous electronic monitoring was utilised to capture physiologic parameters in this study, and this provided the ability to capture more of these events than the standard patient care report. The authors theorised that the focus on first pass procedural success might lead to diminished situational awareness and possibly encouraged unwarranted prolongation of the first attempt, leading to an increased incidence of adverse physiologic events. They concluded that their findings supported the notion that FPS rates are an incomplete and potentially deceptive measure of intubation quality^{39,40}. Measures of success should thus be interpreted together with available records of patient vital signs in the peri-intubation period as well as any record of adverse events in order to provide a more useful analysis of the success or failure of the intervention.

Overall success refers to the situation where the patient was successfully intubated but the provider may have required multiple attempts in order to accomplish this. Many studies⁴¹ have discussed the relationship between multiple intubation attempts and adverse events.

Repeated attempts at intubation have been associated with severe patient complications such as regurgitation and aspiration, prolonged hypoxia, bradycardia and cardiac arrest. Multiple attempts are also associated with a higher occurrence of failure to secure the airway³⁹.

Despite these limitations, the first intubation attempt is still a critical event in airway management and FPS is a quality indicator when assessing the standard of PHAAM provided. From the literature it is clear that the first attempt at intubation is often the best or most successful attempt⁴². The 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society^{43–46} done in 2011 is considered by many to be the current benchmark of quantitative research related to the epidemiology of complications with respect to airway management, has emphasized the need for optimisation of the first attempt at intubation, and has suggested steps that should be taken in order to achieve this important endpoint.

BENEFIT OR HARM?

Of all the controversies that abound in the literature regarding prehospital ETI, it is the issue of whether it is ultimately of harm or benefit that remains hotly contested and that raises many questions that are still far from being answered. One of these questions is whether there is even a need for advanced airway management and ETI in the prehospital environment in the first place. There are multiple studies indicating that the provision of PHAAM offers benefit over more conservative measures^{47,48}, some suggesting harm^{49–52}, and some suggesting equivalence between the two^{53,54}. Despite the numerous contradictions in the evidence, it is clear that a small but significant number of patients who cannot be adequately managed with basic airway manoeuvres alone will benefit from PHAAM, particularly with respect to those with severe trauma. This was determined by identifying patients that arrive in Emergency Centres with clear indications for emergency or urgent tracheal intubation or require this intervention within a few hours of their arrival at hospital³⁸.

Intuitively, it makes sense that the most seriously compromised patients require airway management in order to correct their hypoxaemia. However, these are also the same patients with worse injury severity scores or severe medical conditions and usually fare quite badly in terms of outcomes. This is especially in longer-term outcomes that have real world relevance, such as survival to hospital discharge or functional neurologic outcome.

This association between pre-hospital ETI and worse measures of outcome seemingly suggests that patients receiving the intervention do worse than those who do not. Also, the patient population requiring PHAAM is as diverse as the providers and processes that provide it and considering them to be comparable can easily lead one to make erroneous assumptions. Perhaps one of the reasons for the literature being unable to definitively answer this question is that the question itself is far too broad in scope to be addressed. For

this reason, a discussion of PHAAM in specific patient and provider populations is probably more useful.

PHYSICIAN VS NON-PHYSICIAN

In general, it is found that services that are predominantly staffed by physicians have better procedural success rates and less adverse outcomes than those staffed by non-physicians⁴⁵. A 2012 meta-analysis by Lossius⁵⁵ found that success rates for rapid sequence intubation by non-physicians was 96% compared to 99% by physicians and even suggested that the performance of prehospital intubation be reconsidered if physicians were not available to perform the procedure. This forms the basis of much debate from a patient safety perspective over who should, be performing prehospital airway management. In developed countries, physician led prehospital services are feasible from an economic and human resources perspective. This is unfortunately not the case in South Africa.

It is thought that physicians have greater training exposure to ETI and thus more opportunity to maintain proficiency than do non-physicians. However, a UK study⁵⁶ in 2015 demonstrated almost equivalent intubation success rates for physicians and non-physicians with FPS rates over 90% for both groups. They attributed the high success rate and improved level of performance to a high level of clinical exposure to ETI as well as a robust training program and clinical governance structure. This highlights the observation that training and exposure to ETI may be just as important to the safe provision of this intervention as the type of practitioner that performs it⁴⁸. In our resource and skills constrained setting, this suggests that quality improvement initiatives should focus strongly on improving first pass success rates in our prehospital care providers.

OUT-OF-HOSPITAL CARDIAC ARREST

The best method of airway management for out-of-hospital cardiac arrest patients is also a topic that attracts considerable debate. While prehospital intubation can be performed successfully on the first attempt in most cases, the impact on longer term outcomes such as survival to hospital discharge and functional neurologic outcome is less clear. Some argue⁵⁷ that the focus in these patients should be on providing high quality Cardiopulmonary Resuscitation (CPR) and minimising any interruption in the provision of chest compressions, and thus basic airway management will suffice in this regard. The opposing school of thought asserts that ETI when performed appropriately can maintain airway protection and optimise oxygenation during CPR⁵⁸.

A recent systematic review and meta-analysis⁵⁹ showed that while endotracheal tube use may have resulted in a significant increase in Return Of Spontaneous Circulation (ROSC), there was no convincing improvement in survival to hospital discharge and neurologic outcome. An International Liaison Committee On Resuscitation (ILCOR) commissioned systematic review evaluating the effects of airway management strategy on cardiac arrest

survival and neurologic outcome when advanced techniques (Supraglottic airway (SGA) or ETT) were used compared to basic techniques such as bag mask ventilation showed no difference in 28 day survival⁵⁷. A large Japanese study⁶⁰ investigating advanced airway management in cardiac arrest patients by means of a retrospective audit of a patient registry also found that advanced airway management in cardiac arrest patients was not associated with significant survival benefit in this group. A randomized clinical trial assessing BMV vs ETI for advanced airway management in patients with out-of-hospital cardiac arrest with regards to favourable neurological function demonstrated equivalence between the two techniques²³. Similarly, an observational study comparing the use of SGA vs ETI in out of hospital cardiac arrest (OHCA) patients found no significant difference in neurological outcome⁶¹. However, a study in Taipei showed that successful ETI in non-trauma adult OHCA patients was associated with improved odds of sustained ROSC, survival to hospital discharge, and favourable neurological outcome when compared to BVM or SGA⁶². A prospective study⁶⁰ done on airway strategy in OHCA in Vienna in 2018 suggested again that early ETI should be considered for these patients on scene, or as early as possible.

Many of these studies were retrospective or observational in nature and it can be argued that recommendations based on this are not supported by the highest quality evidence. However, even a large randomised controlled trial⁶³ done on 2043 adult OHCA patients by Jabre et al in a physician based EMS system with very high success rates for ETI, which can be considered to be the optimal setting in which to perform ETI in this patient sub-group, showed no overall difference in 28-day survival or functional neurologic outcome.

Much of the work done on out-of-hospital cardiac arrest patients does not conclusively show greater benefit for advanced airway management techniques over basic airway management techniques. Furthermore, many of these studies have acknowledged the presence of confounding factors affecting the strength of their conclusions despite attempts to adjust for them. The optimal method of airway management in these patients continues to remain in question, and further investigation is required to resolve this issue. What is apparent from the literature is that ETI has been de-emphasized in the management of OHCA patients, and the provision of high-quality cardiac support is now the priority.

The American Heart Association has thus revised their recommendations⁶⁴ for airway management in OHCA patients to address these issues and recommends that either basic or advanced airway management strategies can be used in adult cardiac arrest patients and the strategy used is more dependent on the setting than the type of patient. In settings with poor intubation success rates or limited opportunities for intubation training, the American Heart Association recommends the use of SGA devices, and in settings thought to have good success rates and training opportunities for ETI, they recommend the use of either a SGA or an ETT.

This can be seen as a pragmatic way of approaching airway management in a variety of contexts and re-emphasizes the fact that airway management is not the only priority in these patients. The AHA also recommends ongoing quality improvement and training opportunities for resuscitation providers in order to minimise complications from their chosen intervention. These recommendations are realistic in the South African context and can be easily supported by existing resources and infrastructure.

PAEDIATRIC AIRWAY MANAGEMENT

In high income countries, severely injured paediatric patients are fortunately relatively rare when compared with adult trauma patients. However, not much research is available on paediatric trauma in South Africa, despite the fact that Africa is one of the most dangerous places for children⁶⁵. Pedestrian motor vehicle accidents are a leading cause of paediatric injury in South Africa³.

Paediatric patients have many anatomical and physiological factors that make management of their airways more challenging⁶⁶. Airway management in the paediatric population is another area where conflicting opinions abound. If ETI is clearly indicated, there is general consensus that this should be provided timeously. However, in cases where ETI is not as clearly indicated, it has been found that BVM ventilation is an adequate means of airway support. A 2017 study in the United States tracking intubation success metrics found that intubation success rates for neonates and paediatric patients were much lower than for adults⁶⁷. A small study in Ireland found that many advanced paramedics felt they had infrequent exposure to children who required advanced airway management⁶⁸. The lack of practice and infrequent exposure was found to represent a barrier to the acquisition and maintenance of clinical competence with respect to this skill.

