Prehospital advanced airway management practices by advanced life support providers: A retrospective observational study of emergency medical service providers in South Africa

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ABSTRACT

Introduction: The skill of endotracheal intubation to achieve a definitive airway for critically ill and injured patients in the prehospital setting is frequently performed by advanced life support providers. Several methods may be utilised, including intubation without the use of medication, the use of sedatives or a rapid sequence intubation. There is a paucity of data available that assesses prehospital advanced airway intubation practices in South Africa. The aim of this study is to describe the advanced airway management practices of advanced life support providers across South Africa.

Methods: A retrospective, observational study method was used (chart review). Electronic patient care records were sourced from private and public emergency medical services companies and collated accordingly.

Results: A total of 704 cases were included. Intubation during cardiac arrest was the most common approach to airway management (n=280, 40%) followed by rapid sequence intubation (n=202, 28%), medication-facilitated intubations (n=152, 22%) and a no-medication approach (n=70, 10%). Successful intubation using an endotracheal tube was reported in 197 (98%) of rapid sequence intubation cases, 134 (88%) of the medication facilitated cases, 61 (87%) of no-medication cases and 228 (81%) of cardiac arrest cases. A first-pass success rate was described in 260 (79%) cases, with the cardiac arrest group having a first-pass success of 85%, followed by the rapid sequence intubation group (83%), the no-medication group (71%) and the medication facilitated group (61%). Hypotension and cardiac arrest were the most common adverse events. A total of 496 (70%) patients were alive at hospital handover. The average scene time and transportation time was 42 minutes and 24 minutes respectively for the rapid sequence intubation group, 42min and 27min for the medication facilitated group, 44min and 25min for the no-medication group and 57min and 16min for the cardiac arrest group.

Discussion: The study described the prehospital airway management practices by advanced life support providers in South Africa. Rapid sequence intubation had the highest endotracheal intubation success rate overall and the lowest prevalence of adverse events. There was no statistical difference in survival between the rapid sequence intubation, medication facilitated and no-medication group. Due to a lack in standardised treatment guidelines, differences in fluid administration, post-intubation care, confirmation of placement and ventilation were noted. No standard approach to record keeping was found, with the quality of patient care records being variable. A standardised advanced airway management report would be beneficial as it would improve the quality of data recorded and allow for better comparisons to be made.

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ACRONYMS AND ABBREVIATIONS

AHA	American heart association
ALS	Advanced life support
BLS	Basic life support
BP	Blood pressure
BURP	Backward, upward and rightward pressure
CCA	Critical care assistant
ECP	Emergency care practitioner
ECT	Emergency care technician
EC	Emergency Centre
ELM	External laryngeal manipulation
EMS	Emergency Medical Services
$ETCO_2$	End-tidal Carbon Dioxide
ETI	Endotracheal intubation
ETT	Endotracheal Tube
GCS	Glasgow coma scale
HIC	High-income countries
HPCSA	Health Professions Council of South Africa
HR	Heart rate
ILS	Intermediate life support
IV	Intravenous
LT	Laryngeal Tube
LMIC	Low- and middle-income countries
MAP	Mean arterial pressure
MILS	Manual in-line stabilisation
PCR	Patient care record
RR	Respiratory rate
RSA	Republic of South Africa
RSI	Rapid sequence intubation
SAD	Supraglottic airway device
SBP	Systolic blood pressure
SI	Shock Index
SPO_2	Peripheral capillary oxygen saturation
TBI	Traumatic brain injury
UCT	University of Cape Town

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CHAPTER 1: INTRODUCTION

1.1 Background

Endotracheal intubation has become the definitive airway management procedure for most critically ill and injured patients in the prehospital setting.(1,2) Prehospital advanced airway management, with or without the administration of pharmacological agents, is a skill frequently performed by advanced life support (ALS) providers.(3) There is a small but identifiable group of severely ill or injured patients in whom basic airway interventions do not provide adequate oxygenation and ventilation prior to hospital arrival and that will need advanced airway management.(3) The ability to secure a patient's airway is one of the most important skills in a paramedic's armamentarium.(4,5)

Low- and middle-income countries (LMICs), including South Africa face challenges due to financial and resource constraints.(6) These challenges might lead to prolonged prehospital times and an increased need for earlier critical care interventions, such as advanced airway management.(6,7) The healthcare sector in South Africa is divided into a private and public sector. The private sector provides healthcare services, including prehospital emergency medical care to patients with medical insurance, while the public sector provides healthcare to all other patients. Results released by Statistics South Africa, showed that only approximately 22.6% of people in South Africa are covered by medical insurance.(8)

The Health Professions Council of South Africa (HPCSA), which regulates the South African emergency medical services (EMS), only allows for ALS providers to perform advanced airway interventions. Within the South African EMS, there are several categories of ALS providers, distinguished on their level of training and scope of practice and registry at the HPCSA. These qualifications include emergency care technicians, paramedics and emergency care practitioners. An emergency care technician (ECT) is accredited with a national certificate. An ECT may insert a supraglottic device only in an unconscious or pulseless patient and may not use any pharmacological agents to facilitate advanced airway management.(9) A paramedic is accredited with either a critical care assistant (CCA) certificate or a national diploma in emergency care qualification. A paramedic may facilitate advanced airway management by the administrations of sedative agents.(9) An emergency care practitioner (ECP) is accredited with a four-year bachelor's degree from an accredited university and may perform a rapid sequence intubation (RSI).(9)

A deep sedation intubation, or medication-facilitated intubation, is defined as the administration of a sedative or anaesthetic drug as an induction agent, for the purpose of advanced airway management, without the use of a paralytic (neuromuscular blocking agent).(2,3) Rapid sequence intubation is defined as a technique where a sedative or induction

agent is administered intravenously followed rapidly by the administration of a quick-acting neuromuscular blocking agent.(3,5) This is performed for creating optimum conditions to facilitate endotracheal intubation and to minimise the adverse physiological effects of airway manipulation.(5)

Prior to the introduction of RSI in 2009 by the HPCSA, advanced airway manoeuvres were performed by means of deep sedation.(4) There is an associated risk when performing a RSI due to the neuromuscular blocking agents rendering the patient apnoeic and due to the loss of airway patency.(10) However, the benefit outweighs the risks in the prehospital setting, due to the fact that prehospital RSIs provide improved intubating conditions compared with intubation with deep sedation only, it takes less time for intubation, and that it uses a safer combination and dosage of drugs.(2,3,10) It is for these reasons that RSI is preferred to intubations facilitated by deep sedation in the prehospital setting.(10)

There is limited data regarding the success of deep sedation intubations, but several international studies do indicate a poor endotracheal intubation success rate– 85% in one study and 67.5% in another.(2) Success rates reported with rapid sequence intubation tend to be higher.(2) One aeromedical study reported a very large difference, a success rate of only 25% when etomidate was administered alone, compared to 92% when the same dose of etomidate, plus a paralytic agent, was used. RSI is associated with less adverse reactions and complications, as compared to deep sedation intubations.(2) Another in-hospital study showed a greater number and severity of complications when a neuromuscular blocking agent was not used; these complications included aspiration (15%), airway trauma (28%), and death (3%). None of these complications were noted when rapid sequence intubation was utilised.(2) Overall, prehospital advanced airway management is associated with a variety of complications including hypoxia, hypotension, tracheal tube misplacement, oesophageal intubation, vomiting and aspiration, cardiac arrhythmias and bleeding.(3)

There is a paucity of data available that assesses prehospital advanced airway intubation practices in South Africa.(4,6,11) A study by Roos et al. assessed prehospital intubation success rates in the Western Cape in 2006, three years before the implementation of prehospital RSI.(12) Roos et al. found that South African paramedics perform advanced airway management more frequently, than compared to some high-income countries (HICs).(12) Botha et al. assessed prehospital intubation success rates for intubations done in Johannesburg during 2011 but did not describe the prehospital practices.(13) A study by Gunning et al. focused on the safety and success of prehospital RSI.(6) A research paper by Stein described the RSI practices of ECP students at the University of Johannesburg, and not the practices of qualified ECPs.(4) A collective review on the use of pharmacological agents of choice for RSI was published in 2016 but did not look at the practices surrounding the RSI.(7)

This study will provide more insight into current airway practices and can form part of continues clinical governance and development in the South African healthcare setting.

1.2 Aims

The aim of the study was to describe the advanced airway management practices of advanced life support providers across South Africa.

1.3 Objectives

The objectives of the study were (All variables were based on the Utstein airway template):

1. To describe the demographics, prehospital diagnosis and indication for the advanced airway management.
2. 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.
3. To describe the trends in vital signs observed prior to the advanced airway management, immediately post the advance airway management and at the time of handover.
4. To compare adverse events that occurred for each method of advance airway management.
5. To calculate the overall success rate and the rate of failed airways.

1.4 Motivation for the study

The motivation behind this study was to assess prehospital advanced airway practices in South Africa as this evidence is limited. South Africa has numerous healthcare challenges due to financial and resource constraints, which is why we need to assess the practices in our own setting, as information from studies for high-income countries (HICs) will likely not be applicable to our setting. To improve prehospital critical care and develop evidence-based guidelines, research on standardised high-quality data is important.

1.5 Summary

Prehospital airway management in South Africa is performed by different categories of prehospital providers, each deploying a different strategy to facilitate the successful placement of an advanced airway. There is a paucity of data available on the prehospital airway management practices in South Africa. Internationally, prehospital airway management remains a controversial topic. The HPCSA is currently undertaking a task to change how

prehospital airway management is performed in South Africa. Assessing current airway practices can aid in developing further policies and guidelines.

Chapter 2 provides a literature review that will describe advanced airway management in the prehospital context, as well as challenges and factors affecting airway management in the prehospital setting. Chapter 3 describes the methodology utilised to conduct this study. All findings are summarised in chapter 4, while the interpretation and discussion of the findings are described in chapter 5. Chapter 6 provides a conclusion based on the findings of the results, and chapter 7 lists future research recommendations.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter will review the current available literature on prehospital airway management practices. The literature will be based on the objectives as set out below.

2.2 Objectives

- To describe advanced airway management within the prehospital context
- To assess the different approaches in which advanced airway management can be achieved
- To describe the safety of prehospital advanced airway management
- To review the current literature on South African prehospital advanced airway management

2.3 Inclusion criteria

- Study designs: Systematic reviews, meta-analysis, randomised control trials, case-series, retrospective studies and prospective studies
- Participants: Humans
- All ages
- Publication date: 2014-2019
- Publication date for South African research 2003-2019
- Language: English

Limited published data is available on advanced airway management in the South African prehospital environment. A broader publication date range was used only for literature focusing specifically on advanced airway management in South Africa, as a great deal of the literature was published prior to 2014.

2.4 Exclusion criteria

- Non-study articles: Letters to editors
- Publication date: Prior to 2014

2.5 Literature search strategy

A search of Medline was done using five search strings. Institutional access to Medline was gained through the University of Cape Town.

- Search string 1: (("Emergency Medical Technicians"[Mesh]) OR "Emergency Medical Services"[Mesh]) AND "Intubation, Intratracheal"[Mesh]
- Search string 2: (("Emergency Medical Technicians"[Mesh]) OR "Emergency Medical Services"[Mesh]) AND "Rapid Sequence Induction and Intubation"[Mesh]
- Search string 3: ((("Emergency Medical Technicians"[Mesh]) OR "Emergency Medical Services"[Mesh]) AND "Deep Sedation"[Mesh]) AND "Intubation, Intratracheal"[Mesh]
- Search string 4: "Emergency Medical Services"[Mesh])) AND "Intubation, Intratracheal"[Mesh]) AND "adverse effects" [Subheading]
- Search string 5: ((("Emergency Medical Technicians"[Mesh]) OR "Emergency Medical Services"[Mesh]) AND "Intubation, Intratracheal"[Mesh]) AND "South Africa"[Mesh]

