An investigation of endotracheal intubation and alternative intubation devices for use by paramedics in out-of-hospital care.

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Abstract

For patients in cardiac arrest, early chest compressions and adequate airway management to ventilate and oxygenate patients' lungs is essential and can be achieved through endotracheal intubation (ETI). This said, there is debate around whether ETI is required during cardiac arrest (CA) management with arguments for and against whether CA outcomes are improved when ETI takes place. There is further debate as to whether paramedics should carry this skill out in practice, corresponding to the effectiveness of ETI attempts in the out-of-hospital environment. There are several complications associated with ETI and alternative intubation devices (AIDs) are available to help overcome a number of these, though are not currently used in paramedic practice. There is a limited amount of current research that studies the use of AIDs in paramedic practice. This thesis aimed to explore current out-of-hospital practice in relation to airway management and ETI and critically examine and compare the use of AIDs by paramedics.

A three-stage approach was undertaken. A retrospective case note review established current airway management practices in one area of the UK, over the period of a year. An online survey sought paramedics' opinions on airway management and ETI. Finally, a prospective, experimental study compared four AIDs (a video-optic, standard blade laryngoscope (SBL), retroglottic tube and intubating laryngeal mask airway), through observed intubation attempts by paramedics using each device. Preference ranking and comments provided reflections on the practical application of the devices.

The research project has shown that a range of airways are used in the out-of-hospital care environment, with varying success rates. ETI was attempted on less than half of 2,779 patients in cardiac arrest, with a 77% success rate. Opinion survey findings indicated that 79% of 181 paramedics would commonly perform ETI on a patient in cardiac arrest. In the same sample, 83% believed ETI to be gold standard airway management. On examination and comparison of four AIDs, no one device proved to be more successful than another when used by paramedics. The Airtraq, SBL and Combitube were equally successful, with success rates of over 97%. In comparison the iLMA was least successful, with a 65% success rate ($p \leq 0.001$). No statistically significant differences were identified between the devices in terms of number of attempts needed for successful intubation. Time to intubate with the devices was between 42 seconds (MBL) and 86 seconds (iLMA), with statistically significant differences between the iLMA and all the other devices. Paramedic participants preferred the video-optic device, which was attributed to the good view of the vocal cords the device provided, alongside the ease of use. Further research on ETI and the use of AIDs by paramedics in clinical practice is required, as this was a mannikin study carried out in a controlled environment. Recommendations for a comprehensive training programme and predetermined skill maintenance plan when introducing any new device into practice, are suggested.

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I am grateful to my family for their support, encouragement and understanding throughout the whole of my doctoral studies. Your words and 'shoves' kept me going and I will continue to strive to make you proud with all my professional and personal accomplishments. Thank you especially to my 'proof readers', totally appreciated.

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To my colleagues, who must be fed up of me talking about 'my work', for your support and backing throughout the writing of my study. The time out was valued and well used.

Preface

The researcher is an Emergency Nurse and Senior Lecturer, who at the time of carrying out the research was working in education (as a Senior Lecturer in paramedical, urgent and emergency care) and then as the Matron of an Emergency Department (ED). She has an advanced level of clinical emergency and urgent care knowledge, with understanding of the critical nature that interventions have on patient survival, putting her in an ideal position to carry out a study in this field. Her personal values and work ethics are centred on effective and safe patient care provision and she has carried out a number of audits and evaluations to investigate patient care in the urgent and emergency care environment. The outcomes of these have improved patient care and thought to have helped reduce incidences of harm. Many of the key concepts [of urgent and emergency care] are applicable across nursing and paramedic practice and highly related to professional practice.

This research focussed on an element of professional practice that is topical, relevant and applicable to clinical practice and patient care. It is recognised that the subject is one of many areas that could have been investigated in terms of evidence relating to a skill in practice; the execution of the skill, resources, requirements and professionals' opinions. The investigation of airway management and endotracheal intubation in out-of-hospital cardiac arrest was selected as it met the above ideas and is unique to paramedic practitioners as an additional skill undertaken to improve patient care.

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Abbreviations and glossary of terms

Abbreviation	Abbreviation in full	Explanation
AA	Association of Anaesthetists	A group representing the medical and political views of anaesthetists
AID	Alternative intubation device	A device or method used to facilitate laryngoscopy and or ventilation
ANOVA	Analysis of variance	Statistical test
AWS	Airway scope	A video laryngoscope
BHF	British Heart Foundation	A charity organisation funding cardiovascular research
BOS	Bristol Online Survey	Online survey platform
BVM	Bag-valve-mask	A self-inflating bag used to provide artificial ventilation
CA	Cardiac Arrest	When the heart suddenly stops pumping blood around the body
CARES registry	Cardiac Arrest Registry to Enhance Survival	CARES was developed to help communities determine standard outcome measures for OHCA
Cormack Lehane	--	A system which classifies views obtained by direct laryngoscopy based on the structures seen
CPR	Cardiopulmonary resuscitation	An emergency procedure that combines chest compressions often with artificial ventilation
DAS	Difficult Airway Society	--
DOH	Department of Health	--
DNACPR	Do Not Attempt Cardiopulmonary Resuscitation	An advanced decision which provides immediate guidance to those present on the best action to take (or not take) should the person suffer cardiac arrest
DPA	Data Protection Act	A UK Act of Parliament developed to control how personal information is used
EAST	Eastern Association for the Surgery of Trauma	A medical association of American trauma surgeons
ECG	Electrocardiogram	A method used to assess the hearts rhythm and electrical activity
ED	Emergency Department	Part of hospital that deals with accidents and emergencies
EMAS	East Midlands Ambulance Service	Ambulance service provider in East Midlands region
ETI	Endotracheal intubation	Advanced airway management technique
ETT	Endotracheal Tube	Airway adjunct used when performing ETI
FOIA	Freedom of Information Act	A UK Act of Parliament that creates a public 'right of access' to information
HCPC	Health and Care Professions Council	Registering and regulating body for paramedics

Abbreviation	Abbreviation in full	Explanation
HEE	Health Education England	An organisation which supports the delivery of excellent healthcare and health improvements
HEI	Higher Education Institute	An organisation providing education postsecondary level (e.g. University)
iGel	iGel®	A supraglottic airway device
IHCD	Institute of Health and Care Development	An organisation offering academic and vocational qualifications and testing through other examining bodies
iLMA	Intubating laryngeal mask airway	A supraglottic airway device through which an ETT can be passed
JRCALC	Joint Royal Colleges Ambulance Liaison Committee	A committee that provides robust clinical oversight and expert clinical advice to UK ambulance services
King LT	King Laryngeal tube	A retroglottic airway device
LAS	London Ambulance Service	One of eleven ambulance Trusts in the UK
LMA	Laryngeal mask airway	A supraglottic airway device
MBL	Macintosh Blade Laryngoscope	Type of blade used in standard blade laryngoscopy
MRC	Medical Research Council	Works to improve the health of the people in the UK (and around the world) by supporting science and scientists
NHS	National Health Service	Publicly funded healthcare system in the UK
NMC	Nursing and Midwifery Council	Registering and regulating body for nurses
NPA	Nasopharyngeal airway	A simple airway adjunct
NWAS	North West Ambulance Service	One of eleven ambulance Trusts in the UK
OHCA	Out-of-hospital cardiac arrest	A medical emergency (where a person's heart stops) in a public place
OPA	Oropharyngeal airway	A simple airway adjunct
POGO	Percentage of glottic opening	Represents the percentage of glottic opening visualised during laryngoscopy
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses	An evidence-based minimum set of items for reporting in systematic reviews and meta-analyses
RCT	Randomised controlled trial	A study design that randomly assigns participants to a group
RDB	Research Degree Board	Group that offers quality assurance procedures at a local level
REC	Research Ethics Committee	Body responsible for ensuring that research is carried out in an ethical manner
---	Retroglottic device	An airway adjunct that sits behind the glottis and larynx

Abbreviation	Abbreviation in full	Explanation
ROSC	Return of spontaneous circulation	The resumption of sustained perfusing cardiac activity associated with significant respiratory effort of cardiac arrest
RSI	Rapid Sequence Induction	Performing ETI following the use of relaxation drugs
SBL	Standard Blade Laryngoscope	A device used to help view the airway of a person during ETI
SGA	Supraglottic airway	An airway adjunct that sits above the glottis
UK	United Kingdom	The collective countries England, Scotland, Wales and Northern Ireland
VAS	Visual Analogue Scale	A psychometric response measurement instrument
VL	Video laryngoscope	An alternative intubation device method

Chapter 1 Introduction and Background

1.1 Introduction to the research area

Airway management is the maintenance of a clear passage through which air can flow into the lungs (Difficult Airway Society, 2018). It has been recognised that early airway management interventions help to ensure adequate ventilation and oxygenation of patients' lungs (Idris *et al.*, 1995; Lossius *et al.,* 2011). In emergency care provision, a step-wise approach is taken to airway management, with advanced techniques used in the latter steps. Endotracheal intubation (ETI[1]) is one of the advanced airway management techniques used by healthcare professionals, which involves inserting a tube into a patients' trachea to open and maintain a patent airway (Nicholson *et al.*, 2013).

Intubation is commonly performed in hospital; in theatres and Emergency Departments (EDs), predominantly by anaesthetists or ED doctors, with the ultimate aim of enhancing patient care (Steel, 2005). In the out-of-hospital care environment it is often paramedics, as initial responders to emergency situations, who are required to perform ETI to provide patients with safe, effective treatment (Peate, 2015). Paramedics (and other prehospital care providers) have carried out the critical intervention for a number of years, not only to maintain patient safety, but to optimise service delivery and contribute towards effectual professional practice.

There is much debate around whether ETI is required during cardiac arrest management and whether paramedics should carry out this skill in practice (Nolan and Soar, 2008; Lyon *et al.*, 2010; Hasegawa *et al.,* 2013; Mulder *et al.*, 2013; McMullan *et al.,* 2014; Taylor *et al.,* 2016; Carlson and Wang, 2017). There are studies that argue against intubation, finding that it does not improve cardiac arrest survival rates or good neurological outcome following cardiac arrest (Egly *et al.*, 2010; Kajino *et al.*, 2011; Jeong *et al.*, 2016). This said, many studies have shown that performing ETI can improve patient outcomes and chances of survival, providing it is performed in a timely, proficient manner (Cook *et al.,* 2011; Shin *et al.*, 2012; Wang *et al.,* 2012; McMullan *et al.*, 2014; Benoit *et al.,* 2015; Kang *et al.*, 2015).

Alongside the above, there is a body of evidence suggesting that paramedics may not be the best people to perform the skill of intubation (Katz and Falk, 2001; Garza

[1] Also referred to as intubation.

et al., 2003; Wang *et al.*, 2005b; Deakin *et al.*, 2009; Arslan *et al.*, 2010; George *et al.*, 2012). The main reasons these authors suggest this corresponds to the number of complications and impediments associated with ETI, which hinder the effectiveness of the intervention, some of which relate to the uncontrolled nature of the out-of-hospital care environment (Warner *et al.,* 2009; Hubble *et al.,* 2010; Cook *et al.,* 2012; Henlin *et al.*, 2014).

Accessing patients in unconventional positions or locations is a problem prehospital care providers might have to overcome (Hubble *et al.*, 2010; Henlin *et al.*, 2014). Patient variations are vast, which can complicate intubation given different anatomical and physiological patient presentations (Goldman and Ferson, 2005; Wang *et al.,* 2005a; Ollerton *et al.,* 2006; Perry and Morris, 2008; Warner *et al.,* 2009). A considerable amount of training and development is required to establish the skill and prevent skill-fade. The training paramedics receive is inconsistent and skill maintenance is contentious (Deakin *et al.,* 2009; Strote *et al.*, 2009), further exacerbated by the often-low exposure to regular tracheal intubation (Henlin *et al.*, 2014). In agreement with this statement is the JRCALC Airway working group (2008), who indicate that in practice most paramedics perform ETI an average of one to three times a year. Obstructions in the airway (due to fluid), difficulties in viewing the vocal cords and airway trauma are further complications that can lead to ineffective intubation (Cook *et al.,* 2012; Freund *et al.*, 2012). Essentially, an ineffective intubation (such as unrecognised oesophageal intubation or prolonged intubation attempts) can lead to hypoxic brain damage or death (Wang *et al.,* 2011; Xanthos *et al.,* 2012).

However, the reality is that whilst ETI is recommended for patients in cardiac arrest, despite the complications and impediments, paramedics are required and expected to intubate patients in the prehospital environment if appropriate, as they are the only healthcare professionals available. This is reinforced by national guidelines (Resuscitation Council, 2015; Brown *et al.,* 2016) and local policies (North West Ambulance Service (NWAS), 2017; East Midlands Ambulance Service (EMAS), 2018), which recommend ETI for patients in cardiac arrest as part of advanced life support interventions. There is however a lack of evidence to suggest how the above policies and guidelines are best applied or implemented by paramedics, to enhance the effectiveness of ETI in out-of-hospital cardiac arrest (OHCA) and improve outcomes for patients. Similarly, there is an absence of evidence that captures the views of paramedics on ETI and potential methods of improving practice.

Alternative intubating devices and methods have been developed and introduced to clinical practice to increase the effectiveness of ETI (Smith *et al.*, 1999; Maldini *et al.,* 2016; Ducharme *et al.*, 2017). They can make intubation feasible in extreme situations, such as awkward patient positions, environmental constraints and difficult airway views. The devices have been found to decrease the number of attempts required for successful intubation and therefore increase the speed of endotracheal tube (ETT) placement in the trachea, simultaneously reducing the likelihood of other complications (Maldini *et al.,* 2016). At the same time, the difficulties of effectively inserting an ETT with concurrent chest compressions can also be overcome with alternative intubation devices (AIDs), by offering better control of the tube (Aziz, 2013; Truszewski *et al.,* 2016). Furthermore, these devices have the potential to compensate for differences in levels of skill, competence and experience.

The research project has been designed to investigate airway management and ETI, as well as examine the use of AIDs in the out-of-hospital environment by paramedic practitioners. Exploring paramedics opinions of ETI and examining methods to potentially overcome complications and impediments, is aimed at enhancing paramedic practice and improving patient care by adding to existing knowledge in this field.

1.2 Aims, objectives and outline of thesis

Given the preceding introduction to airway management and ETI, particularly in the out-of-hospital environment, the intentions of the research and how these will be achieved are presented in the form of four aims and corresponding objectives.

Aim 1) Identify current practice relating to airway management and endotracheal intubation in the out-of-hospital environment.

a) Explore the current evidence available
b) Investigate current practice in a specific area of the UK

Aim 2) Ascertain paramedics' opinions on airway management and endotracheal intubation in the out-of-hospital environment.

a) Investigate current practice according to UK paramedics
b) Identify any associations between opinions and demographic data

Aim 3) Examine and compare the ability of paramedics to effectively use alternative intubation devices (AIDs).

a) Examine paramedics using AIDs in terms of first-time successful intubation
b) Examine paramedics using AIDs in terms of intubation time
c) Examine paramedics using AIDs in terms of adverse effects

Aim 4) Investigate the preferences of paramedics for alternative intubation devices

a) Investigate preference of devices according to paramedics' opinions
b) Identify any associations between preferences and demographic data

The research project was designed to meet these aims and objectives and the thesis unfurls as follows. Chapter One defines the key terms used throughout the thesis and sets the context to inform the reader of the importance and requirement for additional research in the field of ETI and alternative intubation methods. An explanation of airway management processes and methods used in practice both in and out of hospital, has been offered, succeeding the aims and objectives (Sections 1.3-1.4). Chapter Two discusses reviews of the literature which were undertaken to determine the evidence for and against the use of ETI for patients in cardiac arrest and establish the existing evidence about the use of alternative intubation methods by paramedic practitioners. Key themes emerged relating to patient outcomes, success rates of airway management techniques, time to ventilation and paramedics' opinions of AIDs when used in practice. The literature reviews identified certain gaps in available evidence that this research project sought to fill.

The methods of a three-stage approach are discussed and justified in Chapter Three. This chapter offers an in-depth account of the data collection methods applied within the thesis, including sample recruitment and approaches to data analysis at each stage. A case note review was carried out in order to identify current airway management techniques, including the frequency and success rate of ETI, in the out-of-hospital environment. An opinion survey was used in stage two, to seek paramedic opinions of ETI in out-of-hospital cardiac arrest. In the final stage, an experimental comparative study, four alternative intubation methods were examined and compared, whilst gaining paramedics' opinions of the devices. The ethical considerations for the research are offered at the end of Chapter Three (Section 3.5).

The results of the analytical methods described for each stage of the research project are presented in Chapter Four. The results from the case note review and opinion survey are presented in turn (as well as in conjunction with other) and form the basis

of discussion around airway management and ETI in prehospital care by paramedics. The findings of the comparative study are presented and clarified in the form of short narratives, graphs and tables in Section 4.4. This section of the results presents the examination and comparison of alternative intubation devices when used by paramedics, as well as the correlations with demographic information and paramedic preferences.

Chapter Five offers a comprehensive discussion exemplifying airway management, ETI and alternative intubation methods. Numerous concepts are explored and discussed, including airway management techniques, success rates, time to intubate and paramedics' opinions. The discussion synthesises the findings from the literature reviews presented in Chapter Two with the results from each stage of the author's research, specifically relating these to airway management practices by paramedics in the out-of-hospital care environment. The final chapter revisits the research aims in summarising and concluding findings and discussion of the thesis. Contributions to knowledge, suggestions for further study and recommendations for practice are made, as well as a summary of the research limitations.

1.3 Airway management in patient care

The assessment and management of a patients' airway is the foremost element of a clinical care episode (The Advanced Life Support Group, 2001). It is imperative to ensure a clear airway is obtained and maintained, to allow for ventilation, oxygenation and life (American College of Surgeons, 2011). For patients who have a compromised airway, due to trauma, being unconscious or in cardiac arrest; interventions are required to open and maintain the airway. In clinical practice, these interventions include manual manoeuvres, simple adjuncts, supraglottic airway devices and ETTs, which are used in a systematic order to manage a patients' airway (Figure 1-1) (Resuscitation Council, 2015).

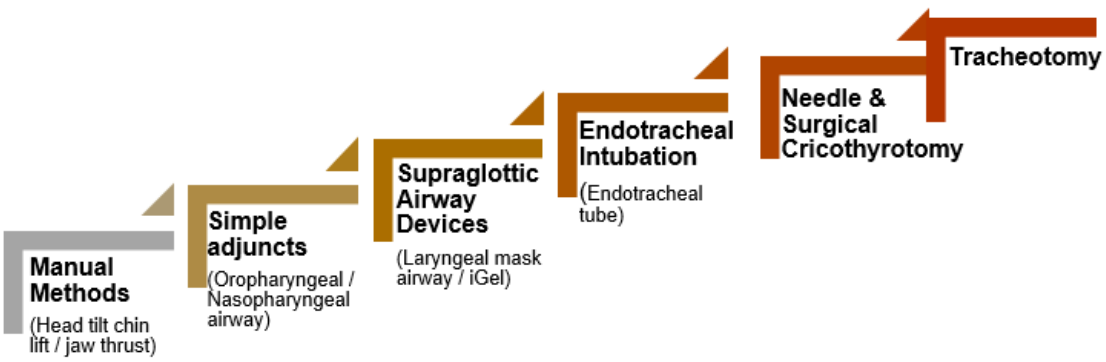


Figure 1-1: The step-wise approach to airway management used in clinical practice

Once a patent airway is established, a self-inflating bag is used to ventilate a patient (if required) (Dorges *et al.*, 2003). With simple adjuncts such as oropharyngeal and nasopharyngeal airways, a mask is connected to the bag and a seal created around the patients' mouth and nose. With this technique, it is inevitable that air will be pushed in to the stomach due to human anatomy (Smally *et al.*, 2002). Hyper-gastric inflation is likely to cause the patient to regurgitate, or vomit, particularly if they require chest compressions as part of the cardiac arrest management algorithm (Resuscitation Council, 2015; Jabre *et al.*, 2018). By replacing a simple adjunct with a supraglottic airway (SGA), the chances of pushing air into the stomach are much less[2], as the self-inflating bag can be connected directly to the SGA device (Ramachandran and Kumar, 2014).

Supraglottic devices sit on top of the glottis (Figure 1-2 illustrates this (Premier Healthcare and Hygiene Ltd, 2014)). Advantages include; quick insertion times; high success rates and maintenance of adequate oxygenation and ventilation in some cases (Guyette *et al.,* 2007; Cook and Howes, 2011; Fawzy *et al.,* 2012). Experience and extensive use of the devices [by healthcare professionals] is not required for efficiency and the interruption of chest compressions is minimal when used in cardiac arrest (Häske *et al.,* 2013), particularly when compared to ETI (Wang *et al.,* 2009b). This is of considerable value, as during OHCA of cardiac origin in adults, significantly interrupting chest compressions for the purposes of advanced airway management, may have a negative impact on patient survival and neurological outcome (Bobrow and Spaite, 2009; Wang *et al.,* 2009a; Henlin *et al.,* 2014).

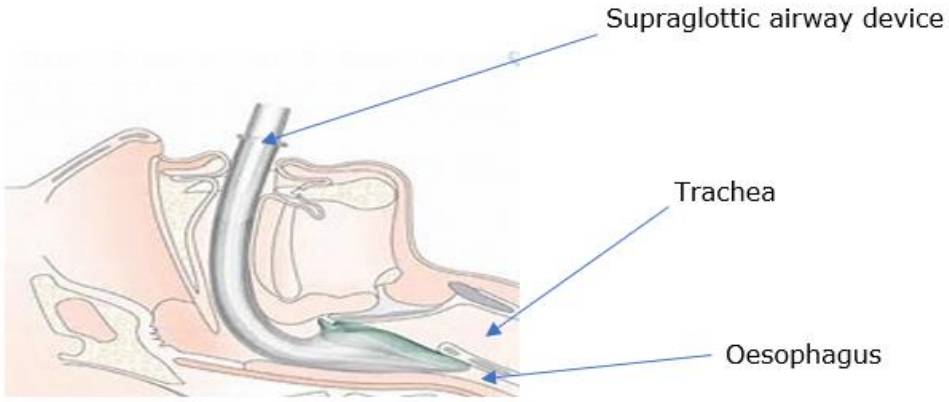


Figure 1-2: Lateral view of a supraglottic airway situated in the upper airway[3]

[2] although the evidence is conflicting regarding increased risk of hypergastric inflation when SGAs are used (Yu and Beirne, 2010).
[3] Image reference: Colombage (2014).

However, for all their benefits, SGAs do not wholly protect the lungs from foreign body entry or aspiration, which occurs in three quarters of patients in cardiac arrest (Simons *et al.,* 2007; Piegeler *et al.,* 2016; Jabre *et al.*, 2018). Regurgitation and subsequent aspiration, is associated with decreased chances of survival from cardiac arrest, alongside poor neurological outcome (Piegeler *et al.,* 2016). This said, SGA devices have evolved in complexity and functionality through new generation designs; they have become easier to use and should provide protection against aspiration of gastric contents (Guyette *et al.,* 2007; Williams *et al.,*2013). Still, higher peak inspiratory pressures would be required when using a SGA to overcome laryngospasm (sometimes present in patients at the early stage of cardiac arrest), which might exceed the maximal seal pressures of the SGA causing a significant leak or ineffective ventilation (Guyette *et al.*, 2007; Henlin *et al.*, 2014). Leaks have also found to be present with SGAs with ongoing chest compressions, as well as ineffective in providing controlled ventilation in patients with very low chest compliance and high rigidity (Häske *et al.,* 2013). Interventions that can prevent these occurrences, such as the insertion of an ETT, may improve patient outcomes following cardiac arrest (Cook *et al.,* 2011; Wang *et al.,* 2012; Benoit *et al.,* 2015). This said, the ideal method for managing the airway during OHCA remains an area of controversy (Carlson and Wang, 2017) and the arguments for and against the use of SGAs and ETTs have been investigated in a number of studies (see Section 2.2).

1.4 Endotracheal intubation

Endotracheal intubation is the technique used to insert an ETT into a patients' trachea, securing their airway, whilst enabling free flow of air directly to the lungs and diminishing the risk of aspiration, hypoxia and hyper-gastric inflation (Asai, 2012; Nicholson *et al.*, 2013). It is historically carried out using a standard rigid blade laryngoscopy technique, with Macintosh (curved), Miller (straight), or McCoy (articulating tip) blades (Foregger, 1966).

Performing the skill requires preparation of the necessary equipment, preparing the patient by opening the airway with manual manoeuvres and simple adjuncts (see previous Section 1.3) and pre-oxygenating the patient as best possible (Pandit *et al.*, 2003; Weingart, 2011; Jung *et al.*, 2012). The patients' head should be placed into the levitan position (see Figure 1-3) (Levitan *et al.*, 2003) and a laryngoscope used to visualise the vocal cords (by lifting the tongue and epiglottis forward and laterally). A gum elastic bougie is inserted through the vocal cords and into the trachea (Latto *et al.*, 2002; Morton *et al.*, 2002). The ETT is then introduced over the top of bougie,

whilst maintaining visualisation of the vocal cords and watching the tube pass through the vocal cords into the trachea (Figure 1-3) (Macintosh, 1949).

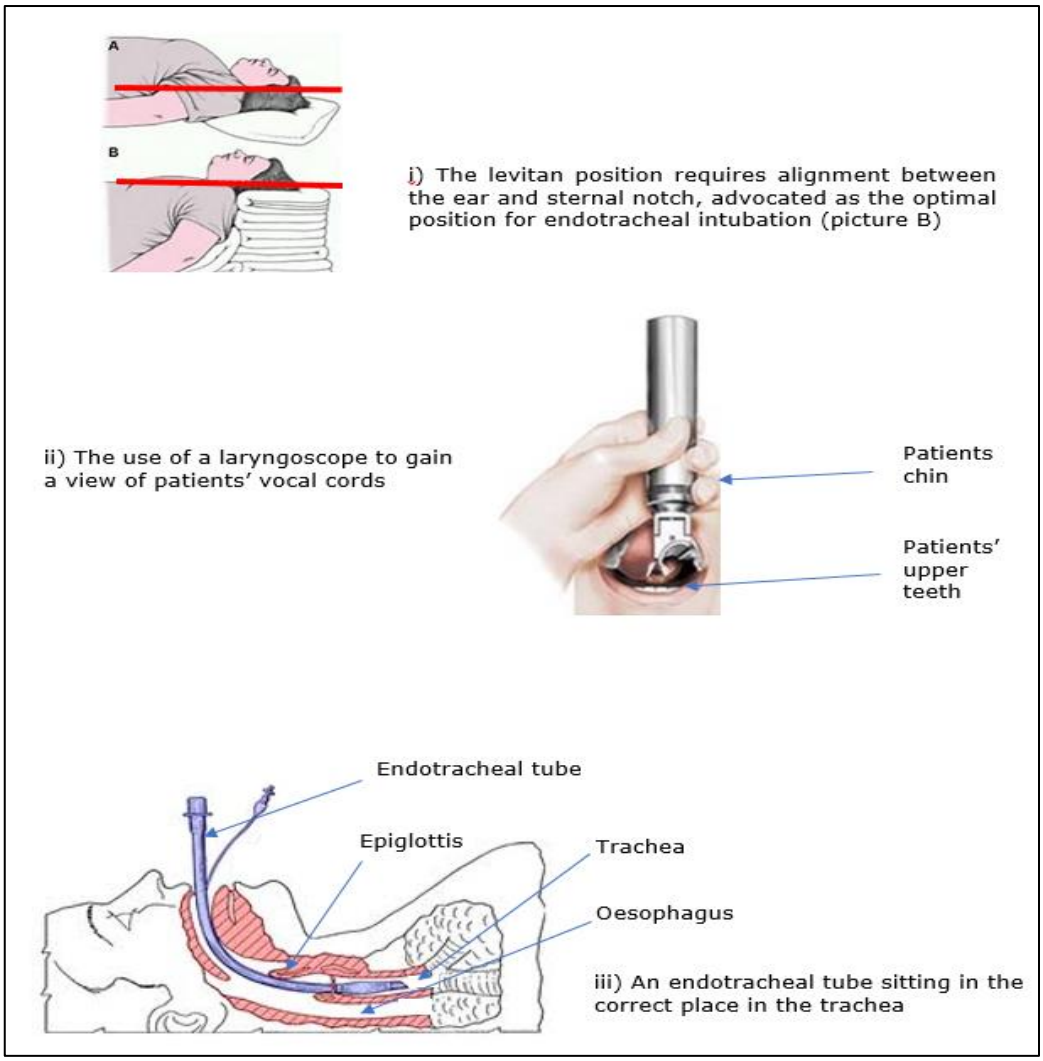


Figure 1-3: The process of endotracheal intubation

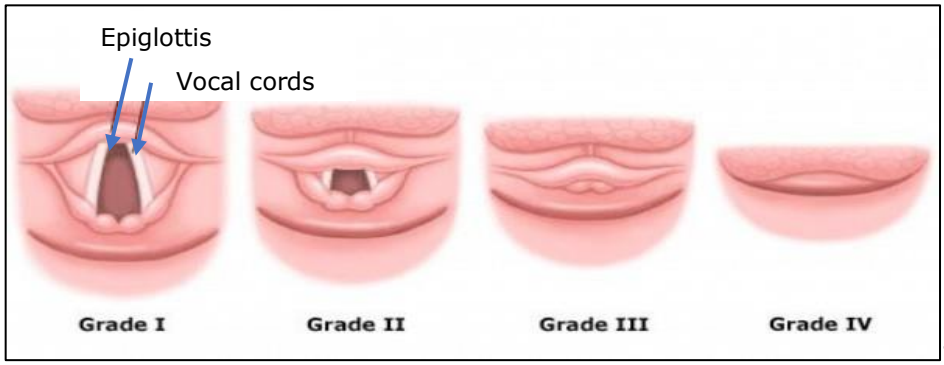
Performing ETI on patients in practice can be difficult due to anatomical differences in airways, the clinical care environment, application of chest compressions and the skill level of practitioners (Warner *et al.,* 2009; Hubble *et al.*, 2010; Cook *et al.,* 2012; Henlin *et al.*, 2014).