Another study⁶⁸ looking at paediatric trauma intubations (albeit in a combat environment) also found that many prehospital providers have limited paediatric experience. This opinion was echoed by a US prehospital paediatric patient safety survey in 2016. Many studies⁶⁹ concerning management of the paediatric airway in prehospital setting suggest enhanced protocols and paediatric intubation specific checklists as well as routine waveform capnography to address the safety gaps thought to be present when managing the paediatric airway in the emergency unit environment. These quality improvement initiatives may well be just as successful at improving patient outcomes in the prehospital environment. In fact, significant improvements in neonatal intubation proficiency and time to intubation was found in an air transport service following the use of a neonatal intubation checklist⁷⁰.

EMS systems that are staffed by physicians tend to have better success rates when intubating paediatric patients and also have the benefit of having access to specialist paediatric trauma centres, which are a rarity in South Africa. Even more so than usual, the divide in the quality and availability of paediatric services between high income and lower to middle income countries is vast and much of the research from high income countries simply fails to translate into our setting. Quality improvement measures such as the use of paediatric specific checklists as discussed in the literature on paediatric prehospital airway management do not require much in the way of resources and these can readily be applied to the South African context.

TRAUMATIC BRAIN INJURY

Patients with traumatic brain injury often require ETI either in the prehospital environment or on admission to the Emergency Department due to a decreased level of consciousness. The

best method of airway management for these patients is often debated. Patients with moderate to severe TBI almost invariably require advanced airway management in the prehospital setting. An argument to support the practice of prehospital ETI in these patients often rests on the fact that these patients spend a shorter amount of time in the emergency department before they receive essential neuroimaging. However, this may be at the expense of longer on-scene times⁷¹. Despite earlier control of the airway and ventilation, no significant survival advantage was found when compared with emergency department intubation in this study.

In 2016, a large cohort-matched analysis examining prehospital ETI outcomes in patients with isolated severe blunt traumatic brain injury, found that patients receiving ETI had significantly longer on scene times, lower emergency department Glasgow Coma Scores and higher mortality. The study was retrospective in nature. It is unsurprising that patients intubated in the prehospital setting would have a lower GCS when assessed in the emergency department, as they may still be experiencing the effects of whatever medication was used to facilitate intubation. On scene times appeared to be prolonged by only one minute, in comparison with similar patients who did not receive prehospital intubation⁷², so the clinical relevance thereof is debatable.

A systematic review by Bossers et al. in 2015 that examined the effects of prehospital intubation on mortality found that intubation by providers with limited experience was associated with an approximately twofold increase in the odds of mortality⁷³. Again, the finding that intubation by paramedics who are not well skilled to do so, increases mortality is perhaps unsurprising. The authors recommended that prehospital intubation of TBI patients should only be performed by providers that have adequate training, skill, and experience in performing this intervention. Similarly, a 2011 study using data from the Los Angeles County trauma system database found a nearly five-fold increase in mortality when performing prehospital intubation of TBI patients³¹. Both studies attempted to control for confounding factors, but it is highly likely that patients with more severe injuries are more likely to receive prehospital intubation and also that more severely injured patients are likely to have higher in-hospital mortality.

A 2013 retrospective chart review done in Cape Town by Sobuwa et al. found that patients with TBI who had received basic airway management in the prehospital period had better outcomes than those who were intubated³¹. This again introduces the concern of selection bias in these studies as associations are often found in patients with moderate to severe TBI who have had prehospital ETI and unfavourable neurologic outcomes. However, early ETI for patients with a decreased GCS is currently the standard of care and it is ethically unfeasible to conduct a study in which this intervention is withheld from these patients. Many authors agree that the prevention of secondary brain injury in these patients should be given high priority and the methods of airway management that they receive should facilitate this objective. Once again, this is an area which requires further studies yielding high quality evidence in order to draw firm conclusions about the safety and efficacy of early ETI in this patient group.

QUALITY IMPROVEMENT AND PATIENT SAFETY INITIATIVES FROM THE LITERATURE

Of course, not all aspects of prehospital airway management are contentious. There are many issues that have benefited from consensus. Most of the traditional methods of airway assessment such as the Mallampati Score⁷⁴ were developed primarily for patients presenting for elective surgery, often require adequate time to be performed, and rely on a conscious and cooperative patient. These methods are often not feasible or have limited application in the prehospital context and emergency airway assessment in this environment is challenging. Much focus in this area has been placed on the efficient identification of difficult airway predictive factors and the development of cognitive tools to aid in the early identification of patients in whom these are present^{75,76}.

Another area in which there is considerable agreement is the usage of airway adjuncts to facilitate airway management, particularly in the potentially difficult intubation. Many algorithms suggest second generation supraglottic airway devices to be used as rescue airways in these cases. A study done in 2018 by Driver et al also advocates the routine use of a bougie or similar adjunct to facilitate intubation in the difficult airway as this has been found to significantly raise first pass success in these patients⁷⁷. This study was conducted in an emergency department and the results have not been validated in the prehospital context. Another study by Kingma et al confirms this recommendation⁷⁸.

Detailed protocols for the adequate pre-oxygenation of emergency intubation patients also abounds, with the common goal of prolonging safe apnoea time and patient desaturation. This is also thought to improve first pass success rates and generally decrease adverse events that are associated with multiple attempts at intubation. Many strategies can be employed to prevent peri-intubation hypoxia. These include optimal patient positioning, apnoeic oxygenation using high flow nasal cannula oxygen in addition to standard pre-oxygenation, and the usage of positive end expiratory flow pressure on a bag-valve-mask device when performing pre-oxygenation⁷⁹. Another strategy that is fast gaining traction particularly with the management of dyspnoeic or agitated patients is a modification of traditional sequence intubation that employs the use of a sedative dose of ketamine to facilitate patient anxiolysis allowing pre-oxygenation, followed by the delayed administration of an induction agent and neuromuscular blocking agent. This is referred to as a delayed sequence intubation (DSI)⁸⁰. A study undertaken in Texas in 2015 saw a ground-based EMS system implement a clinical bundle consisting of these elements in addition to performing goal directed oxygenation in order to investigate whether these interventions were associated with less peri-intubation desaturation⁸¹. They found favourable results when compared to patients receiving their standard pre-intubation protocol. The study is limited by a relatively small sample size of 87 patients, and they included non-arrest patients only. Nevertheless, it still has important implications for the improvement of pre-oxygenation strategies.

Video laryngoscopy is another topic that is enjoying much interest and is generating a lot of new data^{69,82-85}. However, despite much hope that this modality would be the solution to many airway management dilemmas, it is now becoming apparent that while this technology

has its place in the difficult airway armamentarium, it is not a panacea for all airway difficulties⁸⁶. Most of the difficulties encountered with its use in the prehospital environment are related to its limited utility in scenarios where blood or gastric contents are present in the airway as this severely impedes the optical ability of the device being used.

After the success following the implementation of the WHO Surgical Safety Checklist in 2008, checklists have been created for many other clinical scenarios and adherence to checklists has found to be useful in reducing the cognitive burden that healthcare providers face when performing high risk procedures. PHAAM literature has many examples of checklists that have been created for specific contexts³². So far, it has been found that this low cost and easy to implement intervention has made a positive impact on improving the quality of care provided⁸⁷.

THE SOUTH AFRICAN LITERATURE ON PHAAM

Despite the practice of prehospital ETI being around for close to two decades and RSI being within the scope of practice for ECPs since 2009, there is a paucity of data examining this issue in South Africa. The studies that were done are retrospective in nature and on a fairly small scale, painting a very sparse and incomplete picture of the current state of the practice of prehospital ETI in South Africa.

Stein et al undertook an observational study examining the practice of prehospital RSI done on 367 patients by university paramedic students during their clinical learning experiences⁸⁸. A high overall success rate of 99.6% was found but a FPS rate of 87.9%, although relatively high for non-physicians given their limited exposure to ETI, was thought to be inadequate for operational practice. The author thus suggested that EMS systems that deploy newly qualified ECPs provide an environment that supports the skills development of these ECPs whilst not compromising patient safety. While this study provided useful data with respect to measures of intubation success, it only examined these in paramedic students so the performance of more experienced paramedics is still unknown.

Stassen et al examined the prevalence of hypotension and hypoxaemia in prehospital patients with blunt TBI by means of a retrospective review of 299 patients in Johannesburg. They found that while the prevalence of hypotension in their sample was comparable to that found in similar patients in international studies, the presence of hypoxaemia at 37.9% was higher than the international rate which raised concerns of secondary brain injury³¹. The authors suggested the development of further protocols to guide prehospital intubation in this patient group. Sobuwa et al also studied prehospital airway management in patients with TBI (please refer discussion on TBI above)⁸⁹. This study was conducted in the Western Cape Metropole only, thus providing a limited view of prehospital airway management in TBI patients. Given that South Africa has a high burden of TBI with most patients being in the economically active population⁸⁸, the prehospital management of these patients warrants more examination.

In 2012 Gunning et al examined the safety and efficacy of RSI by South African paramedics by reviewing a case series of 80 patients³⁴. It was found that self-reported measures of

success were comparable with those found in the international literature but that the Adverse Event rate of 22% was concerning. This is one of the first studies to examine AEs and highlight a potential issue relating to patient safety. However, no follow up studies addressing this issue have been carried out yet.

In 2018 Stassen et al performed a retrospective chart review of prehospital ETI carried out by Helicopter Emergency Medical Services crews over a 16-month period⁹⁰. In a modest case series of 48 patients, it was found that overall success rates and FPS rates were equivalent to those found internationally. This study also discussed airway assessment and adverse events relating to ETI in addition to other intubation-related data but did so in the context of HEMS which may limit extrapolation of the conclusions to ground-based EMS.