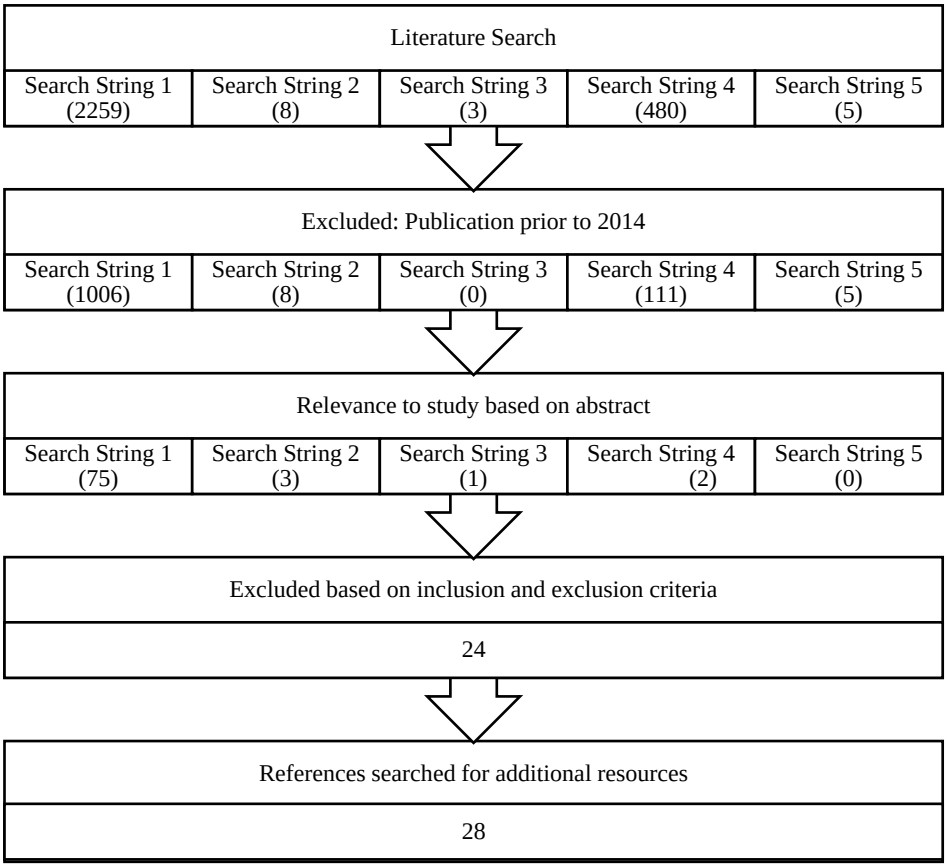

Figure 1: Search Strategy

2.6 Summary of literature

2.6.1 Prehospital endotracheal intubation

Endotracheal intubation (ETI) with a correctly placed tracheal tube is the reference standard for securing a patient's airway in the operating theatre, emergency centre (EC) as well as the out-of-hospital setting.(1,14) ETI in the prehospital setting is usually performed to optimise oxygenation, ventilation and to prevent aspiration in the critically ill or injured patient.(15) Prehospital ETI has become an integral part of stabilising critically ill patients.(16) Airway management procedures range from basic airway manoeuvres to more invasive airway manoeuvres.(4) There is a small but identifiable group of critically injured or ill patient in whom basic airway manoeuvres do not provide adequate oxygenation or ventilation and advanced airway management is indicated.(1) ETI in the prehospital setting is a critical skill performed by suitably qualified emergency medical services (EMS) personnel and this ability, to secure a patient's airway, is considered one of the most important skills in a paramedics armamentarium.(4,17) Historically, advanced airway management in the prehospital setting was only performed on patients in cardiac arrest and for those without intact airway reflexes and was associated with poor outcomes.(18) The quality of prehospital airway management has improved over the years, as the number of patients requiring prehospital airway management has increased.(18) A meta-analysis published in 2010 reported a total of 54 933 prehospital intubation attempts, while a subsequent meta-analysis from 2006-2016 reported a total of 125 177 intubation attempts.(18) Several factors related to the austere environment and unscreened patient population contribute to prehospital ETI being more challenging as compared to other settings.(19) ETI in the prehospital setting is considered a high-risk procedure, complicated by a critically ill and injured patient population, limited availability of recource to manage adverse events and variable training for EMS personal. (14,17) Prehospital ETI and first-pass success rates are further complicated by significant physiological and or anatomical derangements, the requirements for cervical spine precautions, associated co-morbidities and that most of the patients requiring emergency intubation are not fasted.(16,20) As a result, the increased number of intubation attempts in the prehospital setting, may lead to serious adverse events, such as hypoxia, bradycardia and cardiac arrest.(19) Paramedics often intubate in a challenging environment, with limited access to the patient.(21) Intubations performed by physicians are typically performed with the patient on a stretcher, that can be adjusted to heights considered optimal by the treating physician. Paramedics often have to intubate on the ground or with the patient on a low stretcher.(21) A study by Clemency et al. showed that the position of the patient during intubation does affect the first-pass success rate.(21)

Despite the controversies surrounding prehospital ETI, it remains a common practice in EMS systems worldwide.(15) A study in the United Kingdom reported that as much as 57% of trauma patients had a compromised airway on arrival at hospital.(18) Studies in the United States of America, showed that 10% of patients that arrived at the ED needed ETI within five hours, with half of these patients presenting with a decreased level of consciousness, hypoxia, hypoventilation or an acute airway obstruction.(18,22) This supports the hypothesis that prehospital ETI remains a necessary intervention.

2.6.2 Rapid sequence intubation vs deep sedation intubation

RSI is a technique whereby a rapidly acting sedative is administered, followed by a paralytic drug to facilitate the placement of an endotracheal tube.(23) The process of a RSI is performed to optimise conditions for emergency ETI and first-pass success.(10,23) Medication-facilitated intubation involves the administration of a sedative only for the purpose of intubation.(24) RSI has been shown to be more effective than medication-facilitated intubation.(10,23,24) In the South African EMS setting, medication-facilitated intubation is done by administering a combination of morphine and midazolam. A prospective study involving 2 365 patients by Okubo et al., reported a higher success rate for patients in emergency centres using a RSI approach compared to a medication-facilitated approach (73% vs. 63%, $p<0.001$).(24) In-hospital data suggest that RSI provides better intubation conditions than medication-facilitated intubations.(24) Some of these benefits include abducted vocal cords, no vocal cord movement, easier laryngoscopy and absent cough and/or gag reflexes.(24) The same study by Okubo et al. also reported that there was no significant difference in the risk of complications.(24) RSI does, however, include a safer combination of drugs as compared to medication facilitated intubations.(10) Prehospital RSI is considered a high-risk procedure, with an increased risk of severe complications, compared to in-hospital settings.(20) Higher rates of failed intubation, failure of oxygenation, transient hypoxia, hypotension and the need for a surgical cricothyroidotomy have been associated with prehospital RSI.(20) Despite the high-risk, prehospital RSI has been shown to be effective and has been associated with improved patient outcomes.(16) Prehospital RSI is performed in several EMS systems across the world, such as in Australia, Europe, the United States of America and South Africa.(20,23) The Emergency Medicine Society of South Africa (EMSSA) released a position statement in which prehospital RSI is supported, provided it is done within an appropriate frame work of clinical governance. A retrospective study done in Australia for patients that underwent a RSI by intensive care flight paramedics showed that appropriately trained paramedics can safely perform a RSI in the prehospital environment.(16)

A total of 795 cases were included and had a first-pass success rate of 89.4% and an overall success rate of 99.4%.(16) Hypotension (5.2%), hypoxia (1.3%) or both (0.1%) were observed in 6.6% of the patients that underwent a RSI.(16) A similar study done at a South African private Helicopter EMS (HEMS) reported an overall success rate of 98% (47/48 cases) with a first-pass success rate of 79% (n=38).(25) Hypoxia (n=6), hypotension (n=7) and bradycardia (n=2) were the most commonly observed adverse events, and at least one adverse event was seen in 27% of cases.(25)

2.6.3 Supraglottic airway devices vs endotracheal intubation

ETI is the standard practice for advanced airway management in the prehospital setting, but a low success rate and undetected oesophageal intubations have raised concerns over the use of an endotracheal tube (ETT).(26) It is for this reason that the use of a supraglottic airway device (SAD) has been accepted as a rescue device and a primary airway device.(26) Previous studies showed high success rates for placing a SAD, but a study by Martin-Gill et al. showed an overall success rate of 84.9%.(26) The presence of an intact gag-reflex was associated with unsuccessful SAD placements.(26) SAD in a patient with an intact airway reflex is not recommended, and a RSI approach is recommended when a SAD is used as a primary airway device.(26) When comparing the insertion of a laryngeal tube (LT) (a type of SAD) vs. an ETT as an initial airway management approach in patients with out-of-hospital cardiac arrest, the LT group showed a higher 72-hour survival rate (18.3% vs 15.4%; p=0.4).(27) Contradicting to this study, the AIRWAYS-2 trial showed that a strategy of advanced airway management with a SAD did not result in a favourable outcome at 30 days.(28) Kempema et al. (29) compared the outcomes of blunt trauma patients that underwent prehospital ETI or airway management by means of the insertion of a SAD. A total of 162 patients were included in the study, and showed a higher prevalence in cardiac arrest for the SAD group.(29) The study concluded that there was no difference in the overall survival for patients managed by means of ETI or a SAD.(29)

2.6.4 Physician vs. non-physician airway management

Advanced airway management needs to be done by suitably qualified and experienced clinicians. Out-of-hospital advanced airway management by non-physicians (such as paramedics and nurses) remains controversial.(23,30) A meta-analysis in 2012 compared success rates for prehospital emergency ETI between different provider-types and training and reported a higher success rate for physicians over non-physicians.(30)

A recent meta-analysis published by Crewdson et al. (30) in 2017 concluded that although the overall success rate for prehospital intubation has improved, there was still a higher success

rate associated with physician intubations vs. non-physician intubations. The crude median reported ETI success rate for non-physicians were 91.7%, and for physicians, were 98.8% (p=0.003).(30) Another meta-analysis by Fouche et al. (23) published in 2017, also reported a higher intubation-first pass and success rate for physicians vs non-physicians (88% vs. 78%). Paramedic experience with performing ETI plays a vital role in explaining the different success rates and survival in literature.(31) Limited research is available reporting on how frequently paramedics perform intubations, with some research suggesting that paramedics only perform between 1-8 intubations per year, while physicians performed more than 150 intubations per year.(31) Studies in HIC settings have reported that out of 12 527 cases which EMS responded to, only 150 (0.01%) of the patients required advanced airway interventions.(32)

2.6.5 The context within the South African health system

LMICs such as South Africa face unique challenges due to resource-restraints, often resulting in prolonged transportation times and limited access to definitive care.(6,7) These prolonged prehospital times increases the need for earlier critical care interventions and advanced airway management, as it has been shown that a delay in intubations increases mortality in certain patient populations.(6,7) The healthcare system in South Africa is divided into a private and public sector. The private sector provides healthcare services, including prehospital emergency medical care, to only 22.6% of the South African population.(8) The remainder 77.4% of the populations receives healthcare services from the public sector. No evidence is currently available to describe the distribution of paramedics working for the private or public healthcare sector. The HPCSA regulates the training and scope of practice for prehospital emergency care providers within the South African EMS environment (both public and private). Prehospital emergency care providers are divided into basic life support (BLS), intermediate life support (ILS) and advanced life support (ALS) providers. The HPCSA currently only allows ALS providers to perform advanced airway management in the South African prehospital environment. Several categories of ALS providers exist, distinguished by their level of training and scope of practice. The first level of ALS provider is an ECT. An ECT is accredited with a national certificate and may only insert a SAD in a patient without an intact airway reflex. No pharmaceutical agents may be administered for the purpose of advanced airway management. A paramedic is accredited with either a certificate or a national diploma. A paramedic may administer a combination of opioids and benzodiazepines to facilitate the process of ETI (known as medication facilitate intubation or deep sedation intubation).

A paramedic may also insert a SAD and perform a surgical cricothyroidotomy. University-graduate ALS providers, known as an ECP, may perform the process of RSI since it was introduced into the scope of practice by the HPCSA in 2009. Performing advanced airway management is part of the national paramedic/ ECP training programs. This is done in various settings, including theatre (under the supervision of an anaesthesiologist), ED and in the prehospital setting. The minimum amount of ETI and insertion of a SAD that a student will need to have completed successfully is regulated by the HPCSA. Currently, the HPCSA requires a total of 30 ETIs to be performed, as well as the insertion of 10 SADs.(4) This is significantly more, compared to the some of the national paramedic training programs in HICs countries, which only require five intubations.(32) The HPCSA recently released a new proposed scope of practice, only allowing ECPs to perform ETIs using a RSI approach. Paramedics are only allowed to insert a SAD for patients without an intact airway reflex or perform a surgical cricothyroidotomy. The HPCSA currently has a total of 2 434 paramedics, 1 223 ECTs and 851 ECPs on its registry. It is important to note that the HPCSA registry does not distinguish between ALS providers currently abroad or those not currently practising anymore. The actual numbers of ALS providers currently practising in South Africa will be lower. Physicians do not commonly practise in the prehospital environment in South Africa.

2.6.6 Airway management in South Africa

A retrospective study involving 86 RSI cases by Gunning et al.(6) in South Africa, reported a high success rate (100% self-reported success rate) but was associated with a high complication rate (22%). These complications included haemodynamic instability (11.6%), tension pneumothorax (3.5%), and hypercapnia (1.2%).(6) A retrospective study by Stein et al. (4) reported on prehospital RSI cases done by ECP students at the University of Johannesburg. Although these cases were all done by students, they were supervised by qualified clinicians. Out of a total of 351, a success rate of 99.7% was recorded. The first-pass success rate (done by either the student or the supervising clinician) was 87.9%.(4) The study reported that 5% of the cases were associated with cardiac arrest.(4) Prior to RSI, 16% were hypotensive, and 34% had hypoxia.(4) At the time of handover, 12% of the patients were still hypotensive, while 12% were still hypoxic.(4) A study published by Sobuwa et al. (33) described the outcome of traumatic brain injury (TBI) patients that underwent different airway management manoeuvres in the prehospital setting in Cape Town, South Africa. A total of 124 patients were enrolled in the study of which 30% were managed with basic airway management, 7% were intubated without any pharmacological agents, 44% were intubated with a medication-facilitated approach, and 11% underwent RSI.(33) A total of 11 (9%) failed intubations, and an overall mortality rate of 38.7% were recorded.(33)

Patients who were intubated without the use of any medication had the highest proportion of poor outcomes (88%), followed by the RSI group (62%).(33) A bigger proportion of patients that were intubated using a medication-facilitated intubation had a good outcome compared to the RSI group (62% vs. 38.4%).(33) The data collection period for this study was from 2009-2011, while prehospital RSI was only introduced in 2009 in SA. In another study done in Germany with a total of 21 242 patients with a traumatic brain injury (TBI) and a Glasgow coma scale (GCS) of ≤8, 18 975 (89.3%) were intubated prehospitally.(34) The study concluded that the observed mortality in the intubated group was lower compared with the non-intubated group.(34) A similar study by Haltmeier et al. (35) reported that prehospital ETI was associated with a higher mortality rate compared to in-hospital ETI (OR 1.4, $p<0.001$).