1.4.1 Difficulties with patients' airways

One of the difficulties when carrying out ETI, is the variation in anatomy and often unconventional presentation of patients (Frascone *et al.*, 2011). Older or bigger patients, those with pre-disposing conditions or comorbidities, or head or facial injuries, may need alternative management to overcome physiological differences (Goldman and Ferson, 2005; Wang *et al.,* 2005a; Ollerton *et al.,* 2006; Perry and

Morris, 2008). It will often be the inability to obtain a view of the glottis during laryngoscopy, with the afore-mentioned hindrances, that will impede intubation, leading to prolonged attempts and misplaced ETTs (into the patients' oesophagus) (Katz and Falk, 2001; Wang and Yealy, 2006a). Mismanagement of and complications in airway management compromise patient care and add extra strain on the National Health Service (NHS) and local service providers, increasing the resources required to counteract any complications (Wang *et al.*, 2010).

For a higher likelihood of successful intubation, a full view into the airway and of the glottis is required. The Cormack-Lehane classification system is a method of grading the difficulty of views, relating to visibility of the glottis (Cormack and Lehane, 1984; Yentis and Lee, 1998); grade I being the best view (Figure 1-4).



[4]

Figure 1-4: Cormack-Lehane grade classification of the airway view during direct laryngoscopy

Alongside the clinical patient-related impediments to successful intubation, the environment in which patients are cared for, including patient position or accessibility, can also hinder intubation (Hubble *et al.,* 2010).

1.4.2 The prehospital or out-of-hospital care environment

Ambulance services and health care professionals have been called to respond to emergencies in the United Kingdom (UK), since before the founding of the National Health Service in 1948. Patients present in a variety of places, medical states and conditions, with personal expectations. Due to the urgent and episodic nature of emergency calls, responders do not have the luxury of developed patient and care-provider relationships and are often required to provide care in a patients' best interests (Blaber, 2012). The nature of ambulance service response and paramedic practice has evolved over time, with the development of additional skills and use of

[4] Picture from MD Nexus (see reference list)

alternative care pathways when indicated, to prevent patients from travelling to an ED (thus providing out-of-hospital care) if possible. In emergency situations, patients may well require care interventions and transport to hospital, for instance if they are in cardiac arrest and being resuscitated (thus receiving prehospital care). Due to the nature of the clinical topics discussed; the terms 'prehospital' and 'out-of-hospital' are used equivalently throughout this thesis.

1.4.3 Out-of-hospital cardiac arrest

It is estimated that 60,000 patients suffer an out-of-hospital cardiac arrest (OHCA) each year in the United Kingdom (UK), around half of which are treated by emergency services (Resuscitation Council, 2014). These patients are unable to protect their airway and rely on emergency care providers to instigate resuscitative interventions, including airway management. Data from the Warwick out-of-hospital cardiac arrest registry indicated that less than half (47%) of these patients receive a resuscitation attempt by UK ambulance services (The University of Warwick, 2018) with survival to hospital discharge rates ranging from 2% to 12% (Perkins and Cooke, 2012). In 2016, London Ambulance Service (LAS) attended 10,116 patients in cardiac arrest, with just under a third of these patients surviving to leave hospital. This is attributed to the defibrillator accreditation scheme and specialist cardiac centres in London (LAS, 2018). The chain of survival indicates that early chest compressions and defibrillation are key to survival, maintaining cardiovascular support. Alongside this, airway management is essential to allow ventilation and subsequent delivery of oxygen, conveyed to body cells throughout cardiopulmonary resuscitation (CPR) (Henlin *et al.,* 2014).

Current research provides contradictory evidence for the best method of airway management during cardiac arrest (Hasegawa *et al.,* 2013; McMullan *et al.,* 2014). Some researchers have found that ETI is associated with improved survival rates and neurological outcomes compared to other methods of airway management (Wang *et al.*, 2010; Cook *et al.,* 2011; Shin *et al.*, 2012; Wang *et al.,* 2012; Tanabe *et al.*, 2013; Benoit *et al.*, 2015; Kang *et al.*, 2015). However, others have found that when paramedics carried out the skill in practice, failed and prolonged attempts negatively affected patient outcomes (Kajino *et al.,* 2011; Mulder *et al.,* 2013; Henlin *et al.*, 2014). In particular, Henlin *et al.* (2014) found that attempted intubation may cause significant interruptions to chest compressions, whilst the Resuscitation Council (2015) suggest uninterrupted chest compressions are required during the resuscitation of non-traumatic cardiac arrests. The pause in chest compressions, to insert an airway adjunct (including an ETT or SGA) should be less than five seconds,

with attempts to intubate being no longer than 30 seconds (American Heart Association, 2012; Difficult Airway Society, 2015). Thus, intubation should be well practiced to ensure the best chance of effective execution of the skill.

1.4.4 Paramedic professional practice

Paramedic skill set has grown and there are currently two training routes to gain registration as a paramedic with the regulating body (the Health and Care Professions Council (HCPC)). These include higher education institute (HEI)[5] training, following an accredited curriculum, or in-service training, following the IHCD (Institute of Health and Care Development) programme. Paramedics that take the in-service training route may add to their professional qualification, by studying for an academic qualification at an HEI. With both training routes, paramedics demonstrate competence with ETI skills across the country and are encouraged to maintain this skill with continued professional development (CPD) time (HCPC, 2012). This said, the best methods for achieving and assessing the intubation skills of paramedics are unclear (Carlson and Wang, 2017).

Advanced skills such as ETT insertion, require a considerable amount of training and development to establish the skill and prevent skill-fade (Deakin *et al.,* 2009; Strote *et al.,* 2009) and to ensure paramedics remain up to date with current evidence, research developments and changes in practice. However, there is significant variation within the evidence and no national mandated standard relating to the development of competence in intubation (College of Paramedics, 2018). Clinical competence is particularly important when providing care and delivering clinical interventions in stressful, uncontrolled conditions, to enhance and provide best evidence-based care, whilst minimising risks and complications (Wang and Yealy, 2006b).

Much as there are guidelines, policies and evidence suggesting ETI is a requirement for patients in cardiac arrest, alongside the notion that paramedics are best placed to carry out the intervention in the out-of-hospital environment, there are few studies that investigate the perceptions and abilities of paramedics (see Chapter Two).

[5] Also referred to as University

1.4.5 Alternative intubation methods

When executed in the prehospital environment, ETI is not without associated complications (Section 1.3) and there is evidence to suggest that some of these complications could be counteracted with alternative or assisted intubation devices. These enable management of the unpredicted difficult airway and some can increase success rates of intubation, by providing an enhanced view of the vocal cords despite patient anatomy, physiology, comorbidities and presenting complaints.

A range of devices and methods are used in clinical practice, by a variety of healthcare professionals, to help ensure an effective intubation (Appendix-i). Video and fibre optic laryngoscopy are two methods of alternative intubation, both involve viewing the airway on a separate video screen or on the end of laryngoscope. They optimise airway views and success rates of intubation (Smith *et al.,* 1999; Maldini *et al.,* 2016; Ducharme *et al.,* 2017) and have been used in the anaesthetic room or by anaesthetists for a number of years. Flexible scope fibre optic intubation is considered the gold standard intubation technique in American theatres (Sowers and Kovacs, 2016). Other devices, such as the intubating laryngeal mask airway (iLMA) and retroglottic devices, allow for blind intubation, speeding up advanced airway management procedures with minimal adverse effects (Brown *et al.*, 2017).

Throughout this thesis, these methods and devices shall collectively be termed alternative intubation devices (AIDs) with the process referred to as intubation (given the nature of inserting a tube to enable ventilation). Currently, practitioners are using AIDs in practice, to manage difficult and standard airways in hospital theatres and EDs across the world (Difficult Airway Society, 2015). In the prehospital environment and military services; critical care paramedics, army medics and doctors have been researching and using AIDs as rescue methods, as well as first-line intubation techniques (Wallace *et al.,* 2017). In the UK, ambulance services and frontline paramedics are not commonly using AIDs in practice. This could be due to limited evidence focussing on paramedics and ETI (including AIDs) in the UK, to prove or disprove the benefit of its use in prehospital care.

Chapter 2 Literature Review

2.1 Introduction

Chapter Two offers the context for the thesis, drawing from academic, policy and third sector literature. At the outset of the project, two literature reviews were undertaken using five databases[6] relevant to the area of study. The first review investigated the use of endotracheal intubation (ETI) in out-of-hospital cardiac arrest (OHCA). The second looked at the use of alternative intubation devices (AIDs) by paramedics. PRISMA[7] guidelines were followed to identify and select appropriate studies and produce a narrative review of the literature that is in context with the previous and following chapters of the thesis (after Moher *et al.*, 2009). Whilst Chapter One provided the framework and rationale for the review, explicit questions underpinned both literature searches in Chapter Two. Eligibility criteria were developed and used alongside a range of search terms to select relevant, applicable studies for examination (after Moher *et al.*, 2009; O'Connor *et al.,* 2011; Booth *et al.,* 2016). The studies selected in each review are drawn from a broad range of literature and the results of study selection and characteristics are presented in the corresponding sections of Chapter Two (Sections 2.2 and 2.3). Following reading the studies, a table was used to enable the presentation of the study details, any individual risk of bias within them, summary measures and key findings. Structured, comprehensive critiquing methods were employed, to gain understanding of the concepts and allow for comparative evaluation of the studies (Burns and Groves, 1987; Morrison, 1991; Webb and Roe, 2007). A summary of the main findings are presented, with an assessment of any bias that may have affected the cumulative evidence (after Moher *et al.*, 2009).

In the first review a large focus on the comparison between Endotracheal Tubes (ETTs) and supraglottic airway devices (SGAs) has been acknowledged (Section 2.2). In the second, the focus was the use of alternative intubation devices (AIDs) by paramedics, whereby three key themes emerged; the success rate of AIDs; time taken to intubate; and paramedics' opinions of the devices (Section 2.3).

[6] Medline, CINAHL, AMED, Computers and Applied Sciences Complete and Education Research Complete were the data bases used.
[7] Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

2.2 Endotracheal intubation or supraglottic airway devices

To underpin the initial aim of the research: to identify current practice relating to airway management and endotracheal intubation in the out-of-hospital environment, a global review of the literature was undertaken to answer the question 'is ETI superior to a SGA in OHCA?'. The methods followed PRISMA guidelines (Moher *et al.*, 2009) (see Appendix-ii) and the number of studies screened, assessed for eligibility and included in the review are illustrated in Figure 2-1 and Appendix-iii.

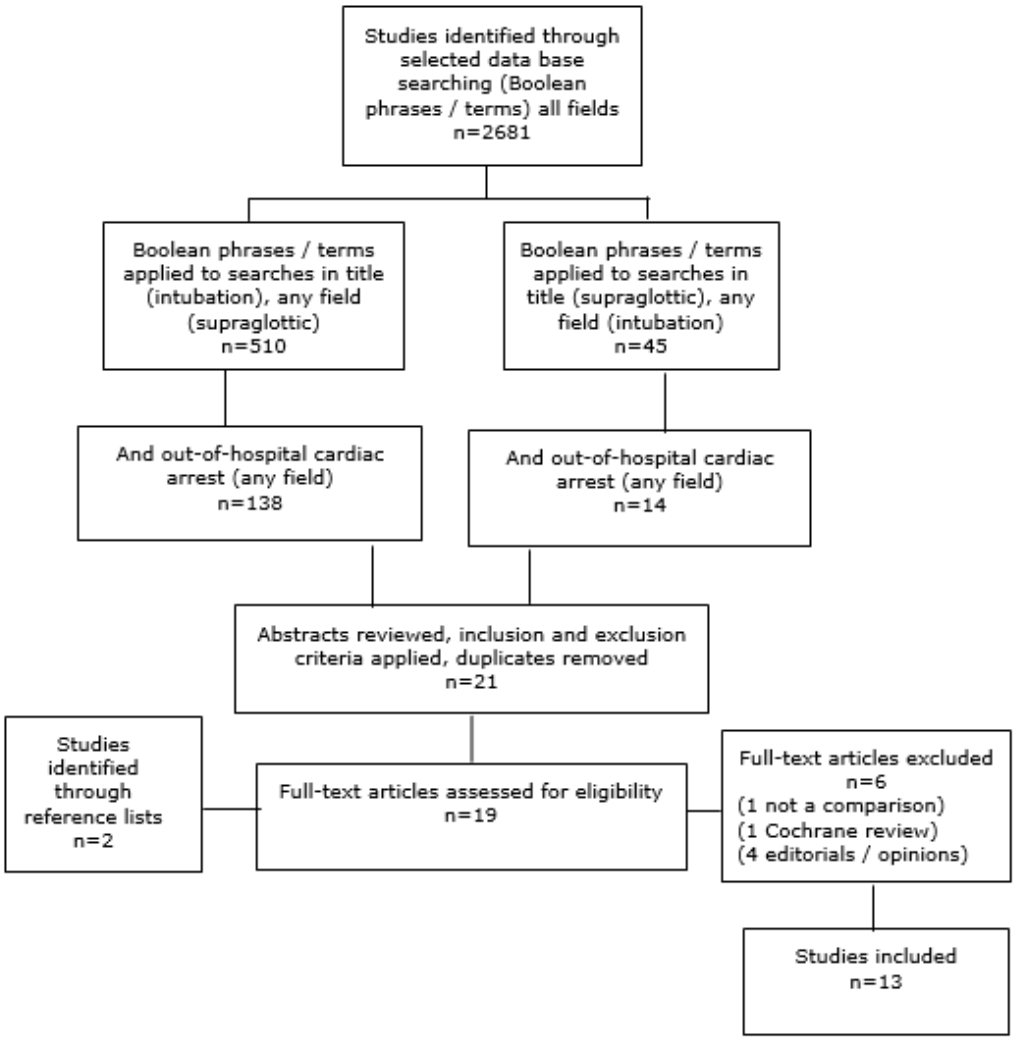


Figure 2-1: Prisma diagram to illustrate the number of studies screened and included in the initial literature review

Most published studies were non-randomised or retrospective citing ethical reasons for this, see for example Egly *et al.*, 2010; Wang *et al.*, 2010; Tanabe *et al.*, 2013; Dyson *et al.*, 2017. A number of studies reviewed existing data or used meta-analysis methods (Wang *et al.*, 2012; McMullan *et al.*, 2014; Benoit *et al.*, 2015; Jeong *et al.*,

2016). Key findings related to patient outcomes and the effectiveness of the airways, between which associations were found. Some authors found that effectively managing an airway will lead to improved patient outcomes, which have been measured by return of spontaneous circulation (ROSC) and survival to discharge with good neurological outcome (Section 2.2.1). Effectiveness was also determined by success rate and time taken to intubate or insert a device in some studies, though the airway management method that proved most effective was not consistent throughout the studies (Section 2.2.2). Some researchers considered confounding and influencing factors such as patient demographics and the level of paramedic experience. The main themes arising from these studies are described below (Sections 2.2.1 and 2.2.2).

2.2.1 Patient outcomes

A number of studies considered patient outcomes in terms of sustained ROSC, survival to hospital admission and or discharge and the level of neurological integrity. Henry Wang has carried out a number of studies with colleagues (Wang and Yealy, 2006b; Wang *et al.,* 2010; Wang *et al.,* 2012), investigating ETI and airway management during OHCA. In 2010 their retrospective analysis of 62,586 patients found that the adjusted odds of survival were higher for intubated patients, though this study only accounted for successful intubations. This may have impacted results as it was previously recognised by Wang that up to 15% of out-of-hospital ETI efforts may fail, potentially increasing time without oxygen and interruptions to CPR in the patients without an ETT. This is similar to the study by Tanabe *et al.* (2013) who carried out a vast nation-based observational study in Japan comparing outcomes of patients receiving either an ETT or SGA. The use of SGAs was associated with significantly worse neurological outcome than ETI, though the devices documented were those in use on arrival to the hospital, rather than those intended for use in the field. Therefore failed ETI attempts were either excluded or could be grouped in the SGA use, thus potentially skewing results and misrepresenting out-of-hospital practice.

Egly *et al.* (2010) studied the influence of prehospital intubation on survival of patients with OHCA; their retrospective analysis included 1,515 cases of OHCA. Patients with ventricular fibrillation or ventricular tachycardia who were intubated showed lower survival rate to discharge while, in the whole cohort, there was no difference found between intubated and non-intubated subjects. Similar results were found in an observational, population-based cohort study that used a prospective, cohort database (Kajino *et al.*, 2011) in Japan. A total of 5,377 patients received

either an ETT (31%) or SGA (69%). Findings indicate no differences in either survival or incidence of good neurological outcome between either method.

In comparison, McMullan *et al.* (2014) considered all the aforementioned patient outcomes whilst reviewing over 10,000 cases from the Cardiac Arrest Registry to Enhance Survival (CARES) database[8]. ETI achieved higher sustained ROSC, survival to hospital admission and discharge with good neurological outcome, in comparison to those patients who received a SGA. The year before, Wang *et al.* (2012) had used similar methods and performed a secondary analysis of data related to airway management. Data was from the Resuscitation Outcomes Consortium (ROC) Prehospital Resuscitation using an Impedance valve and an Early vs. Delayed analysis (PRIMED) trial[9]. The authors used the data from a similar sized sample to that of McMullan *et al.* (2014) to perform multivariable logistic regression and adjusted for confounders. The results indicate that successful ETI was associated with better early survival and higher hospital discharge rates, compared to when a SGA was inserted during OHCA. In both studies the numbers of ETT, SGA and simple adjuncts used were uneven across the cases, with a higher proportion of patients being intubated, which could have positively skewed results. Also, in Wang *et al.'s* study the data did not account for any errors during airway management such as ETT misplacement or duration of airway insertion attempts, exacerbating one of the limitations in observational studies to compare outcomes between ETI and SGA.

The suggestion that a higher proportion of airways used in one group of patients skewed results is not supported when reviewing other studies that compared ETI to the use of a SGA or simple adjuncts with a bag-valve-mask (BVM). Kang *et al.* (2015) used multivariate logistic regression in 32,513 patients and Shin *et al* (2012) studied the outcome of 5,278 patients in OHCA. In both studies there were a higher proportion of patients in the BVM group (91% and 88% respectively). The results from both found the odds of neurologically favourable survival to discharge was significantly higher in the ETI groups, compared to the BVM and SGA groups. In further support, the study by Piegler *et al.* (2016) found that during cardiopulmonary resuscitation (CPR), ETI offers superior protection against regurgitation and pulmonary aspiration of gastric contents than SGA devices or bag-valve ventilation,

[8] The CARES registry evaluates only OHCA events of presumed cardiac aetiology that involve persons who received resuscitative efforts, including CPR or defibrillation (McNally *et al.*, 2011).

[9] The ROC PRIMED study was one of the largest prospective out-of-hospital controlled trials ever performed, testing the effects of two strategies of electrocardiogram (ECG) analysis and the impedance threshold device upon outcomes after OHCA (Aufderheide *et al.,* 2011; Stiell *et al.,* 2012)

thus leading to greater chances of survival (see also Benoit *et al.*, 2015 and Jabre *et al.*, 2018).

In an attempt to determine the comparative effectiveness of ETI versus SGA during OHCA, Benoit *et al.* (2015) carried out a large meta-analysis study. All of the studies evaluated by the authors were observational and of low or very low quality of evidence (Carlson and Wang, 2016). Benoit *et al.* found that patients who received ETI had statistically significant higher odds of ROSC, survival to hospital admission and neurologically intact survival compared to SGA. In comparison, a Korean meta-analysis review (Jeong *et al.*, 2016) found a decrease in survival rates in patients in cardiac arrest when a SGA or ETT was used (rather than a BVM with simple adjuncts). However, this study could not exclude paediatric patients, which could have influenced results given that paediatrics in OHCA have better outcomes than adults, despite decreased frequency (Berg *et al.*, 2008; Nitta *et al.*, 2011). At the same time paediatric cardiac arrests predominantly follow respiratory arrests, of which simple airway adjuncts can be more effective during management (Hansen *et al.*, 2017; Jones *et al.*, 2017).

As the majority of these studies used large amounts of observational data, which can help understand airway management strategies and identify areas for further study, the methods are not always able to account for all the sources of potential bias (Carlson and Wang, 2016) and potential confounding factors based on clinical considerations (Goldman and Ferson, 2005; Wang *et al.,* 2005a; Ollerton *et al.,* 2006; Perry and Morris, 2008). A randomised design is better suited, such as the REVIVE study which indicates that a prospective trial of alternative airway management strategies in OHCA, cluster randomised by paramedics, is feasible (Benger *et al.*, 2016). Further studies are investigating the comparison of ETI and SGA devices using RCT methods (Taylor *et al.,* 2016) with data analysis to be completed. Additionally, influencing factors such as the amount and type of training paramedics have undergone, their experience and proficiency in performing effective airway management for patients in OHCA, have been found to affect ETI in the prehospital environment (Deakin *et al.,* 2009; Stroke *et al.,* 2009; Wang *et al.,* 2010). There are RCTs and other studies that investigate ETT placement time and success rates which was a second theme that emerged during this literature review, with reference to complications during airway management, including ETI, by paramedics.

2.2.2 Effectiveness of endotracheal intubation by prehospital paramedics

The effectiveness of ETI has been related to patient outcomes (see above) which relies on precise and successful advanced airway management. In 2009, Wang *et al.* investigated errors in ETI, finding that the key error events were ETT misplacement or dislodgement, multiple ETI attempts and failed ETI. These errors were not directly linked to increased mortality, though failed ETI was associated with increased odds of pneumonitis. In addition, from their review, Henlin *et al.* (2014) established that attempts for tracheal intubation can be timely (and may cause significant interruption to chest compressions during CPR for patients in OHCA), which can negatively affect patient outcomes. However, Henlin *et al.* also surmise that the insertion of a SGA in OHCA is probably associated with worse patient outcomes than other methods of airway management. This phenomenon was further investigated by other researchers; Kajino *et al.* (2011), Frascone *et al.* (2011) and Mulder *et al.* (2013). Kajino *et al.* used a prospective cohort design with 5,377 patients and found time to insert an ETT was significantly longer than a SGA (the time referred to the time from patient collapse to insertion of an airway). Frascone *et al.* carried out a prospective randomised prehospital clinical trial and found that overall placement success rates were equal, though with no statistical significance in median time to placement. On the other hand, Mulder *et al.*'s randomised controlled trial (2013) found that when a SGA is placed by paramedics, it is faster, safer and thus more effective than ETI. An advantage of this study is that both groups of patients (ETT or SGA) were comparable in terms of sex, age and the starting of chest compressions (CPR). The latter two studies had relatively small sample sizes in comparison to other studies, though the RCT methods were useful to compare the two airway management methods.

Wang and colleagues had considered Emergency Medical Service (EMS) personnel experience in ETI in relation to patient survival, in a large retrospective analysis (Wang *et al.,* 2010). This method does not come without its limitations, such as using case note data without unique identifiers. The authors acknowledge this and attempt to overcome this with broadening the sample and geographical area, as well as using longitudinal methods. Their adjusted odds (accounting for variations in severity of illness only) of survival were higher for patients intubated by personnel with very high ETI experience and it is established that ETI in the hands of experienced operators is still a reliable method. This was further investigated in 2017 by Dyson *et al.*, who found that previous intubation experience was associated with intubation success and first pass success rate though not with patient survival. Their study used a retrospective case note analysis method as well as gathering

information on paramedic experience. Logistic regression estimated the association of intubation experience to successful intubation (95%) and first pass success (80%), indicating experience influences the effectiveness of ETI and could be further investigated.

Another study evaluated the number of attempts needed for successful tracheal tube placement in the prehospital setting (Wang and Yealy, 2006a). More than one attempt was required in more than 30% of patients. Cumulative success rate in OHCA for the first three intubation attempts was 69.9%, 84.9%, and 89.9%, respectively. However, the success rate for tracheal intubation was significantly higher in OHCA patients than in the scenario of non-arrested subjects requiring sedation. This infers that ETI can be successful for patients in cardiac arrest (CA) and influencing factors should be considered.

A range of alternative intubation devices (AIDs) or methods are available to help improve the effectiveness of ETI, despite the level of paramedic experience. These have been found to decrease complications during ETI (Smith *et al.,* 1999; Maldini *et al.,* 2016; Ducharme *et al.,* 2017), though their use in the out-of-hospital environment is not common practice in the UK. The following section in this Chapter offers a summary of the findings in the literature of the effectiveness of AIDs (success rate and time to intubate) when used by paramedics for patients in OHCA. An additional theme relating to paramedics' opinions of the devices was apparent and is also discussed (Section 2.3.3).

2.3 Paramedics using alternative intubation devices in the out-of-hospital environment

The third and fourth aims of the author's thesis are: to examine and compare the ability of paramedics to effectively use AIDs and investigate the preferences of paramedics for AIDs in the out-of-hospital care environment. In order to address these, a literature search was designed to answer the question ' is there a difference in effectiveness between alternative intubation devices when used by paramedics in the out-of-hospital environment?'. The literature search methods can be found in Appendix-iv and are illustrated in Figure-2.2. The studies reviewed reflect different country settings, several methods and both mannikin and real patient studies (see Appendix-v).

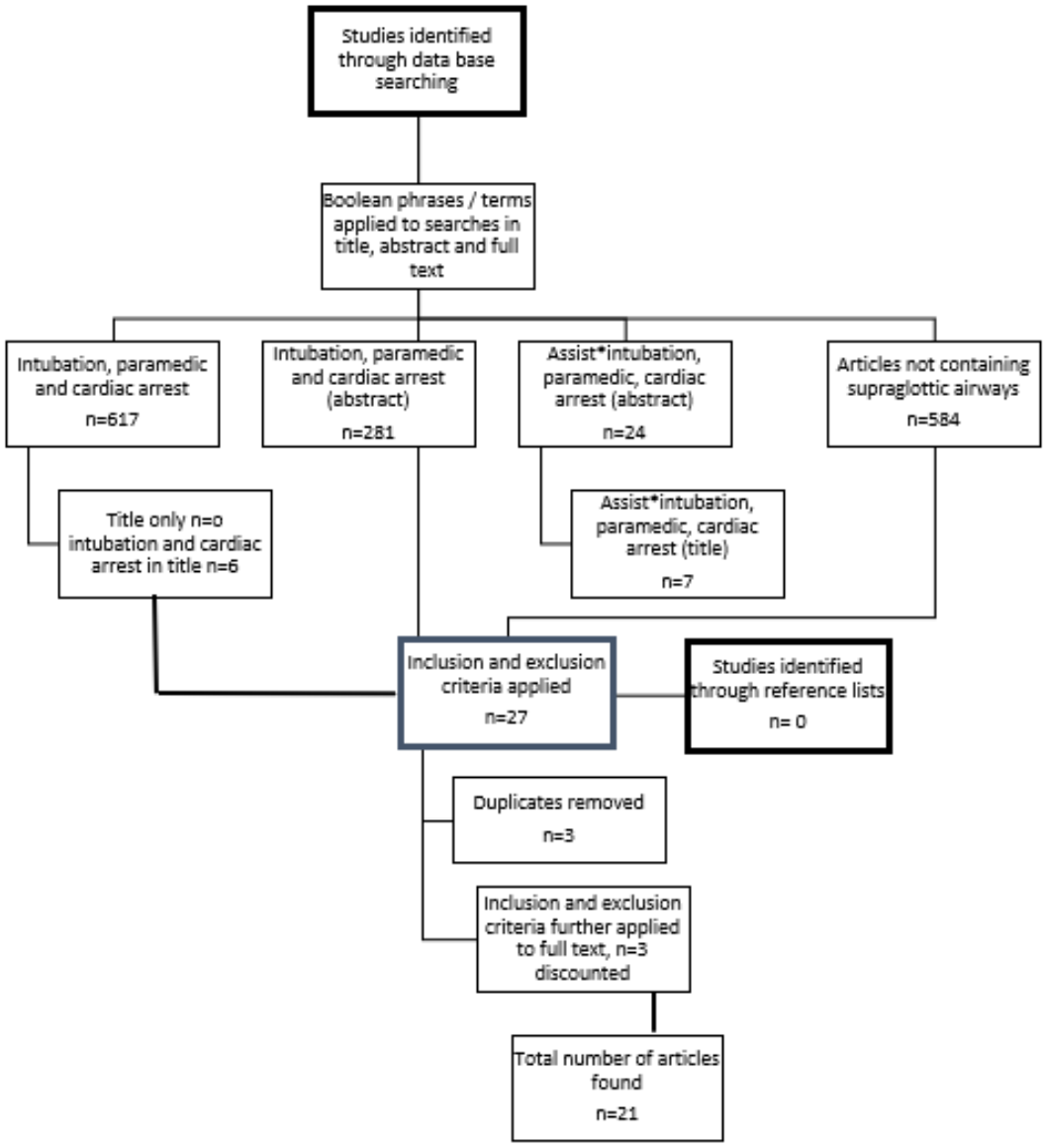


Figure 2-2 Prisma diagram to illustrate the number of studies screened and included in the second literature review

Results identified just three studies that have been carried out in the UK, two in Northern Ireland (Nasim *et al.,* 2009a and b[10]) and one in England (Butchart *et al.,* 2011). Broadly, the studies compared two different types of AIDs, though one study (Wallace *et al.,* 2017) compared a range of video laryngoscopes (VLs) only. The majority compared a SBL (Mackintosh or McCoy blade) to a VL, a further three evaluated a retroglottic device in comparison to a SBL and the final two compared a fibre optic device or the intubating laryngeal mask airway (iLMA).