ANAESTHESIA AND PHAAM

The discipline of anaesthesia places much emphasis on airway assessment and management. As anaesthesia has evolved over the years from being almost solely practised in the operating theatre to a far broader range of sites such as outpatient departments, cardiac catheterisation suites, radiology suites and also the prehospital environment, anaesthetists have had to update their skillset to match the changing environments of the many different places they might be required to provide anaesthesia and airway management. In countries that have the benefit of being able to staff their pre-hospital trauma services and helicopter emergency service crews with anaesthetists, quality indicators have shown high rates of intubation success and low rates of adverse events and often use these as a benchmark or the gold standard when making comparisons across EMS systems.

Anaesthetists are involved in the training of first responders in basic and advanced airway management techniques both locally and abroad. Furthermore, their training in the provision of analgesia, resuscitation, advanced patient transfer and point of care diagnostics closely mirrors the skillsets that are valuable in the prehospital setting⁹¹. Recent developments in anaesthesia provider training in the domain of non-technical skills or human factors are also of great benefit to the prehospital provider. Guidelines developed for the provision of PHAAM assert that the standard of care provided for these patients should be equivalent to that of in hospital patients receiving anaesthesia and emergency airway management⁹¹. These provide clear rationale for anaesthesia involvement and input in the provision of prehospital airway management. As authorities in the fields of airway management and patient transfer, anaesthetists can make a valuable contribution to the knowledge and skill base of prehospital providers in South Africa.

CONCLUSION

The international literature, despite being extensive, still leaves many key issues unresolved. Furthermore, its limited applicability to the South African context is also a major shortcoming.

South Africa has a real need for research in this area in order to understand how our practices are affecting prehospital patients and how our providers measure up to global standards. With this knowledge, key role players in the provision of quality prehospital care can be informed of the current position of service delivery in this country which can have a beneficial impact on future policy and training endeavours. With the insights obtained from this literature review, the author embarked on this descriptive study on prehospital advanced airway management in South Africa in an attempt to address the important knowledge gaps on the practice of ETI in this country. The aim of this is to characterise on whom these interventions are performed, how they are performed, how successful they are and what adverse events occur during their performance.

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A RETROSPECTIVE DESCRIPTIVE ANALYSIS OF PREHOSPITAL ADVANCED AIRWAY MANAGEMENT IN A SOUTH AFRICAN PRIVATE EMERGENCY MEDICAL SERVICE

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ABSTRACT

Introduction: Endotracheal Intubation (ETI) is an intervention that has been performed widely in the prehospital (PH) setting for over two decades in South Africa. Despite this, the performance of PHETI remains highly controversial, especially with regards to its safety and impact on patient outcomes. Furthermore, there is a paucity of data on this intervention in South Africa. This study describes the practice of PHETI in one private emergency medical medical service in South Africa.

Methods: A retrospective chart review of prehospital ETI performed by non-physician prehospital providers over a 12-month period was performed. The setting was a ground-based private emergency medical service that operates on a national level on South Africa. Data extracted from scanned, handwritten records were subjected to descriptive analysis and the first pass and overall success rates were calculated.

Results: Of the 806 cases recorded in the study period, 686 (85.1%) met the criteria for analysis. Male patients accounted for 471 (69.0%) of the cases. Trauma patients accounted for the majority of PHETI performed (n=383, 55.8%). The most common indication for intubation was for decreased level of consciousness (n=430, 62.7%), followed by cardiac arrest (n=190, 27.7%). Rapid sequence intubation was the method used to intubate 34.3% (n=235) of patients, while drug facilitated intubation and intubation during cardiac arrest (without medications) were the methods to intubate 29.9% (n=205) and 25.2% (n=173) of patients, respectively. The first pass success rate was 74.3% (n=510) and the overall success rate was 97.5% (n=669).

Conclusion: The majority of patients intubated were trauma patients, and the most common indication for intubation was a decreased level of consciousness, followed by cardiac arrest. Approximately a third of patients were intubated by means of an RSI technique, with another third receiving DFI and the remaining proportion of patients being intubated without drugs whilst in cardiac arrest. Overall success and first pass success rates compare favourably with those reported in the literature.

BACKGROUND

Emergency medical services (EMS) have evolved over the past two decades from merely providing patient transport to healthcare facilities to the provision of advanced emergency care interventions on scene or en route to a healthcare facility[1]. Endotracheal intubation is one of the advanced airway management interventions that is offered by some EMS systems to the most injured or compromised patient groups[2]. Globally, the practice of prehospital endotracheal intubation (PHETI) has been the subject of intense scrutiny in the last decade,, as concerns exist over its safety, efficacy and impact on both short- and long-term patient outcomes.

ETI can be performed in a number of ways using a variety of pharmacological agents, techniques, equipment and numerous airway devices and adjuncts. These are all employed in order to achieve the same endpoint: the passage of an endotracheal tube into a patient's trachea. This variation in practise introduces a degree of complexity to this intervention. Globally, much heterogeneity exists in the performance or conduct of prehospital ETI with respect to geographic and environmental factors, EMS system design, EMS practitioner training, experience and skill level, procedural protocols and algorithms, patient characteristics, and clinical governance.

There is also a distinct lack of standardisation with respect to data collection methods when evaluating the literature relevant to this topic. Despite the many studies that have been done internationally on Prehospital Advanced Airway Management (PHAAM), these inconsistencies affect the quality of conclusions drawn about such data and makes comparisons between research very difficult. This manifests as ongoing uncertainty within the medical community on the best method of PHAAM and its relationship to patient outcomes.

Despite being within the scope of practice of South African prehospital providers for over 20 years, PHETI has not yet been audited on a national level. This observational study of a national ground-based EMS aimed to describe the practice of PHETI in South Africa with respect to patient characteristics, indications for intubation and methods of PHETI employed. Success rates and clinical adverse events that occur as a result are also described.

METHODS

A retrospective chart review of pre-hospital ETIs performed by non-physician ground based prehospital providers, between the periods of 01 January 2017 to 31 December 2017, of a national private emergency medical service was performed.

Setting

This private EMS operates at a national level across South Africa using both road ambulances and emergency aircraft. The service transports both private (medical aid/insurance) and state patients as well as Road Accident Fund (RAF) and Workman's Compensation Act (WCA) patients from the primary scene, as well as performing inter-facility transfers. The service transports approximately 13 000 patients a month, and approximately 1% of these patients require ETI.

Within this service, prehospital providers follow a standardised protocol whenever a pre-hospital intubation is attempted or planned. General indications for ETI include any patients who need an airway to be established or secured, the provision of oxygenation and ventilation when this is deemed to be required and in patients who are expected to have a

deterioration in their clinical condition. While the service does have some guidelines for ETI, the decision to intubate patients is dependent on the discretion of the treating clinician.

Patients received pre-oxygenation for 3-5 minutes while airway assessment was performed. During this time, equipment was also checked and prepared and if necessary, pre-medication (e.g. analgesia) was administered. Some patients also received apnoeic oxygenation, as this was included in the protocol in the second half part of the data collection period.

Patients were intubated with no medication when their clinical condition was severe enough to allow this. If this was not the case, they either received drug facilitated intubation (DFI) or modified rapid sequence intubation (RSI). RSI can be performed by degree-qualified paramedics who use either ketamine or etomidate for induction and either suxamethonium or rocuronium for primary neuromuscular blockade. During the study period, certificate or national diploma qualified paramedics were licensed to perform deep sedation-only ETI, using midazolam as the sole agent or morphine and midazolam synergistically.

Sample and sampling

Scanned hand-written patient report forms (PRFs) of all patients who were intubated by non-physician prehospital providers, between the periods of 1 January 2017 to 31 December 2017 were eligible for analysis. A standard checkbox on the patient report form indicates that intubation was performed, as well as the number of intubation attempts. Both of these are captured onto a central billing system before the form is scanned for archiving. This allowed for the easy identification of intubated patients. The study is specifically concerned with ground based paramedic intubation therefore any patients who were intubated by a physician and those intubated on the aeromedical platforms were excluded from analysis. Patients who were intubated by crew members from another service who were attending to the same scene were also excluded. Cases were included even when some data variables were omitted from the PRF. These variables were simply omitted for that entry.

Data extraction and definitions

A data capturer with experience in clinical administration received specific training in the research aims, objectives, data variables and the contents of the PRFs. Data was then extracted according to a dedicated, standard data extraction form. Regular meetings between the data capturer and the investigators were held to ensure credibility of the extraction process. The data extraction form was based on the Utstein reporting guidelines for prehospital airway management[3].

An intubation attempt was defined as the placement of a laryngoscope blade into the oral cavity with the aim of exposing the glottis. An intubation success was defined as placement of the distal end of the endotracheal tube into the patient's trachea as confirmed by waveform capnography and/or chest auscultation. First pass success (FPS) refers to the situation where intubation was successful on the first attempt. If intubation was successful after more than one attempt, this was referred to as overall success (OS). A failed intubation was defined as an inability to intubate the patient successfully.

For specific clinical variables, the PRFs were assessed and interpreted by one of the investigators with clinical experience in anaesthesia and prehospital care. If there was a

case in which there was uncertainty regarding any variable in the PRF, the investigators discussed that case in order to make a joint decision on the variable in question in order to resolve the uncertainty, by consensus.