2.6.7 Prehospital airway data reporting

As part of ongoing quality control measures, clinical records involving prehospital advanced airway management should be reviewed. (10) In order to improve prehospital advanced airway management and develop evidence-based guidelines, research on standardised, high-quality data is required.(36) In 2009, the Utstein-airway template was published by an international airway expert group to ensure standardised data is recorded for prehospital advanced airway management.(36) An updated Utstein-template was published in 2018 and includes 32 operational variables and 6 system variables.(36) For the purpose of airway-data, advanced airway management is defined as "*any airway management beyond manual opening of the airway and the use of simple adjuncts, such as an oropharyngeal airway"*.(36) This includes ETI, the use of a SAD and a surgical airway.(36) Within the South African EMS, each service is responsible for its own clinical governance and operating procedures. Although the HPCSA regulates scope of practice for EMS providers, there is no standard for data reporting. The data reported on, and the way in which it is recorded, is done at each service's own discretion.

Based on the revised Utstein-template, the following data variables should be recorded for prehospital advanced airway management:(36)

- Time variables: response time, on-scene time and transport time
- Age and gender
- Patient category
- Indication for advanced airway management
- Risk factors for difficult intubation and any aggravating conditions present
- Peripheral oxygen saturation level (SpO_2): Initial, lowest prior to airway management, lowest during airway management and after finalised airway management

- Blood pressure (BP): Initial, lowest prior to airway management, lowest during airway management and after finalised airway management
- Respiratory rate: Initial
- GCS: Initial and lowest prior to airway management
- Use of a checklist for airway management and if there is an established airway management procedure
- Oxygenation strategy for airway management
- Sequence of providers performing airway management and the highest level of EMS provider on scene involved in the airway management
- Sequence of airway devices used for airway management and devices available
- Airway management result
- Types of tracheal tube confirmation techniques used within the service
- Airway manoeuvres following failed airway attempt
- Drugs used to facilitate airway management as well as the drugs available to facilitate airway management
- Adverse events encountered
- Total number of successful endotracheal intubations the providers have performed in patients
- End-tidal carbon dioxide ($EtCO_2$) after finalised airway management
- Total number of successful ETI the provider has performed
- Ventilation after finalised airway management
- Survival to hospital

CHAPTER 3: METHODOLOGY

3.1 Study design

A retrospective, observational study method was used (chart review). Electronic and paper-based patient care records (PCR) were scrutinised retrospectively.

3.2 Study setting

Emergency medical services in South Africa are rendered by both public and private service providers – public EMS services are usually governed provincially with limited private EMS services operating on a national level.(37) Public EMS services are generally under-resourced, understaffed and poorly equipped to service the large areas which they cover.(37) Although the private EMS in SA primarily only caters for the insured patient population (approximately 17 out of 100 patients), it is not uncommon for private EMS to render emergency medical care to uninsured patients. Prehospital emergency medical care in SA can be provided by road (mainly), intensive care unit (ICU) helicopter emergency medical services (HEMS) or fixed-wing aeromedical services.

3.3 Study population

Data from all patients who underwent advanced airway management that was performed by ALS providers employed by selected organisations were included. Data were collected from selected EMS companies with operations across South Africa as well as a local public EMS provider. Each EMS company is responsible for their own clinical governance and record keeping. It was for this reason that data from selected EMS providers were used, as it would have been logistically challenging to obtain data from various other EMS providers. Several private companies as well as a local government EMS were approached. Only companies that responded within a certain time frame were included. Private companies with national and local operations were approached. Several of these companies have road operations, as well as aeromedical operations.

3.4 Study sampling

Inclusion criteria: Advanced airway management done by ALS providers (ECT, Paramedic or ECP) including those that have been performed in the prehospital, in-hospital (during interfacility transfers) and aeromedical environment.

Advanced airway management performed between 01 January 2017 and 31 December 2017 for all neonatal, paediatric and adult patients were included.

Exclusion criteria: Advanced airway management that was not performed by ALS providers. Patients already intubated prior to EMS arrival (for interfacility transfers).

3.5 Data collection and management

A letter requesting permission to access data was sent out to the preidentified companies (Appendix 1). A total of eight companies were approached, of which only two companies responded. Institutional approval was obtained from the different companies. (Appendix 2 and 3).

Electronic PCRs were obtained (no hard copies were provided). Each PCR was analysed individually, and the data were extracted as set out in the objectives. All PCRs were anonymised prior to being made available. The data was collected from the various companies by the researcher.

The researcher acted as the chart abstractor. No blinding was done prior to the chart review. A data abstract form was created on an electronic spreadsheet (Microsoft Excel, Microsoft Corporation, Redmond, VA) and was used for all chart reviews. The data was monitored by the research supervisors. IBM SPSS Statistics version 26 was used to analyse the data. Categorical data were presented as frequency and proportions (%) and continuous variables as a means. Categorical were compared with the use of the Fisher's exact test or the Chi^2 test, depending on the characteristics of the variables. Continuous variables were compared with Student's t-test or a non-parametric alternative. Statistical significance was defined as $p<0.05$.

The research supervisor acted as a second reviewer, by extracting information from a random 5% of PCRs. An insignificant error of less than 1% were corrected within the random sample, and no further steps were taken.

3.6 Variables

Variables were recorded based on the Utstein airway management dataset.
The following variables were recorded:

- Age: Defined in years, rounded up or down to the closest year. If the age is unknown, the patient's age will be described as neonate, paediatric or adult.
- Gender: Male, female or unknown.
- Patient category: Trauma – blunt, trauma – penetrating, trauma - head injury (including traumatic brain injury), trauma – other (including burns, strangulation, drowning, or asphyxiation), medical - cardiac arrest, medical - respiratory distress or breathing difficulties, medical – intoxication, medical - infection (including sepsis), medical - other (e.g. endocrinology or other medical emergencies),

neurology - stroke (including cerebral haemorrhage or infarction), neurology - other (excluding stroke), psychiatry (e.g. agitation/psychosis), obstetrics, other emergencies or unknown.

- The indication for intubation: Decreased level of consciousness, hypoxemia, ineffective ventilation, existing airway obstruction, impending airway obstruction, combative or uncooperative, humanitarian (e.g. relief of pain or distress), cardiac arrest, pre-existing airway device not working adequately or other.
- Setting in which advanced airway management was done: Prehospital, in-hospital (during interfacility transfers) or aeromedical.
- Difficult airway predictors: No risk factors for difficult intubation, prior difficult intubation, reduced neck mobility, neck-immobilisation device or manual in-line stabilisation (MILS), severe obesity or thick/short neck, limited mouth opening or inter incisor distance < 4 cm, short thyroid-mental-distance (< 6.5 cm), significant maxillofacial or upper airway trauma, blood, vomit, mucus or hypersalivation in airways, pre-existing airway device not working adequately, other or risk factors not assessed or described.
- Aggravating conditions for airway management: Patient entrapped during airway management, no 360-degree access to patient during airway management, suboptimal provider positioning, bright light/sunlight, darkness, hostile environment, in moving helicopter/ambulance, in stationary helicopter/ambulance or other.
- Advanced airway management approach: RSI, medication facilitated, no-medication or cardiac arrest.
- Pharmacological agents: Which pharmacological agents were used to facilitate the advanced airway management as well as the pharmacological agents administered for sedation and analgesia post advanced airway management. The volume of and type of intravenous fluid administered to the patient prior to the placement of the advanced airway device.
- Airway management results: Successful airway management with an ETT as planned, successful airway management with a SAD as planned, successful airway management with surgical airway as planned, failure of primary airway plan and airways secured by alternative technique, final airway management failed (loss of airways) or unknown.
- Airway manoeuvres following failed airway attempt: Cricoid pressure released, backward, upward, and rightward pressure (BURP)/ external laryngeal manipulation (ELM) manoeuvres, release MILS, reposition patient, ramping patient or none.
- Vital signs: The following vital signs were recorded:
  i) Respiratory rate (RR): Initial.

ii) SpO_2: Initial, lowest prior to airway management, during airway management and post airway management.

iii) Glasgow coma scale: Initial and lowest prior to airway management.

iv) End-tidal carbon dioxide ($ETCO_2$): Post airway management.

v) Heart rate (HR): Initial, highest prior to airway management, lowest prior to airway management, during airway management and post airway management.

vi) Blood pressure (BP): Initial, lowest prior to airway management, during airway management and post airway management.

In cases where the time of intubation was not recorded, the data will be extrapolated by describing the vital signs that correlates with the time of the medication administration. Vital signs during airway management were described as the vital signs that were recorded at the same time the airway management was described as being done (or extrapolated by means of the time of medication administration).

- Adverse events: The following adverse events were described:

  i) ETT misplaced in the oesophagus and corrected immediately.

  ii) ETT misplaced in the oesophagus and not corrected immediately.

  iii) ETT misplaced in the left or right mainstem bronchus.

  iv) Incorrect positioning or difficulty ventilation with SAD.

  v) Dental trauma.

  vi) Aspiration or vomiting during airway management.

  vii) Cardiac arrest during or immediately post airway management.

  viii) Hypoxia during airway saturation level less than 90%. Cases where the saturation levels were less than 90% at the time of the advanced airway management were not included

  ix) BP: Hypotension - systolic blood pressure (SBP) less than 90 mmHg or where there was a reduction in SBP or mean arterial pressure (MAP) of more than 20%. Hypertension: an increase in SBP or MAP of more than 20%.

  x) HR: Bradycardia- HR less than 60/min. Tachycardia were described as an increase of more than 20% in HR or a HR >100/min.

  xi) No complications described during airway management (confirmed).

  xii) Insufficient data recording. Complications unsure.

  The number of adverse events for each type of advanced airway management were compared. Due to the physiological parameters measured, advanced airway management during cardiac arrest was not analysed for adverse events.

- Confirmation of placement: The method that was used by the practitioner to confirm successful placement of the advanced airway device.

This included capnography, auscultation, visualisation of the endotracheal tube passing the vocal cords, oesophageal detection device and misting in the airway device.

- Ventilation: Spontaneous ventilation, controlled manual ventilation, controlled mechanical ventilation (ventilator), mixed ventilation (combination of spontaneous and control ventilation) or unknown.
- Survival to hospital: Dead on-scene after advanced airway interventions. Alive on hospital arrival (including patients that were transported with on-going mechanical or manual chest compressions.
- Duration: The scene time and transport time to hospital were described.

3.7 Ethical considerations

Ethical approval for the research was obtained from the University of Cape Town's Health Science's Human Research Ethics Committee (HREC Ref: 698/2018, Appendix 4). The study was not completed prior to the expiration of the ethical clearance. An extension was granted by the human research ethics committee (Appendix 5).

3.7.1 Risks

Risk to patients: Personal and identifying information was not made available on the PCRs. None of the identifying information was captured on the database. The only personal information that was recorded was age and gender.

Patients included in the sample would not have given prior consent to their data being used in this study. However, the primary purpose of data captured on the PCR was not for research but quality assurance and clinical governance within the respective companies. 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 families. These criteria were met by this study. The study did not, in any way affect the welfare and rights of the participants.

Risk to practitioners: No information about the treating ALS provider was captured.

Risk to companies: No identifying information of the companies were disclosed. Also, care was taken so that the companies' identity would not able to be deduced from the content or the wording of any documents. Consent was obtained from the companies to use their data.

3.7.2 Privacy and confidentiality

All PCRs were anonymised prior to being made available to the researcher. No identifying data was captured.

3.8 Strengths and limitations

The indisputable strength of this research project was the sample size and nation-wide sampling. The data collection period of a year also eliminated potential seasonal or monthly variances. Similar studies have been done but none to this extent or very recently.

This study was a retrospective review, and the quality and accuracy of the findings depended on the integrity of the record keeping. The sample size, however, was big enough to mitigate the potential for selection bias. We were unable to capture the qualification of the ALS provider performing the airway management due to the PCRs being anonymised. Motivations were not always clearly described in the free text section, with variable quality record keeping. No dedicated airway registry exists in South Africa.

3.9 Conflict of interest

The researcher is currently employed by one of the organisations included in the study. The researcher was not employed at the company at the time of obtaining the data.

CHAPTER 4: RESULTS

4.1 Introduction

Findings based on the objectives will be described in this chapter. Categorical data are presented as frequency and proportions (%) and was assessed for non-random associations with the use of the Fisher's exact test or the Chi^2 test, depending on the characteristics of the variables. Statistical significance was defined as $p<0.05$ and data were analysed with the help of IBM SPSS Statistics version 26.

4.2 Study sample

A total of 4 863 electronic PCRs were analysed and a total of 704 (14.5%) were included in the study. The majority of the cases were from a public EMS provider (75%), while 25% of cases were obtained from a private EMS provider. A total of 4 123 (84.8%) of cases were excluded from the study and reasons for exclusion are described in figure 1.