2.3.1 Success rates

Several studies found a standard blade laryngoscope (SBL) to be more successful than other methods (Arima *et al.*, 2013; Russi *et al.*, 2013; Truszewski *et al.*, 2016). Arima *et al.* (2013) carried out a RCT and found that first time success rate was considerably lower with a VL (46%) than a standard blade (75%) (p=0.002). Their sample of 109 patients was over three times larger than Truszewski *et al.'s* (who used cadaver models) using real patients to compare a VL (Pentax AWS) to a SBL. A study in the same year, using prospective observational methods, used participants who were not over familiar with devices and gave their 50 participants minimal training education in using the Airtraq VL (Russi *et al.*, 2013). Results were not statistically significant, though for the 42% of patients where the Airtraq failed to assist intubation first time, a SBL aided intubation in 14 out of 21 patients (66.7%). Both these studies were carried out on real patients which offers more realistic scenarios for intubation. The researchers who carried out their studies on real patients, gave reasons for unsuccessful intubations largely relating to airway obstructions, such as blood or vomit in the airway. These adverse effects would only be experienced on real patients, not on cadavers or mannikins, despite the use of high-fidelity mannikins. Airways with secretions and saliva are different to manage than dry airways in a mannikin. This said, the muscle memory or skill acquisition to carry out intubation is achievable using a mannikin, with equivalent outcomes to that on a real patient (Graham, 2005). Further research on real patients or mannkins would be beneficial to compare alternative intubation devices, though simulation studies should be mindful of the lack of bodily fluids as airway obstructions, when discussing results.

A SBL was comparable to a VL in a RCT carried out on mannikins by Yildirim *et al.* (2017). Forty participants used a variety of scenarios and participants had a 100%

[10] The lead authors are the same for both studies, though additional authors differ (see reference list).

success rate with the VL and McCoy blades, followed by the Macintosh blade with an 85% (n=36) success rate (p=0.002). Other studies also found comparative success rates between the SBL and VLs, though with no statistical significance in ultimate and first-time success rates (Nasim *et al.,* 2009a and 2009b; Gaszynska and Gaszynski, 2014; Bogdański *et al.,* 2015). Larger studies are likely to allow for a higher likelihood of establishing an effect when comparing devices (see Bowling, 2014) and future studies should make this clear to establish relevance in results.

A randomised comparative study in Poland compared two VL devices (the Airtraq and Pentax AWS), recruiting 67 participants (Bogdański *et al.,* 2015). The authors found the AWS the most successful device, with a 79% first time success rate (and moderate statistical significance). In comparison, the Airtraq and McCoy blade laryngoscope had respective 67% (p=0.17) and 66% (p=0.19) first time success rates. Second, third and failed attempts were also comparable across the Airtraq and McCoy blade, indicating no inferiority between these devices. The AWS was superior in this simulated comparative study (94% success rate), though the Airtraq VL similar to the McCoy blade (87% and 85% respectively). Unfortunately, the lack of statistical significance in these results makes applicability to practice difficult.

The lack of statistically significant results in all three studies in 2017, could be due to underpowered studies resulting in an effect not being identified. Smereka *et al.* compared the C-MAC VL and a MBL with 70 participants in normal airway scenarios and found 100% first-attempt success rates with the VL and 96% with a MBL (p=0.643). Similarly, Ducharme *et al.,* who compared the King Vision VL to a SBL with 83 participants and Hodnick *et al.,* whose participants used a GlideScope Ranger, VividTrac and a SBL and completed a total of 281 intubation attempts between them, found comparable success rates between devices, with no statistically significant differences. It is noted that success rate across all devices were higher in Hodnick *et al.*'s study (VividTrac 98.5%, GlideScope 100%, SBL 100%) than Ducharme *et al.*'s findings (King Vision 73.3%, SBL 81.1%), though the sample groups were uneven in the study by Ducharme *et al.* (2017), which was carried out on real patients, limiting significant comparisons between devices. Further research should recruit sample sizes large enough to detect a medium effect of AIDs (see Section 3.4.2), when success is measured.

Similarly, the two studies from Northern Ireland (Nasim *et al.,* 2009a and 2009b), compared two VLs to a SBL in each small study, with 21-25 proficient paramedic participants. In their first study, the authors found no statistical significance in the

overall success rates between the Airtraq, Truview and a SBL (p=0.597) (Table 2-1).

Table 2-1: Success rates of devices in the studies by Nasim *et al* (2009a and 2009b)

Method	**Device**	**Ultimate success rate**	**First Time success rate**
Standard Blade Laryngoscope	Macintosh	100%	96%
Standard Blade Laryngoscope	Macintosh	100%	95.3%
Video Laryngoscope	Pentax AWS®	100%	100%
Video Laryngoscope	GlideScope®	100%	96%
Video Laryngoscope	Airtraq®	95%	90.5%
Video Laryngoscope	Truview®	90.5%	66.7%

The TruView required the greatest number of attempts, with 19% of participants needing three attempts, though the Airtraq and a MBL were comparable in terms of success rate and number of attempts required. In their second study, similar success rates between the GlideScope, AWS and a MBL were identified (Table 2-1).

In comparison, two retrospective case note analysis studies found moderately statistically significant results, with superior success rates with VLs (the King Vision and GlideScope Ranger) (Wayne and McDonnell, 2010 and Jarvis *et al.,* 2015). Both studies took into account participant demographic information, to try and minimise influencing factors and used 615 and 514 patient records respectively. Wayne and McDonnell found similar overall success rates were found for both methods (97% for the VL and 95% for the SBL), though the number of attempts required was less with the GlideScope (n=1.2), compared to the SBL (n=2.3) (p=0.05), demonstrating improved first-time success rates with the VL. On the other hand, Jarvis *et al.* (2015) found that the VL was superior in terms of overall success rate (91.5%) and first-time success rate (74.2%) (p=≤0.01), compared to a MBL which had a 64% ultimate and 43.8% first time success rate. The retrospective, non-randomised methods, coupled with the potential for training effect in the VL group in these studies, makes it difficult to apply results to practice. A randomised, crossover, comparative method is likely to provide more relevant results (Bowling, 2014), though variables must be accounted for to ensure complete robustness to enable application to practice. Of course this is only possible in mannikin studies, which, as mentioned, do not come without their limitations.

In 2011, Butchart *et al.* carried out a comparative study and found similar results to the case note reviews, though with a much smaller sample and on mannikins. Their 30 participants had a 97% success rate with two different VLs (the Venner AP Advance and GlideScope Ranger), compared to 70% with a SBL. It is noted that one of the authors was a co-inventor of the Venner AP Advance VL and the results in this study were not statistically significant. A SBL was found to be more successful than a retroglottic airway in a study by Calkins *et al.* (2006) and less successful in two further studies (Bollig *et al.*, 2006; Russi *et al.*, 2008) all three with statistically significant results. Despite the large sample size of real patients, just 2.2% of the sample received a Combitube airway in the initial study, though the study offers some useful findings in the context of this research in that up to 162 patients had a Combitube inserted and 70% (n=113) were successful. In comparison, 108 patients were successfully intubated using a SBL with an 84% success rate. Although the sample groups varied in size, the number of successful intubations was higher when using a SBL (Calkins *et al*., 2006). The two studies that found a Combitube device to be more successful than a SBL were carried out on mannkins with small sample sizes. Success rate to ventilation was significantly lower with a standard blade (87%) than a Combitube or EasyTube (99% (combined)) in Bollig *et al.'s* study. It is suggested that this relates to the efficiency of retroglottic devices as blind intubation techniques (Bollig *et al.*, 2006). In Russi *et al.'s* study, all the scenarios were carried out on mannikins, with in-line cervical-spine immobilisation, which may have impacted on outcomes. At the same time, in both studies, the small sample sizes may not have detected a small difference between devices, though the authors still found statistically significant results. The King LT had 100% success rate, the Combitube had an 82% success rate and a SBL intubation had a 69% success rate ($p \leq 0.001$). It is noted that all these studies were carried out over 10 years ago, at about the time that Combitube devices were becoming more common for airway management in practice. New research is required, in line with new developments of alternative intubation devices, to investigate the use of retroglottic airways.

Another older study and the only one to compare the intubating laryngeal mask airway (iLMA), was by Swanson *et al.* (2004), who compared the iLMA to a MBL. The authors used a prospective, randomised crossover trial method, on a high-fidelity mannikin, which incorporated a variety of simulated conditions. The results demonstrated that success rates were comparable between each device, with just one failed intubation attempt with the iLMA, out of the 45 intubations made with the device. However, the first pass success rate for the iLMA was 89% with four instances requiring a second attempt alongside the one failed attempt for the MBL.

Unfortunately, the sample contained just seven paramedics (and eight nurses), restricting transferability to practice. Research with the iLMA for use by paramedics is extremely limited and further research is required to study the efficacy of this device for use in prehospital practice. Given this, the iLMA is included in the author's research study for comparison with other AIDs.

2.3.2 Time to intubate

Time taken to intubate was measured in most of the studies reviewed, again results are varied and conflicting; there was no one method found to intubate quicker than another overall. The quickest methods were found in a study comparing two VLs to a SBL (Nasim *et al.,* 2009b), demonstrating intubation times of 7 and 8 seconds respectively (with the Pentax AWS VL). In their other comparative study, Nasim *et al.* (2009a) found time to intubate was significantly longer with a VL (the Truview, 17 seconds), whereas a SBL was the quickest taking on average 9 seconds ($p=0.004$). Other mannikin studies that compared more than one VL to a SBL found similar results in that a SBL offered quicker intubation (see Gaszynska and Gaszynska, 2014; Smereka *et al.*, 2017; Yousif *et al.,* 2017).

Smereka *et al.* (2017) carried out a randomised crossover trial on mannikins, setting up different scenarios including cervical spine immobilisation, to compare the C-MAC VL and direct laryngoscopy with a blade. In the normal airway scenario, time to intubate was similar with both methods by 70 participants; 18 seconds and 16.5 seconds respectively; the standard method being slightly quicker ($p=0.067$). When cervical spine immobilisation was introduced, the C-MAC VL enabled quicker intubation times ($p=\leq 0.05$). Analysing data with and without the scenario interventions was appropriate, as is keeping variations and variables to a minimum. Another randomised comparative study, by Gaszynska and Gaszynski (2014), found intubation was over 10 seconds quicker with a MBL when compared to the Truview EVO2 VL. Within their small sample of 30 participants, time to intubate on first attempt was 28.6 seconds with the VL, compared to 17.1 seconds with the MBL ($p=0.0080$). Yousif *et al.* (2017) also found longer intubation times with VLs in their small randomised crossover study on mannikins, their results were statistically significant. The authors compared the GlideScope and King Vision to a MBL, finding the mean time to intubate with the MBL was 25.7 seconds ($p\leq 0.0001$). This was 10 seconds quicker than the GlideScope ($p\leq 0.0001$) and 4 seconds quicker than the King Vision ($p=0.033$). The crossover method of their study was robust, though the

small sample size of 20 participants wearing level C personal protective equipment[11], makes changing practice difficult based on these results.

It is noted that these studies were on mannikins, which could have affected the speed of intubation attempts. A RCT by Arima *et al.* (2013), took place using 109 real patients in cardiac arrest in Japan and also reported lengthier intubation times with a VL. The researchers found that intubation with the VL took on average 35 seconds longer than with a MBL (2 minutes 35 seconds with the VL and 2 minutes with the MBL, p=0.095). These times to intubate are excessive, being that the suggested maximum time for intubation attempts is 30 seconds (Difficult Airway Society, 2015). This could be attributed to the real patients used; oral contamination, poor view of the glottis or skill level of user (Arima *et al.,* 2013). A further two studies were carried out on cadaveric models and neither support nor refute the above findings (see Appendix-vi).

Other mannikin studies reported opposing results to the above studies, finding a VL quicker to intubate than a SBL (Butchart *et al.*, 2011; Bogdański *et al.*, 2015; Wallace *et al.*, 2017; Yildirim *et al.*, 2017). The aforementioned studies carried out comparative studies using a variety of VLs between them. Butchart *et al*. (2011) had the smallest sample of the four and found the average time to intubate with a SBL over twice as long as with a VL in their mannikin study. Time to intubate was 49 seconds with a SBL, 19 seconds with the GlideScope and 20 seconds with the Venner APA ($p \leq 0.0001$). Yildirim *et al. (*2017) compared the C-MAC VL to two SBLs and found quicker intubation times with the VL (14.62 seconds) compared to the Macintosh (22.57 seconds) and McCoy (17.67 seconds) blade laryngoscopes ($p \leq 0.001$). Despite having a robust method and statistically significant results, these randomised, cross over simulation studies had a relatively small sample sizes of 30 and 40 participants respectively, though the latter study considered the experience of their participants and all had over two years' experience. Bogdański *et al*. (2015) found time to intubate with the AWS was significantly quicker at 25.4 seconds, compared to the Airtraq (35.6 seconds) and the McCoy blade (38.5 seconds) ($p \leq 0.001$). The sample of 67 paramedics was credible, though all were novice practitioners and therefore the findings are not fully transferrable to more experienced users in the field.

[11] Level C Personal protective equipment (PPE) includes: full-face or half-mask, air-purifying respirator, chemical resistant clothing, gloves, outer, chemical resistant, gloves, inner, chemical resistant, boots, steel toe and shank, chemical resistant.

A study that just compared VLs (Airtraq, AWS, C-MAC, Coopdech and GlideScope) by Wallace *et al*. (2017) used simulation with high-fidelity mannikins and altered the difficulty of the airway view and lighting in various environments. The authors divided the participants into novice and experienced practitioners and investigated time to tracheal successful intubation. The extensive results are complex to interpret, though consider the experience the participants had and demonstrate that novice paramedics intubated quickest with the AWS and Airtraq and slowest with the Coopdech. In the expert group, the GlideScope Ranger led to the quickest intubation times and again the Coopdech was the slowest. The authors found that intubating on the ground in darker conditions had a statistically significant, negative impact, on time to intubate[12]. The results from this recent study imply that taking experience into account during data analysis is essential, particularly when transferring results to practice. This said, transferring results from the study by Wallace *et al*. (2017) to practice is difficult, as results from novice practitioners are not likely transferable to experienced practitioners and vice versa. The author of this thesis considered both the training effect and experience of practitioners in the design of the research project presented in this thesis, with data analysis techniques accounting for variations (see Section 3.4.4).

Three studies carried out on real patients also recognised the impact differences in the experience of practitioners, as well as a potential training effect could have on outcomes (Russi *et al.*, 2013; Jarvis *et al.*, 2015; Ducharme *et al.*, 2017). These researchers also recognised differences in familiarity with AIDs, though this was not referred to or considered during their data analyses. At the same time, due to the methods employed with these real patient studies, it was not possible to measure the time taken to intubate with the AIDs. The only study using real patients that measured time to intubate with VLs and SBLs was by Wayne and McDonnell (2010) who suggested that a VL is quicker than a SBL (it is unclear which blade the participants used). Their results show that when over 600 participants intubated real people, the average time to intubate with the GlideScope VL was 21 seconds, which was half the time required to intubate with a standard blade (42 seconds).

The studies that compared retroglottic devices found inconsistent times to intubate and ventilate; a range of 25 – 53.7 seconds was found from two of the three studies which investigated retroglottic devices such as the Combitube. These results come

[12] The times included in the synopsis of Section 2.4 are taken from the 'normal' airway scenario; on the ground, with the lights on, taking an average of the times from expert and novice paramedics.

from studies which took place in simulation, on mannikins, therefore there were no airway contaminations[13]. Authors Bollig *et al. (*2006) carried out a small study in Norway, comparing a SBL to two retroglottic devices; the Combitube and EasyTube. They found that mean time for successful intubation was longer using a blade (45.2 seconds), compared to the EasyTube (38 seconds) and Combitube (26 seconds) (p=0.002). A SBL was also found to be slowest to successfully intubate in the study by Russi *et al. (*2008), who compared the King Laryngeal Tube (King LT) and a standard Combitube, to endotracheal intubation using a SBL. Their study took into consideration the experience of the practitioners involved in the study; basic medical providers and professional paramedics. For this review, just the results of the paramedics are compared, though the findings similar success rates were apparent for both groups. When paramedics used a SBL, the mean time to intubate was over 90 seconds (twice as long as the time in Bollig *et al.'s* study). The King LT was quickest to insert and then ventilate at 27 seconds, with the Combitube in the middle of the three methods, taking a mean time of 53.7 seconds to successfully place (Russi *et al.,* 2008). The Combitube device has been used in hospitals in the UK, though is no longer commonly used in-hospital or in prehospital care. It would be useful to have further research to determine whether a retroglottic device is comparable to intubation in terms of success rate and time, when used by paramedics. Retroglottic devices have historically been used in the UK and the author has accounted for this in the research study design (presented in this thesis), given that there is currently no research on paramedics using a retroglottic device in this country.

There was just one study (that met the review inclusion criteria) that compared an intubating laryngeal mask airway (iLMA) to standard methods of intubation (by Swanson *et al.,* 2004). The iLMA technique involves the insertion of a laryngeal mask airway (LMA), prior to the insertion of an endotracheal through the LMA. Despite the sample being small (15 participants), the methods were robust with the researchers setting up three scenarios, allowing for the devices to be used 45 times each. The study was carried out on mannikins, with paramedic participants, though the field setting was for an emergency helicopter service. The results found that using a SBL was significantly quicker than the iLMA; 12 seconds compared to 39 seconds respectively. The longer time to intubate could be attributed to the two-step process of inserting a supraglottic device, followed by a blind intubation with an endotracheal tube. The participants also had much less exposure to the iLMA than standard methods, which could have contributed to longer intubation times. This said, the

[13] The third study that investigated retroglottic devices by Calkins *et al.* (2006) used real patients and did not measure time of tube insertion.

authors took this into consideration during data analysis, having established mean ratings of previous exposure to the devices, using a visual analogue scale.

Another way of using visual analogues scales was to gain paramedics opinions of AIDs, particularly in terms of the view of the airway each gave, which led to the final theme of the literature review.

2.3.3 Paramedics' opinions

Around two-thirds of the studies reviewed measured paramedics' opinions of AIDs, in terms of ease of use or the view of the glottis; using visual analog scales, Cormack-Lehane classification[14] or percentage of glottic opening (POGO) scores. Also measured in some studies was the incidence of dental force when performing intubation. The results of paramedic opinions largely come from mannikin studies unless specified.

Self-reported measures of satisfaction were evaluated on a 0% to 100% visual analog scale (VAS) by Yousif *et al. (*2017). The authors identified marginally greater satisfaction with the King Vision VL (87%) and GlideScope VL (73%) over the Macintosh blade (70%) ($p=0.05$), but reasons for preferences were not sought. Similarly, participants in Bogdański *et al.'s* (2015) study indicated that between the Airtraq VL, AWS VL and McCoy standard blade, the preferred method was the AWS, with over half (54%) of the participants favouring this method. This was followed by the Airtraq and the least preferred was the SBL (McCoy blade) ($p\leq0.001$), again their participants did not offer reasons for preferences. The cadaveric study by Hodnick *et al. (*2017) measured paramedics' opinions extensively and found similar results (see Appendix-vi). Wallace *et al. (*2017) carried out a survey, asking their participants to rank the devices on a scale of one to five, according to the perceived ease of use. In their study, solely VL devices were used and the AWS and GlideScope were documented as easiest VLs to use by all their participants. Some of the attempts required additional manoeuvres and manipulation to allow for effective intubation with the VLs, more so when intubating mannikins on the ground. The results were not statistically significant. Nasim carried out two studies with colleagues in 2009, comparing VLs to a Macintosh blade laryngoscope (MBL), using a total of four VL AIDs (two in each study), in simulated easy and difficult intubations. The small sample sizes reduce the power of this study, which indicates that a VL is

[14] The Cormack-Lehane grading system classifies airway views based on the anatomical structures seen, grade 1 being the best view and 4 the worst. Also explained in Section 1.4.1, Figure 1-4.

favoured, though the Truview VL required more optimisation manoeuvres (Nasim *et al.,* 2009a). Using a VAS limits the amount and quality of data gained in terms of paramedics' opinion of AIDs; asking for justification of the scores given would significantly enrich data.

Opposing previously mentioned preferences, Arima *et al. (*2013) found no significant difference in difficulty of intubation when comparing the AWS VL to the MBL ($p=0.066$) on real patients. Four years later, Smereka *et al.'s* 70 participants preferred a SBL to the C-MAC VL ($p=0.009$) when used on mannikins. However, when cervical spine immobilisation was introduced, 93% of participants preferred the VL ($p\leq0.001$). Similar scenarios were created in the study by Yildirim *et al. (*2017), who also measured degree of difficulty. Comparing two standard blades to the C-MAC VL, they found comparable results with the standard blades; median difficulty scores 4 (McCoy) and 5 (Macintosh) out of 10. A difficulty median score of 1 (range 0-9), was found with the C-MAC ($p\leq0.001$). Again, the degree of difficulty rose when cervical spine immobilisation was in place for the standard blades, though the median remained a constant with the VL throughout the scenarios. For all these studies, the preference of the VL in cervical spine immobilisation conditions is likely related to the view of the airway the VL offers, that is not present with a SBL given restrictive neck movements to adequately position a patient.

For blind airway management techniques such as a retroglottic device or iLMA, a view of the airway is not required, instead ease or difficulty of insertion was measured. Russi *et al. (*2008) reported findings on ease of use using a scale of one to five in their study, which compared successful intubation rates and times between Combitube, King Laryngeal Tube (King LT) and ETT intubations. Most paramedics reported intubation with an ETT (using a SBL) as difficult, the Combitube as neither easy nor difficult and the King LT as easy or very easy. 'Comfort levels' of the devices were also sought, this related to physical ease of use; paramedics were similarly comfortable with a SBL or Combitube.

In the one study that compared the iLMA to SBL, difficulty ratings were recorded on a VAS of 1-100mm. Inserting the LMA and the blind intubation were more difficult than standard blade laryngoscopy (Swanson *et al.,* 2004). The participants rated the SBL at 13mm, inserting the iLMA at 23mm and intubating through the iLMA at 17mm; suggesting the techniques were easy to perform. This said, the SBL was favoured in terms of ease of use, which is surprising as participants in this study were not positioned at the 'head end' of the mannikin, thus obtaining a good view of

the glottis was made more difficult, whereas a view is not required when inserting and intubating though the LMA. The researchers noted changes in position and apparent difficulties, not referred to by the participants, on observation. Further research to explore the use of an iLMA and determine whether the device is liked by paramedics is required and as mentioned earlier, has been incorporated into the comparative study design presented in Chapter Three.

In the studies reviewed, the scales used were rating scales for the individual devices, to measure satisfaction levels, rather than ranking devices in order of preference. Although data analysis allows for comparison of satisfaction scores, there is an opportunity to look at ranked preferences for several devices, gaining paramedics' opinions on a range of methods and devices. The researcher has taken this opportunity and designed a research study to rank AIDs in comparison to each other.

Whist trying to obtain a view of the glottis, adverse incidents such as dental trauma can occur, though at different rates and pressures with different devices. Authors Yildirim *et al. (*2017) measured the pressure exerted on teeth whilst intubating, as an adverse effect. Whilst using a Macintosh blade, 90% of 40 participants caused severe tooth pressure, compared to 23% using the C-MAC VL (and 78% when using a McCoy blade). Butchart *et al. (*2011) found that no additional force was found when participants used a VL, compared to 13% (n=4) with a SBL (with no statistical significance). Smereka *et al. (*2017) also measured dental compression, their findings were considerably different to those of Yildirim *et al.* and Butchart *et al.* Their results show only 3% of 70 participants caused severe tooth compression with both standard and video alternative methods of intubation, indicating that using a SBL does not necessarily increase dental trauma. However, this number increased significantly when cervical spine immobilisation was applied using a collar, with 67.1% of attempts causing severe dental compression with a MBL, compared to 21.4% with a VL.

There are no further recent studies that investigate the use of AIDs by paramedics. This could be due to the increasing number of AIDs being developed, the difficulties in controlling variables during studies, deterrents in recruiting paramedic participants and restrictions in researching in the out-of-hospital care environment (Burges *et al.*, 2012.)

2.4 Summary

The choice of airway management technique in OHCA remains controversial and the effect of prehospital advanced airway management on neurological recovery, particularly that of ETI, is still unclear. Although BVM ventilation (with simple airway adjuncts) has been repeatedly associated with better survival, including better neurological function, than advanced techniques of airway management, the risk of regurgitation and aspiration cannot be underestimated (Piegler *et al.*, 2016; Jabre *et al.*, 2018). The insertion of a SGA device in OHCA is likely to be associated with worse patient outcomes than other methods of airway management (Wang *et al.*, 2010; Shin *et al.*, 2012; Tanabe *et al.*, 2013; Henlin *et al.*, 2014; Benoit *et al.*, 2015; Kang *et al.*, 2015). It is suggested that ETI in the hands of experienced operators is still a reliable method and this should be considered when further researching the phenomenon (Wang and Yealy, 2006a; Walls *et al.*, 2013; Henlin *et al.*, 2014).

Studies investigating AIDs in the out-of-hospital environment, using paramedic participants, are limited. Up to date research using paramedic participants is required to add to the current body of knowledge. This is even more necessary in the UK, where just three studies have taken place (two of which were in Northern Ireland). The author's research is relevant to UK practice, given the nature of ambulance services, equipment provided and training and development systems. In the studies discussed in the literature review, a variety of methods were used with a range of sample sizes. Prospective, randomised comparative designs were common and considered to be a suitable method for comparing AIDs. The author's research has followed a prospective observational design using mannikins for simulation, which is in line with the majority of existing studies. Sample sizes of published studies were varied and it is recommended that a sample size large enough to reveal a medium effect, if it exists, should be used in future studies.

A summary of the findings of AIDs success rates when used by paramedics, in the studies considered in section 2.3.1 is presented in Table 2-2.

Table 2-2: Summary of success rates of alternative intubation devices, used by paramedics

KEY: ◇ = mannikin study, 😊 = real patients, Ö = Cadavers, SBL = Standard Blade Laryngoscope, VL = Video Laryngoscope, iLMA = intubating laryngeal mask airway

Method	Device	Ultimate success rate	First Time success rate	Authors
VL	Pentax AWS◇	100%	100%	Nasim *et al.,* 2009b
VL	C-MAC◇	100%	NA	Yildirim *et al.,* 2016
Fibre scope	Bonfils😊	100%	100%	Byhahn *et al.,* 2007
VL	GlideScope◇	100%	96%	Nasim *et al.,* 2009b
SBL	Macintosh◇	100%	96%	Nasim *et al.,* 2009b
SBL	Not stated◇	100%	96%	Nasim *et al.,* 2009b
SBL	Macintosh◇	100%	95.7%	Smereka *et al.,* 2017
SBL	Macintosh	100%	95.3%	Nasim *et al.,* 2009a
SBL	Macintosh 😊	100%	75%	Arima *et al.,* 2013
SBL	Macintosh	100%	73.3%	Gaszynska & Gaszynski, 2014
VL	GlideScope Ö	100%	68.8%	Hodnick *et al.,* 2017
SBL	Not stated Ö	100%	64.5%	Hodnick *et al.,* 2017
VL	C-MAC◇	100%	100%	Smereka *et al.,* 2017
SBL	McCoy	100%	NA	Yildirim *et al.,* 2016
Combitube	King LT◇	100%	NA	Russi *et al.,* 2008
Combitube	Combitube◇	99% (combined)	NA	Bollig *et al.,* 2006
	EasyTube◇		NA	
VL	VividTrac Ö	98.5%	60%	Hodnick *et al.,* 2017
Intubating LMA	iLMA◇	98%	89%	Swanson *et al.,* 2004
VL	Venner APA	97%	100%	Butchart *et al.,* 2011
VL	GlideScope	97%	80%	Butchart *et al.,* 2011
VL	GlideScope😊	97%	NA	Wayne & McDonnell, 2010
VL	Pentax AWS😊	96.4%	46%	Arima *et al.,* 2013
VL	Airtraq	95%	90.5%	Nasim *et al.,* 2009a
SBL	Not stated😊	95%	NA	Wayne & McDonnell, 2010
VL	Pentax AWS◇	94%	79%	Bogdański *et al.,* 2015
SBL	Not stated😊	92.8%	85.7%	Russi *et al.,* 2013
VL	King Vision	91.5%	74.2%	Jarvis *et al.,* 2015
VL	Truview	90.5%	66.7%	Nasim *et al.,* 2009a
VL	TruView	90%	63.3%	Gaszynska & Gaszynski, 2014
VL	Pentax AWS Ö	88.6%	97.1%	Truszewski *et al.* 2016
SBL	Not stated◇	87%	NA	Bollig *et al.,* 2006
VL	Airtraq◇	86.6%	67%	Bogdański *et al.,* 2015
SBL	McCoy◇	85.1%	66%	Bogdański *et al.,* 2015
SBL	Mackintosh	85%	NA	Yildirim *et al.,* 2016
SBL	Not stated😊	84%	NA	Calkins *et al.,* 2006
Combitube	Combitube◇	82.2%	NA	Russi *et al.,* 2008
SBL	Not stated😊	81.1%	66.7%	Ducharme *et al.,* 2017
SBL	Macintosh Ö	77.1%	94.3%	Truszewski *et al.* 2016

VL	King Vision😷	72.5%	62.5%	Ducharme *et al.,* 2017
SBL	Not stated◇	70%	NA	Butchart *et al.,* 2011
Combitube	Combitube😷	69.8%	NA	Calkins *et al.,* 2006
SBL	Not stated◇	68.9%	NA	Russi *et al.,* 2008
SBL	Not stated😷	64.9%	43.8%	Jarvis *et al.,* 2015
VL	Airtraq😷	62%	58%	Russi *et al.,* 2013

Overall no device has been found to be more successful than another, when used by paramedics across the globe. Reasons for unsuccessful intubation were related to obstructions in the airway (such as blood or vomit), poor views of the glottis and a lack of familiarity using some AIDs. Obstructions in the airway were only apparent in studies on real patients, whereas difficult intubations could be simulated on high-fidelity mannikins. There appeared to be no significant consistency between the results produced with either type of study, further indicating that mannikin studies are appropriate to compare AIDs. The research (outlined in Chapter Three) has been designed as a simulated mannikin study and aims to examine the use of AIDs for prehospital practice. The author is mindful of the lack of bodily fluids as airway obstructions in mannikin studies and this is considered when discussing results.