As no specific fields in the PRF denoted expected or predicted airway difficulty, this was assessed as follows :

- Some practitioners explicitly included airway assessment in their Primary and Secondary patient surveys. Their observations were matched with the relevant predicted airway difficulty Utstein category and recorded as such on the data capture spreadsheet.
- If the practitioner did not explicitly document an airway assessment but recorded observations in their notes that inferred possible airway difficulty, then this was also recorded in the relevant category e.g. Swollen jaw observed on primary survey was recorded as “Significant maxillofacial trauma” on data capture.
- Similarly, for Utstein aggravating factors, there were no specific fields on the PRF to document these, so practitioner notes were examined and interpreted when they inferred that aggravating factors were present. For example: if the PRF documented that the incident scene was at the roadside at night, it was inferred that poor ambient light was a potential aggravating factor for a difficult intubation. Similarly, if the PRF mentioned that the patient was intubated en route to the health facility, it was inferred that the patient was intubated in a moving vehicle.

As it was difficult to ascertain when endotracheal intubation was performed (see discussion) adverse events were defined as follows:

- The first set of recorded vital signs and level of consciousness, as assessed with the Glasgow Coma Score (GCS), were considered to be baseline or initial measurements taken before any intervention and drug or fluid administration.
- Subsequently recorded vital signs recorded were interpreted as being affected by medical intervention e.g. oxygen administration or the administration of analgesic, sedative or vasoactive drugs where this was documented.
- Subsequent recordings of vital signs following intubation were examined for evidence of a haemodynamic response to intubation or the vasodilatory effects of induction agents and fluctuations were recorded as adverse events if they fit the definition as per the Utstein guidelines.
- Where an end-tidal carbon dioxide (CO₂) measurement was obtained, it was inferred that the patient had been successfully intubated just prior, as the actual time of intubation was not record

Clinical adverse events were identified by fluctuations from the baseline measurements and were defined as:

- Hypoxia: SpO₂ < 90%
- Hypotension: systolic blood pressure (SBP) < 90mmHg or decrease in SBP or mean arterial pressure (MAP) by ≥ 20%
- Hypertension: SBP or MAP increase by ≥ 20%
- Bradycardia: heart rate below 60 beats per minute
- Tachycardia: heart rate increase ≥ 20% from baseline value.

If the patient was receiving inotropic support or vasoactive medication, haemodynamic changes were not recorded as adverse events as medication effects could be a possible confounding factor. Patient status at the time of handover was recorded as either Dead or Alive. If the patient was transported to hospital but cardiopulmonary resuscitation (CPR) was being performed on handover, this was recorded as such.

Lastly, a 10% sample was drawn for manual verification of accuracy of the data capturer. Further manual verification of all discrepant and missing data was undertaken. Where necessary, any uncertainty were resolved by a third investigator.

Data analysis

Data were extracted onto a Microsoft Excel (Microsoft Corporation, Redmond, Washington, United States) spreadsheet and subjected to simple descriptive analysis. Success rates between the different methods of intubation were compared using the Chi-square test, and significance was set at $p < 0.05$.

Ethical approval with a waiver of consent for this study was obtained by the Human Research Ethics Committee of the University of Cape Town (HREC ref: 706/2018). Specific organisational approval was also granted from the EMS to access the PRFs.

RESULTS

A total of 806 PRFs of patients who received ETI were reviewed. After applying the eligibility criteria, 686 (85.1%) cases were included in the final analysis.

The largest proportion of patients intubated consisted of adult males ($n=471$, 69.0%). The most common category of patients requiring intubation were trauma patients ($n=383$, 55.8%) of which head injury ($n=307$, 44.8%) was the type of trauma that most commonly occurred. The remaining patients were predominantly medical ($n=245$, 35.7%), with patients in cardiac arrest (154, 22.4%) accounting for the largest proportion (62.8%) of medical patients. Table 1 displays patient demographic data while Table 2 shows the patient categories.

Table 1 Demographic data

Gender, n (%)	Male	471 (69.0%)
	Female	202 (29.0%)
	Not recorded	13 (2.0%)
Age, mean (SD)		45.5 (21.8)
If age was unknown, n (%)	Adult	54 (84.4%)
	Infant	6 (9.4%)
	Neonate	4 (6.3%)

Table 2 Patient category, n(%)

Trauma		383 (55.8%)
	Head Injury	307 (44.8%)
	Blunt	51 (7.4%)
	Penetrating	13 (1.9%)
	Other	12 (1.7%)

Medical		245 (35.7%)
	Cardiac arrest	154 (22%)
	Intoxication	45 (7%)
	Respiratory arrest	41 (6%)
	Other (e.g. Endocrinology)	5 (1%)
Neurology		58 (8.4%)
	Stroke	35 (5%)
	Other (e.g. Seizures)	23 (3%)

The most common indication for intubation was a decreased level of consciousness (n=430, 62.7%), while cardiac arrest (including traumatic cardiac arrest) was the indication for intubation in 190 (27.7%) patients. Combative behaviour accounted for 5.1% (n=35) of indications. The frequency of the indications for intubation are listed in Table 3.

Table 3 Indication for intubation, n(%)

Decreased level of consciousness	430 (62.7%)
Cardiac Arrest	190 (27.7%)
Combative or uncooperative	35 (5.1%)
Hypoxemia	10 (1.5%)
Ineffective ventilation	9 (1.3%)
Humanitarian	6 (0.9%)
Existing airway obstruction	3 (0.4%)
Impending airway obstruction	3 (0.4%)

A modified Rapid Sequence Intubation approach was used in 235 (34.3%) of patients while 205 (29.9%) received a drug facilitated intubation using deep sedation. The rest of the patients were intubated in cardiac arrest (n=173, 25.2%) or received no medication during intubation (n=72, 10.5%). Table 4 displays the method of intubation. Patients in cardiac arrest were treated according to advanced cardiac life support (ACLS) protocols.

Table 4 Intubation method, n(%)

RSI	235 (34.3%)
Deep Sedation	205 (29.9%)
Cardiac Arrest	173 (25.2%)
No Medication	72 (10.5%)
DSI	1 (0.1%)

RSI=rapid sequence intubation, DSI = delayed sequence intubation

At least one predictor of a difficult airway was present in 64.4% (n=442) of patients, the most common of which was restricted neck mobility or manual in line stabilisation (MILS), occurring in almost half (n=341, 49.7%) of patients. Yet, no risk factors for predicted airway difficulty was recorded in 34.5% (n=237) of patients. It was found that 161 patients (23.5%) were documented to have fluid in the airway. Table 5 displays the factors related to predicted airway difficulty (a single case can have more than one predicted difficulty).

Table 5 Predicted airway difficulty, n(%)

Reduced neck mobility or MILS	341 (49.7%)
Risk factors not assessed	237 (34.5%)
Fluid in the airway	161 (23.5%)

Significant maxillofacial or upper airway trauma	61 (8.9%)
Other, incl. burns or tumours	23 (3.4%)
Severe obesity or thick/short neck	14 (2.0%)
Pre-existing airway device (e.g. SAD) ineffective	9 (1.3%)
Limited mouth opening or inter incisor distance < 4 cm	6 (0.9%)
No risk factors for difficult intubation	3 (0.4%)
Prior difficult intubation	1 (0.1%)

Factors that were present that might aggravate predicted difficult intubation are summarised in Table 6 (more than one possible factor per patient). Most patients (n=489, 71.2%) had no documented aggravating factors. When documented, the most common aggravating factor for difficult intubation was a lack of adequate lighting (n=97, 14.1%), followed by intubation during entrapment (n=42, 6.3%).

Table 6 Aggravating factors, n(%)

Not recorded	489 (71.2%)
Darkness	97 (14.1%)
Patient entrapped	42 (6.3%)
Hostile environment	40 (5.8%)
In moving ambulance	21 (13.1%)
In stationary ambulance	18 (2.6%)
Bright light/sunlight	12 (1.7%)
Not 360-degree access	6 (0.9%)
Suboptimal provider positioning	2 (0.3%)

Regarding induction or sedative agents, a combination of morphine and midazolam was used in almost half of patients (n=217, 49.3%) who were giving medication for intubation, followed by ketamine, which was used in 129 (29.3%) of patients. Regarding those patients given paralytics, suxamethonium was used most commonly for primary neuromuscular blockade (n=183, 77.9%), followed by rocuronium (n=51, 21.7%). Tables 7 and 8 outline the sedative and induction, and paralytic agents, respectively.

Table 7 Anaesthesia induction/sedative agent, n(%)

Morphine and Midazolam	217 (49.3%)
Ketamine	129 (29.3%)
Midazolam	52 (11.8%)
Etomidate	32 (7.3%)
Morphine	8 (1.8%)
Diazepam	2 (0.5%)

Table 8 Neuromuscular blocking agent, n(%)

Suxamethonium	183 (77.9%)
Rocuronium	51 (21.7%)
Vecuronium	1 (0.4%)

The first pass success rate was 74.3%, and the overall success rate was 97.5%. In 6 (0.9%) patients, intubation had failed and an alternative airway (supraglottic airway device) was used successfully. Two failed intubations only had one attempt at intubation. There were no cases in which patients could not be intubated or oxygenated. In one patient, successful primary emergency surgical airway was obtained, while 4 (0.6%) of patients had a successful primary supraglottic airway placed. Table 9 displays the number of intubation attempts, while Table 10 outlines the success rates cross-tabulated with the intubation method. Neither first pass ($p=0.68$) nor overall success rates ($p=0.99$) were influenced by method of intubation.