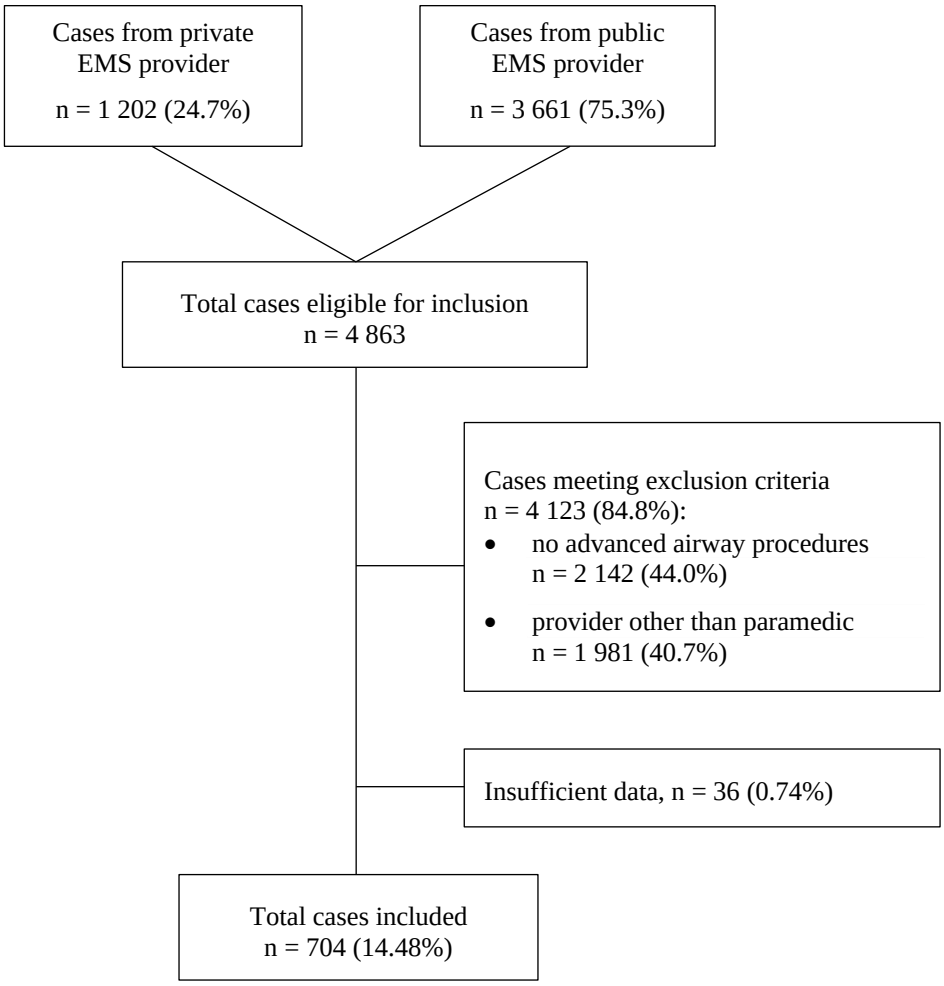

Figure 2: Flowchart of study population

4.3 Patient demographics

Table 1 describes the demographics and category of all included patients (n=704) stratified into the different settings where the advanced airway procedures were performed. 93% (n=653) of all advanced airway procedures occurred on primary prehospital calls, while interfacility transfers and aeromedical transfers comprised of 2% (n=15) and 5% (n=36) respectively.

Table 1: Patient demographics and category stratified between call type (n = 704)

n (row %)	Prehospital n=653 (93%)	Interfacility transfer n=15 (2%)	Aeromedical n=36 (5%)	p
Age				
<18	44 (85%)	2 (4%)	6 (12%)	
18-25	46 (90%)	1 (2%)	4 (8%)	
26-35	72 (97%)	0	2 (3%)	
36-45	75 (94%)	2 (3%)	3 (4%)	
46-55	78 (92%)	2 (2%)	5 6%)	.094
56-65	87 (94%)	4 (4%)	2 (2%)	
66-75	77 (94%)	1 (1%)	4 (5%)	
>75	62 (97%)	1 (2%)	1 (2%)	
Unknown adult	104 (93%)	2 (2%)	6 (5%)	
Unknown paediatric	8 (73%)	0	3 (27%)[A]	
Gender				
Male (n =214)	202 (94%)	5 (2%)	7 (3%)	
Female (n=462)	427 (92%)	10 (2%)	25 (5%)	.138
Not documented (n=28)	24 (86%)	0	4 (14%)[A]	
Trauma (n=291)	257 (88%)	6 (2%)	28 (10%)[AB]	.000
No trauma (n=413)	396 (96%)[C]	9 (2%)[C]	8 (2%)	
Trauma (n=291)				
Blunt (n=171)	152 (89%)	2 (1%)	17 (10%)[A]	
Penetrating (n=27)	25 (93%)	0	2 (7%)	
Head injury (n=56)	49 (88%)	3 (5%)	4 (7%)	
Other trauma (n=37)	31 (84%)	1 (3%)	5 (14%)[A]	
Medical (n=347)				
Cardiac arrest (n=225)	224 (100%)[B]	1 (0%)	0	
Respiratory distress (n=48)	44 (92%)	3 (6%)	1 (2%)	
Intoxication (n=47)	46 (98%)	0	1 (2%)	
Sepsis (n=3)	3 (100%)	0	0	.000
Other (n=24)	22 (92%)	1 (4%)	1 (4%)	
Neurology (n=62)				
Stroke (n=43)	39 (91%)	2 (5%)	2 (5%)	
Other neurology (n=19)	14 (74%)	2 (11%)[A]	3 (16%)	
Psychiatric (n=2)	2 (100%)	0	0	
Obstetrics	0	0	0	
Other	0	0	0	
Not documented (n=2)	2 (100%)	0	0	

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

There was no difference in gender and age distribution between the three groups. More females underwent advanced airway management than males (66% vs 30%). More non-trauma cases (medical and neurological combined) received advanced airway management than those with trauma (59% vs 41%). Of the trauma cases, blunt trauma (59%, n=171) was the most common cause for airway management, followed by head injuries (19%, n=56), other trauma (13%, n=37) and penetrating trauma (9%, n=27). Cases with cardiac arrest (32%, n=225) contributed the largest proportion, of which all except one case were from the prehospital category.

4.4 Approach to airway management and indications for airway management

Airway management during cardiac arrest was the most common form of approach to airway management (40%, n=280) as depicted in Table 2. More non-RSI's (medication facilitated and no-medication) were performed than RSI's (32% vs 28%). RSI was the most common approach in the aeromedical and IFT setting (92% and 66%) compared to only 24% (n=159) in the prehospital category. Inadequate ventilation (27%, n=192) a decreased level of consciousness (32%, n=224) and cardiac arrest (39%, n=274) were the most common indications for advanced airway management.

Table 2: Airway approach for each indication and setting (n=704)

n (row %)	RSI n=202 (28%)	Medication facilitated n=152 (22%)	No-medication n=70 (10%)	Cardiac arrest n=280 (40%)	P
Trauma (n=291)	145 (50%) BCD	74 (25%)D	27 (9%)D	45(16%)	.000
Setting					
Prehospital (n=653)	159 (24%)	147 (23%)A	68 (10%)A	279 (43%)A	.000
IFT (n=15)	10 (66%)D	3 (20%)	1 (7%)	1 (7%)	
Aeromedical (n=36)	33 (92%)BC	2 (6%)	1 (3%)	0	
Indications					
Level of consciousness (n=224)	114 (51%)D	78 (35%)D	30 (13%)D	2 (1%)	.000
Hypoxia (n=2)	0	2 (100%)	0	0	.063
Inadequate Ventilation (n=192)	76 (40%)D	75 (39)D	40 (21%)A D	1 (0,5%)	.000
Existing Airway Obstruction (n=93)	39 (42%)D	36 (39%)D	14 (15%)D	4 (4%)	.000
Impending Airway Obstruction (n=67)	43 (64%)BD	12 (18%)D	8 (12%)D	4 (6%)	.000
Combative (n=31)	25 (81%) BCD	4 (13%)	1 (3%)	1 (3%)	.000
Humanitarian (n=1)	1 (100%)	0	0	0	.477
Cardiac Arrest (n=274)	1 (0,4%)	0	1 (0,4%)	272 (99%)AC	.000
Failure of Airway Device (n=3)	2 (67%)	1 (33%)	0	0	.361
Other (n=0)	0	0	0	0	

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

D: non-random difference with cardiac arrest category (p<0.05)

4.5 Predicted difficulties and aggravating conditions

Overall, only 280 (40%) cases were assessed for risk factors prior to airway management. Most of the cases where no airway assessment for risk factors were performed, were from the cardiac arrest group (n=212, 50%). Blood, vomit, mucous or hypersalivation in the airway prior to airway management, was the most common risk factor present (15%, n=107). Only 77 (10%) of cases had no risk factor present. No aggravating conditions were assessed or described in 550 (78%) cases. Airway management in a stationary ambulance/ helicopter (14%, n=101), airway management in a moving ambulance/ helicopter (4%, n=26) and not having 360-degree access to the patient (5%, n=32) were the most common aggravating conditions.

Table 3: Risk factors and aggravating conditions (n=704)

n (row%)	RSI n=202 (28%)	Medication Facilitated n=152 (22%)	No-medication n=70 (10%)	Cardiac Arrest n=280 (40%)	P
Risk Factors					
None (n=77)	32 (42%)[D]	18(23%)	10 (13,0%)	17 (22%)	.005
Prior difficult intubation (n=13)	6 (46%)	5 (39%)	0	2 (15%)	.092
Reduced neck mobility (n=65)	35 (54%)[D]	18 (28%)[D]	6 (9%)[D]	6 (9%)	.000
Severe obesity/ short neck (n=12)	7 (58%)	1 (8%)	0	4 (33%)	.108
Limited mouth opening or inter incisor distance < 4 cm (n=7)	2 (29%)	2 (29%)	2 (29%)	1 (14%)	.286
Short Thyroid-Mental-Distance (< 6.5 cm) (n=3)	3 (100%)	0	0	0	.058
Significant maxillofacial/ upper airway trauma (n=28)	13 (47%)[D]	11 (39%)[D]	2 (7%)	2 (7%)	.001
Blood, vomit, mucus or hypersalivation in airways (n=107)	37 (35%)	26 (24%)	8 (8%)	36 (33%)	.271
Pre-existing airway device not working adequately (n=2)	2 (100%)	0	0	0	.173
Other (n=0)	0	0	0	0	
Not Assessed (n=422)	83 (20%)	83 (20%)	44 (10%)[A]	212 (50%)[AB]	.000
Aggravating conditions					
Not Assessed (n=550)	134 (25%)	119 (22%)	53 (10%)	244 (44%)[A]	.000
Patient entrapped during airway management (n=5)	0	2 (40%)	2 (40%)	1 (20%)	.063
Not 360-degree access (n=32)	13 (41%)	5 (16%)	4 (13%)	10 (31%)	.384
Suboptimal provider positioning (n=8)	0	2 (25%)	1 (13%)	5 (63%)	.325
Bright light/ sunlight (n=0)	0	0	0	0	
Darkness (n=1)	1 (100%)	0	0	0	.477
Hostile environment (n=4)	1 (25%)	1 (25%)	0	2 (50%)	.909

Moving ambulance/ helicopter (n=26)	9 (35%)	7 (27%)	2 (8%)	8 (31%)	.712
Stationary ambulance/helicopter (n=101)	52 (52%) [BD]	21 (21%)	10 (10%)	18 (18%)	.000

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

D: non-random difference with cardiac arrest category (p<0.05)

4.6 Medications used for airway management

Ketamine (n=157, 75%) and etomidate (n=47, 23%) were the most commonly used sedative agents for RSI. Morphine (n=118, 78%) and midazolam (n=146, 96%,) were the most commonly used medication for medication facilitated intubations. Suxamethonium was used more than rocuronium as a primary paralytic agent (69% vs 33%). The paralytic agent used in two of the RSI cases were not recorded. Both these cases involved a paramedic attending to the patient, with an ECP performing the RSI and immediately handing the patients back over to the paramedic. Rocuronium was used more commonly as compared to suxamethonium as a secondary paralytic. Two patients (1%) that were intubated using a medication facilitated approach, received rocuronium post-intubation. A significantly higher portion of the medication facilitated group did not receive any further medication post the intubation attempt as compared to the RSI group (54% vs 11%). A higher portion of the RSI group received ketamine, morphine and midazolam post-intubation.