There was no one device that was superior to others in terms of time to intubate. Studies found a range of intubation times with different devices. The quickest time to intubate was with a video laryngoscope (VL), on a mannikin, taking just seven seconds, closely followed by standard blade laryngoscopes (SBL), also on a mannikin, at eight and nine seconds. The VL Pentax AWS was the slowest to intubate at 155 seconds on real patients and in the same study, a Macintosh blade laryngoscope took 120 seconds. These times are extensive and attributed to the study using real patients. The only study to explore the intubating laryngeal mask airway (iLMA) found it took 39 seconds to intubate. A range of devices successfully intubated in less than 30 seconds, including the Combitube, SBLs and other VLs (see Table 2-3). In one study the same methods took over 120 seconds to intubate on real patients (Arima *et al.,* 2013). Reason for differing times to intubate, could be the experience of paramedics and or the training effect or exposure they had to the AIDs. The only study to explore the intubating laryngeal mask airway (iLMA) found it took 39 seconds to intubate.

Table 2-3: Summary of times to intubate with alternative intubation devices, when used by paramedics

KEY: ◇ = mannikin study, 😊 = real patients, Ö = Cadavers,
SBL = Standard Blade Laryngoscope, VL = Video Laryngoscope,
iLMA = intubating laryngeal mask airway

Method	Device	Time to intubate (seconds)	Authors
Video Laryngoscope	Pentax AWS◇	7	Nasim *et al.,* 2009b
SBL	Macintosh ◇	8	Nasim *et al.,* 2009b
SBL	Macintosh ◇	9	Nasim *et al.,* 2009a
Video Laryngoscope	Airtraq◇	11	Nasim *et al.,* 2009a
Video Laryngoscope	GlideScope◇	11	Nasim *et al.,* 2009b
SBL	Not stated◇	12	Swanson *et al.,* 2004
Video Laryngoscope	C-Mac◇	14.6	Yildirim *et al.,* 2016
Video Laryngoscope	Airtraq◇	14.9	Wallace *et al.,* 2017
Video Laryngoscope	GlideScope◇	15	Wallace *et al.,* 2017
SBL	Not stated◇	16.5	Smereka *et al.,* 2017
Video Laryngoscope	Truview◇	17	Nasim *et al.,* 2009a
SBL	Macintosh◇	17	Gaszynska & Gaszynski, 2014
SBL	McCoy◇	17.7	Yildirim *et al.,* 2016
Video Laryngoscope	Pentax AWS◇^	17.8	Wallace *et al.,* 2017
Video Laryngoscope	C-Mac◇	18	Smereka *et al.,* 2017
Video Laryngoscope	C-MAC◇^	18.5	Wallace *et al.,* 2017
Video Laryngoscope	Coopdech◇^	18.6	Wallace *et al.,* 2017
Video Laryngoscope	GlideScope😊	21	Wayne & McDonnell, 2010
SBL	Macintosh◇	22.6	Yildirim *et al.,* 2016
SBL	Macintosh Ö	24	Truszewski *et al.* 2016
Video Laryngoscope	Venner APA◇	25	Butchart *et al.,* 2011
Video Laryngoscope	Pentax AWS Ö	25	Truszewski *et al.* 2016
Video Laryngoscope	Pentax AWS◇	25.4	Bogdański *et al.,* 2015
SBL	Macintosh◇	25.7	Yousif *et al.,* 2017
Combitube	King LT◇	27	Russi *et al.,* 2008
Video Laryngoscope	Truview ◇	28.6	Gaszynska & Gaszynski, 2014
Video Laryngoscope	King Vision◇	29.9	Yousif *et al.,* 2017
SBL	Not stated Ö	33.7	Hodnick *et al.,* 2017
Video Laryngoscope	Airtraq◇	35.6	Bogdański *et al.,* 2015
Video Laryngoscope	GlideScope◇	35.8	Yousif *et al.,* 2017
Combitube	Combitube◇	36	Bollig *et al.,* 2006
Combitube	EasyTube◇	38	Bollig *et al.,* 2006
Video Laryngoscope	GlideScope Ö	38	Hodnick *et al.,* 2017
SBL	McCoy◇	38.5	Bogdański *et al.,* 2015
Intubating LMA	iLMA◇	39	Swanson *et al.,* 2004
SBL	Not stated😊	42	Wayne & McDonnell, 2010
Video Laryngoscope	VividTrac Ö	42.2	Hodnick *et al.,* 2017
SBL	Not stated◇	45.2	Bollig *et al.,* 2006
Video Laryngoscope	GlideScope◇	46	Butchart *et al.,* 2011
Combitube	Combitube◇	53.7	Russi *et al.,* 2008
SBL	Not stated◇	71	Butchart *et al.,* 2011
SBL	Not stated◇	91.3	Russi *et al.,* 2008
SBL	Macintosh😊	120	Arima *et al.,* 2013
Video Laryngoscope	Pentax AWS😊	155	Arima *et al.,* 2013

Paramedic experience varied in the samples recruited by researchers, though was not always analysed adequately in terms of the effect this had on outcomes. The potential training effect should also not be underestimated and this research has considered both (training background and experience), with analysis of the associations between these and outcomes (see Section 3.4.4). This is likely to enable better transferability of results to practitioners in prehospital practice.

Participant opinions of the AIDs were gathered using visual analogue scales and Cormack-Lehane grades or percentage of glottis opening (POGO) scores to establish comfortability, perceived ease of use and grade of view. Throughout the studies results are inconsistent, with little statistical significance. Paramedics were similarly comfortable with the SBL and Combitube device in the study by Russi *et al*. (2013). Other studies found marginally greater satisfaction with VLs over a SBL, which is surprising as paramedics are more familiar with SBLs, though this is attributed to the view of the glottis VLs provided. VLs were found to be superior in terms of view, particularly when alternative situations such as chest compressions and cervical spine immobilisation were introduced. The main adverse incident measured was dental pressure, of which VL was superior in comparison to a SBL, offering little to no force.

The studies in the literature review compared just one type of device to another and obtained paramedics' views on individual devices. There is a research opportunity (that has been up taken by the author) to compare more than two methods of intubation and gain paramedics' opinions by ranking devices in order of preference. The author has also asked paramedics to justify their decision in their own words, which could considerably enrich the data collected. The following chapter presents the methods of a three-stage research project designed to answer the research aims (offered in Section 1.2) and contribute to the existing body of knowledge, addressing some of the issues identified in the literature reviews.

Chapter 3 Methods

3.1 Introduction

This chapter presents and critiques the methods applied during the research project, designed to respond to the aims and objectives presented in Section 1.2. A three-stage approach was developed, using primarily quantitative methodology (a case note review, paramedic opinion survey and experimental study). The survey and experimental study incorporated the collection and analysis of some qualitative data (see Morse & Niehaus, 2009).

Sections 3.2-3.4 discuss and justify each stage of the research, including sampling, data collection and data analysis. Reflections throughout these sections identified some of the weaknesses associated with the design, as well as limitations of the research which arose from these. The chapter concludes with a comprehensive exploration of the ethical issues considered throughout (Section 3.5).

3.1.1 Methodology

The methods applied within this research followed a dynamic, positivist, fixed (rather than emergent) approach (Creswell, 2009; Ross, 2012). These were representative of a design process that combined and interrelated multiple components from existing typologies of research methodologies. The initial stages (a case note review and opinion survey) gathered the supporting evidence on which the final stage (a comparative experimental study) was based. This inductive approach allowed for an element of qualitative data collection and analysis in stages two and three, to determine paramedics' opinions of ETI. The final stage of the research project was carried out to systematically and rationally explore and compare four alternative intubation methods (after Berger* et al., *2009) and the preferred method for use in practice. The approach led to a robust methodological design to answer the research aims, whilst maintaining focus on the purpose of the research, conceptual framework and interrelationships among the methodological components (after Maxwell and Loomis, 2003 and Creswell and Plano Clark, 2011).

Figure 3-1 gives a diagrammatic representation of the methodological approaches taken at each stage, aligned with the aims and objectives.

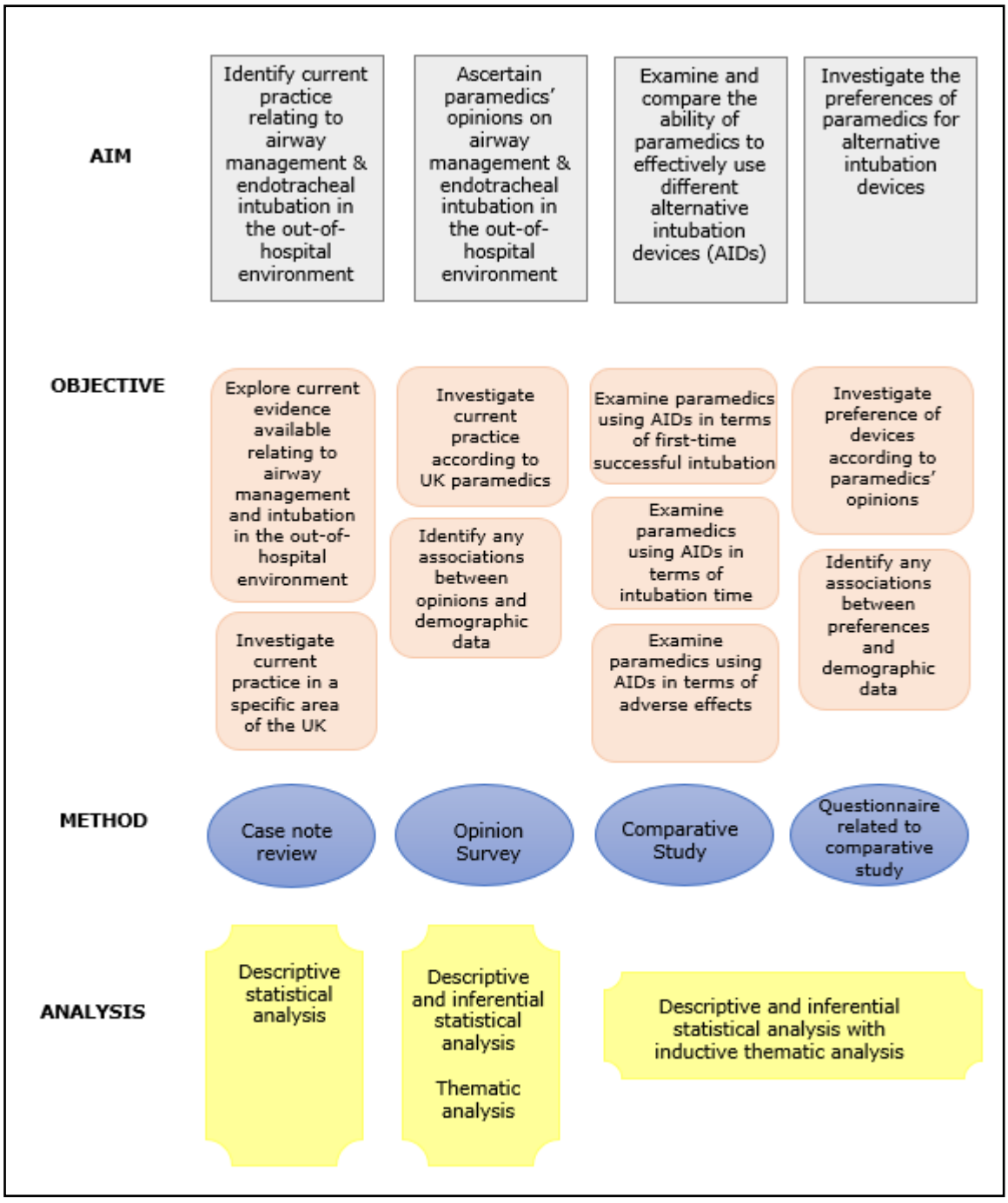


Figure 3-1: The association between methodologies, objectives, research approach and data analysis

3.2 Case note review (stage one)

A retrospective case note review was completed to explore airway practices in the out-of-hospital environment, whilst underpinning the subsequent stages of the project (the opinion survey and experimental study: see also Yin, 2009). The processes used in this method are outlined and justified in Section 3.2, alongside reflections on its application. A summary of the processes is presented in Figure 3-2.

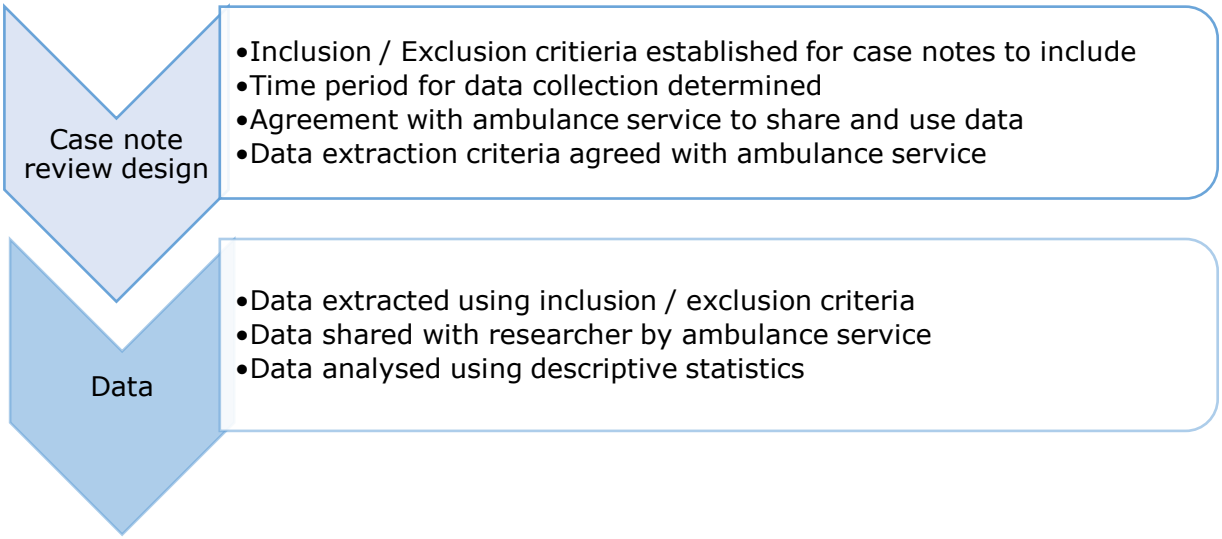


Figure 3-2: Case note review process (stage one)

Retrospective data were collected by asking specific questions of the case notes, identifying airway management and ETI practice in the out-of-hospital environment. It was not possible to audit the ETI practices, because there are currently no specific standards indicating when a patient should be intubated in the out-of-hospital environment. There are however, a number of guidelines and standards that are used elsewhere, for the preparation and procedures to be carried out during the process of intubation (Royal College of Anaesthetists (RCA), 2013); Association of Anaesthetists, 2017; Eastern Association for the Surgery of Trauma (EAST), 2002). Ambulance services use other guidelines for clinical practice, from the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) (Brown *et al.,* 2016) and the Resuscitation Council (UK) (2015). These guidelines give key indications for the clinical approach to intubation, as well as preparation and post intubation checks required.

The case note review offered salient data relating to airway management techniques used by paramedics in practice for patients in cardiac arrest in practice (after Crowe *et al.,* 2011; Green and Thorogood, 2013). The review therefore offered a real-world perspective of the practical application of care interventions drawing on the most detailed data available for study: case notes. Further, it allowed for an assessment of variations from

quality standards, as well as adverse incidents (Hutchinson *et al.,* 2010). It is understood that this method (that allows for descriptive accounts of practice) may not offer rich enough data about airway management techniques used for patients in cardiac arrest; largely related to difficulties in balancing internal and external validity, subjective interpretation and suboptimal documentation (see Yin, 1994; Denscombe, 1998; Ducket *et al.,* 2013; Phelan *et al.,* 2013). Suggestions have been made to overcome these limitations (Section 3.2.3-3.2.5 and Chapter Five) and the subsequent stages of the research are used to merge and build upon the findings from the case note review (see Sections 3.3 and 3.4). This method of triangulating methods provides a sound framework to address the research aims and objectives, offering a diverse and more comprehensive view of the phenomena (see Gorard and Taylor, 2004; Creswell and Plano Clark, 2011).

Patients in cardiac arrest were selected for review because, according to existing clinical guidelines (Resuscitation Council, 2015; Brown *et al.,* 2016), all of these patients should have had airway management intervention(s). It is important to note from the outset that quality care may be given, even when the patient's outcome is poor and vice versa. To help overcome any potential bias in the data arising from this reflection, all case notes that fell within the data collection timeframe were included (see Section 3.2.3), rather than solely patients with positive cardiac arrest outcomes. The area selected for study was the East Midlands region (Section 3.2.1) and the case notes resided with East Midlands Ambulance Service (EMAS), whose paramedics, emergency medical technicians and emergency care assistants, had provided the interventions and care for patients in cardiac arrest. Permission was obtained from EMAS for collation and sharing of relevant data, and the data were compiled for analysis by the research and development team at EMAS, in compliance with Trust governance requirements (see Section 3.2.4).

3.2.1 Region of study

Given the barriers to retrieving nationwide case notes, such as negotiating access to data from each ambulance service, the case note review was carried out in one region of the UK. The notes from one region are in some respects unique, though are also a single example of a broader class of notions (from Yin, 1994). It is recognised that studying notes from one region may be considered a limitation, in that the extent to which findings can be generalised to other areas may be restricted. The applicability of the findings from the case note review in the East Midlands region will depend on how much the sample shares with other regions in terms of patient profiles, geographical area, response times, level of response staff (for instance paramedic or emergency care technician). Studying case notes from one region has allowed for a focussed effort, limiting data collection to an area where out-of-hospital care is provided by one National Health Service (NHS) Trust. Therefore, has acknowledged that there are occasional differences between local

guidelines and policies which may affect decisions in airway management choices (for example, some ambulance services have taken the decision to withdraw ETI as a mandatory component of paramedic practice (London Ambulance Service (LAS), 2016)) and has provided insights, but limits generalisability. Inclusion and exclusion criteria were developed and a time frame set, to select the cases to be reviewed (see Sections 3.2.2 and 3.2.3). These methods could be reapplied in other regions of the UK.

3.2.2 Inclusion and exclusion criteria for case note selection

Inclusion and exclusion criteria were set to determine which patients' notes were to be reviewed, to reduce subjective bias (after Hutchinson *et al.*, 2010). An explanation of the criteria, alongside supportive justification, is offered in Table 3-1.

Table 3-1: Inclusion and exclusion criteria applied to case notes for the case note review

Criterion	Justification of criterion
Cases where patients have suffered a **cardiac arrest** were used.	Research and guidelines suggest intubation is gold standard airway management for patients in cardiac arrest[15].
Cases involving **adult** patients (above the age of 18) were used, cases involving paediatric patients were excluded.	Airway management of paediatric cardiac arrests non-comparable to adults and requires additional skills and equipment, which are not always available in the Urgent and Emergency Care setting (Bingham and Proctor, 2008; Resuscitation Council, 2015).
Cases where patients required **rapid sequence induction (RSI)**[16] were included (if the RSI took place).	If an airway was deemed to require intubating, this was an important consideration for the remit of this project; to establish whether an intubation took place.
Cases where patients were transferred to the nearest **specialist centre** (trauma or cardiac) were included.	Traumatic injuries feature on the list of reasons to intubate and these patients are considered entirely relevant to be included (Eastern Association for the Surgery of Trauma (EAST), 2002)

[15] Cook *et al.*, (2011); Wang *et al.*, (2012); Benoit *et al.*, (2015); Resuscitation Council, (2015); Brown *et al.*, (2016)

[16] RSI requires the administration of drugs prior to intubation and is practised in the prehospital environment by qualified professionals / paramedics.

3.2.3 Time period for data collection and extraction

A retrospective data collection period of twelve months was set to enable representative estimates of the data. Gathering data over this extensive period increases the likelihood of collecting data from a wider range of EMAS staff (after Weinger *et al.,* 2003), whilst still reflecting contemporary practice. When determining the data collection period, it was necessary to consider the National Airways-2 (Taylor *et al.*, 2016) (see Appendix-vii), which involved paramedics selecting either an endotracheal tube (ETT) or a supraglottic airway (SGA) device, for airway management in cardiac arrests. Collecting data during this period would distort any data that was to be extracted in the case note review, causing bias in the overview of current practice. Therefore, no data were extracted and reviewed during or after the Airways-2 trial period, which commenced in June 2015. The year preceding the trial was used, from April 2014 to March 2015. The criteria and the time period were agreed by EMAS and a data sharing agreement established.

3.2.4 Agreement with ambulance service

At the outset of the research, an agreement was reached with EMAS, to share retrospective data on airway management during cardiac arrests. This was revisited before data collection, to establish the researcher's requirements, data availability and the format the data would be presented in. It was made clear that procedures relating to airway management and intubation were the focus of the research. There was no intention to cause detriment to the ambulance service or paramedic professionals throughout the project. Ultimately, a final data sharing arrangement was completed (Appendix-viii), the ethical aspects and governance requirements of which are discussed in Section 3.5. The retrospective data were collected from all areas within EMAS, though was housed in a central data-base within the Trust.

3.2.5 Questions asked of the case notes selected for review

Objective questions were used to establish the data required for extraction from the case notes, relating to each cardiac arrest case that EMAS responders attended. The explicit (criterion-based) method, rather than selection on a pragmatic or circumstantial (implicit) basis was not deployed, to reduce bias in case selection (see Hutchinson *et al.*, 2010). The subsequent questions were asked to discover typical cases that responded to the initial aim of the research project (to identify current practice relating to airway management and ETI in the out-of-hospital environment). These were based on the literary content findings presented in Chapter Two (to minimise the influence of the researcher, after Bowling, 2014). The questions were agreed between the research and development team at EMAS and the researcher:

a) Which cardiac arrests attended by EMAS personnel were resuscitated?
b) Of the cardiac arrests, which airway devices were used during the resuscitation (case related)?
c) How many successful and unsuccessful intubations were performed (if intubation was selected for airway management)?
d) Were standards and guidelines followed during intubation procedures?

Due to the retrospective nature of the methods used, it was not possible to extract data to answer the fourth question as this information was not documented. As previously discussed, there are no set standards for out-of-hospital intubation by paramedics, though there are guidelines to follow (JRCALC guidelines, 2016; Resuscitation Council (UK), 2015). A statement from EMAS specifies[17]:
"with regards to guidelines, EMAS follows JRCALC and the UK Resus guidelines, which both use a stepwise approach in terms of airway management.
All clinical operational staff are expected to use this approach without question"
(EMAS, 2017, email correspondence)

The central data-base housing the data required for the case note review was only accessible to EMAS personnel and therefore it was not possible for the researcher to access and extract the data herself. The data extraction was made by a healthcare professional, working in research and development with EMAS. This, combined with the use of criteria, led to consistency in the data extracted (after Hutchinson *et al.,* 2010). The researcher requested that the data be presented in its rawest form, to allow for comprehensive case by case data analysis.

3.2.6 Data extraction, presentation and analysis

The data were provided to the author in a Microsoft Excel spreadsheet. Unfortunately, the data were not presented in its raw form, but in summary form; giving the number of patients suffering cardiac arrests, airway adjuncts used and intubation success rate (if attempted). The author made further requests for the raw data, however these were not successful. The availability and arrangement of data allowed for descriptive statistical analysis only.

The data were grouped according to: number of cardiac arrests, airway adjuncts used in cardiac arrest situations and number of successful airway management techniques (including endotracheal intubation). Because the data were not available on a case by

[17] In this statement 'clinical operational staff' refers to all ambulance response staff, including paramedics.

case basis, further analyses (to investigate associations for example) were not possible. Descriptive statistics were used to report on the data according to type and frequency of airway adjuncts used, as well as success rates of these and intubation. The results have been illustrated using graphs and charts in Section 4.2, with narrative explanations. The results are also discussed in conjunction with those of the opinion survey, to help explore and explain airway management practices (as per Creswell and Plano Clark, 2011) (see Chapter Five).

3.3 Opinion survey (stage two)

The aim of the second stage of the research was to ascertain paramedics' opinions on airway management and intubation. These were gathered using a structured questionnaire (Figure 3-4), with eight carefully considered questions, to ensure validity and reliability (see Carter *et al.,* 2000). This was disseminated online, using Bristol Online Surveys (BOS), 2015), to paramedics in the UK. Initially a convenience sample was used, with a chain referral technique to further disseminate the survey (Denscombe, 1998). Explanation of how the survey measured the construct of paramedic opinions on intubation, as well how the method was consistent and reproducible, are outlined in this section (after Carter *et al.,* 2000). Figure 3-3 provides a summary of the process.

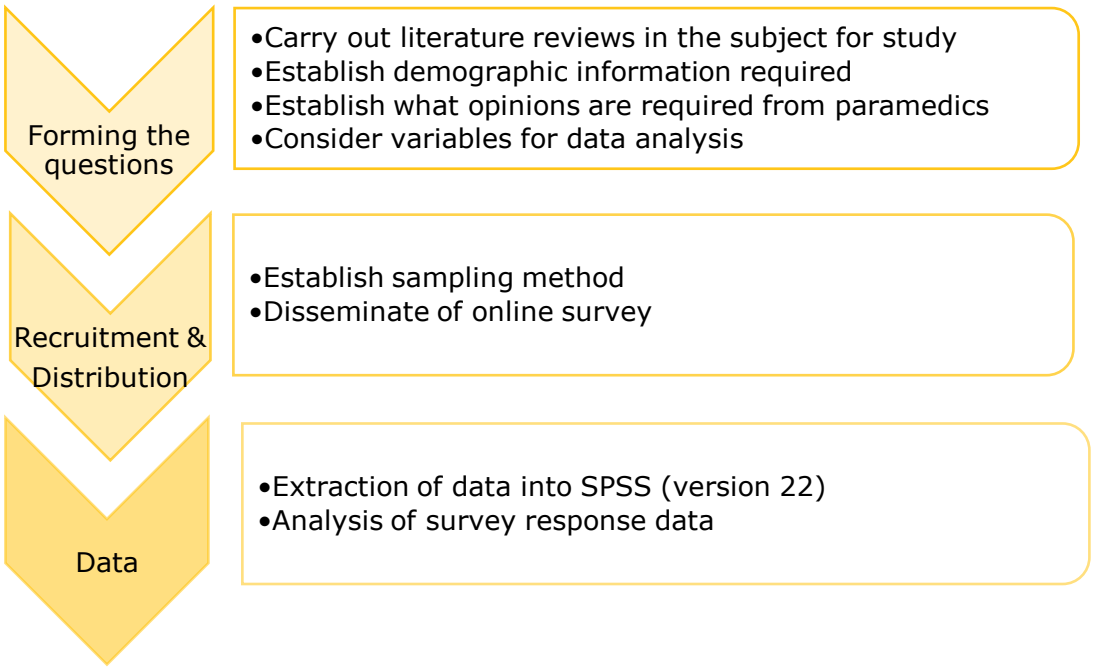


Figure 3-3: Opinion survey overview (stage 2)

A survey was considered to be an appropriate method to collect paramedics' opinions, given the nature of the research aims (after De Vaus, 2002). There are identified limitations and weakness in components of the survey method, which are explored. Structured survey questions allowed for a range of response types, leading to quantitative and qualitative data collection and analysis, to support the understanding of airway management situations and paramedic behaviours (see De Vaus, 2002).

3.3.1 Questions

A review of the key concepts and outcomes required of the research was carried out to guide the development of the questions (Figure 3-4).

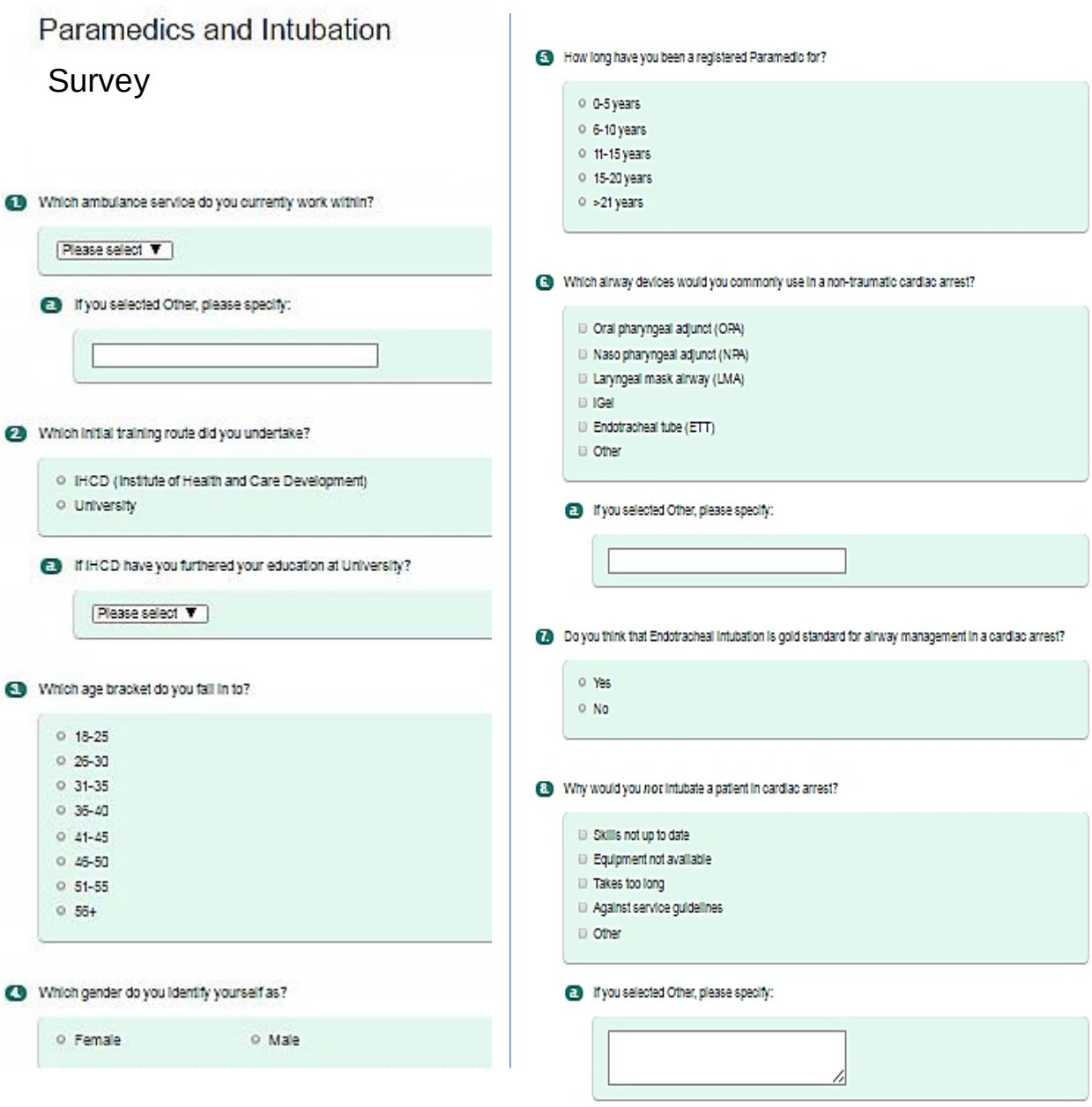


Figure 3-4: Questions used in the online opinion survey

The structured questions have occupational and professional relevance and gather contextual information, rather than generating new knowledge (as per Gough *et al.,* 2012). They allowed for the collection of valid, factual and descriptive information, relating to opinions on airway management and ETI, through construct validity (Bowling, 2014).