Table 9 Number of Attempts, n(%)

1	507 (74.3%)
2	134 (19.6%)
3	31 (4.5%)
4	1 (0.1%)
Not documented	8 (1.2%)
Surgical Airway	1 (0.1%)

Table 10 Intubation method and first pass success, n(%)

	First pass success rate	Overall success rate
RSI	181 (77.0%)	229 (97.4%)
Deep Sedation	146 (71.2%)	200 (97.5%)
Cardiac Arrest	129 (74.6%)	169 (97.7%)
No Medication	53 (73.6%)	70 (97.2%)
DSI	1 (100%)	1 (100%)
TOTAL	510 (74.3%)	669 (97.5%)

Corrective steps taken during difficult intubation were poorly documented and only documented in 18 patients. Alternative techniques or airway adjuncts used were similarly

poorly documented, being noted in only 37 cases (5%). Amongst those cases where adjuncts were documented, a bougie, introducer or intubating stylet were the most common adjuncts used.

Auscultation (Table 11) was most commonly used to confirm successful intubation (n=593, 86.4%) while capnography was used to confirm intubation in 451 (65.7%) patients. Some patients received more than one method to confirm intubation.

Table 11 Methods of confirmation, n(%)

Auscultation	593 (86.4%)
Capnography	451 (65.7%)
Visualisation	37 (5.4%)
Misting in ETT	24 (3.5%)
Oesophageal Detector Device	1 (0.1%)

Adverse events that were not explicitly recorded on the PRF were inferred and are noted in Table 12. At least one adverse event occurred in 15.0% (n=103) of patients. The most common adverse event was hypotension (n=41, 6.0% of patients).

Table 12. Adverse events

Hypotension	41 (6%)
Hypertension	36 (5.2%)
Cardiac Arrest	14 (2.0%)
Tachycardia	12 (1.7%)
Hypoxia	4 (0.6%)
Bradycardia	3 (0.4%)
Self-extubation en route	1 (0.1%)
Aspiration	1 (0.1%)
Reintubation required	1 (0.1%)

Survival to hospital is presented in Table 13. The majority of patients (n=526, 76.7%) survived to hospital handover, while 22.7% (n=156) either died on scene or were handed over to hospital pulseless undergoing CPR.

Table 13 Prehospital survival

Alive	526 (76.7%)
Dead	147 (21.4%)
CPR in progress	9 (1.3%)
Handed over to Helicopter Emergency Services	4 (0.6%)

DISCUSSION

The aim of this retrospective study was to describe the practice of pre-hospital advanced airway management in a South African national private ambulance service. This descriptive analysis is one of the first studies to investigate this practice on a national level, and attempts to address the knowledge gap that exists in this field in South Africa. Demographic details, patient categories and indications for intubation were examined. The methods of advanced airway management and usage of pharmacologic agents were also examined. Trends in vital signs before and after intubation were scrutinised and clinical adverse events are reported. Finally, we reported on the success rates.

Most patients that received prehospital intubation in this study were trauma patients and this can be seen as a striking reflection of the high burden of traumatic injury seen in South Africa generally,[4] and amongst young males in particular. Although South Africa does not yet have a national trauma registry, studies done in various South African urban settings confirm that males under the age of 40 account for the majority of trauma statistics, both from motor vehicle accidents and interpersonal violence[5].

Trauma patients often present more challenges with airway management than do medical patients as they may have injuries that cause blood to be present in the airway or have injuries causing distorted airway anatomy[6]. The vast majority of trauma patients also require precautions to prevent potential spinal cord injury in the form of MILS, restricting the range of motion of the cervical spine which means that many patients have to be intubated in a less than ideal position. At worst, these measures may prove to cause severe difficulty leading to failure of the intubation attempt[7]. Though not explicitly documented, this accounted for the largest inferred predictor of a difficult airway, in our study. One reason for this lack of documentation could be because for paramedics, this situation is more the norm than the exception[8]. This is further supported in our study as more than half of patients intubated sustained trauma.

In severely injured patients, haemorrhage and chest trauma can lead to cardiovascular instability and potential haemodynamic collapse on induction and with the initiation of positive pressure ventilation. For this reason, trauma patients are prone to adverse events during and after intubation[9]. Furthermore, it is encouraged that these patients reach definitive care in the shortest possible time and intubation on scene may delay their reaching the trauma centre in the shortest time possible. A risk-benefit analysis needs to be made for each of these patients, and intubation should only occur on scene if the benefits of the procedure clearly outweigh the risks of delaying airway control, especially when erratic and often prolonged transit times to the trauma centre commonly occur, as is often the case in South Africa. Likely due to poor reporting, only a small number of patients in our study developed hypotension.

The vast majority of patients were intubated because they had a decreased level of consciousness. Despite the many controversies that surround pre-hospital intubation, this is in keeping with many local and international guidelines that support this practice if certain prerequisites are met, such as appropriate resources and skill level of practitioners[10]. As patients in the pre-hospital environment are undifferentiated, patients with a decreased level

of consciousness from a variety of causes would fall into this category and this would include patients with major trauma as well as medical patients with significant medical pathology.

During the data collection period of this study, prehospital EMS providers were licensed to intubate patients using a modified rapid sequence intubation (RSI) technique or drug facilitated intubation (DFI) technique. Patients already in cardiac arrest or deeply unconscious were intubated without the use of pharmacological agents. In late 2019, the Health Professions Council of South Africa (HPCSA) made the decision to remove DFI from the scope of practice of all prehospital providers and subsequently prehospital intubation can only be performed by emergency care practitioners (ECPs, or paramedics with a degree in Emergency Medical Care) using the RSI technique. Currently, there are only 850 ECPs registered with the HPCSA, yet it is unclear how many of them are still practicing in South Africa, or how many are still in clinical practice[11]. Nevertheless, this amounts to roughly one ECP per 67 000 South African population. Considering that roughly a third of all intubations in this study were performed by an ECP (licensed to provide neuromuscular blockade), the current regulations impose considerable restrictions on the advanced airway management options available to the prehospital patient population in this country.

Notwithstanding the above, intubation without the use of neuromuscular blocking agents generally requires larger doses of sedative or hypnotic medication in order to induce loss of consciousness and minimise patient effort[12]. This often leads to adverse haemodynamic effects such as vasodilatation and hypotension in the peri-intubation period. Furthermore, intubation without muscle paralysis is often fraught with difficulty as optimal conditions for facilitating intubation are not present and patient effort can severely hamper the success of the intubation attempt[13]. These issues might underlie the rationale for the removal of DFI from clinical practice. However, this was not demonstrated in our study.

Emergency intubation in the prehospital environment is a complex intervention with severe complications if it is poorly planned or performed, so optimising all factors involved prior to intubation makes sense. This would include allowing only well trained, competent individuals with adequate skills and experience to perform ETI[14]. While it can be seen as a commendable decision to reserve intubation for the highest qualified paramedics, in reality this could translate into around two thirds of patients not having access to this potentially life-saving intervention early in the course of their care and having to wait until their eventual arrival at a healthcare facility for the provision of a definitive airway and ventilatory control. This may be a very undesirable situation particularly in traumatic brain injury patients who are at risk for secondary brain injury, who in this study make up a considerable portion of trauma patients, accounting for 45% of all patients in our sample. The consequences of removing access to prehospital ETI in these patients warrants urgent examination.

Patients in circulatory arrest on arrival are sometimes intubated without induction agents or muscle relaxants as intubation can usually be accomplished without drugs in these patients. These patients usually require cardiopulmonary resuscitation (CPR) and vasoactive medication. Many resuscitation guidelines for out-of-hospital cardiac arrest patients have de-emphasized intubation and have prioritised the provision of high quality, minimally interrupted CPR[15], [16]. However, endotracheal intubation might still be desirable when there are limited resources available on scene (such as in South Africa), allowing for asynchronous CPR. Cardiac arrest was the indication for roughly a third of the intubations in

this sample. This patient group is usually found to have poor to dismal outcomes, both in the short and the long term[17].

Reliable, quick and accurate placement of an endotracheal tube is one important indicator of the quality of advanced airway management provided by an emergency medical system and can be seen as a reflection of the effectiveness of that system as well as a marker of patient safety[18]. For this reason, first pass success rates receive a lot of attention in studies that evaluate PHAAM. Overall success rates acknowledge multiple intubation attempts and are a more lenient measure of intervention success.

Because of heterogeneity in EMS system design in terms of staffing preferences and variability in provider skill level and experience, comparisons of intubation success rates across systems can be difficult. Nevertheless, some studies have made attempts to make fair comparisons between similar provider level, patient groups and intubation methods. A 2010 meta-analysis by Hubble et al. found that the overall success rate for non-RSI intubations in non-physicians was 86.3% but did not assess first pass success rates[19]. Another meta-analysis that followed in 2012 by Lossius et al found that the median overall success rates for PHETI was 90.5%[20]. This included both physician and non-physician manned services.

More recently in 2017, Crewdson et al evaluated non-physician PHETI in 101 439 patients, and found that the median overall success rate was 91.7%[21]. The same study also found that the first pass success rate for non-physicians was 69.6%. Our study yielded a first pass success rate of 74% and an overall success rate of 98%. Whilst there is always room for improvement, these metrics are an encouraging sign that South African prehospital providers compare favourably on an international level.