Table 4: Medication used for airway management (n=704)

	RSI	Medication facilitated	P
n (column %)	n=202	n=152	
Medication			
Ketamine (n=157)	152 (75%)[B]	5 (3%)	.000
Morphine (n=119)	1 (1%)	118 (78%)[A]	.000
Midazolam (n=149)	3 (2%)	146 (96%)[A]	.000
Suxamethonium (n=133)	133 (69%)[B]	0	.000
Rocuronium (n=67)	67 (33%)[B]	0	.000
Lidocaine (n=6)	0	6 (4%)	.004
Etomidate (n=48)	47 (23%)[B]	1 (1%)	.000
Post-intubation paralytic			
Rocuronium (n=32)	30 (15%)[B]	2(1%)	.000
Suxamethonium (n=3)	3 (2%)	0	.131
Post-intubation sedation			
None (n=105)	23 (11%)	82(54%)[A]	.000
Ketamine (n=73)	67 (33%)[B]	6 (4%)	.000
Morphine (n=142)	102 (51%)[B]	40 (26%)	.000
Midazolam (n=211)	145 (72%)[B]	66 (44%)	.000

Etomidate (n=5)	4 (2%)	1 (1%)	.297

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

D: non-random difference with cardiac arrest category (p<0.05)

4.7 Fluids

Ringers Lactate was the most used intravenous (IV) fluid during airway management for all different approaches (76%, n=532). NaCl 0.9% was the second most commonly used IV fluid (17.6%, n=124). Balsol (balanced solution crystalloid) were used in 20 cases (3%). Platelets and blood were both used twice during airway management. A colloid solution was administered three times during airway management (0.4%). The RSI group had the highest average volume of fluid administered as compared to the other groups.

Table 5: Type and average amount (ml) of fluid administered

	RSI	Medication facilitated	No-medication	Cardiac arrest	P
n (row %)	n=202 (28%)	n=152 (22%)	n=70 (10%)	n=280 (40%)	
Fluid					
Ringers lactate (n=532)	171(32%) [B C D]	109 (21%)	44 (8%)	208 (39%)	.001
Modified ringers (n=18)	5 (28%)	6 (33%)	1 (6%)	6 (33%)	.629
Balsol (n=20)	8 (40%)	7 (35%)	0	5 (25%)	.121
Normal saline 0,9% (n=124)	16 (13%)	32 (26%)[A]	18 (15%) [A]	58 (47%) [A]	.000
Colloids (n=3)	1 (33%)	0	1 (33%)	1 (33%)	.000
Platelets (n=2)	1 (50%)	0	0	1 (50%)	.501
Blood (n=2)	2 (100%)	0	0	0	.801
Neonatalyte (n=2)	0	0	2 (100%)	0	.173
Unknown (n=21)	2 (10%)	2 (10%)	6 (29%)[A B]	11 (52%)	.005
Average volume of fluid administered (ml)	817	638	579	703	

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

D: non-random difference with cardiac arrest category (p<0.05)

4.8 Vital signs

The mean initial respiratory rate/ minute was 18, 17 and 13 for the RSI, medication facilitated and no-medication group, respectively. Figure 3 shows the mean saturation levels for all different phases of airway management. The mean initial saturation levels were <90% for all groups. The saturation levels post airway management were higher for the RSI (96%) group, vs the medication facilitated intubation group (93%) and the no-medication group (90%). The lowest SPO_2 prior to airway management was 88% for RSI group, 87% for the medication facilitated group and 84% for the no-medication group. The lowest mean SpO_2 was statistically higher for the RSI group vs the no-medication group. The no-medication group had the biggest drop in SPO_2 during airway management, which was not observed in the RSI or medication facilitated group. The initial GCS was higher for the RSI group (7/15) vs the medication facilitated (5/15) and no-medication group (4/15). The mean lowest GCS scores prior to airway management was 6/15 for the RSI group, 5/15 for the medication facilitated group and 4/15 for the no-medication group. The mean $ETCO_2$ post final airway management was 43mmHg for the RSI group, 44mmHg for the medication facilitated group and 38mmHg for the no-medication group. No heart rate during airway management was recorded for the no-medication group (Figure 4). The mean HR for the RSI and medication facilitated group remained higher than the no-medication group in all the phases of airway management. The highest average heart rate/min prior to airway management was 107/min for both the RSI and medication facilitated and 85/min for the no-medication group. The lowest average heart rate/min prior to airway management was 100/min for the RSI group, 103/min for the medication facilitated group and 82/min for the no-medication group. The lowest average blood pressures were 121/75 mmHg for the RSI group, 126/79 mmHg for the medication-facilitated group and 111/68 mmHg for the no-medication group (Figure 5 and 6). The variation in the systolic and diastolic blood pressure for RSI was negligible. The medication facilitated group had a significant decrease of 31mmHg in the systolic blood pressure and an 11mmHg increase in the diastolic blood pressure during airway management, with a narrowing pulse pressure during airway management. The no-medication group had a drop of 54mmHg in the systolic blood pressure during airway management. Figure 7 shows a comparison of the shock index (SI) between the different groups of intubations. The SI was the highest prior- and post airway management for the medication-facilitated group (0.94 and .099), and it was the highest during airway management for the RSI group (0.99). No data available for the SI during airway management for the no-medication group. The RSI group had a negligible change in SI from baseline to post-intubation of less than 10%. The medication facilitated group had an increase of more than 10% from the SI recorded during airway management, to the SI recorded post airway management.

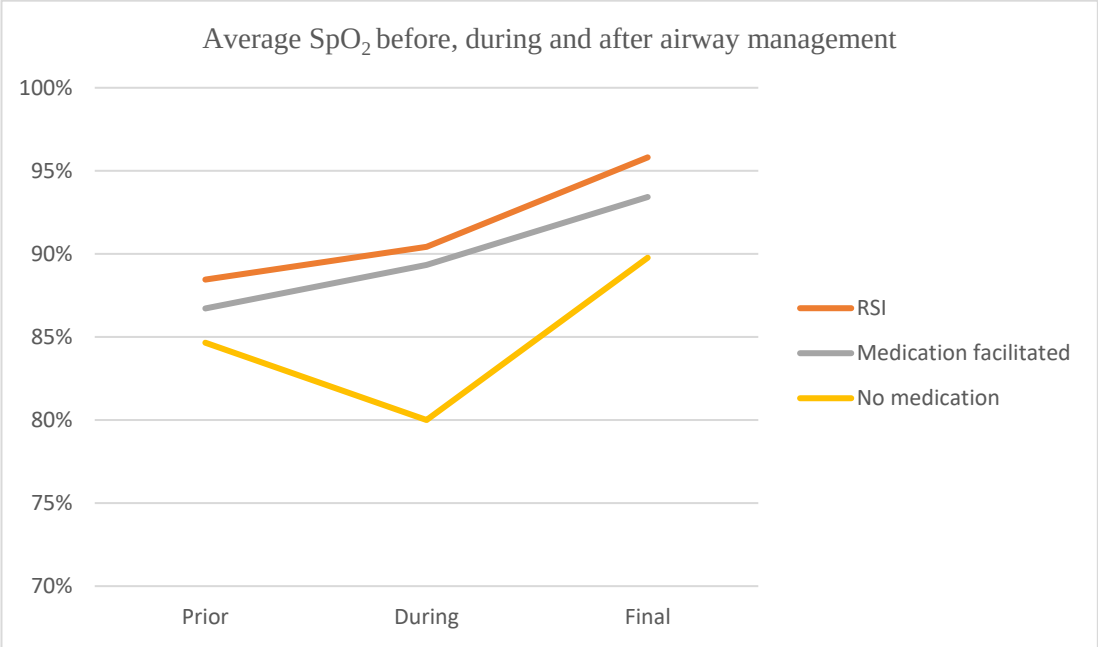

Figure 3: Average SpO_2 before, during and after airway management

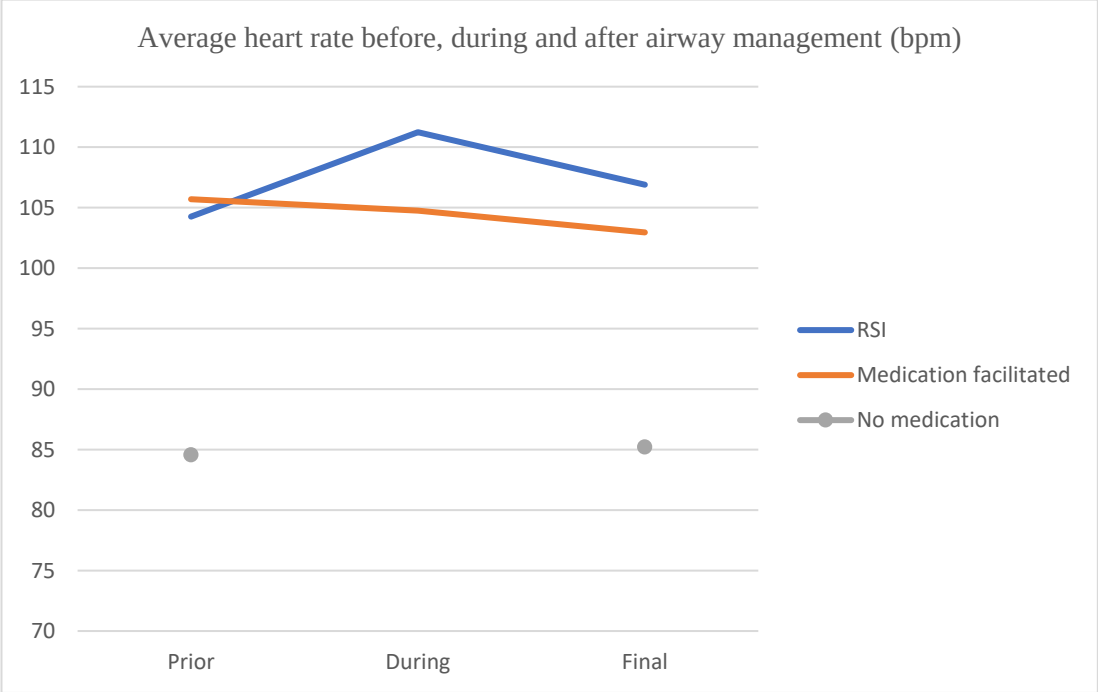

Figure 4: Average heart rate before, during and after airway management (bpm)

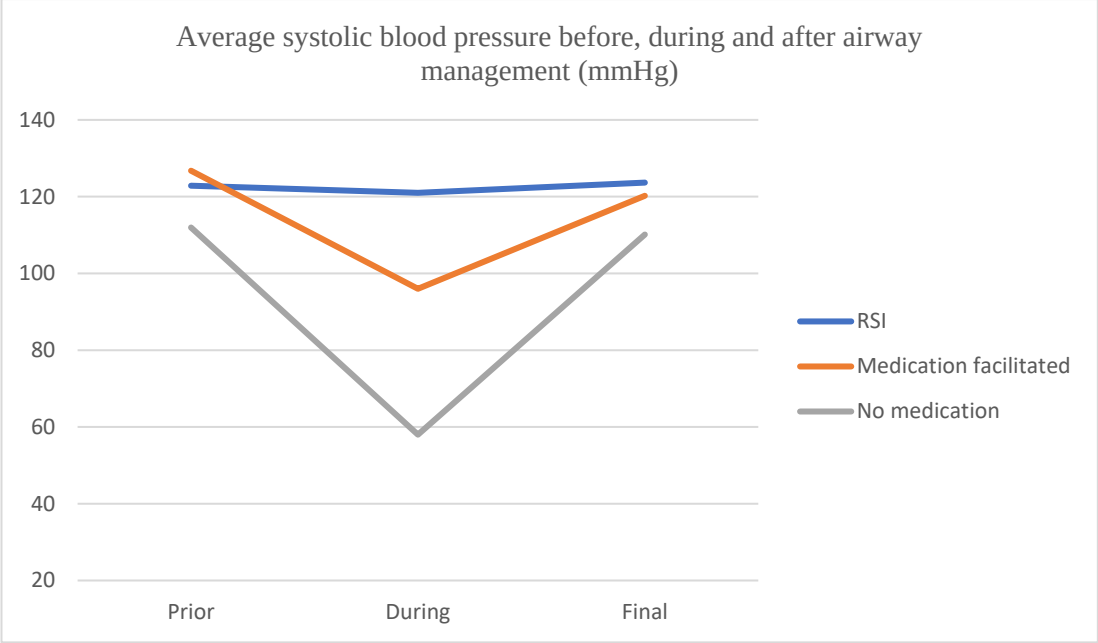

Figure 5: Average blood pressure before, during and after airway management (mmHg)

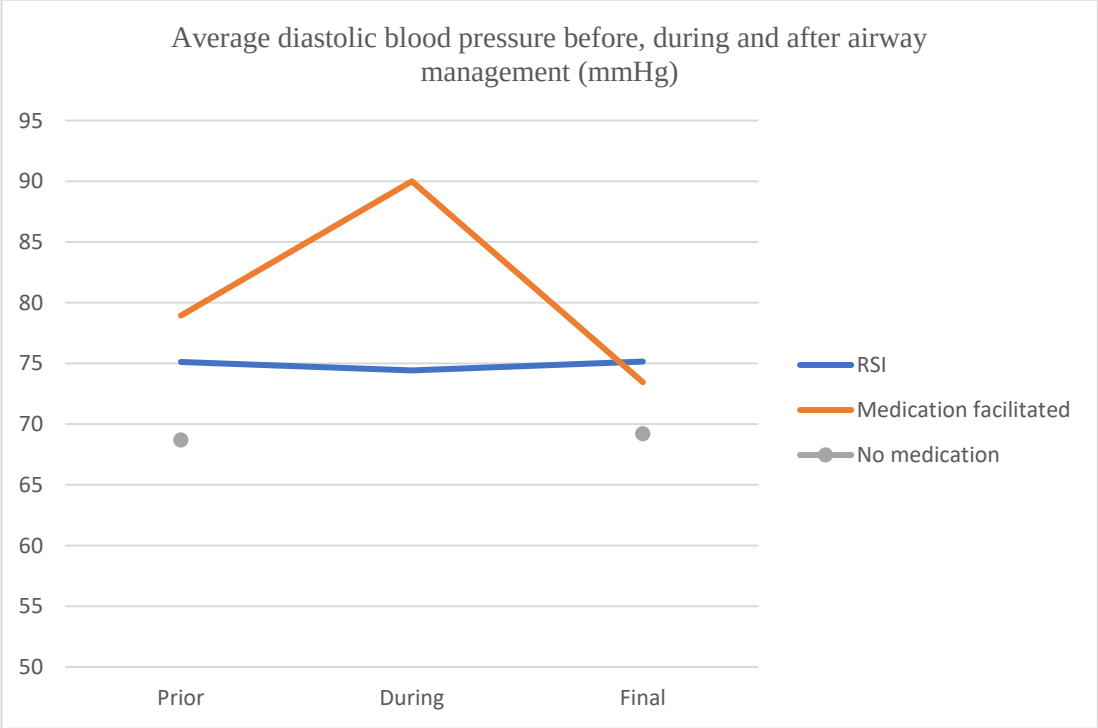

Figure 6: Average diastolic blood pressure before, during and after airway management (mmHg)