This was important to ensure the data collected were purposeful (Abbot and Sapsford, 1998). As suggested by Braun and Clarke (2013), the five initial demographic questions (which capture the characteristics of the survey participants) were placed at the beginning of the survey to ease the participant into the survey response process.

The final three questions had multiple choice answers: for accounts of practice, a perception of good practice and reasons for not performing intubation. Content validity was ensured by the author through acquired knowledge about the topic and further supported with peer expertise. A supervisor, who is expert in this field (Consultant anaesthetist), was asked to verify the questions to judge the relevance and accuracy (after Le May and Holmes, 2012). Face validity was imposed by sharing the questions with paramedic colleagues, which confirmed accurate interpretation of the questions. Because the survey was not posed to paramedics more than once and was anonymous, the test-retest reliability measure could not be used. However, offering participants anonymity when they complete surveys can afford an opportunity to gather honest accurate responses (see Lowe, 1993). Alongside this, an element of internal consistency helped to ensure reliability, by asking paramedics about whether they would intubate during a cardiac arrest and their opinion of gold standard airway management.

The survey was designed to be completed in a short timeframe (2-3 minutes), in order to ensure accuracy and consistency of the data collected, thus evoking reliability (see Bowling, 2014). This encouraged effective participation, given the brief time frame for focus and honest answers (see Creswell, 2013). Equivalence testing was not used due to time limitations. This may have increased reliability, however it could also have reduced the number of respondents with participants having to complete two surveys or a longer survey (after Le May and Homes, 2012).

The final question of the survey asked for reasons for not intubating in practice. This was a multiple-choice question, with the options given being drawn from the review of literature at the outset of the research. In order to ensure that any reasons that paramedics had for opting not to intubate were captured and to reduce the potential for researcher bias, an 'other' box was added, with the opportunity to enter an alternative response in their own words (free text). Although this may have led to short responses, using qualitative survey questions was an appropriate method of obtaining opinion related information from the respondents (Braun and Clarke, 2013). The inverse relationship between the quantity of data collected and the quality of that data, suggests that a larger number of respondents would produce strong, reliable evidence (Carter *et al.,* 2000).

3.3.2 Distribution and sampling

To recruit respondents, a chain referral method, also referred to as a snowball sampling technique, was used (after Denscombe, 1998 and Streeton *et al.*, 2004). The author distributed the survey link to a convenience sample of paramedics, who referred the link to further paramedics. The snowballing process was used effectively with the researcher having knowledge of the social situation under investigation and targeting registered paramedics. Other sampling methods, such as random sampling from a central register (as suggested by Abbott and Sapsford, 1998), were not possible due to the lack of a central register and data sharing issue. Snowball sampling was a practical method of reaching a wide range of voluntary respondents, that might otherwise be hard-to-reach given geographical and occupational limitations (see Heckathorn, 2011). At the same time, by using this sampling method, the recruitment process was taken out of the researcher's control after the initial round of direct contacts, reducing bias in terms of selection.

The potential for bias in referring the survey link along a line of contacts who may be giving similar information is acknowledged, though Streeton *et al.* (2004) suggest this weakness is balanced by the benefits of encompassing participants working in various geographical areas, which allowed for the collection of a range of opinions on airway management, from broader professional perspectives. A limitation of the method is that it cannot be relied on to recruit a probability sample, though for the purpose of this research a select group of voluntary respondents were required; registered paramedics working in clinical practice. Using a snowballing sampling technique in this instance aided the verification of the eligibility of respondents with paramedics referring to paramedic colleagues. However, despite the inclusion criteria being clearly stated at the beginning of the survey, this would not prevent a technician from answering the questions. It was also not possible to prevent participants from responding to the survey more than once, nor recognise if participants had as the responses were anonymous, which is a recognised limitation of the survey recruitment method.

Streeton *et al.* (2004) found that responses may increase when potential participants were referred by someone they knew and trusted, as per this research. The initial recruitment led to 164 responses and a second distribution was instigated when the comparative survey commenced (Figure 3-5). Participants were asked by the researcher if they would complete the online survey (if they had not already done so) and share the link with colleagues. The sample size was not predetermined, due to the permissive nature of chain sampling (see Abbot and Sapsford, 1998). The recruitment finished after a period of seven months, with a total of 181 paramedics completing the survey. A sample of this

size enables the estimation of the population percentage answering each question, to within approximately ±7%.

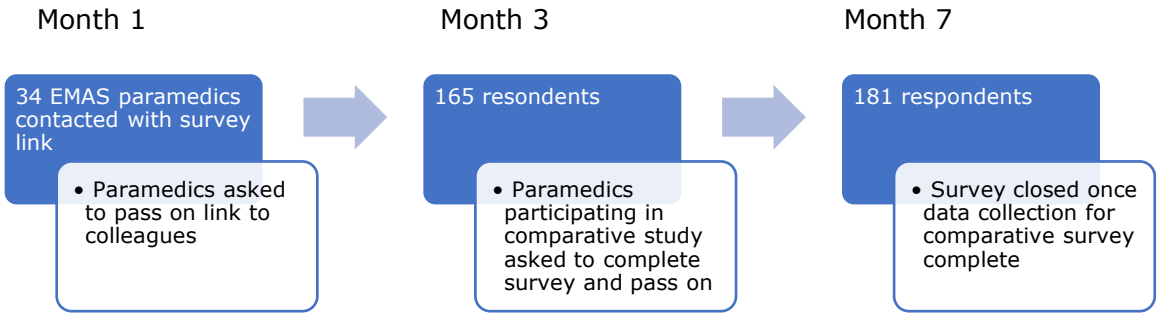


Figure 3-5: Overview of opinion survey recruitment and participation

3.3.3 Analysis of data

The data from the opinion survey were downloaded from the Bristol Online Survey platform, into SPSS version 22. Following coding, the data were checked for accuracy by using histograms to give a visual representation of frequencies. The design of the online questions ensured accuracy by using multiple choice options. A new variable was created to indicate those respondents that had studied at University (either as their initial training route or following their professional registration). As suggested by Carter *et al.* (2000), a list of variables (dependent and independent) and measures of influencing factors, were drawn up and used to plan potential relationships to be analysed (see Appendix-ix). The descriptive statistical tests used were frequency reporting for each question and the responses. The demographic information was cross tabulated with the opinion responses in questions six, seven and eight, using Chi-Square analysis, to establish any associations (as originally specified in the aims and objectives (Section 1.4)), results are presented in Section 4.3).

The final question in the survey allowed paramedics to suggest their own reasons for not intubating in cardiac arrest, these responses were analysed using inductive thematic analysis (after Clarke and Braun, 2013). Out of the 181 respondents, 99 opted to give an individual reason for not intubating. Each free text response was analysed to identify themes that enabled the capture of recurring patterns across the data set (after Patton, 1990). The themes are summarised and illustrated using quotations (see Section 4.3.5).

3.4 Comparative study (stage three)

There is limited existing published research on the use of alternative intubating methods by paramedics in the UK, hence there is no clear evidence as to the most effective for use in practice. The aim of this stage of the research was to examine and compare the ability of paramedics to effectively use alternative intubation devices. The review of the literature (Chapter Two) identified key elements that should be considered when measuring the effectiveness of AIDs, which were factored into the study design.

A prospective, experimental, comparative study was conducted, gathering quantitative and qualitative data, by means of a randomised repeated measures design (after Murad *et al.,* 2016). Throughout this section, explanations of the methods used to collect and analyse the data are given. Figure 3-6 gives a diagrammatic outline of these processes.

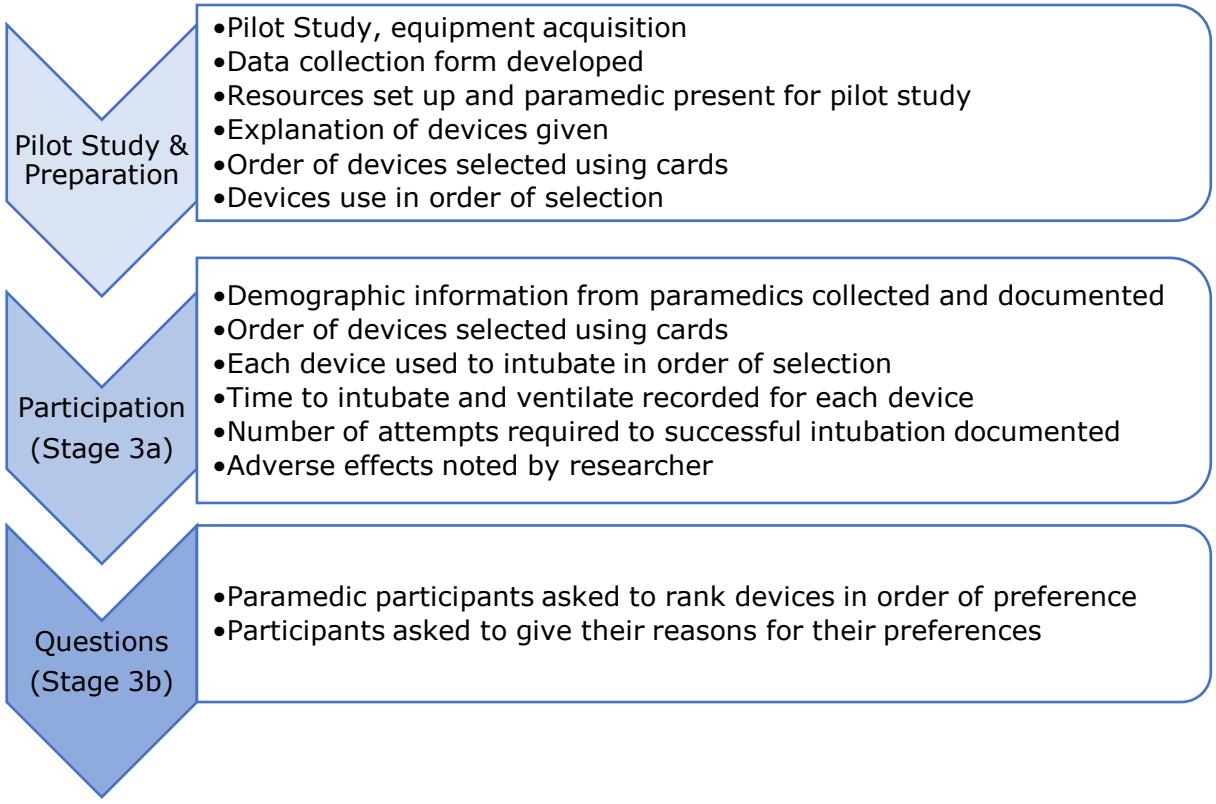


Figure 3-6: Process of prospective, experimental, comparative study (stage 3)

3.4.1 Equipment and preparation

Four methods of intubation were selected for comparison in this stage of the research project. The Airtraq device is a video-optic device, which allows the user to look down the top of the device into the airway, rather than into the patient's mouth. This device was selected due to its applicability to prehospital practice, combined video-optic design and

availability to the researcher. A retroglottic device (the Combitube) was included; the design of which allows for the tube to be passed behind the larynx and glottis (in the oesophagus). Different to supraglottic devices, a retroglottic device creates a seal above and below the laryngeal inlet, providing a direct conduit for ventilation (Laurin and Murphy, 2016). This device was considered appropriate, due to its extensive use worldwide as well as historic use in the UK, for comparison to other devices. An intubating laryngeal mask airway (iLMA) was included due to the lack of research carried out on this device, particularly in the prehospital environment. This technique involves the insertion of a supraglottic airway (the laryngeal mask airway (LMA)) and the passing of an endotracheal tube through the LMA. The aforementioned devices were compared to the fourth method; a standard blade laryngoscope. In this research a Macintosh blade was used, being a commonly used blade in UK frontline paramedic practice (on adult patients) (Gregory and Mursell, 2010).[18] The devices and a stop-watch were bought by the researcher and a mannikin head borrowed for the duration of the project. The researcher's personal portable computer was used to document collected data on a data collection form.

A data collection form was constructed in Microsoft Excel (Appendix-x). Sample characteristics were collected (age, gender, education background and experience of participants) to allow for analysis of associations with outcome variables, as specified in Section 3.4.4. The order of the devices was randomised to prevent serial bias and this was also documented on the data collection form. The measurements relating to the primary outcome variables of success rate and time to ventilate were documented, with author's notes on adverse effects observed during intubation attempts. The same data collection form was used to collate the paramedics' ranking of the devices and reasons for these, as well as any other comments. The data collection form was completed electronically and each column formatted to allow for coding at point of data entry to help reduce data inputting errors. Statements and comments made by the participants were input by the researcher as free text in the preference reasons and additional comments columns. These were recorded verbatim, with no prompting to prevent researcher influence. Data were checked at point of data entry for accuracy and again prior to data analysis. No personal identifiable data were collected on the electronic data collection form (see Section 3.5.5). The data collection process was tested in the pilot study.

A pilot study was carried out to help establish the processes to be used within the experimental, comparative study (as per Creswell, 2013). A paramedic who had not taken part in the online survey, nor would participate in the actual study, completed a pilot study

[18] The flexible scope fibreoptic method was not used in the research due to the associated equipment required for its use (which deems it unsuitable for prehospital practice).

with the author. Both practitioners followed the process outlined in Figure 3-6, to identify any procedural issues. The pilot study identified that the selection of devices and intubating a mannikin was not problematic, however the paramedics' knowledge of the devices was limited. The process of practising with the devices was discussed at length and it was decided that explanations of the devices in didactic and diagrammatic form would be used, rather than a 'practice'. This was largely due to time constraints; each participation session took around 12 minutes and it was expected that this would take longer with practitioners less familiar with the devices and research process. Alongside this, demographic data required inputting as well as the preference of the devices in ranked order, leading to further time taken. During the pilot study, minor amendments were made to the data collection form; the format of numbers inputted and an additional response to training background (to make similar to the opinion survey question used in stage two).

3.4.2 Recruitment, the sample and consent

The research took place among the paramedic population from East Midlands Ambulance Service (EMAS). For similar reasons to those presented in explanations of stage one (see Section 3.2) only paramedics in the East Midlands region were recruited for the comparative study and all practicing paramedics in this region were eligible to participate.

Paramedics were initially sampled using an expression of interest request at the end of the survey. However, this was not effective, with five paramedics expressing an interest in participating and just two of these partaking in the comparative study. Quota and convenience sampling were used to recruit participants, which were quick methods of sampling (from Teddlie and Yu, 2007) and a practical approach given limited resources in time and money available for the project. Paramedics that the researcher had recruited by word of mouth made contact and a suitable time to meet and participate was arranged. At the same time, the EMAS training and development lead and local ambulance clinical operations manager were approached and gave permission for the researcher to visit ambulance stations and training schools across the region, to carry out the experimental element of the study (see Appendix-xi). The nature of quota sampling allowed for representation of the requirements for this stage of the research (registered paramedics), with the advantage of just one category of participants being required (see Denscombe, 1998).

Other methods such as random sampling from a register of paramedics were considered, although ideally a stratified sampling method would have been used to ensure each paramedic in the region had an equal chance of being selected to participate. Both methods would have been likely to provide a representative cross-section of the

population. Unfortunately, a central register was not available to select from and given the nature of shift times, the fact that paramedics were taking part in their own time and the limited time and money available to the researcher, random and stratified sampling methods were not possible. To demonstrate that a representative sample was generated (using convenience sampling) and that paramedics were not purposefully sampled according to certain characteristics, demographic information was collected from the participants. These data were analysed using descriptive statistics (see Section 3.4.6) and further interpreted and discussed in relation to the opinion responses given.

It is reasonable to select the most convenient sampling method when there are equally valid methodological options (after Denscombe, 1998), though it is recognised that the convenience sampling method does not justify the selection of participants. Using alternative sampling methods, a pre-determined sample size would have been calculated and used to determine the number of participants required. This was employed by the researcher, to ensure rigour and reduce potential bias in this stage of the research.

An *a priori* calculation was performed at the research design stage in order to determine the sample size required for this experimental study. A repeated measures design was used, where the outcomes for several devices could be compared pairwise for the same participant. The standard deviation of the difference in means for the primary outcome measures was not known in advance and so the required sample size was calculated using minimum detectable difference expressed in terms of the effect size (Cohen's d: the standardised difference in the means (Cohen, 1988)). An effect size of d=0.3 was chosen to represent a small-to-medium difference. The calculation was performed for a paired t-test of two means (i.e. between two devices). A sample size of 71 data pairs from a population of 1000 achieves 80% power to detect a mean of paired differences of 0.3 with an estimated standard deviation of differences of 1.0 and with a significance level (alpha) of 0.05 using a two-sided paired t-test.

Following recruitment, explicit consent was obtained. Those opting to participate in the comparative study were asked to read the participant information sheet and to complete a consent form (Appendix-xii). Further details on ethical considerations and governance are presented in Section 3.5. Paramedics were advised that they were participating in their own time and there was no materialistic incentive, or pressure to partake. It was also made clear (with prior agreement from EMAS), that there would be no impact on their employment. The recruitment and sampling strategy was successful, with paramedics participating out of interest and free-will (after Bowling, 2014). Seventy-two paramedics were recruited, exceeding the target sample size by one.

3.4.3 Data collection

The participants used each of four intubation methods[19] on a mannikin whilst being observed and timed. Figure 3-7 illustrates the equipment used and processes employed for data collection. The participants randomly selected covered cards (closed envelope technique) to identify the order in which they would use the devices, thus preventing serial bias (after Bowling, 2014) and used each device to intubate (size 6.0 endotracheal tubes were provided for use with the Airtraq, iLMA and MBL).

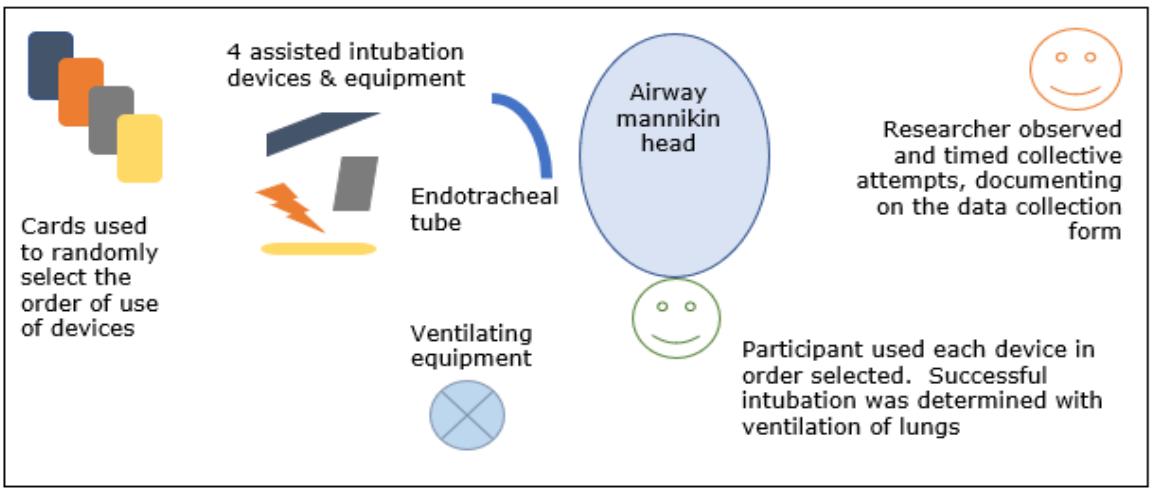


Figure 3-7: Equipment and processes used for comparative study data collection

All participating paramedics were familiar with a Macintosh blade laryngoscope (MBL), though not the other devices (the Airtraq, Combitube and intubating laryngeal mask airway (iLMA)). The MBL technique is currently taught and used in practice nationally. Given the scope and resource limitations of the research project, it was not possible to offer training in the remaining techniques which is notably a limitation of this type of study design. In an attempt to lessen the impact of this difference a brief explanation of the devices and how they work was given to all participants prior to their use, as well as sight of the mannikin that was used for the simulation. Practice attempts were not permitted, and this was consistently applied, to prevent recall or memory bias.

The time taken, number of attempts needed for successful intubation and any adverse effects (for example excessive force used) were logged on the data collection spreadsheet in Microsoft Excel. Time was measured from ceasing simulated oxygen administration with ventilation via a bag valve mask, to lung inflation from simulated ventilation[20]. The

[19] A Macintosh blade laryngoscope (MBL), Airtraq, Combitube and intubating laryngeal mask airway (iLMA)
[20] This emerged as weakness in the study design, discussed in Section 6.2.

number of attempts required to successfully intubate and overall success rate were recorded. A maximum of three attempts for each device was allowed, which follows practice guidelines for intubation (Royal College of Anaesthetists, 2013; Association of Anaesthetists, 2017). If intubation was still unsuccessful after three attempts this was recorded as an unsuccessful intubation. If participants did not proceed to use all attempts following unsuccessful intubation, this was also documented. Throughout the experimental study, a gum elastic bougie was made available for paramedics to use if they wished.

Once each method or device had been used, the paramedics were asked to rank the devices in order of preference, number one being the most preferred and number four the least favourite. They were then asked to give a reason for their choice, as well as any other comments on the devices, which were again documented on the data collection form. The researcher also kept brief observational notes on the actions of participants during their attempts, alongside any commentary that they shared.

3.4.4 Analysis of data

Data from the spreadsheet were imported into SPSS version 22. The data were checked for accuracy (by using histograms to give a visual representation of frequencies) and restructured for analysis. A binary categorical variable was created to represent the 'success or failure' of each device.

The quantitative data were reported on using descriptive statistical analysis, with frequency reporting for the demographic information and the variables relating to success rate and time. To compare success rate, a Cochran's Q test was used and pairwise post hoc tests were performed to investigate any differences between devices. To compare attempts required for intubations between the devices, an analysis of variance (ANOVA) was used to perform a repeated measures comparison.

The mean time to intubate with each device was reported on using the time taken to intubate with all attempts and again with just successful attempts. To compare time to intubate, a repeated measures ANOVA was performed with four conditions (the devices) and no within subject factors. This test was again applied to the data set with all the attempts, as well as just the successful attempts. Mean time difference significance and 95% upper and lower confidence intervals for differences were reported on. The median values for preference rankings given by paramedics were calculated and comparisons made using an ANOVA for repeated measures. The preferences and some of the demographic variables (age, training background and number of years' experience) were correlated using a chi square tests to establish any associations.

Data collection and transcription of free text, qualitative data, was completed by the researcher, using inductive thematic analysis (after Braun and Clarke, 2006). The thematic analysis was data-driven, not complying to any pre-existing coding frame. The comments were read, reviewed and coded using recurring patterns across the data set (see Patton, 1990). The analysis was then re-focused at a broader level, by collating the coded statements into themes (as per Braun and Clarke, 2013). The main themes that emerged were; process of intubation, outcome of intubation, training and exposure to the alternative intubation devices and user friendliness, which related to reasons for most and least preferred devices. Final analysis was present in the narrative write-up of the themed statements and extracts from paramedics' statements have been included (see Section 4.4.6).

3.5 Ethical considerations

The previous sections in this chapter have explained and justified the data collection, recruitment sampling and data analysis methods used in the research. To demonstrate it is also ethically sound, an overview of how local and national ethical guidelines and theories were examined and followed is outlined in Section 3.5, discussed in relation to the methods justified above.

This research project poses a range of ethical challenges, requiring the researcher to examine personal actions, beliefs and values (see Section 3.5.5). The design of the research was underpinned by critical engagement with potential harms and benefits, conflicts and agreements and the justification of decisions (after Comstock, 2016). The multi-faceted nature of the methods entailed various sampling and data collection techniques, with changing levels of participant involvement at each stage of the method. These issues have been systematically interrogated, in relation to participants, data and the researcher, to ensure right and good methodological ethical practice (see Sections 3.5.1 to 3.5.6).

A series of ethical considerations were presented in the initial research proposal which was duly submitted to the Research Ethics Committee (REC) at the University of Northampton. Agreement from the REC ensured certainty and confidence that institutional ethical guidelines had been planned for, in order that no harm would come to participants or the researcher in completion of the research. Ethical review from a Health Research Authority Research Ethics Committee were checked and ethical opinion was not required from the NHS REC for various reasons (NHS HRA REC, 2017) (Appendix-xiii). At all times throughout the research, the codes of conduct from the Nursing and Midwifery Council (NMC) and the Health and Care Professions Council (HCPC) were adhered to (HCPC, 2012; NMC, 2018).

3.5.1 Participants: Recruitment and Rights

There were no patients or vulnerable participants; no people with learning difficulties or disabilities, nor children used in the research. The case note review incorporated the notes of adults over the age of 18 years and the opinion survey and comparative study used NHS paramedic participants, who gave consent before participating (see Section 3.5.3).

The case note review was classified as a service evaluation by the Medical Research Council (MRC, 2017) therefore did not require ethical review from the HRA (NHS) REC. Data were collected about patients suffering cardiac arrests and airway management during the clinical cases. Throughout the case note review, anonymity and confidentiality were

maintained; the researcher was given data which was anonymised at source by EMAS, in line with best ethical practice (Sapsford and Abbott, 2006; Biggs, 2010).

The opinion survey and comparative study recruited NHS staff (registered paramedics) as participants, through convenience and snowball sampling (after Denscombe, 1998). In the online survey, the information collected was again both confidential and anonymous (Sapsford and Abbott, 2006; Biggs, 2010). Paramedics had a right to be included in the research and the survey was not exclusive; sharing of the link to the survey was encouraged between paramedic colleagues working with ambulance services in the UK (as per Long and Johnson, 2007).

In the comparative study, solely EMAS paramedics were asked to participate. Confidentiality was maintained; only the researcher and the paramedic knew of the data collected at this stage. This presented some benefits, in that any further comments could be added to a participant's data set by the researcher at a later point if required (after Bell and Waters, 2014). The researcher kept a record of a participant number, in relation to participant, using a secure technique[21]. This alternative with data checking and these records were destroyed following data checking and analysis. Statements pertaining to confidentiality and the use of data were made clear in the information sheet, prior to gaining explicit consent from the participant (Appendix-xii). There was a participant right to withdraw from the research project at any time prior to data collection (after Biggs, 2010). It was made clear in the information sheet that once a participant had taken part, the anonymised data would be used for analysis.

A risk assessment of the research was undertaken and there were no major risks, nor identified personal benefit for paramedics participating. The potential degree of harm envisaged for participants was low, the risk being possible distress caused by asking questions about one's experiences and demographic information data collection (Department of Health (DOH), 2005). The researcher is a skilled communicator and healthcare professional with 17 years' experience in practice, able to identify distress or difficulties and handle situations using effective interpersonal skills.

3.5.2 Consent

The principle of informed consent was used as a protective element for participants in this research (after Comstock, 2016). For the opinion survey, participants were deemed to have consented to participate after they had accessed the briefing page and proceeded

[21] Coded initials and the environment was used to record participant number in relation to participant

through to the questions. It was made clear that once their answers were submitted, it was not possible to remove them. The initial information also explained that the responses given would be anonymous and confidential. It is recognised that consent may have been given for altruistic reasons, in that there may be a benefit to others in changing future practice (Smith, 2003).

For the comparative study, an information sheet was used and the boundaries relating to confidentiality and use of the data for the purposes of research made clear (after DePoy and Gitlin, 2007) (Appendix-xii). Participants were deemed to be competent, able to decide for themselves and were not coerced into participating (Long and Johnson, 2007). Consent was given with verbal agreement and continuation with the comparative study. It could be argued that written consent should have been gained, though this would have led to personal identifiable data being collected, thus increasing data security risks.

The importance of protecting participants and their views was not undermined, as recommended by Biggs (2010). To support participants, contact details of the researcher were provided at every opportunity (including on the electronic survey and participant information sheet), to support further information requests of participants.