Locally, there is a paucity of data on prehospital ETI. Stein[22] examined PHETI in 367 patients intubated by university paramedic students during their clinical training and found an overall success rate of 99.6% and a first pass success rate of 87.9%. In 2018, Stassen et al[8] examined PHETI in a South African Helicopter Emergency Medical Service (HEMS) and found that 71% of their sample was comprised of young male trauma patients. They also found a first pass success rate of 79% and an overall success rate of 98%. These findings are fairly consistent with those found in our study.

While success rates are a useful way to assess the quality of a service, they can be misleading and even potentially deceptive as they do not take adverse events and patient outcomes into account. Adverse events (AEs) such as severe hypoxaemia and even post-intubation cardiac arrest can occur during an intubation attempt where the successful passage on the endotracheal tube was recorded[23]. The adverse event rate in our study was 15%, with hypotension being the most commonly occurring AE, followed by hypertension and then post-intubation cardiac arrest. It is highly likely that the AE rate is under-estimated due to the self-reporting nature of the PRFs used in this study. This is further evidenced as other smaller South African studies found higher AE rates[8]. Automated electronic patient monitoring is one way of accurately recording patient encounters and has been shown to identify more AEs than self-reporting and manual documentation of patient vital signs on patient records[24].

As we had difficulty elucidating predictors and aggravating factors for difficult intubation and AE rates, improving clinical notes should be a key focus area for future quality improvement and patient safety initiatives. Use of a dedicated airway management form could greatly assist in the accurate and comprehensive capture of the airway intervention. Key fields to include would be airway assessment, estimated BMI in order to rationalise drug choice and dose, and time of intubation in order to track patient physiological status. This would also greatly assist in the development of a prehospital intubation registry, which many have called for some time ago, but has not yet materialised[25].

Limitations

There are several limitations inherent to this study. All data were self-reported and retrospectively analysed. Recall bias on the part of the practitioner and the inherent limitations of retrospective work cannot be avoided. AEs in particular are likely to be under-reported, and our results should therefore be interpreted with extreme caution. Certain data such as factors relating to airway assessment are based on the subjective opinion or judgement of the practitioner performing the assessment and can only be considered as estimates of potential airway difficulty. As the PRFs did not have designated areas for some crucial information such as the exact time of intubation or drug administration, airway assessment or estimated body weight or BMI, the intubation event can be considered to be incompletely captured. Inferences that were thus made with some data or observations missing are also a possible source of bias as they were inferred if not expressly documented. This study acknowledges that documentation on prehospital airway management is generally sub-optimal and re-affirms the need for improved documentation practices in this regard. Lastly, this study presents the data of only one national private EMS, limiting the external validity.

Suggestions for Future Research

The dataset for this paper was combined with another dataset collected by another researcher. Similar data points for the same time were collected across a different patient population, yielding over 1,000 airway management encounters in the combined data set.

To date, this is the largest prehospital airway dataset in South Africa. A number of different studies using this combined data set are being planned :

- analysis of trauma patients
- sub-analysis of out-of-hospital cardiac arrest patients
- evaluation of the compliance of Airway management reporting according to Utstein variables
- analysis of short-term survival of patients, specifically looking at patients with poor outcomes.

We also suggest further refinement of the airway management form, specifically with regards to explicit documentation of the timing of drug administration, patient airway assessment and exact timing of intubation. Another future research opportunity that we would like to suggest is the development of a national pre-hospital intubation registry.

CONCLUSION

This retrospective observational study is the first to examine prehospital intubations performed on a national level by a private ground-based ambulance service over a 12-month period. The majority of patients intubated were trauma patients, and the most common indication for intubation was a decreased level of consciousness, followed by cardiac arrest. More than a third of patients were intubated by means of an RSI technique with less than a third receiving DFI and the remaining 25% being intubated without drugs whilst in cardiac arrest. Overall success and first pass success rates compare favourably with those reported in the literature.

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Appendix 1 – Research protocol

A RETROSPECTIVE, DESCRIPTIVE ANALYSIS OF PREHOSPITAL PROVIDER-PERFORMED EMERGENCY ENDOTRACHEAL INTUBATION IN A SOUTH AFRICAN NATIONAL PRIVATE AMBULANCE SERVICE

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This study is in partial fulfilment of the MMed Anaesthesia degree.

EXECUTIVE SUMMARY

Pre-hospital airway management is a routine component of emergency medical services provided to patients in South Africa. The level of airway interventions performed during transfer of a patient from the primary scene to a hospital facility or between healthcare facilities depends on multiple factors. Some of these include patient factors relating to the severity of illness or injury, and the skill level and qualifications of the emergency medical personnel retrieving and transporting the patient.

An important component of airway management for critically ill or severely injured patients is endotracheal intubation (ETI), which is an advanced and invasive airway management intervention aimed at providing:

1. Airway protection from aspiration of gastric contents or bodily secretions
2. Optimal oxygenation of patient
3. Adequate ventilation of patient

These aims are accomplished by passage of an endotracheal tube into a patient's trachea with the assistance of anaesthetic medication and instrumentation.

This procedure is performed on the severely physiologically compromised patient whose condition warrants immediate resuscitative measures.

ETI by Emergency Medical Services (EMS) in the pre-hospital setting has been evaluated worldwide, mostly in the form of retrospective studies and prospective airway management registries. The data generated from these analyses have reported a wide range of success rates for ETI and much variability in the techniques used to perform ETI. Much of this data is gathered in a developed or first world setting and therefore recommendations cannot simply be extrapolated to a resource constrained country like South Africa.

In South Africa, minimal data is available on this high risk airway intervention in the pre-hospital setting, despite ETI being performed in this environment for over 20 years. This is partly due to the fact that many EMS services have not reported or documented this intervention in a standardized manner.

The aim of this study is to provide a retrospective review of consecutive ETI interventions performed in a private EMS in South Africa since the implementation of a standardized airway data collection form.

Patient demographic information, specifics of the ETI intervention performed, success rates, adverse events and complications thereof will be extracted from anonymised airways data forms, and a descriptive analysis will be performed in order to further characterise this airway intervention in the pre-hospital environment and address the knowledge gap that is present with regards to current practice and performance in this country.

INTRODUCTION

ETI is an established practice in the pre-hospital setting. It is an advanced airway management technique that should be performed by personnel with the appropriate qualifications and skills training.

ETI can be facilitated by a number of pharmacological techniques and numerous airway adjunct devices, which are employed in order to achieve the same endpoint; passage of an endotracheal tube into a patient's trachea. This introduces a degree of complexity into this intervention. However, the impact of these associated techniques on patient outcomes has not yet been clearly defined within the context of the prehospital setting.

The literature suggests that overall success rates of ETI are a commonly-reported measure of intubation proficiency. This variable unfortunately does not provide any further insight into the population requiring ETI, the specifics of the techniques employed to facilitate ETI, nor does it attempt to identify potential areas of focus with respect to patient safety and quality improvement.

LITERATURE REVIEW

Effective airway management is a key component of pre-hospital care for severely injured and ill patients requiring retrieval and transportation to a health care facility or between facilities. It is the first priority in the Airway - Breathing - Circulation tenet that underpins most of emergency medicine ¹. ETI is an advanced and invasive airway management technique used in the most ill and injured patient group. It is also considered to be the gold standard of definitive airway management ².

Although much data on pre-hospital ETI exists internationally, opinions on this intervention differ widely in various countries for very many reasons. Much of the available evidence relating to the best strategy of pre-hospital airway management on patient outcome remains equivocal. A huge amount of heterogeneity exists in geographic and environmental factors, EMS system design, EMS practitioner training and experience, procedural protocols and patient characteristics and there is also a distinct lack of standardised data collection methods. These factors make comparisons very difficult. This manifests as ongoing uncertainty in the medical community with respect to the best method of prehospital airway management on patient outcomes ³.

Pre-hospital care has evolved from mainly providing transportation for patients to or between health care facilities to the provision of urgent medical treatment and emergency care in addition to transportation. Aeromedical transport is now also available in addition to road transport ⁴. Broadly speaking, EMS systems fall into one of two categories. The Anglo-American "Load & Go" approach aims to minimise on scene time and transport the patient to an appropriate health care facility as soon as possible. Paramedics, emergency nurses and emergency medical technicians (EMTs) usually form the backbone of this system and have access to physician support and early access to hospital facilities. The Franco-German model has a higher proportion of emergency physicians or anaesthetists experienced in the provision of out-of-hospital anaesthesia staffing the service. Because of higher provider skill level and experience, a "Stay & Stabilise" approach is utilised where certain critical interventions are performed on scene or en route to a health care facility ⁵. Many countries are now adopting a mix of these two philosophies and South Africa is no exception to this⁵

South Africa is considered to be a low to middle income, developing and resource constrained country⁶. An overwhelming majority of trauma related deaths occur in resource constrained countries and the majority of these occur in the pre-hospital environment, partly due to poor access to health facilities and sub-optimal EMS provision due to economic constraints ⁷.