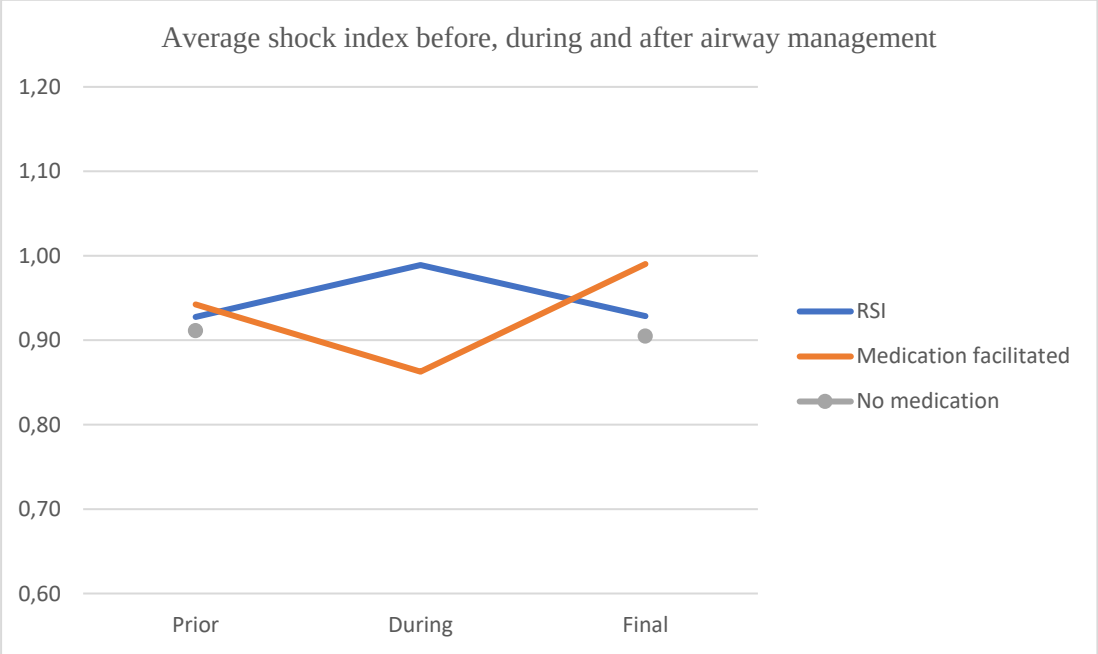

Figure 7: Average shock index before, during and after airway management

4.9 Outcome of airway management and intubation attempts

The overall ETI success for the RSI group (n=197, 98%) was statistically significantly higher than all other airway management groups. The medication facilitated intubation group had the highest failure rate for the primary airway management plan (n=14, 9%). The ETI success rate for the cardiac arrest was 81% (n=228), and the primary use of a SAD was 16% (n=45). No loss of airway was recorded. A total of 373 (53%) cases did not record the number of intubation attempts. These cases were excluded from the first-pass success rate analysis. A first-pass success rate were recorded in 260 (79%) cases. The cardiac arrest group had a first-pass success rate of 85%, followed by RSI (83%), no-medication (71%) and the medication facilitated group (61%).

Table 6: Outcome of airway management and intubation attempts

n (column %)	RSI	Medication facilitated	No-medication	Cardiac arrest	P
Outcome of airway management					
ET success (n=620)	197 (98%)[B C D]	134 (88%)	61 (87%)	228 (81%)	
SAD success (n=54)	0	4 (3%)	5 (7%)	45 (16%)[B]	
Surgical airway (n=0)	0	0	0	0	.000
Failure of primary airway plan (n=30)	5 (2%)	14 (9%)[A D]	4 (6%)	7 (3%)	
Loss of airway	0	0	0	0	

Unknown	0	0	0	0
Number of attempts*				
1	121 (83%)	39 (61%)	17 (71%)	83 (85%)
2	20 (14%)	16 (25%)	3 (13%)	11 (11%)
3	3(2%)	8 (13%)	4 (17%)	3 (3%)
4	1 (1%)	1 (2%)	0	0
5	0	0	0	1 (1%)

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

D: non-random difference with cardiac arrest category (p<0.05)

**calculated by using only documented cases as denominator*

4.10 Corrective actions taken following a failed intubation attempt and confirmation of placement

Table 7 shows the corrective steps taken following a failed intubation attempt. The use of a bougie (1%, n=8), repositioning of the patient (1%, n=6) and changing of healthcare providers (1%, n=6) were the most common corrective actions taken. Other steps included releasing cricoid pressure (n=1), backward, upward and rightward pressure/ external laryngeal manipulation (BURP/ELM) manoeuvres (n=2) and performing a blade change (n=2). Auscultation was the most common method of confirming placement (n=501). The use of capnography was significantly higher in the RSI-group (n-=83, 41%) than in all other groups. An oesophageal detection device was used on only 5 cases.

Table 7: Corrective action taken following failed intubation attempt and confirmation of placement

n (row %)	RSI	Medication facilitated	No- medication	Cardiac arrest	P
Action taken					
Cricoid pressure released (n=1)	1 (100%)	0	0	0	.477
BURP/ELM manoeuvres (n=2)	2 (100%)	0	0	0	.173
Release MILS (n=0)	0	0	0	0	
Reposition patient (n=6)	4 (67%)	2 (33%)	0	0	.092
Ramping patient (n=0)	0	0	0	0	
Use bougie (n=8)	5 (63%)	2 (25%)	0	1 (13%)	.134
Perform blade change (n=2)	2 (100%)	0	0	0	.173
Change provider (n=6)	2 (33%)	2 (33%)	0	2 (33%)	.778
n (row %)	RSI n=202 (38%)	Medication facilitated n=152 (26%)	No- medication n=70 (11%)	Cardiac arrest n=280(25%)	P
Confirmation					
Auscultation (n=501)	179 (36%)[D]	133 (27%)[D]	58 (12%)[D]	131 (26%)	.000

$ETCO_2$ (n=452)	183 (41%) [B C D]	112 (25%)[D]	44 (10%)[D]	113 (25%)	.000
EDD (n=5)	1 (20%)	4 (80%)	0	0	.014

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

D: non-random difference with cardiac arrest category (p<0.05)

4.11 Adverse events

A total of 125 (32%) adverse events were recorded out of a total of 386 cases. The cardiac arrest group was excluded from the adverse events analyses due to being unbale to assess for adverse events associated with physiological parameters. From the RSI, medication facilitated and no-medication group, a total of 38 cases had insufficient data to assess for adverse events. These cases were excluded from the analysis. The no-medication group (n=40, 68%) had the highest prevalence of adverse events, followed by the medication facilitated group (n=47, 37%) and the RSI group (n=38, 19%). The RSI group had significantly more cases with confirmed no adverse events occurring (n=167, 84%) as compared to the medication facilitated group (n=88, 69%) and the no-medication group (n26, 44%) Hypotension was the most common adverse event (n=38, 10%), The medication facilitated, and no-medication group had a significantly higher prevalence of cardiac arrest than the RSI group (9% and 15% vs 1% respectively). The medication facilitated group had the highest prevalence of hypotension (n=20, 16%), which was statistically higher than the RSI group (n=10, 5%). Hypoxia was reported in 11 cases (3%) with no significant difference between the groups. The no-medication group had a statistically higher incidence of bradycardia (12%) and tachycardia (12%), as compared to the RSI and medication facilitated group.

Table 8: Adverse events

n (column%)	RSI n=199 (100%)	Medication facilitated n=128 (100%)	No- medication n=59 (100%)	P
Adverse Event*				
Oesophageal intubation corrected (n=8)	3 (2%)	4 (3%)	1 (2%)	.701
Oesophageal intubation not corrected (n=0)	0	0	0	
Main stem bronchus intubation (n=1)	1 (1%)	0	0	.576
Dental trauma (n=0)	0	0	0	
Aspiration (n=5)	2 (1%)	1 (1%)	2 (3%)	.349
Cardiac arrest (n=22)	2 (1%)	11 (9%)[A]	9(15%)[A]	.000
Hypoxia (n=11)	6 (3%)	3 (2%)	2 (3%)	.834

Bradycardia (n=12)	3 (2%)	2 (2%)	7 (12%)[A B]	.000
Tachycardia (n=18)	8 (4%)	3 (2%)	7 (12)[B]	.022
Hypotension (n=38)	10 (5%)	20 (16%)[A]	8 (14%)	.123
Hypertension (n=10)	3 (2%)	3 (2%)	4 (7%)	.004
Surgical airway complications (n=0)	0	0	0	
None (n=392)	167 (84%)[B C D]	88 (69%)[C D]	26 (44%)	.000
Insufficient data recording	3 (1%)	24 (16%)[A]	11 (16%)[A]	.000

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

D: non-random difference with cardiac arrest category (p<0.05)

**calculated by using only documented cases as denominator*

4.12 Survival

A significantly higher portion of the cardiac arrest group (n=187, 67%) died on the scene, while 3% (n=5) from the RSI group, 4.% (n=6) from the medication facilitated group and 9% (n=6) from the no-medication group died on the scene. The RSI group had the highest survival to hospital rate (n=196, 98%), followed by the medication facilitated group (n=145, 96.%), the no-medication group (n=63, 91%) and the cardiac arrest group (n=92, 33%).

Table 9: Survival

n (column %)	RSI n=202 (100%)	Medication facilitated n=152 (100%)	No-medication n=78 (100%)	Cardiac arrest n=280 (100%)	P
Survival					
Dead on scene (n=204)	5 (2%)	6 (4%)	6 (9%)	187 (67%)[A B C]	
Alive at hospital arrival (n=496)	196 (97%)[D]	145 (95%)[D]	63 (90%)[D]	92 (33%)	.000
Unknown (n=4)	1 (0.4%)	1 (1%)	1(1%)	1 (0.3%)	

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

D: non-random difference with cardiac arrest category (p<0.05)

4.13 Ventilation

Controlled manual ventilation were the most common method of ventilation (90%, n=633). The use of a mechanical ventilator was the most common amongst the RSI group (n=48, 24%).

Table 10: Ventilation

n (column %)	RSI n=202	Medication Facilitated n=152	No-Medication n=70	Cardiac Arrest n=280	P
Ventilation					
Spontaneous (n=5)	0	3 (2%)	1 (1%)	1 (0,4%)	.000
Manual ventilation (n=633)	154 (76%)	138 (91%)[A]	67 (96%)[A]	274 (98%)[A B]	
Mechanical ventilation (n=66)	48 (24%)[B C D]	11 (7%)[D]	2 (3%)	5 (2%)	
Mixed (n=0)	0	0	0	0	
Unknown (n=0)	0	0	0	0	

A: non-random difference with prehospital category (p<0.05)

B: non-random difference with interfacility transfer category (p<0.05)

C: non-random difference with aeromedical category (p<0.05)

D: non-random difference with cardiac arrest category (p<0.05)

4.14 Scene and transportation times

The mean and median scene time for the RSI group and the medication facilitated group were similar (42min and 40min). The mean transportation time for the RSI group was 24 minutes and 27 minutes for the medication facilitated group. The no-medication group had a mean scene time of 44 minutes and a mean transportation time of 23 minutes. The cardiac arrest group had a mean scene time of 57 minutes and a mean transportation time of 16 minutes. Airway management done in the prehospital setting, had a mean scene time of 49 minutes, with a mean transportation time of 23 minutes. The IFT setting had a mean scene time of 71 minutes with a mean transportation time of 40 minutes.

Table 11: Average scene and transport time (minutes)

	Scene time		Transport time	
	Mean	Median	Mean	Median
Setting				
prehospital	49	46	23	16
IFT	71	62	40	27
Aeromedical	26	20	18	14
Approach				
RSI	42	40	24	19
Medication facilitated	42	40	27	18
No-medication	44	35	23	15
Cardiac Arrest	57	52	16	10

CHAPTER 5: DISCUSSION

This study described the demographics, prehospital diagnosis and indication for advanced airway management. The method of intubation, the pharmaceutical agents used to facilitate airway management, and vital signs trends were described. Adverse events and overall success rates were reported on as well.