3.5.3 Data management

All the data collected was relevant and for use in this research only. The data collected in the retrospective case note review contained no personal identifiable information of patient or practitioner, therefore no participants in stage one of the research were distinguished from others (as per the Data Protection Act (DPA), 1998 (Gov.UK, 2018), which was the leading data protection legislation at the time that the research was carried out). The data sharing agreement that had been drawn up by the researcher and EMAS was adhered to and the researcher agreed to terms set by the ambulance service, which stated that data protection legislation would be followed throughout the research project.

In the opinion survey and comparative study, primary data were collected and again there was no personal identifiable information in any of the data collection forms. The data were used to identify sample characteristics that might be associated with results, such as age or experience, none of which would have an ill effect on the participants or organisations involved in the research. The individual's right to privacy, in particular with respect to the opinions that they shared, was sustained throughout the research project (after Bell and Waters, 2014).

Questions posed to the participants following the comparative study (stage three) asked for the devices to be ranked, with reasons for preferences. The study was designed to ensure that participants could articulate, as freely as possible, their opinion. The researcher did not pose judgement on these statements and at the same time confidentiality was maintained. If, during intubation attempts, dangerous practice was witnessed, the researcher proposed to disclose this to the head of training and development at EMAS. Participants were made aware of this limit of confidentiality during the informed consent process.

3.5.4 Conduct of the research and data storage

The researcher worked within local and national guidelines set by the University of Northampton, NMC and HCPC (HCPC, 2012; NMC, 2018). Further to this, advice and guidance was taken from the head of clinical governance, audit and research at EMAS, as well as from academic supervisors. Although ethical review was not required from the NHS REC, the researcher worked within the research governance framework at all times (DOH, 2005).

The Freedom of Information (FOIA) (2000) and Data Protection Acts (DPA) (1998) both have clauses that relate to personal data, which was neither collected nor stored. However, the clauses underpin the principles of non-identifiable data used and stored for throughout this research project. The eight key principles given by the DPA about information storage were adhered to and the data were processed and stored with ethical integrity (Gov.UK, 2018) (Appendix-xiv).

The raw data were low risk to participants and would not harm the ambulance service or University's reputation. Data were stored securely by the researcher, in password protected files accessible only by the researcher. The electronically stored data will be destroyed and deleted no longer than three years post-successful completion of the award.

3.5.5 The researcher

The author reflected on personal and professional obligations throughout the research to ensure an ethically balanced approach (as per Bell and Waters, 2014) and to minimise risks of bias. Upholding personal and professional integrity and personal morals was imperative throughout the research process (after Doherty and Purtilo, 2016). As an Emergency Nurse and an educator within the field of urgent, emergency and paramedical practice, the researcher had a duty to uphold the Nursing and Midwifery code and professional standards of practice (NMC, 2018). Through both roles the researcher has gained knowledge and insight into airway management techniques used both in and out of hospital and is able to reflect on clinical decisions made and justify approaches used.

The researcher's own values and morals, which include traits such as honesty and dependability, as well as preventing harm and providing good) have been upheld throughout the research process and are central defensible approaches to research (Long and Johnson, 2007).

It is understood that researchers are also exposed to potential harm, which has been minimised throughout this research project. For example, at no point was the researcher lone working when collecting data, as this was always carried out in a safe familiar environment[22]. This ensured that should a participant become distressed or angry, the researcher was protected in the form of other professionals nearby. Contact was made using the researcher's mobile telephone, to contact people known to the participant only. Personal telephone numbers or address details were not divulged to other participants, though the email and work address of the researcher was clear. The email address used was solely for use during the research project by the researcher, in a student capacity.

3.5.6 Researcher positionality

Throughout the thesis and in particular in the discussion chapter (Chapter Five), the issue of positionality and therefore potential bias (in terms of researcher subjectivity) has been considered. Bias as an inclination or prejudice for or against one position, is more prominently related to qualitative research (and non-positivist studies), though the notion has been considered throughout this thesis. The researcher understands that bias exists in all research across study designs, for example design bias, selection/participant bias, data collection, measurement or analysis bias. Researcher bias is defined as personal experiences, ideas, prejudices and personal philosophies, which may affect the research outcomes (see Smith and Noble, 2014). Further, knowledge relating to effective patient care, clinical practice and professional understanding are consequences of positionality (reflecting the personal beliefs and motives the author may have) (after Sánchez, 2010). These have been examined through the principle of reflexivity. Several possible biases have been considered (listed above), leading to the modification of wording in each chapter to ensure suggestive outcomes are not made. A systematic literature review approach (using the PRISMA guidelines) was used to extract the papers that support the rationale for the study. The aims have been continually scrutinised to ensure that they offered a neutral stance, as were the questions posed at the beginning of the literature reviews. The reflective process allowed for revision of the thesis and the removal of leading phrases or wording.

[22] The areas used were ambulance stations, training school rooms, University classrooms and the researchers place of work.

Study design and methodological approaches have the potential for introducing bias. This was taken into account in the planning of each stage of the study, where the research methods and processes were critically analysed (after Green and Thorogood, 2009). The methods used have attempted to minimise any potential bias through sampling and sample sizes. Some potential biases have been identified in stages two and three of the study, where participants were actively involved. In stage two (opinion survey), despite the consideration of the validity and reliability of the survey, some of the questions asked may have been interpreted as 'leading' questions. For example, questions six 'which airway devices would you commonly use in a non-traumatic cardiac arrest?' suggests that airway devices would be used in OHCA. Question seven asks if paramedics 'think that endotracheal intubation is gold standard for airway management in cardiac arrest', again implying that there is a gold standard airway management practice for patients in OHCA. Much as some of the evidence presented in Chapter Two supports this, the conclusion of the literature review is that the choice of airway management technique in OHCA remains controversial. The final survey question asked 'why would you not intubate a patient in cardiac arrest', which may also be considered leading in terms of wording used. The analysis of the qualitative responses followed the principles and practice for thematic analysis. The themes were extracted from the survey text with due regard to researcher positionality.

In stage three of the study, the participants were asked to rank the AIDs in order of preference and justify this in their own words. Not priming the participants with words or ideas helped to prevent bias or influence from the researcher or through leading or question-order bias (see Chapter 3.4), which has been further reflected upon in Chapter 5.4. The reflexive approach has helped to validate the discussions within the thesis (after Mantzoukas, 2005) and enabled identification of the limitations and weaknesses, particularly in stages two and three of the study. It is suggested that the biases that have emerged through this process could be addressed in future research (see Chapter 6.3).

3.5.7 Dissemination

The researcher maintains responsibility for the results of the research and dissemination of these. When considering the ethics around research dissemination, the researcher acknowledges that papers of a similar nature may be submitted to satisfy professionals, patients and other researchers as readers. Additional forms of dissemination may include conferences, which will reveal similar concepts to the original piece of work. The original piece of work with minimal modifications (to prevent self-plagiarism) will be used with all dissemination methods (after Long and Johnson, 2007).

3.6 Summary

This chapter has introduced the three-stage approach used to meet the research aims and objectives outlined in Chapter One. The distinct methods used for the research built upon and combined methodologies at each stage and follow a dynamic, positivist approach, underpinning the reality of airway management and systematically exploring the phenomenon (Shanks and Parr, 2003). A comprehensive overview of the association between method, objective, research approach and analysis has been provided, with explanations of how the research design uses primarily quantitative data collection methods and incorporates elements of qualitative data analysis.

A case note review at stage one was appropriate to gather retrospective data, providing an overview of current practices relating to airway management in the prehospital environment (Crowe *et al.,* 2011; Yin, 2009). The retrospective nature allowed for data to be collected from the East Midlands region in the UK. Using one area in the UK accounted for occasional differences between local guidelines and policies, which may have affected decisions in airway management choices. However, it is recognised that studying notes from one region may limit the extent to which findings can be generalised to other areas. The inclusion criteria discounted children from the research, though included adults in cardiac arrest and traumatic cardiac arrest patients, focussing on the airway management during the events (Resuscitation Council, 2015). Collaboration with the ambulance service (EMAS) for data sharing and governance agreements, was a key element of this stage. Questions and criteria were developed for data extraction, that befitted both the researcher and EMAS (after Hutchinson *et al.,* 2010). Data were collected over a period of a year, avoiding the national Airways-2 trial, which commenced in June 2015. Data were extracted and presented to the author in the form of summarised information, on a spreadsheet. Unfortunately, raw data were not able to be extracted and presented. Data were analysed using appropriate descriptive statistics, to report on the data according to type, frequency and success rates of airway adjuncts used.

An online survey was used to gather data from paramedics on their opinions of airway management and endotracheal intubation in practice. This was deemed the most appropriate method to provide rich data from the population (as per De Vaus, 2002 and McNeil and Chapman, 2005). The eight questions were carefully constructed to ensure reliability and validity in results, to generate new knowledge. The survey was short in length which was likely to lead to a higher number of respondents (Creswell, 2013). Distribution was via a chain referral sampling technique, beginning with paramedic practitioners accessed by the researcher and these paramedics referring the survey link to practitioner colleagues. Voluntary responses lead to 181 respondents completing the

survey. The demographic data were presented using descriptive frequency reporting in SPSS version 22, with Chi-square tests used to compare the demographic and opinion related variables. The free text responses in the final question were extracted and analysed using inductive thematic analysis (after Braun and Clarke, 2006).

A prospective comparative study was carried out in stage three, to examine and compare the use of alternative intubating methods by paramedics. Equipment was gathered and preparations made, to carry out a pilot study and develop a comprehensive data collection form. A cohort of 72 paramedics from East Midlands Ambulance Service (EMAS) were recruited, using a quota and convenience sampling methods. An information briefing sheet informed the participants of the study and consent was explicit by continuing to partake in the research. Participants were given a brief explanation of each device, before selecting the devices in a random order, to prevent serial bias. The paramedics were asked to intubate a mannikin head using each alternative intubation device, to the point of lung ventilation. Predominantly quantitative data were collected, though quantitative methods were used to gather a small but meaningful selection of data for qualitative analysis, in order to explore findings (after Creswell and Plano Clark, 2011). Data were analysed in SPSS and frequency reporting carried out on the demographic information, device success rates and mean times to intubate. Inferential statistical analyses were carried out, including Cochran's Q tests and analysis of variances to further examine the data. Inductive thematic analysis was applied to the free text comments, first by coding responses, before broad themes emerged for reasons given for most and least favoured devices (after Braun and Clarke, 2006).

Section 3.5 outlined the ethical dimensions considered throughout the methods employed during the research. No vulnerable groups were recruited and personable identifiable data were not collected. The need for NHS HRA REC (NHS, 2017) approval was negated, though local agreement was sought and agreed from the REC at the University of Northampton. Codes of ethics and conduct from professional bodies, namely the NMC and HCPC, were adhered to (HCPC, 2012; NMC, 2018). The recruitment process saw no wrongs with allowing participants that fitted the criteria to be included in the research, in accordance with their right to participate. At the same time, informed consent was gained and the participants demonstrated explicit consent at stages two and three of the research. Storage of data met DPA (1998) legislation and no personal identifiable information was stored or shared throughout the research project. The researcher undertook responsibility for protecting participants as well as herself whilst collecting and disseminating research findings. The methods outlined in this chapter were followed, encompassing the ethical considerations explained. The results of the data analyses from each stage are presented in the following chapter.

Chapter 4 Results

4.1 Introduction

The previous chapter gave detailed accounts of the methods and ethical considerations applied to collect and analyse the data. A three-stage approach was undertaken: a case note review, opinion survey and an experimental comparative study, which led to the collection of predominantly quantitative, with a small amount of qualitative, data. The results of the data analyses are presented in this chapter and discussed in Chapter Five, in the context of the existing literature (presented in Chapter Two).

4.2 Results of the case note review (stage one)

The aim of the case note review was to discover current practice relating to airway management and intubation in the prehospital environment (Section 3.2). Data were gathered about the cardiac arrests that East Midlands Ambulance Service (EMAS) attended over the period of a year and the airway management techniques used during resuscitation attempts. Unfortunately, data collection and sharing limitations did not allow the collection of raw data from each cardiac arrest case. Instead, summary data were provided, which allowed for descriptive statistical analysis only.

4.2.1 Airway devices used in cardiac arrest

Throughout the year, EMAS personnel attended a total of 3,872 cardiac arrests, of which, 2,779 (72%) patients had resuscitation methods delivered. Data were provided on the airway adjuncts[23] used and the success rate of these during the cardiopulmonary resuscitation attempts (Figure 4-1). A total of 3,065 airway devices were used (more than one airway adjunct may have been used in each arrest, if a step-wise approach was taken to airway management). For the simple airway adjuncts; 493 (17.6%) of patients received an oropharyngeal airway (OPA) and 69 (2.4%) of patients had a nasopharyngeal airway (NPA) inserted. The success rates were; 99.4% for OPA and 95.7% for NPA insertions. Supraglottic airways (SGAs) were also used (see Section 4.2.2), these airways are generally used in prehospital clinical practice after or instead of simple airway adjuncts and before endotracheal intubation (ETI), in the step-wise airway management approach. Endotracheal tubes were the most commonly used airway devices (n=1,157) and had the lowest success rate (see Section 4.2.3).

[23] The airway adjuncts included oropharyngeal (OPA) and nasopharyngeal (NPA) airways, supraglottic devices (SGA); laryngeal mask airways (LMA) or iGels and Endotracheal Tubes (ETTs).

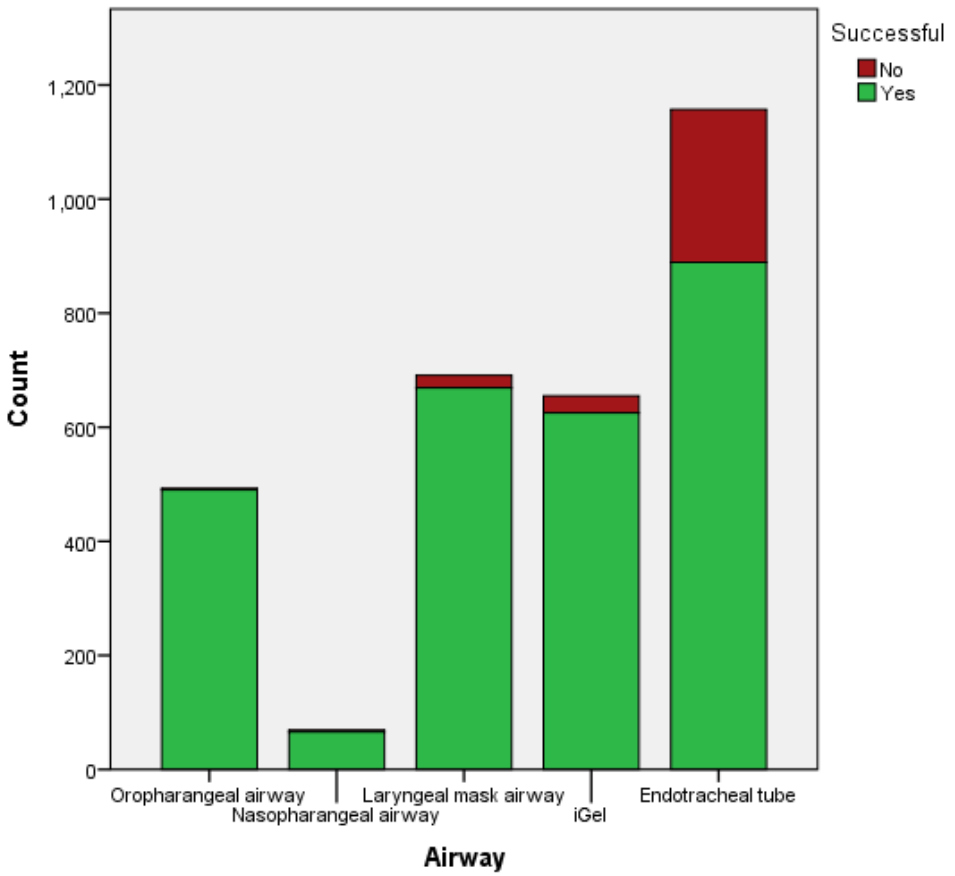


Figure 4-1: Frequency of airway devices used during cardiac arrest, with numbers of successful and unsuccessful uses

4.2.2 Supraglottic airway devices used for patients in cardiac arrest

It was not possible to determine whether the personnel that attended the cardiac arrest were emergency care assistants (ECA), emergency medical technicians (EMT) or paramedics. ECAs and EMTs do not intubate as part of their skill set, though are able to insert supraglottic airways (a Laryngeal Mask Airway (LMA) or iGel). The data indicates that a LMA was used in 691 (24.9%) and an iGel in 655 (23.6%) of cardiopulmonary resuscitations (see Appendix-xv). The data show that in total, less than half the patients in resuscitated cardiac arrest had a SGA inserted (n=1,346, 48.4%), success rates were 97% (LMAs) and 95% (iGels).

4.2.3 Endotracheal intubation for patients in cardiac arrest

The number of ETI attempts made during cardiac arrests over the data collection period was 1,157 (41.6%) (Figure 4-2), of which 268 (23.2%) were unsuccessful (Figure 4-3). Consequently, less than a third of the 2,779 patients in cardiac arrest were successfully intubated (n=889, 32%).

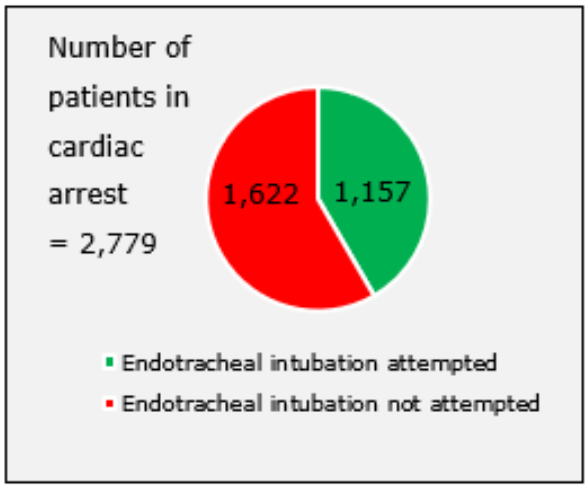


Figure 4-2: Endotracheal intubation attempts for patients in cardiac arrest

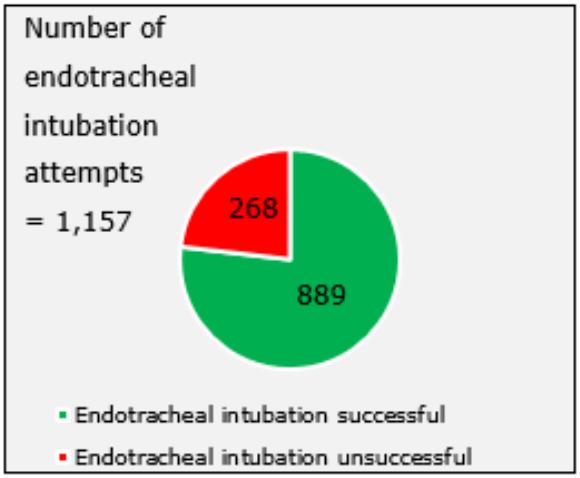


Figure 4-3: Successful and unsuccessful endotracheal intubation attempts

4.3 Results of opinion survey (stage two)

The case note review showed that a high proportion of patients were not successfully intubated but there were no data that might suggest why this might be the case. Stage two of the research project explored paramedics' personal experience and opinions of ETI. Information was collected from paramedics across the country using a survey (see Section 3.3), the results of which are presented subsequently. A total of 181 participants who responded to the survey were recruited using a snowball sampling technique (as outlined in Section 3.3.2).

4.3.1 Sample characteristics

The initial five questions of the survey asked for demographic information[24] to establish the characteristics of the sample, as well as enabling further analysis of paramedics' opinions. Most of the respondents were from East Midlands Ambulance Service (EMAS) (n=125, 69%), with a further seven NHS ambulance Trusts represented in the sample (Appendix-xvi). There were four respondents who selected 'other' for the service they work for; two of these were hospital based and two were critical care paramedics working with a charity.

There were approximately equal proportions of men and women among the paramedic respondents: 47% female and 53% male. The age range, rather than actual age, was requested in the survey question. The respondents had a positively skewed age distribution (Figure 4-4), with over half (n=96, 53%) between the age of 18 and 35 years old. This distribution was similar to that of the number of years' experience the respondents had (Figure 4-5). Over half of the respondents had less than six years' experience as a paramedic (n=93, 51.4%).

[24] Demographic information collected: the ambulance service worked for, age group, gender, training background and number of years' experience.

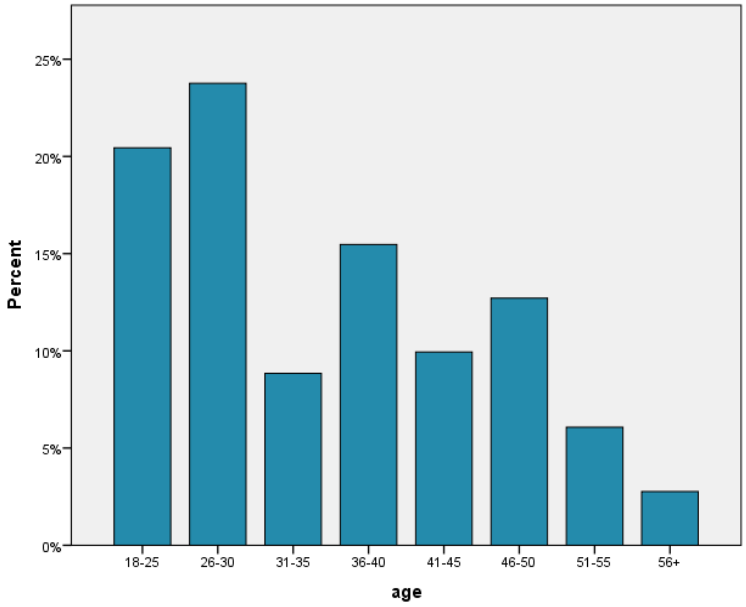


Figure 4-4: Distribution of age of opinion survey respondents

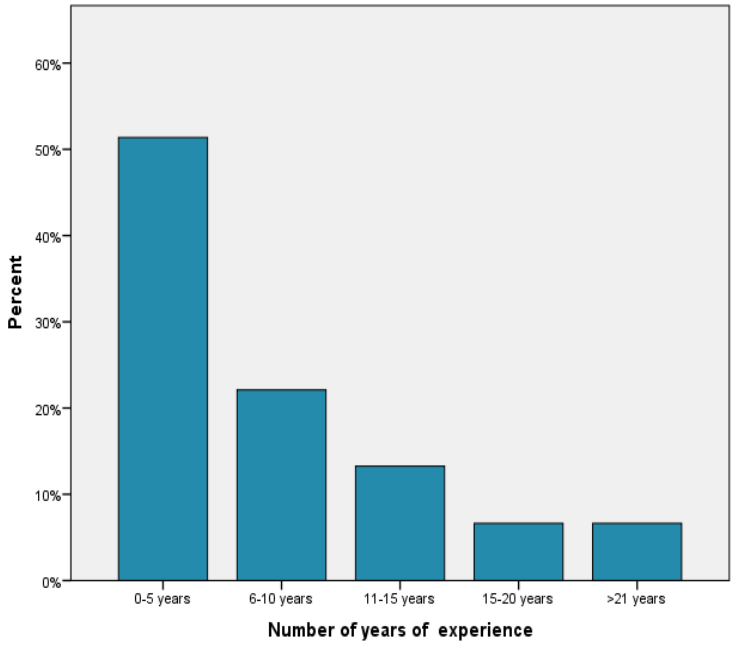


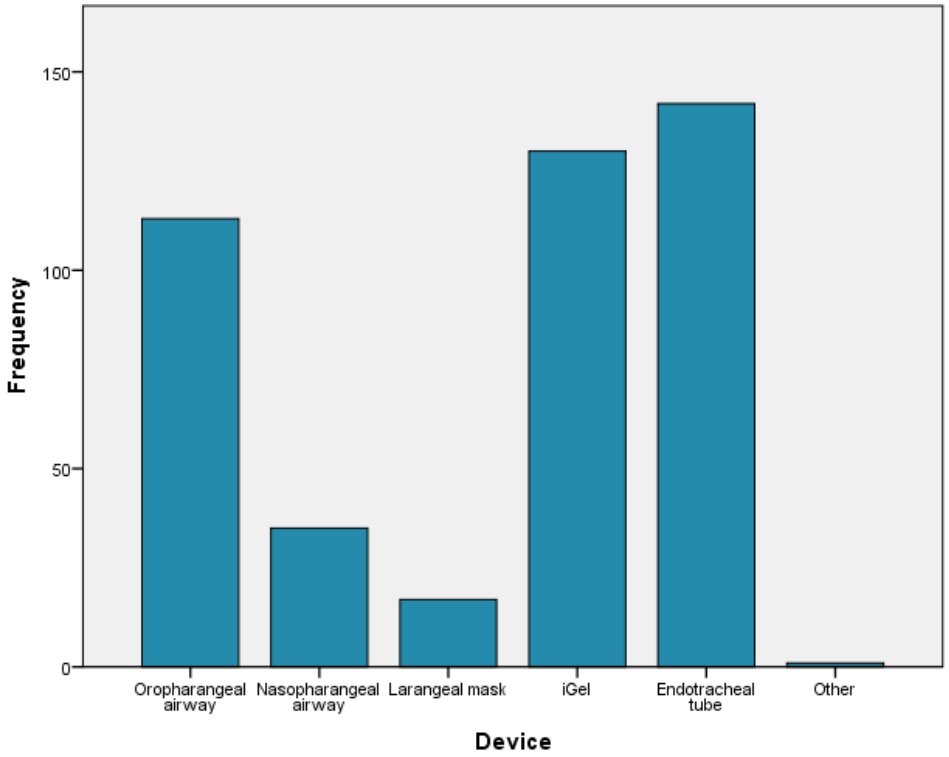
Figure 4-5: Distribution of number of years' experience of opinion survey respondents

To gain paramedic registration, professional training courses undertaken 'in-service' are available, in addition to courses at University, which also provide an academic qualification (diploma or degree). In the sample, 97 (53.6%) paramedics trained at University and 84 (46.4%) were trained 'in service'. Of the latter, 51 had proceeded to add to their professional training with an academic qualification at University. A total of 33

respondents (18.2%) had completed their initial training with no further academic study (Appendix-xvii).

4.3.2 Airway management devices used in cardiac arrest

In the opinion survey, a question asked was; 'which airway devices would you commonly use in a non-traumatic cardiac arrest'. Respondents could select multiple responses and Figure 4-6 illustrates the responses given.



[25]

Figure 4-6: Airway devices commonly used in cardiac arrest, as reported by paramedics

Of the 181 respondents, 113 (62.4%) stated they would commonly use an oropharyngeal airway (OPA) and 35 (19.3%) a nasopharyngeal airway (NPA). OPAs and NPAs can be used together or as alternatives. It is not possible to identify from the data whether the respondents would use these simple airway adjuncts independently or simultaneously.

In a systematic approach to airway management, the next step is the insertion of a supraglottic airway (SGA), which could also be used in place of a simple adjunct. In the survey, 147 (over 80%) of the respondents stated they would commonly use a SGA; either

[25] The 'other' response relates to one paramedic suggesting they would commonly perform a surgical cricothyroidotomy in cardiac arrest.

an iGel (n=130) or a laryngeal mask airway (LMA) (n=17). A similar number of respondents (n=142, 78.5%) indicated they would perform endotracheal intubation (ETI) during cardiac arrest.

4.3.3 Endotracheal intubation during cardiac arrest

From the 181 respondents, 151 (83%) answered that they considered 'endotracheal intubation to be gold standard airway management during cardiac arrest'. An additional nine (4%) had not indicated they would commonly perform ETI in a cardiac arrest situation, though believed ETI to be gold standard airway management. Opinions around potential reasons for this and other aspects of ETI (in OHCA) were investigated in the final question of the survey (see Section 4.3.5).

4.3.4 Association of demographic information with endotracheal intubation opinions

The opinion survey data were further analysed to establish whether the demographic data were associated with opinions and reported use of ETI. This was in line with the second aim of the research; to ascertain paramedics' opinions on airway management and ETI in the out-of-hospital environment and identify any associations between opinions and demographic data (Section 1.2). Table 4-1 summarises the results of the statistical comparisons between the demographic variables and paramedics' responses to the questions relating to ETI in cardiac arrest.

Table 4-1: Comparison of demographic variables and opinions of paramedics in terms of endotracheal intubation during cardiac arrest

Demographic variable	Opinion of Paramedic	
	Commonly use endotracheal intubation in cardiac arrest	Endotracheal intubation is gold standard
Age	No differences	Statistically significant difference: Older paramedics were more likely to consider ETI to be the gold standard airway management, in cardiac arrest
Training background	No differences	Statistically significant difference: Paramedics that initially trained through the in-service route were more likely to consider ETI to be gold standard airway management in cardiac arrest than those who trained at University
Number of years' experience	No differences	No differences

4.3.5 Paramedics' opinions of endotracheal intubation during out-of-hospital cardiac arrest

The final survey question asked for reasons not to intubate a patient during cardiac arrest. The optional answers were devised following comprehensive consultation of the literature, which identified key concepts and potential reasons for not carrying out intubation in practice. Respondents selected as many options as they felt appropriate (Table 4-2) and were also offered the opportunity to give their opinion on ETI in OHCA. The percentages given in the text below refer to the percentage of the total sample size; 181 respondents (they add to more than 100% because of the facility to choose more than one option).

Table 4-2: Response rates for reasons not to intubate during cardiac arrest, as given by paramedic respondents

	Skills not up to date	Equipment not available	Takes too long	Against service guidelines	Other
Number of responses	21	53	33	10	99
Percentage of respondents	11.6%	29.3%	18.2%	5.5%	54.7%

The free text responses given by paramedics were analysed and coded (see method Section 3.3.3). The themes that emerged were recoded and inserted into the SPSS data file. Descriptive statistical analysis with frequency tests demonstrate six themes plus an 'other' category from the responses (Figure 4-7). The thematic analysis findings are outlined subsequently.