South Africa experiences some of the highest trauma related deaths worldwide mostly due to road traffic accidents and interpersonal violence. This is also expected to increase with increasing urbanization. In addition to trauma, communicable diseases, HIV/AIDS and tuberculosis and the increasing prevalence of non-communicable diseases, South Africa's health care system is faced with the quadruple burden of disease.⁸

Pre-hospital EMS systems differ considerably between developed and resource constrained countries, especially with respect to readily available access to health care facilities with adequate trauma and emergency management capabilities and training and expertise of EMS providers. EMS providers in South Africa (and other low-and middle income countries),

although arguably well skilled and well experienced, face formidable challenges; high workloads, difficult access to scenes and to facilities due to informal or incomplete road networks, personal danger due to criminal activity , unpredictable transport times and overburdened Emergency Centres on their arrival at a health care facility ⁹. For these reasons, EMS in South Africa has adopted a Franco-German approach and allows for the provision of critical advanced interventions in certain patients when indicated, by appropriately qualified personnel. Prehospital endotracheal intubation has already been included in the scope of practice of paramedics since the early 2000s. In 2009, the Health Professions Council of South Africa (HPCSA), which is the regulatory body for the medical profession including EMS providers, approved the rapid sequence intubation approach for use by a certain cadre of prehospital providers, the emergency care practitioner ¹⁰.

Pre-hospital ETI by non-physicians is a controversial subject globally and the literature is replete with experts advocating either for it where positive patient outcomes are demonstrated or advising against it where patient outcomes are poorer than expected or it has been shown to have^{11,12} no benefit when compared to less risky and less invasive methods of airway management .^{13,14}

It is unsurprisingly then that although many bodies recognise the need for ETI in certain situations , they emphasize the need for this practice to occur within a system of rigorous clinical governance^{15,16}.

In addition, there are numerous pharmacological techniques and airway adjunct devices that are used to facilitate ETI and often studies do not discuss the specifics of the techniques employed, which again makes comparisons difficult.

Furthermore, the lack of standardised, objective recording of airway interventions by most EMS providers further clouds the issue¹⁷.

Although some efforts have been made to analyse the practice of pre-hospital ETI in South Africa, many of these studies have been limited to a specific patient population eg.head injury¹⁸ or cardiac arrest ¹⁹or have evaluated ETI in a specific context eg.HEMS only²⁰ or specific geographic ^{21,22}locations and this implies limited external validity. Small sample sizes have also limited their generalisability.

The study that is the subject of this proposal intends to provide a larger sample of airway management encounters on a nationwide scale, across different platforms and paramedic skillsets.

As this study is part of a collaborative effort evaluating the same variables in another dataset, the data obtained from this study will be merged with that of the other study and a pooled analysis will be performed thereby aiming to provide a more comprehensive analysis of pre-hospital intubation in South Africa.

Much of the international data is in the form of retrospective audits and airway registries where the most commonly used variable to describe clinical efficacy and quality is the first pass success rate. This kind of reporting is potentially misleading as it does not describe the physiological responses and sequelae of intubation attempts, some of which can even be considered adverse events eg. cardiac dysrhythmias, hypotension and desaturation. In fact, minimal data is available to describe the frequency and severity of these deleterious events.

To ensure patient safety, it is generally accepted that pre- hospital anaesthesia and intubation should be practiced according to in-hospital standards²³ . Optimal and successful pre-hospital care relies on the ability to make advanced diagnostic assessments and perform complex interventions in multiple domains of emergency medicine such as airway management, haemodynamic resuscitation, pain control and patient transfer. These skill sets form a huge part of anaesthesia specialist training²⁴ . Anaesthetists are often required to train ECPs from the second year of their EMS degree and often provide in hospital assistance in Emergency Centres. This provides the rationale for the involvement of anaesthesia services in EMS, particularly with patients who require critical care^{25,26}

The complexity and wide variation of ETI in the South African context therefore warrants more rigorous examination in order to better define and characterise this high-risk intervention from a quality improvement and patient safety perspective.

AIM AND OBJECTIVES

The aim of this study is to describe the ETI practices of ER24, a national private ambulance service. To this end, the objectives are:

- To describe the demographics, diagnosis and indication for the advanced airway management
- To describe the method of advanced airway management (medication-facilitated, rapid sequence intubation or without the use of pharmacological agents) and the pharmacologic agents used to facilitate the advanced airway management
- To describe the trends in vital signs observed prior to the advanced airway management, immediately post the advanced airway management and at the time of handover.
- To compare adverse events that occurred for each method of ETI.
- To quantify the first past success and overall success rates of pre-hospital ETI in this patient sample.

RESEARCH METHODOLOGY

Study design

A retrospective cross-sectional chart review will be employed by extracting data from clinical records of ER24.

Study setting

ER24 is private EMS that operates at a national level across South Africa using both ambulances and rescue aircraft. ER24 transports both private and state patients, as well as Road Accident Fund (RAF) and Workman's Compensation Act (WCA) patients from the primary scene in addition to performing inter-facility transfer. ER24 transports approximately 13 000 patients per month and approximately 1% of these require endotracheal intubation. ER24 collects data on and monitors endotracheal intubation practices nationwide as part of their clinical governance procedures. Airway encounters are voluntarily reported by ALS on a standard airway management form. Further information can be found on the patient report form.

Sample

All patients intubated by ER24 prehospital, advanced life support (ALS) providers during 01 January 2017 and 31 December 2017 will be included in this retrospective chart review. The inclusion and exclusion criteria for case selection are described below.

Inclusion Criteria

- Advanced life support performed endotracheal intubation,
- Between 01 January 2017 and 31 December 2017,
- Patients of all ages,
- Intubations performed during primary ground and aeromedical responses, as well as during interfacility transfer (if performed by ALS)

Exclusion Criteria

- Endotracheal intubation not performed by ALS,
- Patients intubated during interfacility transfer, prior to arrival by ALS

Data collection and Data Management

Completing either an airway management form and a patient report form, or a patient report form only is mandatory for every patient encounter in ER24. These forms are sequentially numbered and tracked. Quality assurance measures ensures that none of these forms go missing.

Anonymised, scanned copies of hand-written patient report forms and/or electronically captured airway management forms will be obtained from ER24, spanning the period between 01 January 2017 and 31 December 2017. Only patients that were intubated will be included. A standard checkbox on the patient report form indicates that intubation was performed, as well as the number of intubation attempts. This is captured electronically, and patients who were intubated can therefore easily be identified through a simple search in the ER24 billing system.

Documents will be interrogated and data variables will be extracted according to the objectives stated earlier. Data variables extracted and their definitions are contained in Appendix A, and are based on the 2018 Utstein reporting guidelines form prehospital airway management²⁷. Variables will be extracted in duplicate to a standard Excel Spreadsheet (Appendix B, Microsoft Corporation, Redmond, Washington) by the MMed student. A 10% random sample will be extracted by an employed data capturer. The data capturer will sign a non-disclosure agreement and will receive specific training on the information contained on the patient report and airway management forms, as well as the data variables and extraction procedures. The data capturer will also be a student in a medical discipline (medicine, emergency care, nursing) in order to ensure an understanding of some of the physiological variables. Data will be compared and any disputes will be resolved by a third party during monthly extraction calibration and monitoring meetings. Interrater reliability will be calculated and reported on for the 10% random sample. Data will be backed up on a secure cloud-based server and stored in a password protected file on a computer only accessible to the researchers. As there is no hypotheses or comparisons being tested, the data capturers are not blinded.

According to Gilbert and Lowenstein (1996)²⁸, there are eight essential elements that should be considered and reported on to ensure acceptable methodological rigour and minimising risk of bias. These eight elements are training, case selection, definition of variables, abstraction forms, meetings, monitoring, blinding and agreement (26). All of these have been specifically addressed in the design of this study.

As the current Utstein guidelines are new (2018), it is expected that not all data variables will be recorded in the dataset sampled. In the case where certain fields are omitted, that data will not be recorded, but the rest of the data from the form will be captured as it remains valid for the particular fields populated. Finally, we will report on the percentage of omitted fields as a measure of compliance and feedback for future development in airway management reporting.

Data Analysis

Data has not yet been extracted and analysed so it is difficult to predict which tests will be most appropriate for analysis since the distribution characteristics of the variables are still unknown. Categorical data will be presented as frequency and proportions (%) and continuous variables as mean and standard deviation. Summary statistics will be used to represent frequency (frequency tables). Categorical data will be compared with the use of the Fisher's exact test or the Chi² test, depending on the characteristics of the variables. Continuous variables will be compared with Student's t-test. Vitals before and after advanced airway management will be compared by using paired samples t-tests.

Statistical significance will set at $p < 0.05$ and 95% confidence intervals will be provided if applicable. Data will be analysed with the help of IBM SPSS Statistics version 24 (IBM, New York).

LIMITATIONS

Due to the self-reporting and retrospective nature of this study, validity may be threatened in that providers could record a false representation of patient stability or not accurately account the entire patient treatment encounter. Unfortunately, there is no other feasible way of completing this study. Further, as it is descriptive in nature, these threats are accepted. Recall bias can further threaten validity. This effect is minimised by requiring that EMS providers complete forms immediately after completion of patient treatment. Patient report and airway management forms are standardised across the ER24 service, and providers have received in-service training on how to complete these forms. For this reason, good reliability is expected. Notwithstanding, we are further recording instances of missing data as our final objective in order to determine compliance of current airway management

ETHICAL CONSIDERATIONS

Ethical approval for the study will be requested from the Faculty of Health Sciences Human Research Ethics Committee at the University of Cape Town. Provisional approval to access the ETI data has already been obtained by ER24 (Appendix C).