In contradiction to other local studies which reported a higher prevalence of males undergoing airway management, this study demonstrated a higher prevalence of females undergoing airway management. (4,25) These studies often described male patients suffering from trauma-related injuries that underwent airway management.(4,24) The difference in gender prevalence in this study compared to other local studies can be attributed to the addition of a large subgroup of cardiac arrest patients which was never described in these studies.(4,25) Excluding the cardiac arrest group, trauma (specifically blunt trauma), was the leading subgroup of patients undergoing airway management in this study. This is in keeping with other studies and reflects the high burden of trauma-related cases seen in South Africa.(4,25,38)

A higher prevalence of RSI was seen in the aeromedical setting as compared to the prehospital setting. The subgroup of patients seen in each setting was different from each other. Trauma-related cases were more prevalent in the aeromedical settings, while cardiac arrest related cases were more prevalent in the prehospital setting. This could because in South Africa, cardiac arrest is not included in the aeromedical dispatch criteria.(39) Private HEMS companies in South Africa will always be crewed by an ECP, making the option of RSI available on all cases. In contrast, an ECP will not always be available in the prehospital setting. HEMS may also be dispatched for airway management, specifically to perform a RSI, should this not be available immediately to ground EMS.(40) The difference in the patient subgroups and practitioners will account for the significant difference of RSI prevalence seen in the aeromedical setting as compared to the prehospital setting (92% vs 24%).

Despite more paramedics being available in South Africa as compared to ECPs, RSIs were more prevalent than medication-facilitated intubations. The debate surrounding RSI vs medication-facilitated intubations is an ongoing issue in the South African prehospital setting. The prevalence of RSI and the availability of the RSI-skill is clinically relevant as the HPCSA proposed that only ECPs may facilitate ETI by means of a RSI. The higher prevalence of RSI can indicate that an ECPs assistance to perform an RSI is being requested more often or should RSI not be available, advanced airway management is being withheld. No studies could be found comparing the progression of the prevalence of RSI since its introduction in 2009. A total of 222 patients (excluding cardiac arrest) underwent airway management using an

approach other than RSI. Further studies will be needed to assess whether this patient subgroup (which was more prevalent than the RSI subgroup) will be managed safely with basic airway manoeuvres, should RSI not be available.

The average initial SPO_2 levels were less than 90% for all approaches. This is in keeping with inadequate oxygenation and/or ventilation being one of the main indications for airway management in this study. The RSI group had the highest average GCS score, with the no-medication group having the lowest average GCS score. The reported GCS scores prior to intubation are in keeping with other studies in South Africa, ranging from GCS 5/15 to 7/15.(25,41) The level of consciousness might have influenced the approach used to facilitate airway management. It might have been perceived that a GCS of 4/15 (no-medication group) would not necessitate medication administration as the patient is unresponsive. In contrast, a GCS of 7/15 (RSI group) was more responsive and would need pharmacological agents to facilitate airway management. This is reflected in literature, suggesting a decreased induction dose in unresponsive patients.(42) The variations in blood pressures in the medication facilitated group was greater to that of the RSI group. This might be explained by the different medications used to facilitate the airway management, which is why RSI has been described as having a safer combination of medication as compared to a medication facilitated approach. The no-medication group was the only group where the saturation levels decreased during airway management to a level lower than the initial saturation levels. No specific reason could be found for this. These patients did have the lowest initial saturation levels, showing that they were already in a hypoxic state prior to airway management. Poor vital sign recording was observed in the no-medication group. This could have led to falsely low saturation levels being observed.

Ringers lactate and normal saline are commonly available in the South African prehospital setting and is reflected in the results, showing that ringers lactate was the most frequently administered crystalloid, followed by normal saline. This is in keeping with in-hospital studies, showing that ringers lactate and normal saline is favoured as crystalloid of choice for pre-intubation resuscitation. Part of the resuscitation prior to emergency ETI, involves the administration of a fluid bolus. However, no standard guideline exists for the fluid administration prior to emergency ETI (43) Although not part of the primary outcomes, during the analysis of the vital signs, it was found that the average shock index (SI) within the RSI, medication facilitated and no-medication group was >0.9 prior to intubation. Clinically, this indicates a degree of shock present prior to airway management and would necessitate resuscitation prior to intubation. This can be achieved by the administration of a fluid bolus. The average fluid boluses for all approaches, ranged from 579ml-817ml. This was the total amount of fluid administered during the entire duration of the call, and not necessarily prior to

airway management. Considering most of the patients were adults and trauma being the second leading subgroup of patients, it can be argued that the patients were not adequately resuscitated prior to intubation. This means that during the entire duration of management of these patients, a total fluid bolus of less than 1000ml was administered. The study did not assess for the administration of adrenaline as means of resuscitation prior to airway management.

From the medication-facilitated group, five patients received ketamine, and four patients received etomidate, indicating an ECP was in attendance but elected to withhold a paralytic. Although no specific reason was mentioned in the free-text section, this might have been due to clinical reasons. Patients with an anticipated anatomical difficult airway or an intrinsic laryngo-tracheal pathology might benefit from the administration of a sedative only, allowing the patient to breath spontaneously while attempting airway management.(42,44) A combination of morphine and midazolam is commonly used by paramedics to induce a state of unconsciousness for an advanced airway device to be inserted. This does not inhibit the airway reflexes as with the administration of a sedative combined with a paralytic.(2)

Suxamethonium was the paralytic of choice as a primary paralytic agent (n=133, 69%), which is similar to a study by Stassen et al.(25), while other studies reported suxamethonium being used as a primary paralytic agent in 96%-98% of cases.(4,16) In 2015, a shift from suxamethonium to rocuronium (combined with fentanyl and ketamine) was suggested based on studies done in a physician-led HEMS service.(45) This suggested change can account for the difference seen in the use of suxamethonium as primary paralytic agent. The data collection period for this study was done two years after the release of the study by Lyon et al. (45), showing there has been a change in practice. Suxamethonium is often favoured as the paralytic agent of choice due to its rapid onset of action and short duration of action.(7,46,47) Rocuronium has been proposed as a good alternative to succinylcholine because of its pharmacokinetic properties. When used at a dose of 1.2 mg/kg, rocuronium has a similar onset time to suxamethonium, with the added benefit of having fewer contraindications. (47) Rocuronium was administered as a secondary (post-intubation) paralytic agent in 32 (9%) of cases. This is similar to a study done in the Australian HEMS setting (8%), but less than the reported administration of rocuronium as a secondary paralytic by Stein (19%).(4) This can be due to the majority of patients described in Stein's paper (4) receiving a suxamethonium (short-acting paralytic) as a primary agent, while a higher prevalence of rocuronium (long-acting paralytic) was used in this study, eliminating the need for additional secondary paralytic administrations.

A significantly higher portion of the RSI group received post-intubation sedation and analgesia. Although it can clinically be argued that the 11% of patients that did not receive post-intubation sedation or analgesia is still too high, it is lower than the reported 23% of

patients not receiving analgesia or sedation in emergency centres.(48)

Currently, no specific post-intubation care protocol exists, and this is done at the discretion of the treating healthcare provider, or companies may implement their own clinical guidelines to address this shortfall.(4) Current guidelines emphasize analgesia sedation as opposed to benzodiazepine only strategies in the intubated patient with opioids being the most prevalent analgesic agents used.(48) Midazolam was the most frequently administered post-intubation medication, showing that a benzodiazepine only strategy is being used, despite evidence recommending differently.

Non-physician first-pass success rates varies in literature and rangers from 47%-98%.(4,16,25,49,50). The first-pass success rate of 79% is identical to other reported first-pass success rates in local studies incorporating airway approaches other than RSI only.(25) The first-pass success rate of 83% is lower than the first-pass success rate of 88% reported for RSIs performed by South African ECPs.(4) Although the first-pass success rate is in agreement with other studies, it is important to note that only 47% of cases recorded the number of intubation attempts. The low reported intubation attempts might have skewed the data, with the first pass success rate possibly being higher, such as seen in international literature. During the analysis, it was found that 21 cases had three or more intubation attempts, with one case reporting five intubation attempts. This can either indicate a failure of backup plans or disregarding failed airway algorithms. Airway algorithms suggest that only two attempts should be made at ETI before changing the approach or device used for airway management.(44) Three attempts may only be made should there be a compelling reason, such as when a more experienced clinician arrives.(5).

An overall success rate based on the primary airway plan was reported in 96% (n=674) of cases, which is in keeping with overall success rates of 96-99% described in the literature.(4,16,25,51) The overall successful placement of an ETT was significantly higher for the RSI group (98%, n=197) as compared to the other groups. This is similar compared to other local studies and higher than RSI ETI success rates of 75-99% reported in HICs.(4,25,32,52) SADs were used more frequently as a primary airway device in the cardiac arrest setting as compared to the other approaches. The insertion of a SAD during cardiac arrest is supported by the American Heart Association (AHA).(53) The medication facilitated group had the highest rate of a primary airway failure, with ETI success rate of 61%, which is comparable to other studies evaluating the success rate of medication facilitated approaches.(2) This may be caused by the fact that a medication facilitated approach does not prevent vocal cord movement and airway reflexes such as coughing and a gag-reflex.

Even though this should be the case with a no-medication approach, these patients had a lower level of consciousness, which might explain the higher success rate and first-pass success rate as compared to the medication facilitated group.

No risk factors or aggravating conditions were assessed or described in more than half the cases. It is unknown whether it was simply not assessed or whether it was assessed, but not described by the practitioner. This might have provided more insight into interpreting the first-pass success rate, intubation attempts and the overall success rate for intubations. Blood, vomitus, secretions or hypersalivation in the airway, suboptimal provider positioning and airway management in a moving or stationary vehicle were described as some of the risks and aggravating conditions present during airway management. All of these risk factors and aggravating conditions have been associated with a poor first-pass success rate and multiple intubation attempts. This supports the notion that prehospital airway management is done in an austere environment and can also contribute to the first-pass success rate of less than 80% seen in this study.

Following a failed intubation attempt, using a bougie was the most common corrective step taken by the healthcare provider. This indicates that a bougie was available but reserved as a bailout measure. For patients treated in an EC with preidentified difficult airway characteristics undergoing intubation, the use of a bougie was associated with a significantly higher first-pass success rate as compared to the conventional ETT and stylet approach (96% vs 82%).(54) With prehospital airway management already being performed under challenging circumstances as described earlier, the use of a bougie during the primary airway approach should be considered. The fact that bougies are being used after failed intubation attempts shows that they are available. The lack of use of bougies as a primary device and repositioning patients only after a failed airway attempt indicates that conditions are not optimised as best possible to ensure first-pass success.

Confirmation of placement using auscultation was done most frequently. $ETCO_2$ was used significantly more during RSI than all other approaches to airway management. EMSSA recommendations on prehospital RSI mandates the use of capnography for RSIs.(10) Due to a lack of policies ,capnography or capnometry is not mandated in all other approaches. Capnography should be the gold standard for confirmation of placement and has been shown to be the most reliable method of confirming placement in the prehospital setting.(55)

An adverse events rate of 32% was some of the highest that was reported amongst prehospital studies.(4,6,16,25) The prevalence of adverse events should be interpreted with the reporting culture within the setting. This study had a bigger sample size, included different approaches with different patient subgroups.

These differences might account for the higher prevalence of adverse events noted in this study. Hypotension was the most common adverse events, which is often described in prehospital adverse event studies.(6,25) The hypotension can be due to several reasons.

As noted earlier, the average SI for all groups (excluding RSI) was >0.9, which is considered high. Ketamine was one of the most commonly administered induction agents, and has been associated with hypotension in patients with a SI of ≥ 0.9.(56) An association between midazolam and hypotension has also been found in the literature.(41) Hypotension associated with ketamine and midazolam is dose dependant. However, this study did not assess medication doses. Studies done in an EC demonstrated that a SI of ≥0.8 was reliable in predicting the risk for post-intubation hypotension, while ICU studies, a SI of ≥0.9-1 was associated with post-intubation hypotension and cardiac arrest.(57) Hypoxia was described in 3% of cases, which was lower than the reported hypoxia prevalence rate in other studies.(6,25) The study included a large subgroup of trauma patients and head injuries. The incidence of hypoxia and hypotension has been well established to be detrimental to traumatic brain injury (TBI) patients, with a single hypoxic episode doubling mortality rates in these patients.(41,58) Based on the observed adverse events, it might be more appropriate to use a RSI approach in patients where these adverse events will have a direct negative impact on long term survival.

Manual ventilation was the most common method of ventilation post-intubation (90%), while only 9% of patients were ventilated using a mechanical ventilator. The RSI group had a significantly higher portion of patients being mechanically ventilated. Due to financial reasons, ventilators are not commonly available in the prehospital setting, with ventilators often being reserved for specialist divisions such as HEMS and ICU transfer vehicles. No policy exists mandating the use of ventilators for patients post-intubation, resulting in manual ventilations being the ventilation method of choice. RSI was the approach of choice in the aeromedical and IFT setting, in which both settings a ventilator is readily available. This can also be a reason for the higher prevalence of mechanical ventilation seen in the RSI group.