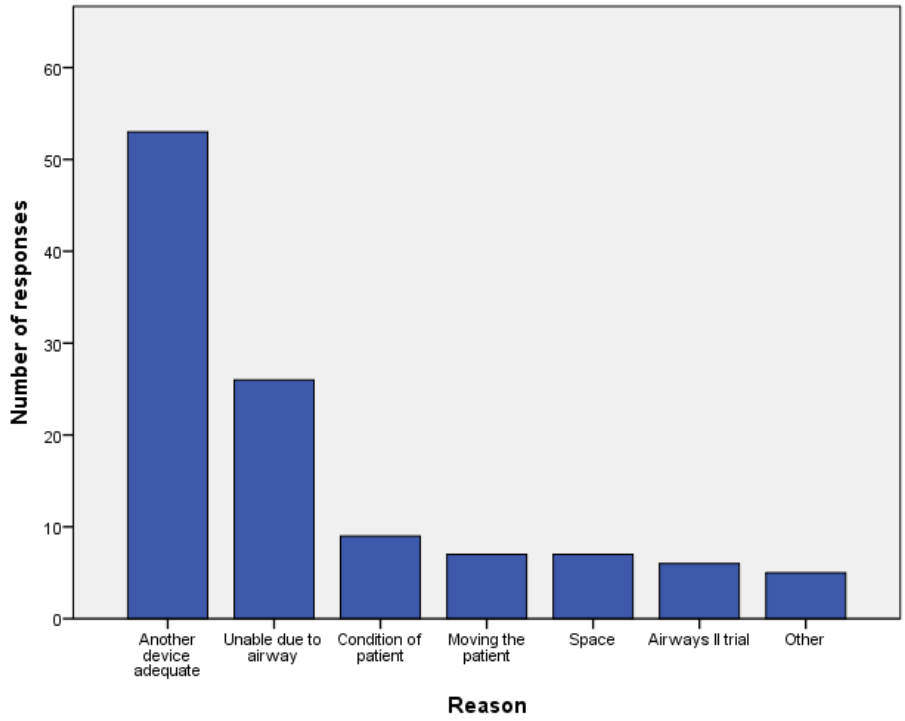


Figure 4-7: Reasons given by paramedic respondents for not performing endotracheal intubation during cardiac arrest

From the 99 paramedics that selected an 'other' reason for not intubating, almost a third of these suggested that if another adjunct, for example a SGA, was adequate, they would not upgrade the airway to an ETT. Many of these responses referred to the step-wise airway management approach, suggesting that stepping up to an ETT would only be carried out if required. Statements from paramedic respondents to the question 'why would you not intubate during cardiac arrest', included: *"if a supraglottic device is adequately ventilating and oxygenating a patient and providing adequate airway protection"* and *"if the airway was sufficiently managed by a supraglottic device"*. Paramedics used the words 'step-wise approach' in their responses with statements such as *"stepwise approach, if an iGel is providing a suitable airway I would not jeopardise this for a tube"* and *"step wise approach, if needed and* [an] *iGel wasn't working then I would upgrade"*. One respondent wrote *"if* [an] *iGel* [is] *sufficient and* [we are] *not moving the patient, or unable to get a reasonable view"*. This statement refers to the effectiveness of a supraglottic airway, the movement or transfer of the patient and the achievement of a 'view' to allow effective intubation. Other paramedics also eluded to difficulties prior to and during intubation attempts, as reasons not to intubate, as well as the action of moving patients.

Responses given by 26 (14%) of respondents for not intubating related to the difficulty of the airway view or complications during intubation attempts. Statements such as *"unable*

to intubate owing to view", *"difficult grade view"* and *"if* [it was a] *difficult intubation resulting in too many/prolonged attempts"* were made by respondents. Difficult views relate to the inability to see the vocal cords, due to patient position, patient anatomy or obstruction in the airway. Related to this was the suggestion that 'space' or patient position is a reason for not intubating, in responses such as; *"lack of space to perform effective intubation"* and *"if lack of space on scene"*.

Some respondents incorporated more than one reason in their responses, for example; "if [an] iGel is seated well, ventilating adequately and the patient has a clean airway i.e. No vomit I wouldn't progress to intubation unless ROSC (return of spontaneous circulation) was achieved and the patient was to be moved". This statement suggests that if another device was adequate and there were no airway obstructions, this would be a reason for not intubating. The statement then mentions a return of spontaneous circulation (ROSC) and moving the patient, which indicates that if the patient were to be resuscitated effectively or need to be moved to a definitive care centre, ETI would be attempted.

Movement, or not, of a patient to a definitive care centre was proposed by paramedics, who suggested they would intubate if ROSC (or revival) was achieved, to secure and maintain a patient's airway. Others suggested they would intubate in an attempt to obtain a ROSC, by correcting hypoxia. The latter statements were incorporated into the theme 'patient condition', as reasons not to intubate.

Several free text responses reiterated that intubation would be performed during the cardiac arrest, if required. Responses such as *"I would always attempt intubation"* and *"I would use intubation where appropriate"* were given. A further six respondents were part of the Airways-2 trial (Taylor *et al.,* 2016) at the time of responding to the survey and provided this information as a reason not to intubate (as they were allocated to the supraglottic airway group). This said, four of these respondents stated they would upgrade to an endotracheal tube if required, given the patient's condition or if the supraglottic airway was not adequate (which was clear in the study protocol).

4.3.6 Case note review and opinion survey findings

Similar questions were asked of the case note data and in the opinion survey regarding the commonly used airway management techniques used in cardiac arrest and whether intubation would take place. The survey responses were compared with the case note review data (Figure 4-8).

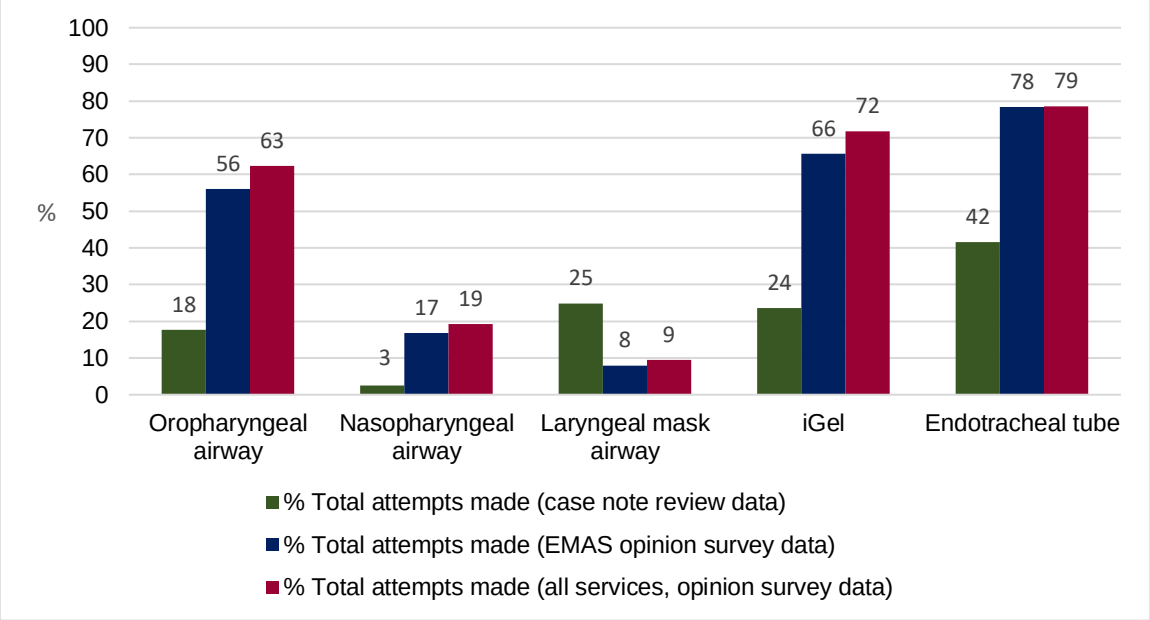


Figure 4-8: Actual and reported use of airway adjuncts in cardiac arrest

The case note review reports on the airways that were actually used in cardiac arrests by EMAS personnel and the opinion survey reports on which airway devices paramedics and all paramedics stated they would use in a cardiac arrest.

As seen in Figure 4-8 the reported and actual use of ETI in cardiac arrest differs significantly. The results of the case note review demonstrated that ETI took place in 42% of cardiac arrests. In comparison, the reported data from the opinion survey found that 79% of paramedics stated they would intubate during cardiac arrest.

It was suggested in Chapters One and Two that some of the difficulties that arise during intubation could be overcome, allowing for a more effective intubation, if an alternative intubation device (AID) was used. The experimental study undertaken (see Section 3.4 for methods) compared four intubation methods to determine effectiveness (measuring success rate and time to intubate) when used by paramedics and established user preference. The results are presented in the following section.

4.4 Results of comparative study (stage three)

A total of 72 paramedics participated in the simulated comparative study, whilst the researcher observed and timed the attempts with each method until ventilation of the lungs of the mannikin was achieved.

4.4.1 Characteristics of participants

Demographic information was collected, to give an overview of the sample of participants, which included age, gender, training background and experience. This data was further used to identify associations between demographic data and measured outcomes (see Section 4.4.5).

A total of 44 (61%) males and 28 (39%) females took part in the comparative study. A wide range of ages were represented Figure 4-9), with a higher proportion of younger participants; 68% between the age of 18 and 40, with the remaining 32% over 40 years of age. This is similar to the national gender proportions and age of the nation's paramedics, according to the Health and Care Professions Council (HCPC), (2017) (see Appendix-xviii)

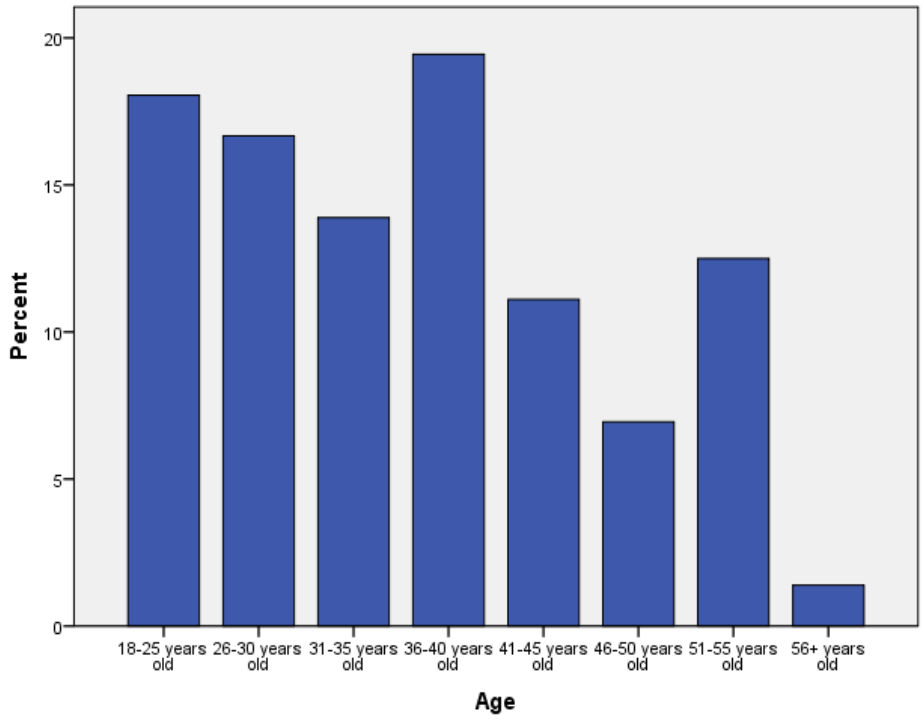


Figure 4-9: Distribution of age of comparative study participants

Younger participants naturally lead to paramedics with less experience taking part (Figure 4-10) (as was also found in the opinion survey sample), although there were some less experienced paramedics in the older age groups.

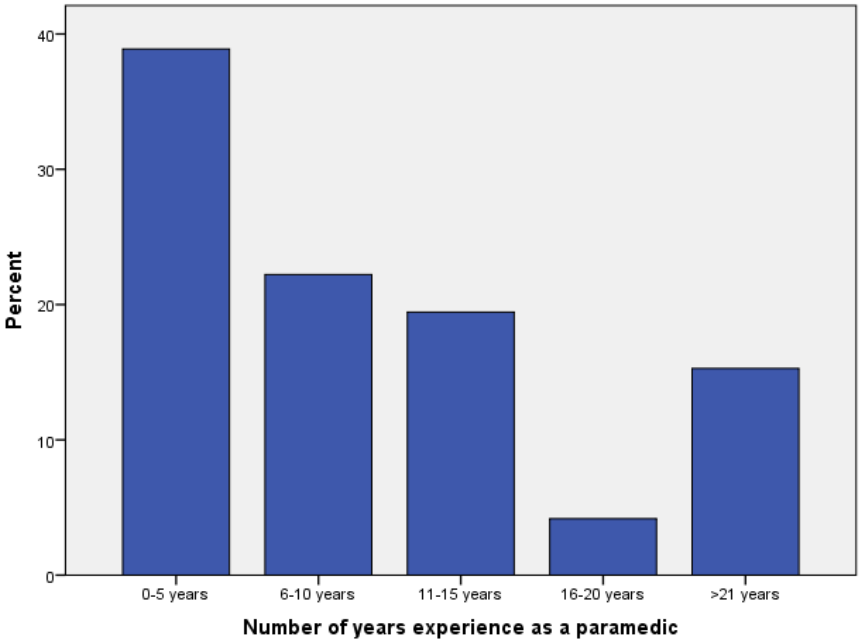


Figure 4-10: Distribution of years' experience of the comparative study participants

Data analysis showed that there was no association between the number of years' experience and training route undertaken by participants in the comparative study, though in the main, participants had studied at University at some point (n=55, 76.4%) (Figure 4-11). This could be due to the increased availability of post-registration courses at Universities, which derives from the recommendation that the education threshold entry level to the paramedic register, is raised to the minimum of an academic diploma by 2020 (Health Education England, 2013). The 'other' column indicates that training was undertaken in a different country; two paramedics initially trained overseas, one had completed post-registration studies in this country at University. The paramedics that trained in-service only, represents the paramedics that had not proceeded to academic study following achievement of their professional registration.

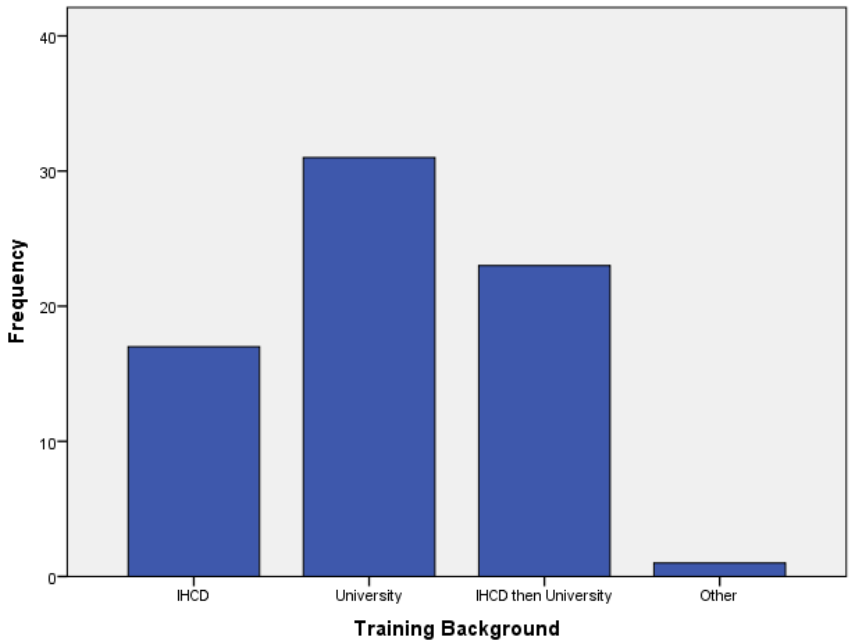


Figure 4-11: Training background of participants in the comparative study – in-service (IHCD) or University

4.4.2 Success rates

The intubation methods or devices were used in a random order, selected by the closed envelope technique (see Appendix-xix). Whether the device was successful or unsuccessful was recorded for each device on the data collection form, determined by effective ventilation of the mannikin lungs. A binary categorical variable was created for successful and unsuccessful intubation with the devices.

The data were analysed to investigate whether there were any differences in the successful intubation rates between the four devices. The null hypothesis for this test was that the distributions of the success rates for all devices are the same. A Cochrane's Q test was used, which is a related-samples test of whether combinations of values between the conditions (devices) are equally likely. This is an equivalent to the repeated measures analysis of variance for binary data.

The Cochran's Q test statistic was 62.630 (n=72, df=3), $p \leq 0.001$, which showed very strong evidence for rejecting the null hypothesis. Pairwise post hoc tests were performed to investigate where the differences lay (Table 4-3). As can be seen, there are statistically significant differences between the proportion of successful intubations of the intubating laryngeal mask airway (iLMA) and all the other devices, but not between any other pairs of devices.

Table 4-3: Post hoc pairwise comparison of distributions of successful intubations between devices

Devices compared	Test statistic	Significance (p value)
Airtraq and Intubating laryngeal mask airway	0.32*	≤0.001
Airtraq and Combitube	-0.02	>0.999
Airtraq and Macintosh blade laryngoscope	0.000	>0.999
Intubating laryngeal mask airway and Combitube	-0.35*	≤0.001
Intubating laryngeal mask airway and Macintosh blade laryngoscope	-0.32*	≤0.001
Combitube and Macintosh blade laryngoscope	0.03	>0.999

*The difference is significant at the 0.05 level

The overall success rates for each device are illustrated in Figure 4-12. It can be seen that for all but the iLMA, the success rates were very high, with only two unsuccessful attempts (2.8%) each for the Airtraq and Macintosh Blade Laryngoscope (MBL) and no unsuccessful attempts with the Combitube.

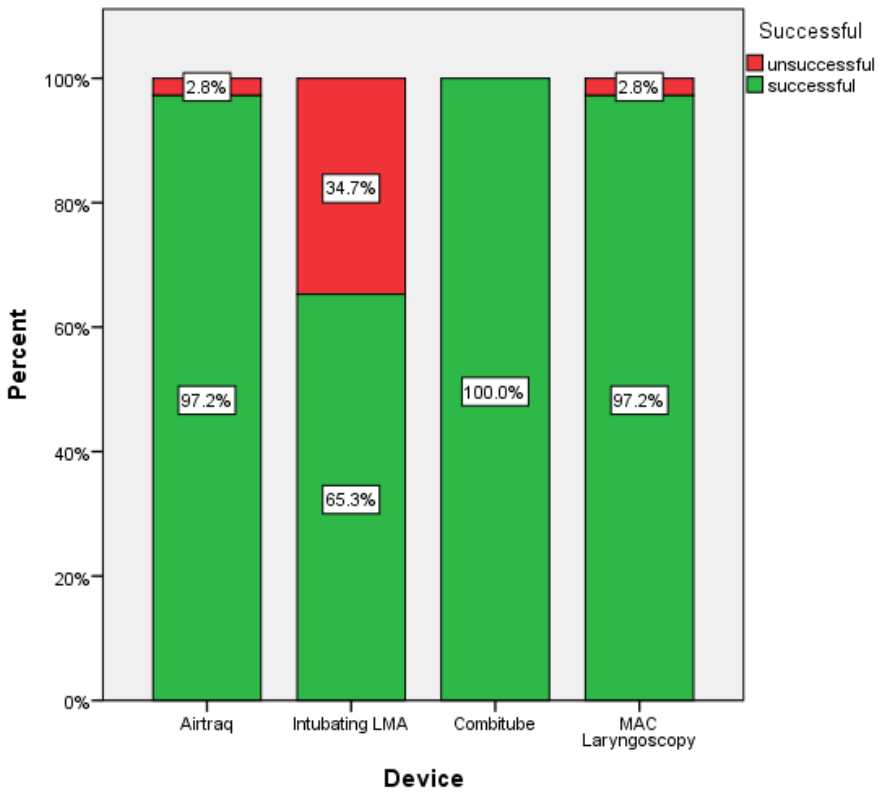


Figure 4-12: Comparison of overall intubation success rates for each alternative intubation device

4.4.3 Number of attempts

The number of attempts required for the achievement of satisfactory ventilation of the mannikin lungs was recorded for each device and is illustrated in Figure 4-13.

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Figure 4-13: The distribution of the number of attempts needed for successful intubation between the devices (including unsuccessful intubation)

New variables were created, which represented the number of attempts to successfully intubate with each device, whilst the number of unsuccessful attempts were considered. The number of attempts was limited to three, after which the intubation was recorded as unsuccessful (see above Section 4.4.2).

Further analysis examined the data associated with successful attempts only to determine if there were any differences in the number of attempts required before a successful intubation was achieved. A Friedman analysis of variance (ANOVA) was used to perform a repeated measures comparison of this ordinal data. The null hypothesis for this analysis was that the distributions of the number of attempts to successfully intubate, were the same across all devices. The test statistic was 1.550 ($n=45$, $df=3$), $p=0.671$. Therefore, there was no evidence to suggest that there are differences between the devices in terms of the number of attempts needed for successful intubation. However, it is noted that the success rate of the iLMA was significantly lower than the other devices.

4.4.4 Time taken

The total time taken by each participant to effectively use or abandon the attempt with each device was recorded, from starting the first attempt to successful ventilation, including the time between unsuccessful attempts. Where the attempt was unsuccessful, the time taken before abandoning the procedure with that device was recorded. Two analyses are therefore presented: one using data from all attempts, whether intubations were successful or unsuccessful and the other just comparing the successful attempts.

To compare time taken to intubate or abandon intubation, a repeated measure analysis of variance (ANOVA) was performed; which requires an assumption of sphericity, namely, the equality of the variances of the paired differences, between devices. Running the analysis with four conditions (the devices) and no within subject factors, gave a value of Mauchly's W of 0.632, $p \leq 0.001$, which indicates that this assumption is violated. In these cases, a more conservative approach was required to avoid inflation of the type-I error

rate. However, in this case the F ratio is so high ($F=41.018$, $p \leq 0.001$) that reductions in the effective number of degrees of freedom, producing the Greenhouse-Geisser estimate (GG epsilon=0.76), does not alter the F ratio value, nor the observed power (100%). Therefore, it can be assumed that the results are not affected by this apparent non-sphericity.

Given that the initial analysis shows that the null hypothesis, stating there are no differences in the mean times to intubate between devices, is not supported ($p \leq 0.001$), post hoc pairwise comparisons were performed to investigate where the difference occurred. Bonferroni corrections for Type I error inflation due to multiple testing were used, which are conservative. The results are shown in Table 4-4, where it can be seen that intubation times are higher for the iLMA than for all other devices.

Table 4-4: Pairwise comparison for post hoc tests for differences in time taken to intubate or abandon intubation between devices

Measure: Time (all attempts)		Mean Difference (I-J) (seconds)	Standard Error	Significance**	95% Confidence Interval for Difference** (seconds)	
Device (I)	Device (J)				Lower Bound	Upper Bound
Airtraq	iLMA	-63.35*	8.71	≤0.001	-86.99	-39.71
	Combitube	3.63	5.32	1.000	-10.82	18.07
	MBL	8.89	5.95	0.837	-7.26	25.03
iLMA	Airtraq	63.35*	8.71	≤0.001	39.71	86.99
	Combitube	66.97*	9.00	≤0.001	42.54	91.41
	MBL	72.24*	8.87	≤0.001	48.17	96.30
Combitube	Airtraq	-3.63	5.32	1.000	-18.07	10.82
	iLMA	-66.97*	9.00	≤0.001	-91.41	-42.54
	MBL	5.26	6.17	1.000	-11.49	22.02
MBL	Airtraq	-8.89	5.95	0.837	-25.03	7.26
	iLMA	-72.24*	8.87	≤0.001	-96.30	-48.17
	Combitube	-5.26	6.17	1.000	-22.02	11.49

Based on marginal means
*The mean difference is significant at the 0.05 level
**Adjustment for multiple comparisons: Bonferroni
iLMA – intubating laryngeal mask airway
MBL – Macintosh Blade Laryngoscope

This difference is also illustrated in Figure 4-14. The mean time taken before successful attempts or abandonment was over twice as high for the iLMA (mean=118 seconds) compared to the other devices (Airtraq mean=55 seconds, Combitube mean=51 seconds, MBL mean=46 seconds).

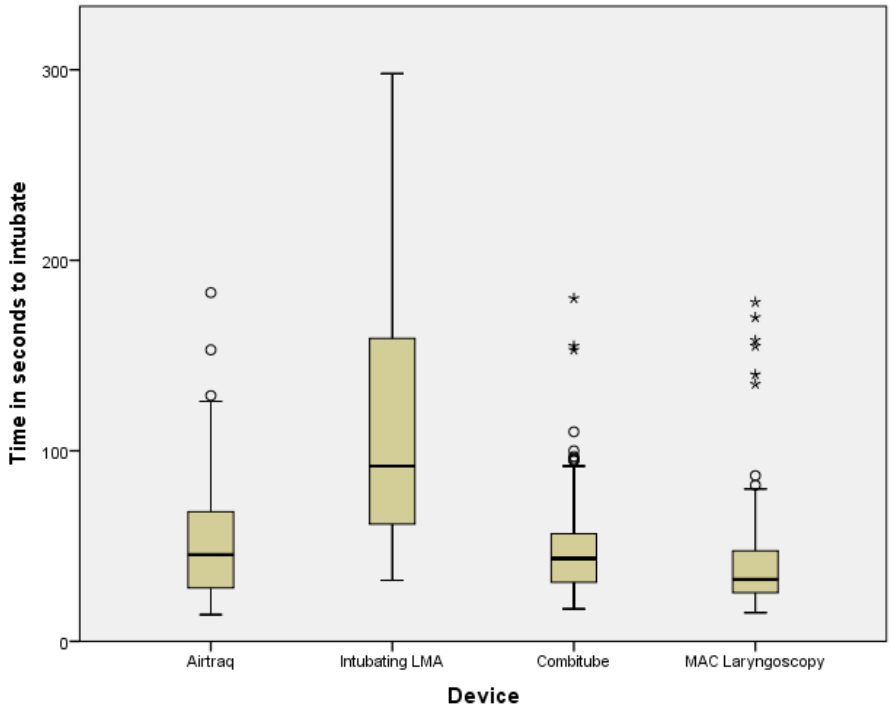

Figure 4-14: Comparison of time taken to intubate between devices (all intubations)

The difference in times may be as a result of the high failure rate for intubation using the iLMA, as the time taken included the time expended for all attempts.

When only the data for successful intubations were analysed, assumptions of sphericity were again violated (Mauchly's W=0.768, p=0.042) but Greenhouse-Geisser corrections did not change the value of F (=12.552, p≤0.001). This is strong evidence that not all mean intubation times for the four devices could be considered equal and post hoc tests (with Bonferroni corrections) were conducted between all pairs of devices, to investigate where the differences lay. The results of these are shown in Table 4-5.

Table 4-5: Pairwise comparison for post hoc tests for differences in time taken for intubation between devices (successful attempts only)

Measure: Time (successful attempts only)		Mean Difference (I-J) (seconds)	Standard Error	Significance**	95% Confidence Interval for Difference** (seconds)	
Device (I)	Device (J)				Lower Bound	Upper Bound
Airtraq	iLMA	-35.70*	8.68	0.001	-59.66	-11.73
	Combitube	-0.41	6.18	1.000	-17.46	16.63
	MBL	7.30	6.49	1.000	-10.62	25.23
iLMA	Airtraq	35.70*	8.68	0.001	11.73	59.66
	Combitube	35.28*	9.27	0.003	9.71	60.86
	MBL	43.00*	8.07	≤0.001	20.74	65.26
Combitube	Airtraq	0.41	6.18	1.000	-16.63	17.46
	iLMA	-35.28*	9.27	0.003	-60.86	-9.71
	MBL	7.72	7.10	1.000	-11.87	27.31
MBL	Airtraq	-7.30	6.49	1.000	-25.23	10.62
	iLMA	-43.00*	8.07	≤0.001	-65.26	-20.74
	Combitube	-7.72	7.10	1.000	-27.31	11.87

Based on marginal means
*The mean difference is significant at the 0.05 level
**Adjustment for multiple comparisons: Bonferroni
iLMA – intubating laryngeal mask airway
MBL – Macintosh Blade Laryngoscope

It can be seen that there are statistically significant differences in the time to successful intubation between the iLMA and all other devices, but no difference between the Airtraq, Combitube and MBL devices.

4.4.6 Preference ranking

The devices were ranked by preference with one being the most preferred and four being the least (see Section 3.4.5). These rankings were compared using a Friedman analysis of variance (ANOVA) for repeated measures. The null hypothesis, that the distributions of the preference ratings for each device are the same, was rejected (test statistic=102.333, df=3, n=7, $p \leq 0.001$). Post hoc pairwise comparisons were made to establish where the differences were (Figure 4-15) and it can be seen that there are statistically significant differences between the iLMA and all other devices, with the iLMA being the least preferred device. There is also a statistically significant preference for the Airtraq over the Combitube.