Patients included in the sample would not have given prior consent to their data being used in this study. However, the primary purpose of the patient report and/or airway forms are to record clinical information and clinical governance processes. Following the National Health Research Council Principles, Processes and Structures for Ethics in Health Research, patients do not need to give new consent if the intention of secondary data use was not for research purposes and if the data are anonymised and results of the research will not pose a risk to patients or their families²⁹. These criteria are met by the proposed study. A waiver of consent will therefore be sought for this retrospective chart review. No identifying patient, practitioner or service data will be recorded. Patients will only be identified by their respective patient report form number; no identifying data will be recorded in a master sheet.

DISSEMINATION OF FINDINGS

This study forms part of a larger collaborative project that aims to provide a full view of ALS performed endotracheal intubation nationally. A Masters in Emergency Medicine student will

do an identical study on another sample. These results will be pooled, analysed and written-up for publication in a peer reviewed journal. A dissertation report will be completed for this project that will be accessible via the UCT OpenArchive repository. The results of the research project will be shared with the ER24 Clinical Governance Team.

TIMELINE

2018-2019	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
DRC	X							
Ethics		X						
Data Collection			X	X	X			
Data Analysis					X	X		
Write-up							X	
Submission								X

BUDGET

Jul 2018- April 2019				
Item	Description	Unit cost	Nº of Units	Total cost
1. Data for online usage	Data package at 10 GB	R299	1	R299
2. Printing	Paper, ink and binding	R500	1	R500
3. Stationary	General Stationary	R200	1	R200
4. Memory stick	Back up	R500	1	R500
5. Data Collector	Secondary data collection, per hour	R200	10	R2000
6. Statistical Support	Statistical analysis, per hour	R550	2	R1100
Total				R4599

The research will be self-funded by the MMed student

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APPENDIX 2. UTSTEIN TEMPLATE:

ABBREVIATIONS

1. EMS: Emergency Medical Service
2. ETT: Endotracheal tube
3. NMBA: Neuromuscular blocking agent
4. SAD: Supraglottic airway device
5. ASA-PS: American Society of Anesthesiologists physical status
6. EMS: Emergency Medical Service
7. GCS: Glasgow Coma Score
8. ED: Emergency Department
9. EMS: Emergency Medical Service
10. ETT: Endotracheal Tube
11. NMBA: Neuro Muscular Blocking Agent

Table 1: Core system variables

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
1	Highest Level of EMS provider on scene	Ordinal	1 = EMS non-Paramedic 2 = EMS-Paramedic 3 = Nurse 4 = Physician 5 = Unknown	Highest level of EMS provider on scene, excluding any non-EMS personnel (bystanders, family, etc)
2	Airway devices available on scene	Nominal	1 = Bag Mask Ventilation 2 = SAD 3 = ETT 4 = Surgical airway 5 = None 6 = Unknown	Airway devices available on scene and provider on-scene who knows how to use it (select all that apply)
3	Drugs for airway management available on scene	Nominal	1 = Sedatives 2 = NMBA 3 = Analgesics/opioids 4 = Local/topic anaesthetic 5 = None	Drugs used for airway management, available on scene and someone competent to administer them (select all that apply)
4	Main type of transportation	Nominal	1 = Ground ambulance 2 = Helicopter ambulance 3 = Fixed-wing ambulance 4 = Private or public vehicle	Main type of transportation vehicle (if multiple selected, vehicle used for the majority of the transportation phase)

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
			5 = Walk-in 6 = Police 7 = Other 8 = Not transported 9 = Unknown	
5	Response time	Continuous	Minutes	Time from when the Emergency Medical Communication Centre operator initiates transmission of the dispatch message to the first resource/unit time of arrival on the scene of the first unit, as reported by the first unit

Table 2: Core patient variables

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
6	Co-morbidity	Ordinal	1 = No (ASA-PS = 1) 2 = Yes (ASA-PS = 2-6) 3 = Unknown	ASA-PS definition 1 = A normal healthy patient 2 = A patient with mild systemic

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
				disease 3 = A patient with severe systemic disease 4 = A patient with severe systemic disease that is a constant threat to life 5 = A moribund patient who is not expected to survive without the operation 6 = A declared brain-dead patient whose organs are being removed for donor purposes
7	Age	Continuous	YY or MM	Years rounded down. Ages under 1 year are reported in decimals (e.g., 6 month = 0.5 year)
8	Gender	Nominal	1 = Female 2 = Male 3 = Unknown	Patient gender
9	Patient category	Nominal	1 = Blunt trauma (incl. burns and strangulation) 2 = Penetrating trauma 3 = Non trauma (incl. drowning and	Dominating reason for emergency treatment

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
			asphyxia) 4 = Unknown	
10	Indication for airway intervention	Nominal	1 = Decreased level of consciousness 2 = Hypoxemia 3 = Ineffective ventilation 4 = Existing airway obstruction 5 = Impending airway obstruction 6 = Combative or uncooperative 7 = Relief of pain or distress 8 = Cardiopulmonary arrest 9 = Other, specify	Dominating indication for airway intervention
11	Respiratory rate, initial	Continuous	Number/ Not recorded	First value recorded by the EMS provider on scene
12a	Systolic blood pressure, initial	Continuous	Number/ Not recorded	First value recorded by the EMS provider on scene
13a	Heart rate, initial	Continuous	Number/ Not recorded	First value recorded by the EMS provider on scene
14	GCS, initial (m/v/e)	Ordinal	Motor 1-6 Verbal 1-5	First value recorded by the EMS provider on scene See also GCS definitions

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
			Eyes 1-4 Not recorded	
15a	SpO ₂ , initial; state: with or without supplemental O ₂	Continuous and nominal	Number/Not recorded 1 = Without supplemental O ₂ 2 = With supplemental O ₂ 3 = Unknown if supplemental O ₂	First value recorded by the EMS provider on scene

Table 3: Core post-intervention variables

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
16	Post-intervention ventilation	Nominal	1 = Spontaneous 2 = Controlled 3 = Mixed 4 = Unknown	How is patient ventilated following airway management? If both spontaneous and controlled, choose mixed.
12b	Post-intervention systolic blood pressure (SBP)	Continuous	Number/Not recorded	First value recorded by the EMS provider after finalised airway management

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
15b	Post-intervention SpO ₂	Continuous	Number/Not recorded	First value recorded by the EMS provider after finalised airway management
17a	Post-intervention EtCO ₂	Continuous	Number/Not recorded	First value recorded by the EMS provider after finalised airway management
12c	Post-intervention SBP on arrival	Continuous	Number/Not recorded	First value recorded by the EMS provider after patient arrives at hospital
13b	Post intervention heart rate	Continuous	Number/Not recorded	First value recorded by the EMS provider after finalised airway management
15c	Post-intervention SpO ₂ on arrival	Continuous	Number/Not recorded	First value recorded by the EMS provider after patient arrives at hospital
17b	Post-intervention EtCO ₂ on arrival	Continuous	Number/Not recorded	First value recorded by the EMS provider after patient arrives at hospital
18	Survival status	Nominal	1 = Dead on-scene or on arrival	Patient survival status: EMS treatment and on arrival at hospital

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
			2 = Alive on hospital arrival 3 = Unknown	
19	Attempts at airway intervention	Nominal	1 = One attempt 2 = Multiple attempts by one provider 3 = Multiple attempts by two or more providers 4 = Unknown	Number of attempts at securing the airway with a supraglottic airway device (SAD) or tracheal intubation (TI).
20	Complications	Nominal	1 = ETT misplaced in oesophagus 2 = ETT misplaced in right mainstem bronchus 3 = Teeth trauma 4 = Vomiting and/or aspiration 5 = Hypoxia 6 = Bradycardia 7 = Hypotension	Problems and mechanical complications recognised on scene and caused by airway management. Physiologic complications (5, 6, and 7) are regarded as such if they were not present before airway intervention and were recorded during or immediately after airway management. The following definitions are used: hypoxia: SpO2 < 90%

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
			8 = Other, define 9 = None recorded	bradycardia: pulse rate <60 bpm hypotension: SBP < 90
21	Drugs used to facilitate airway procedure	Nominal	1 = Sedatives 2 = NMBA 3 = Analgesics/opioids 4 = Local/topic anaesthetic 5 = None	Drugs used to facilitate the airway intervention. Select all that apply
22	Intubation success	Nominal	1 = Success on first attempt 2 = Success after more than one attempt and one rescuer 3 = Success after more than one attempt and multiple rescuers 3 = Not successful	Successful intubation defined as tube verified in the trachea. An intubation attempt is defined as attempted laryngoscopy with the intent to intubate
23	Device used in successful airway management	Nominal	1 = Bag Mask Ventilation 2 = SAD 3 = Oral TI 4 = Nasal TI	Device used to manage successful airway or device in place when patient is delivered at hospital/ED

Data variable number	Data variable name	Type of data	Data variable categories or values	Definition of data variable
			5 = Surgical airway 6 = None 7 = Unknown	

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DESCRIPTION

The *African Journal of Emergency Medicine (AfJEM)* is the official journal of the [African Federation for Emergency Medicine](#). It is an Africa-centric, peer-reviewed journal aimed in particular at supporting emergency care across, you guessed it, Africa. *AfJEM* publishes original research, reviews, brief reports of scientific investigations, case reports as well as commentary and correspondence related to topics of scientific, ethical, social and economic importance to emergency care in Africa. Articles will be of direct importance to African emergency care, but may have originated from elsewhere in the world.

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