LMICs such as South Africa face unique challenges due to resource-restraints, often resulting in prolonged transportation times and limited access to definitive care, justifying the need for earlier critical interventions such as advanced airway management.(6,7) However, this study was associated with prolonged scene times of more than 40 minutes, with an average transport time to hospital of less than 25 minutes for the aeromedical and prehospital setting. This is contradictory to the longer transportation times that was expected. The study did not assess whether the case was done in an urban or rural setting, which can account for the shorter transportation times. With shorter transportation times and prolonged scene times, it can be questioned whether these intubations were absolutely necessary and whether it could have been withheld to be performed in an EC rather.

A study in Sweden on prehospital intubations by a physician-team had an average scene time of 25 minutes for airway management. Prehospital intubation has been associated with an increased scene time, ultimately leading to an increased mortality.(59)

Based on EMSSA recommendations, should a fully equipped and staffed EC be less than 30 minutes away, then prehospital intubation should only be done in cases where there is an immediate threat to the airway, or should the patient require mechanical ventilation.(5) The mean transportation time to hospital in this study was less than 30minutes.

Although the survival rate in this study is lower than other reported studies, a comparison cannot be made as these studies did not include a cardiac arrest subgroup of patients. RSI had the highest survival to hospital rate of 98%, but this was not statistically significant as compared to the medication facilitated and no-medication group. The survival rate only reflects survival at the time of handover, not long-term survival. The prevalence of adverse events were different for each approach, which might have an effect on long term survival and outcome and won't be reflected in the survival to hospital rates. The survival rate for the cardiac arrest was 33%, this does not reflect ROSC rates. Survival to hospital included patients with ongoing chest compressions.

During the analysis, it was found that the quality of the PCRs were variable. More than half the cases did not record intubation attempts, risk factors and aggravating conditions. This has a direct influence on the quality of data and reporting. The no-medication and medication facilitated group had a significantly higher prevalence of insufficient data recording for adverse events. This is important to accurately compare the safety of each approach, especially considering the shift in how intubations will be done in the prehospital setting. Quality record keeping is vital to audit, clinical review, education, legal and patient care reasons.(60) Part of EMSSA's recommendations for quality control of prehospital RSIs, is a clinical review for every RSI performed as well as routine collection and review of statistics on prehospital RSI performance, complications and outcomes.(10) Using a standard airway report form has been shown to reduce missing information and significantly increase the quality of reported data during airway management.(60)

CHAPTER 6: CONCLUSION

The study described the prehospital airway management practices by ALS providers in South Africa. The study supported the idea that prehospital airway management is done in an austere environment, influencing the success rates described.

The highest first pass success rate was seen in the cardiac arrest group. RSI had the second highest first-pass success rate and the lowest prevalence of adverse events. The no-medication and medication facilitated groups had a higher incidence of poor record keeping, which might influence the observed adverse events and first-pass success rate. The RSI group statistically had a significantly higher ETI success rate. Despite the differences in adverse events observed, there was no statistical difference in the survival to hospital seen amongst the groups. The reported survival rate was only to hospital and did not reflect long term survival. It can be argued than the adverse events observed in this study will increase the mortality rates in the long term. Differences in fluid administration, post-intubation care, confirmation of placement and ventilation can be attributed to no standard guideline existing. Recommendations are made by the HPCSA, but every EMS company is ultimately responsible for its own clinical governance. Standard guidelines and protocols might improve safety overall for patients undergoing airway management in the prehospital setting. Airway management was associated with a long scene time and short transportation times, which brings into question whether the decision to perform airway management was appropriate.

No standard approach to record keeping was found, with the quality of PCRs being variable. A standard airway reporting form would be beneficial as it would improve the quality of data recorded and allow for better comparisons to be made.

CHAPTER 7: RECOMMENDATIONS

The quality of the data captured was variable. No standard data reporting format was used, with each company dictating what data should have been recorded. We would suggest that mandatory repositories are created with a predefined data set, allowing for research and improvement to be conducted on a more regular basis.

Future research should be done looking at the practices between different ALS providers, as their level of training and scope of practice is different. Post-intubation care was poorly described in cases. Further research and recommendations are needed on this topic. Further investigations into the adverse events, specifically the incidence of cardiac arrest needs to be done. Medication choices, doses and pre-intubation resuscitation should be evaluated for these patients.

A more standard approach to airway management should be implemented across the prehospital setting. This should include mandatory use of checklists, bougies and capnography. A non-RSI approach is not recommended to be used in the non-arrest patient.

The results of this study will be shared with the companies that were included in the sampling.

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APPENDICES

Appendix 1: Letter of request for data

06 November 2018

Western Cape Emergency Medical Services Research Department

UCT HREC Ref: 698/2018: Request for data for research

To whom it may concern

I, Jan Burke, would like to request access to Western Cape EMS data to complete a research study on assessing prehospital advanced airway practices in South Africa. The research is in partial fulfilment of the MPhil Emergency Medicine (Clinical Emergency Medicine) degree through the University of Cape Town.

The aim of this study is to describe the advanced airway management practices of advanced life support providers across South Africa. This is due to limited research being available on the prehospital advanced airway management practices within South Africa. Due to South Africa facing its own healthcare challenges, studies done in other countries might to be applicable to our setting.

The data my supervisors, Dr Clint Hendrikse and Mr. Craig Wylie, and I would like access to is all patient records containing advanced airway manoeuvres from the 01st of January 2017 unit the 31st of December 2017. This will include any advanced airway management done by emergency care technicians, paramedics or emergency care practitioners within the prehospital environment as well as during interfacility transfers. We would like to request Western Cape EMS to anonymise all patient records prior to our screening and analysis. All data and back-ups thereof will be kept in private folders that only the research supervisors and I will have access to.

The following variables specifically will be recorded:

- Age
- Gender
- Patient category- Specified mechanism of injury or disease
- Indication for intubation
- Setting in which the intubation was performed (prehospital, aeromedical or during an interfacility transfer)
- Difficult airway predictors as described in the free note section
- Any aggravating conditions under which the intubation was performed as described in the free note section
- Approach to airway management: Cardiac arrest, without any pharmacological agents, deep sedation or RSI.
- Advanced airway management results
- Airway manoeuvres following failed airway attempt
- Vital signs prior, during and post the intubation
- Adverse events
- Confirmation of placement
- Ventilation strategy used (mechanical or manual ventilation) including mechanical ventilator mode
- Survival to hospital
- On-scene time and transportation time to the receiving facility.

The results will be compiled into a research paper and submitted to a peer reviewed medical journal. Patients will not be identifiable in any documents, reports or publications. Western Cape EMS's name will be kept anonymous and care will be taken that Western Cape EMS's name cannot be deduced from the content or wording of any documents. Western Cape EMS will have access to the study results should this be requested; however, the results will be combined with data from other companies. No comparisons will be made between the different companies.

The research project has been approved by the UCT Emergency Medicine Departmental Research Committee as well as the Faculty of Health Sciences Human Research Ethics Committee. HREC Ref: 698/2018

Should you have any further questions, please do not hesitate to contact me or one of the research supervisors. The contact details are as follows:

Jan Burke

+97450868889

brkjan005@myuct.ac.za

Dr Clint Hendrikse

clint.hendrikse@uct.ac.za

Mr. Craig Wylie

craig.wylie@uct.ac.za

Kind Regards,

Signature Removed

_____

Jan Burke

Appendix 2: Institutional approval letter: Netcare 911

Netcare Hospital Management (Pty) Limited

Tel: + 27 (0)11 301 0000
Fax: Corporate +27 (0)11 301 0499
76 Maude Street, Corner West Street, Sandton, South Africa
Private Bag X34, Benmore, 2010, South Africa

RESEARCH OPERATIONS COMMITTEE FINAL APPROVAL OF RESEARCH

Approval number: UNIV-2019-0001

Mr Jan Burke

E mail: BRKJAN005@myuct.ac.za

Dear Mr Burke

RE: PREHOSPITAL ADVANCED AIRWAY MANAGEMENT PRACTICES BY ADVANCED LIFE SUPPORT PROVIDERS: A RETROSPECTIVE OBSERVATIONAL STUDY OF EMERGENCY MEDICAL SERVICE PROVIDERS IN SOUTH AFRICA

The above-mentioned research was reviewed by the Research Operations Committee's delegated members and it is with pleasure that we inform you that your application to conduct this research at Netcare 911, has been approved, subject to the following:

i) Research may now commence with this FINAL APPROVAL from the Netcare Research Operations Committee.

ii) All information regarding Netcare will be treated as legally privileged and confidential.

iii) Netcare's name will not be mentioned without written consent from the Netcare Research Operations Committee.

iv) All legal requirements regarding patient / participant's rights and confidentiality will be complied with.

v) All data extracted may only be used in an anonymised, aggregated format and for the purposes of this specific study as specified in the proposal. The data may under no circumstances be used for any other purpose whatsoever.

vi) The research will be conducted in compliance with the GUIDELINES FOR GOOD CLINICAL PRACTICE IN HUMAN PARTICIPANTS IN SOUTH AFRICA (2016).

vii) Netcare must be furnished with a STATUS REPORT on the progress of the study at least annually on 30th September irrespective of the date of approval from the Netcare Research Operations Committee as well as a FINAL REPORT with reference to intention to publish and probable journals for publication, on completion of the study.

Signature Removed

viii) A copy of the research report will be provided to the Netcare Research Operations Committee once it is finally approved by the relevant primary party or tertiary institution, or once complete or if discontinued for any reason whatsoever prior to the expected completion date.

ix) Netcare has the right to implement any recommendations from the research.

x) Netcare reserves the right to withdraw the approval for research at any time during the process, should the research prove to be detrimental to the subjects/Netcare or should the researcher not comply with the conditions of approval.

xi) APPROVAL IS VALID FOR A PERIOD OF 36 MONTHS FROM DATE OF THIS LETTER OR COMPLETION OR DISCONTINUATION OF THE TRIAL, WHICHEVER IS THE FIRST.

We wish you success in your research.

Yours faithfully

Signature Removed 4/2/19

Prof Dion du Plessis
Full member: Netcare Research Operations Committee & Medical Practitioner evaluating research applications as per Management and Governance Policy

Signature Removed

Shannon Nell
Chairperson: Netcare Research Operations Committee
Netcare Hospitals (Pty) Ltd
Date: 10/31/2019

Appendix 3: Institutional approval letter: Western Cape EMS

Health Impact Assessment
Health Research Sub- Directorate
Health.Research@westerncape.gov.za
Tel: +27 21 483 0866; fax: +27 21 483 9895
5th Floor, Norton Rose House, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za

REFERENCE: WC_201902_027
ENQUIRIES: Dr Sabela Petros

University of Cape Town

Anzio Road

Observatory

Cape Town

7925

For attention: Mr Jan Burke, Dr Clint Hendrikse

Re: Prehospital advanced airway management practices by advanced life support providers: A retrospective observational study of emergency medical service providers in South Africa.

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to following people to assist you with any further enquiries in accessing the following sites:

Emerency Medical Services	**Dr Shaheem de Vries**	**021 508 4523**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. By being granted access to provincial health facilities, you are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of your project. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the estimated completion date which was submitted, researchers are expected to complete and submit a progress report

(**Annexure 8**) to the provincial Research Co-ordinator

(Health.Research@westerncape.gov.za).

4. The reference number above should be quoted in all future correspondence.

Yours sincerely

Signature Removed

DR M MOODLEY

DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE: 26 - 2 - 14

Appendix 4: Human Research Ethical Committee approval letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room ES3-46 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone (021) 406 6492
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

29 October 2018

HREC REF: 698/2018

Dr C Hendrikse
Division of Emergency Medicine
F-51
OMB

Dear Dr Hendrikse

PROJECT TITLE: PREHOSPITAL ADVANCED AIRWAY MANAGEMENT PRACTICES BY ADVANCED LIFE SUPPORT PROVIDERS: A RETROSPECTIVE OBSERVATIONAL STUDY OF EMERGENCY MEDICAL SERVICE PROVIDERS IN SOUTH AFRICA (MPHIL Candidate - Mr J Burke)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 November 2019.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period..
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the student: Mr Jan Burke will also be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely

Signature Removed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.

HREC 698/2018

Appendix 5: Human Research Ethical Committee Renewal

HUMAN RESEARCH ETHICS COMMITTEE
15 NOV 2019
HEALTH SCIENCES FACULTY UNIVERSITY OF CAPE TOWN

UNIVERSITY OF CAPE TOWN

FACULTY OF HEALTH SCIENCES
Human Research Ethics Committee

FHS016: Annual Progress Report / Renewal

HREC office use only (FWA00001637; IRB00001938) This serves as notification of annual approval, including any documentation described below.			
☑ Approved	Annual progress report	Approved until/next renewal date	30-11-2020
☐ Not approved	See attached comments		
Signature Chairperson of the HREC	Signaute Removed	Date Signed	15/11/2019

Comments to PI from the HREC

Principal Investigator to complete the following:

1. Protocol information

Date (when submitting this form)	14 November 2019		
HREC REF Number	~~698/2020~~ 2015	Current Ethics Approval was granted until	30 November 2019
Protocol title	Prehospital advanced airway management practices by advanced life support providers: A retrospective observational study of emergency medical service providers in South Africa.		
Protocol number (if applicable)			
Are there any sub-studies linked to this study?	☐ Yes ☒ No		
If yes, could you please provide the HREC Ref's for all sub-studies? Note: A separate FHS016 must be submitted for each sub-study.	N/A		
Principal Investigator	Dr Clint Hendrikse		

(Note: Please complete the Closure form (FHS020) if the study is completed within the approval period)