Table 4-6: Post hoc pairwise comparison of distributions of preference ratings between devices

Devices compared	Test statistic	Significance (p value)
Airtraq* and Intubating laryngeal mask airway*	-2.03	≤0.001
Airtraq* and Combitube*	-0.86	≤0.001
Airtraq and Macintosh blade laryngoscope	-0.33	0.121
Intubating laryngeal mask airway* and Combitube*	1.17	≤0.001
Intubating laryngeal mask airway* and Macintosh blade laryngoscope*	1.69	≤0.001
Combitube and Macintosh blade laryngoscope	0.53	0.085

*The difference is significant at the 0.05 level

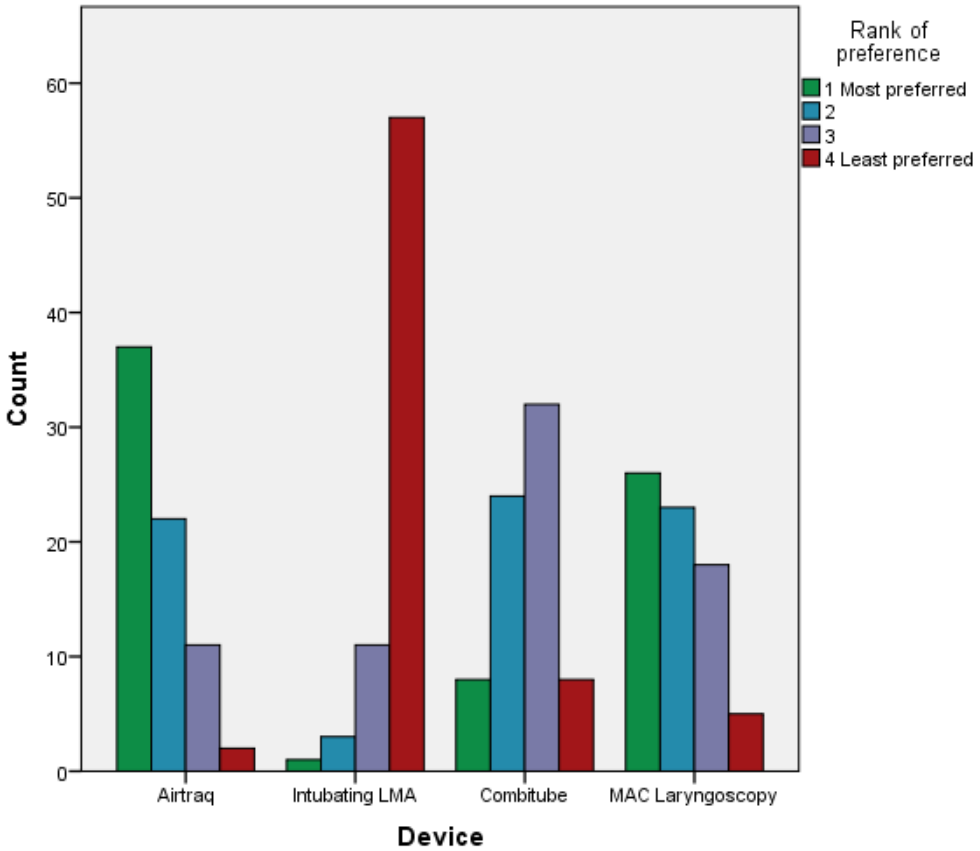

Figure 4-15: Comparison of the distribution of preference ratings between the devices

The median values for the preference ratings were: Airtraq median=1; iLMA median=4; Combitube median=3 and MBL median=2. The differences between ratings for the Airtraq, Combitube and MBL did not reach statistical significance at the 5% level.

Further analysis compared the ranking of devices to the sample characteristics (age, training background and number of years' experience), as per the fourth aim of the research; to identify any associations between preferences and demographic data. Table 4-7 gives a comprehensive presentation of these comparisons[26].

Table 4-7: Comparison of demographic variables to device preference rank

Association of demographic variable and device rank	**Preference rank per device**			
Demographic variable	Airtraq	Intubating Laryngeal Mask Airway	Combitube	Macintosh Blade Laryngoscope
Age df=21	χ^2=25.778 p=0.215	χ^2=35.446* p=0.025	χ^2=19.231 p=0.570	χ^2=27.180 p=0.165
Training background df=9	χ^2=8.839 p=0.452	χ^2=4.026 p=0.910	χ^2=5.727 p=0.767	χ^2=11.617 p=0.236
Number of years' experience df=12	χ^2=6.223 p=0.904	χ^2=12.363 p=0.417	χ^2=19.793 p=0.071	χ^2=15.777 p=0.202

*The association is significant at the 0.05 level

Existing studies have considered age in their studies, though not in terms of associations with device preferences. There was a statistically significant association with younger paramedics ranking the iLMA as their least preferred device, this association (rather than causation) could be further explored.

4.4.6.1 Justification of alternative intubation device ranking

Following the association of the sample characteristics to the preference ranking for devices, reasons were sought from the paramedics themselves for the decisions they made. These were given as free comments, collected and transcribed by the researcher

[26] An omnibus test was performed initially to identify whether any (unspecified) differences were present which minimises Type I error inflation. The post-hoc pairwise tests p-values take into account the inflation due to multiple testing

and analysed through thematic analysis (after Braun and Clarke, 2006). Four themes were identified; process of intubation, outcome of intubation, training and exposure to and user friendliness of the devices.

A number of participants noted the importance of the intubation process during their justification, referring to elements such as the view (of the airway), controlling the tube and watching the tube pass through the vocal cords. The most preferred device was the Airtraq and statements such as *"great view"*, *"clear visualisation of the cords"* and *"really good view of cords"* were made about this device. Similar but less frequent statements were made about the 'view' the Macintosh blade laryngoscope offered. Experienced paramedics stated; *"you can visualise it* [the endotracheal tube] *and you know it's in"* and *"could visualise cords better"* when justifying the MBL as their preferred device.

Further positive process-related reasons given about the Airtraq, were the lack of adverse effects (such as increased pressure or force on the mannikin) experienced when using the device. It was noted from the participants that "[there was] *no pressure needed on scope"*, *"no pressure on hands or patients"* and *"doesn't require as much force as* [a] *laryngoscope"*. These statements were often direct comparisons to the MBL. A more common reason for MBL preference (related to the intubation process) was *"the control of the tube"* the paramedic had when intubating. Statements such as: *"more control, could adjust* [the tube] *easier"* and *"had own control and manoeuvrable"* were made. Process-related concepts were not a feature of the reasons given for the Combitube, instead the outcome and success of the device featured more prominently.

The outcome or success rate of each device was quantified by the ease, speed and reliability of the device, as determined by the participants. For the devices, when selected as favourite, speed was perceived as a reason for preference, despite time to intubate not being shared by the researcher before rankings were given. Ease of use was also frequently stated as a reason for preferred device. Comments such as *"really easy to use, really quick"* and *"got tube straight in"*, were given as reasons for selecting the Airtraq as the preferred device. Similar comments were made by the one participant who selected the iLMA as their favoured device, though these were atypical compared to other participants. From paramedics who selected the Combitube as their preferred device, outcome and success was the main theme deriving from the data. The notion that this device was *"reliable"*, *"you can't go wrong"* and *"it's fool proof"*, was suggested by these participants.

Practitioners who participated in the experimental study were generally aware of the need for efficient intubation to give patients the best chance of survival. The MBL was not often

discussed in relation to efficiency, instead, justification for ranking this method as preferred, largely related to training and exposure to the method. This said, experienced paramedics stated that MBL was their preferred device as *"it's quick"*. There were comments made about the Airtraq such as *"if I had more training I would be better"* and *"I would choose the Airtraq if I was more familiar with it"*. Being familiar with a device, following education and training, it seems would improve the efficacy of AIDs.

A number of comments made when justifying the choice of preferred device related to using the devices and how the participants felt using the device. Concepts such as general feel, versatility and simplicity were expressed by participants. In particular with the Airtraq, comments such as *"amazing, loved it"* and *"by far the best"* were made alongside earlier mentioned statements. *"You don't have to think about visualising anything"*, was stated as a reason for selecting the Combitube as a preferred device. The user friendliness, or lack of, featured more heavily when analysing the reasons given for the least preferred device.

Similar themes as found for the reasons given for preferred devices, were also found in their negative form for the reasons given for least favoured devices. The overarching theme with the justification statements for all the devices, when selected as the least preferred device, related to personal experience whilst using the device. The comments made about the iLMA were that it was *"fiddly"*, *"unusable"*, *"awkward"*, *"too hard"* and *"needs more than one pair of hands"*. The general theme throughout the statements made about the iLMA, was that the device disappointed. There were similar suggestions made about the Airtraq (by participants who selected this as their least favourite device): "[I] *thought it would be better than it was"* and *"it was difficult"* were documented. These statements were made by participants who were unsuccessful intubating with the Airtraq and contradict statements made by the majority of participants about the device being their preferred. The comments made about the Combitube were varied. Of the statements relating to the user friendliness, the Combitube was said to be *"fiddly to inflate two cuffs"* and "[I] *couldn't insert tube straight away"*. Other comments relating to user unfriendliness were that the devices were *"difficult"* to use, as said at least once for each device.

Training and exposure to the devices were not common reasons given for the least preferred devices. A participant mentioned that they *"couldn't insert the tube straight away"* when referring to the Combitube, subsequent discussions about the insertion point and how the device worked, were had between the researcher and participants (see Chapter Five). With reference to the iLMA, a few participants stated they *"would improve with practice"* and *"need to practice more"*, alongside the comments made about the

awkwardness of the device. Participants also stated they were *"out of practice"* with standard laryngoscopy (the MBL), which contributed to their justification of it being their least preferred method. This was alongside statements made about the process and outcomes of intubation, which were also made for each of the devices.

The second most common theme behind user unfriendliness of the iLMA, as the least preferred device, was the outcome of the intubation attempt. Participants referred to not gaining an effective airway, either on first attempt or after all attempts with the device. The main statements made were *"couldn't intubate with it"*, *"no intubation"* and *"it didn't work"*. Similar statements were made about the other devices, albeit in the minority, for the MBL; *"couldn't intubate"* was stated and for the Combitube, statements such as *"difficulty ventilating"* were made by participants. Participants discussed the iLMA in terms of already having an effective airway with a supraglottic device (the laryngeal mask airway) and *"why would you intubate"*. Similar comments were made when a participant couldn't intubate with the Airtraq, they selected this device as least preferred because they *"at least had an airway with the other one* [iLMA]*"*.

When giving reasons for least preferred device, the process of the intubation was mentioned consistently, particularly in terms of the view of the vocal cords, or lack of, when attempting intubation. Participants regularly commented on having *"no view"* and *"can't see in airway"* when discussing the iLMA and Combitube. Further issues with the view was that paramedics *"didn't know how far to insert tube"* and they *"couldn't see what was happening"*. There was a commonality with wariness when removing the laryngeal mask airway device from the tube. Participants stated they *"didn't feel confident* [when] *taking the LMA out that it wasn't going to pull* [the] *tube out"* and "[there is] *nothing holding* [the] *tube"*. Overall, the device was considered to be awkward and unreliable, offering no confidence in successful intubation according to paramedic participants.

Additional reasons relating to process were the adverse effects the intubation attempts were causing, such as the pressure on the mannikins upper airway. Participants that selected the MBL as their least preferred method said the device *"levered on teeth"* and there was a *"risk of* [pressure on] *teeth"*. Process related reasons given for the Combitube also referred to the view, as previously mentioned, though paramedics did state the Combitube "[would be] *good if* [the] *airway* [was] *obstructed"*. This is a fundamental concept of intubation and alternative intubation devices, which is further discussed in Chapter Five.

4.4.7 Researcher's observations

As proposed in Section 3.4.5, the researcher noted pertinent points whilst observing the intubation attempts with each device. The outcomes of the observations are listed in Figure 4-16 and discussed in Chapter Five.

- The use of a gum elastic bougie
- The difference in speed of successful intubation between participants
- Manipulation with Airtraq – temptation to 'rock' with device
- Occasional excessive force on upper airway and teeth with Macintosh blade laryngoscopy (not always recognised by participants)
- The adaptability to using new devices
- Familiarity with the concept of intubation
- Lubrication needed for devices
- Prior preparation (loading Airtraq, connecting syringes for Combitube balloons)
- Inserting the Combitube far enough and adequate balloon inflation for successful ventilation
- The difficulties and frustration with the intubating laryngeal mask airway

Figure 4-16: Researcher's observations during intubation attempts with alternative intubation devices

4.5 Summary

The results of the case note review show that a variety of airways were used, for patients in cardiac arrest over the period of a year, in one region of the UK. It is impossible to identify which adjuncts were used for individual cases, due to the format of the data presentation. Success rates for the use of simple adjuncts (oropharyngeal and nasopharyngeal airways) and supraglottic airway (SGA) devices were high when they were used. This said, less than half the patients in cardiac arrest had a SGA inserted (48%) and it was impossible to ascertain if these patients were intubated instead. Less than a third of the patients in cardiac arrest were successfully intubated (32%) and attempts were not made to intubate 1,622 (58.4% of) patients.

Stage two of the research project explored paramedics' views on and experience of airway management and endotracheal intubation during cardiac arrest, in an attempt to explain the number of intubation attempts and success rates. Opinions were collected from 181

paramedics across the country, in the form of a survey. Two-thirds of the respondents were from one service (EMAS). There was a positively skewed distribution of the respondents age and experience groups; the majority of respondents were younger with less experience. Of the respondents, 148 (81.7%) had received their initial training or furthered their education, at University.

The airway adjuncts that the paramedics reported they commonly used in cardiac arrest ranged from simple adjuncts (oropharyngeal and nasopharyngeal airways) to endotracheal tubes. Over 80% of respondents stated they would use a supraglottic airway (SGA), either an iGel or a laryngeal mask airway (LMA). Alongside SGA use, over three-quarters (n=142, 78.5%) of the respondents indicated they would commonly intubate and 151 (83%) believed ETI to be gold standard airway management in cardiac arrest. These results differed significantly to the results of actual airway adjuncts found in the case note review.

Opinions on ETI and OHCA were sought through multiple choice and free text responses. Nearly a third of paramedics indicated that a lack of equipment is a reason for not performing ETI, with 20% and 11.6% suggesting that time and skill fade respectively, are reasons for not intubating. A further 5.5% of paramedics suggested that guidelines were a reason for not intubating, which could have related to inconsistent or a lack of supporting guidance.

From the 99 free text responses in the survey, the most common reason for not performing ETI was because an alternative airway adjunct was adequate in ventilating the patient. Further reasons given were patient position or access with environmental constraints and a difficult intubation attempt due to the inability to view the vocal cords. Patient condition in terms of return of spontaneous circulation (ROSC) and moving the patient to a definitive care centre, were proposed as reasons to intubate.

The comparative study collected sample demographic data, before collecting data for analysis; to examine and compare the ability of paramedics to effectively use alternative intubation devices. The sample contained more males than females and younger paramedics, with a corresponding lower number of years' experience. Most of the participants had received training or education at University with post registration study, or in order to gain their registration.

Each participant used each device or method of intubating in a random order and statistical analysis was performed on the data collected. There were statistically significant differences between the proportion of successful intubations with the iLMA and all the other

devices. The overall success rates for the Airtraq, MBL and Combitube were over 97%, though the iLMA had a 65% success rate. Not all participants proceeded to have three attempts with each device, in which case this was documented as an unsuccessful intubation. There was no evidence to suggest that there are differences between the devices or methods in terms of the number of attempts needed for successful intubation.

Time to intubate was analysed using all attempts and successful attempts only. In both analyses, there are statistically significant difference in the mean time to intubate between the iLMA and all the other devices. In the first analysis, this difference may be due to the low number of successful intubations. In the second analysis, mean times to intubate were quicker, though all attempts took longer than the recommended 30 seconds (MBL=42 seconds, Airtraq=51 seconds, Combitube=51 seconds and iLMA=86 seconds).

When the demographic variables were associated with success rate of and time to intubate with the devices, there were statistically significant differences with older paramedics and paramedics that had not received education at University, being less successful with the MBL.

The participants were asked to rank the devices in order of preference, justifying their choices in their own words. The most frequently selected as preferred device was the Airtraq, with over half the participants selecting this device as their favourite. This was followed by the MBL, with over two-thirds of participant ranking this method first or second. The least favoured device was the iLMA, with over 79% of participants ranking this device fourth. Post hoc pairwise comparisons established that there are statistically significant differences between the iLMA and all other devices, with the iLMA being the least preferred device. There is also a statistically significant preference for the Airtraq over the Combitube.

Reasons for selecting preferred and least preferred device were analysed and four themes emerged; process of intubation, outcome of intubation, training and exposure to the alternative intubation devices and user friendliness. For the most preferred device (the Airtraq), comments were made about the good view of the vocal cords the device provided as well as the lack of adverse effects.

Reasons for ranking a device as least preferred predominantly related to the lack of user friendliness, in the main relating to the iLMA. A common phrase used was the 'awkwardness' of the devices, for both the iLMA and Combitube. Not being able to intubate with the device also led to this being selected as least favoured. Training and exposure to devices was mentioned, given that all bar the MBL were not commonly used by

paramedics. Participants suggested that they would improve with practice with each of the devices.

This concludes the results chapter, which has presented the results from each stage of the research. Discussion of the results takes place, drawing on the literature review findings, in the following chapter.

Chapter 5 Discussion

Chapter Four presented the results of the case note review, opinion survey and comparative study. Chapter Five evaluates the results presented and discusses them in the light of previous research findings and health service guidelines (see Chapter Two). The structure of the chapter follows the original aims and objectives, which are aligned to the results, to enhance and focus the discussion. The application of the research methods (strengths and limitations) and the implications of the findings are also considered in this chapter.

5.1 Airway management and endotracheal intubation during cardiac arrest, in the out-of-hospital environment

The initial aim of the research project was to identify current practice relating to airway management and intubation in the prehospital environment. In order to investigate this, a case note review was performed in one region of the UK, which identified which airway management techniques were used by paramedics in practice. It was found that resuscitation was attempted on 72% of patients, which is higher than the national average of 60% (The University of Warwick, 2018) (see Section 1.4.3). There are valid reasons for not intervening with resuscitation, such as the presence of an advanced decision to refuse treatment (i.e. a 'do not attempt cardiopulmonary resuscitation' (DNACPR) order) or if the clinical presentation suggests that resuscitative attempts would be futile (the presence of rigour, algor or livor mortis for example). Otherwise, attempts ought to be made to resuscitate patients in out-of-hospital cardiac arrest (OHCA) (Brown *et al.,* 2016; The University of Warwick, 2018). The differences in regional and national data regarding resuscitation attempts in OHCA might vary for a range of reasons, including the various techniques used to manage a patient's airway. These include simple adjuncts and or endotracheal intubation (ETI), which were identified as used in practice in the findings of the case note review.

The results of the case note review reported in this thesis indicate that a range of airway adjuncts are used by paramedics, though simple adjuncts were used in less than 20% of patients. This finding suggests that a step-wise approach to airway management was not commonly taken in practice, which could have been due to a patient being in cardiac arrest on initial assessment, in which case the patient may have been intubated immediately. Unfortunately, the data does not allow for deeper analysis as to whether patients were in cardiac arrest prior to ambulance personnel arriving. The low usage of simple adjuncts

could also be attributed to the introduction and use of supraglottic airway devices (SGAs), which are quick and easy to insert (Cook and Howes, 2011) and may have been used in place of simple airway adjuncts, prior to or instead of ETI. The case note review reveals that less than half of patients in cardiac arrest had a SGA inserted (both iGels and LMAs). The use and skill of inserting SGAs (such as iGels and laryngeal mask airways (LMAs)), was routinely taught in training schools and Universities by 2014, which does not explain the reason for under-use. It is possible that paramedics or technicians who trained prior to the introduction of SGAs may not be familiar with changes in practice, or the use of SGAs, despite an abundance of literature on this subject (Guyette *et al.,* 2007; Cook and Howes, 2011; Fawzy *et al.,* 2012; Häske *et al.,* 2013) (Section 1.3). This said, the success rates of insertion for both types of SGA were over 95%, which may be attributed to the simplicity and lack of associated complications with the devices and is further supported by previous study results, which found that time to insert a SGA was quicker and safer than intubating (Frascone *et al.*, 2011; Kajino *et al.*, 2011) (Section 2.2.2).

Using a SGA could negate the need for further airway management, such as ETI, though a SGA does not protect the airway (trachea) and lungs from aspiration of stomach content, which is a huge risk in a cardiac arrest situation (Simons *et al.,* 2007; Asai, 2012; Nicholson *et al.*, 2013; Jabre *et al.*, 2018) (Section 1.3). The literature review found that the insertion of a SGA device in OHCA is likely to be associated with worse patient outcomes than other methods of airway management (Wang *et al.*, 2010; Shin *et al.*, 2012; Tanabe *et al.*, 2013; Henlin *et al.*, 2014; Benoit *et al.*, 2015; Kang *et al.*, 2015). Patients who did not have a SGA inserted may have been intubated immediately in place of, or following the use of a SGA, in the step-wise airway management approach. Despite resuscitation algorithms and protocols recommending early ETI in out-of-hospital cardiac arrest (see Henlin *et al.*, 2017), results from the case note review indicate that intubation attempts were made in 42% of patients in cardiac arrest. It is not clear whether these patients had other airway adjuncts in place to ensure a patent airway (due to data limitations). It is acknowledged as a weakness that the data includes interventions from a range of ambulance personnel, including technicians and care assistants, who cannot carry out intubation, thus potentially reducing the number of intubations that could take place and documented in practice. At the same time, there are potential limitations in reporting; it has been found that documentation of successful ETI can be suboptimal (Ducket *et al.,* 2013; Phelan *et al.,* 2013).

The use of intubation as an advanced airway management technique has been reported on by a number of authors (see Section 2.2.2). Reviewing the effectiveness (success rate and time to intubate) of intubation has highlighted complications such as misplaced ETTs, multiple attempts to intubate and a lack of user experience (Wang *et al.*, 2009a; Henlin

et al., 2014; Dyson *et al.*, 2017). In this case note review, the success rate of intubation was 77%, which reflects the findings of existing literature (Wang and Yealy, 2006a; Dyson *et al.*, 2017), where success rates ranged from 70% to 95% (Section 2.2.2). The case note review did not identify the number of attempts required and time to intubate, nor the level of experience paramedics had, however this was investigated in the comparative empirical study (see Sections 3.4, 4.4, 5.3).

The case note review results suggest that less than a third of the patients in resuscitated cardiac arrest were intubated (32%). Considering that previous studies (Egly *et al.,* 2010; Cook *et al.,* 2011; Wang *et al.,* 2012; Benoit *et al.,* 2015) and guidelines (Deakin *et al.*, 2010; Brown *et al.*, 2016; Higgs *et al.*, 2017) suggest ETI to be necessary airway management in for patients in cardiac arrest (if a competent practitioner is present), this is a low figure and suggests that best airway practices are not being employed in the out-of-hospital environment, by paramedics in the East Midlands region. Reasons for not attempting intubation, or for failed intubation attempts, were not available in the case note data, though the concepts that emerged from existing literature relating to this are: the availability of equipment, inconsistent guidelines, the time taken to intubate and unreliable training or skill maintenance methods (Wang *et al.,* 2009a; Deakin *et al.,* 2009; Strote *et al.,* 2009; Lockey *et al.,* 2013). These were investigated further on in the research project, using a survey posed to paramedics (Section 3.3).

The reported use of airway adjuncts used for patients in cardiac arrest (in the survey) differed significantly to those found in the EMAS case note review results. In the survey, 113 (62% of) paramedics reported that they would use an oropharyngeal airway (OPA), compared to the 18% documented as used in cardiac arrest (in the case note review). Predicted use of simple airway adjuncts may differ from actual use due to patient's clinical presentations. It is not possible to insert an OPA in to a patient with trismus of the jaw, therefore a nasopharyngeal airway (NPA) might be used. In the survey, 19% of participants suggested they would use a NPA, whereas in the case note review only 2% of patients in cardiac arrest received a NPA. In traumatic cardiac arrests, NPAs are not always advocated with injuries such as facial wounds and or suspected base of skull fractures (Muzzi *et al.,* 1991; Schade *et al.,* 2000). However, airway management takes precedence over other cautions, which is potentially why paramedics suggested they would use the devices and might not have been able to use them in practice.

Further contraindications of the data from the case note review and survey include the actual and reported use of SGA devices. The survey results show that 74% of paramedics suggested they would commonly use a SGA, either a laryngeal mask airway (LMA) (n=17)

or an iGel (n=130)[27]. The reason for the higher number of responses to iGels rather than LMAs is perhaps due to the availability of equipment in a Trust or area. The proposed use of SGAs from respondents might be in line with service guidelines, or through following a step-wise airway management approach. The case note review data indicates that actual use of SGAs in cardiac arrest was less than 50%. Direct comparison between the case note review and survey results is difficult, given the different methods used to collect data and that only paramedics can intubate (whereas case note data included interventions from a range of personnel). However, it is noted that reported use of airway adjuncts, including endotracheal tubes, is higher than those actually used in cardiac arrest (and EMAS guidelines indicate a paramedic would be dispatched to the scene of a cardiac arrest (EMAS, 2019), suggesting that paramedics would be present). The reported use of airway adjuncts could have been influenced by the questions in the survey (see Section 3.5.6), this could be overcome by using alternative methods, such as a prospective observational study. It is recognised that if a survey were to be used, allowing free-text responses (rather than offering multiple choice options) is likely to give a more accurate representation of paramedics' opinions. A further limitation in this comparison is that the case note review data was collected from the East Midlands region, whereas the survey collected opinions from paramedics across the UK. This said, when considering the opinions of the EMAS paramedics only, similar discrepancies are noted (Section 4.3.6). It is also recognised that the opinion survey took place two to three years later than the case note review, which could have affected opinions and experiences (given research developments). Further research on the use of airway management techniques, including SGAs, by paramedics in OHCA could be useful to provide additional information on the airway management techniques used across regions in the out-of-hospital environment.

5.2 Paramedics' opinions of endotracheal intubation in cardiac arrest

The second aim of the research project was to ascertain paramedics' opinions on airway management and ETI. To help answer this, two questions were posed in the survey to this effect, with the majority believing intubation to be gold standard airway management in OHCA and stating they would commonly intubate if required. These results conflict with the findings from the case note review, which reported intubation attempts in less than half (42%) of patients in cardiac arrest. The disparity that suggests paramedics' views differ to their practice, could be due to the survey question posed (which suggested there is a gold standard airway management approach for patients in cardiac arrest (see Section 3.5.6)). Future opinion surveys should avoid potentially leading questions and

[27] Out of the 17 respondents that would commonly use a laryngeal mask airway, 13 of these also stated they would commonly use an iGel. It is not possible to use both simultaneously.

aim to ascertain paramedics' views from open questions and responses. The contradiction in findings from the case note review and opinion survey were further investigated by seeking paramedics' reasons for not attempting and unsuccessful intubation (see below). The opinion responses were further investigated to establish any associations between demographic variables and the opinions reported by paramedics.

The literature review conducted to underpin this research identified no existing studies which consider paramedics' opinions on ETI. Therefore, no associations between demographic information and opinions in previous research have been identified. In this research there was no statistically significant difference in the percentage of paramedics who stated they would commonly use ETI across the age, training background and number of years' experience groups. There were associations with the gold standard view question, in that younger paramedics who trained at University were less likely to have this view. This association could be attributed to advances in airway management and evidence advising the use of SGAs in practice, as well as these paramedics perhaps having better research skills (embedded during University training), to analyse the literature and guidelines available. This said, it may be expected that more experienced paramedics would have a superior analytical approach to managing clinical situations, though there was found to be no association between the paramedics' experience (in years) and views on intubation. This was an observational study so no casual links can be attributed to the associations shown, however, additional research could further investigate whether there are contributory factors that influence paramedics opinions on ETI in OHCA.

Paramedics' views on reason not to intubate were sought through the survey conducted in this research. A disparity between the results of the survey (see Section 4.3.5) and existing literature was found. The evidence suggests that potential reasons for not intubating and failed intubation attempts are: a lack of confidence in performing the skill due to skill fade (not intubating in practice regularly), inadequate equipment availability and the time it takes to intubate (which could relate to skill level) (Deakin *et al.,* 2009; Strote *et al.,* 2009; Wang *et al.,* 2009a; Bingham and Proctor, 2008). However, just 12% of the respondents suggested that a lack of skill was a reason for not intubating in practice and 18% indicated that the time it takes to intubate prevented attempts. Time constraints could relate to time on scene, time to intubate or travel time to hospital (Wang *et al.,* 2009b). The notion of time restricting intubation decisions is logical, given the need to fulfil all the elements of the advanced life support algorithm: continuous chest compressions, the administration of drugs and the rapid transport of patients (Strote *et al.,* 2009). Alongside this, the environmental difficulties associated with ETI in the prehospital environment also prolong intubation times (Gatward *et al.,* 2008; Wang *et al.,*

2009b). Although it may be quicker to insert a SGA, patient's clinical needs should be considered together with restrictions.

In this thesis, the majority reason for why ETI might not take place or be unsuccessful, in the out-of-hospital environment, given by almost a third of paramedics, was 'if another device (such as a SGA) was adequate in managing an airway', followed by a lack of adequate equipment. The Resuscitation Council (2015) state that ETI should be attempted only if simpler airways prove ineffective whereas alternative evidence suggests that intubation is entirely necessary in cardiac arrest (Benoit *et al.,* 2015; Gawlowski *et al.,* 2016). There is ongoing research to identify the optimal airway management technique for patients in OHCA, though many paramedics continue to be taught and use the skill of intubation in practice. In the survey responses, paramedics reported not having adequate resources in terms of laryngoscope blade sizes, capnography monitoring and assistance for intubation. Resource allocation and suppliers change frequently, which at times disrupts the equipment available or accessible to paramedic practitioners. Having appropriate resources has significant implications for practice in terms of paramedics being prepared and equipped to carry out ETI in OHCA.

Alongside equipment resources, paramedics were asked if they would not intubate during cardiac arrest because it is against service guidelines. Some services have excluded the skill of ETI from their training programmes, suggesting it is not a necessary intervention with short travel distances to hospital (London Ambulance Service (LAS), 2016). In comparison, paramedics that work in services that cover a larger area, in rural parts of the UK, have further to travel to hospital with their patients and need to be able to manage clinical presentations effectively. Only 6% of paramedics selected this as a reason for not intubating in the survey. Further investigation could offer a more comprehensive overview of regional airway management and ETI practices, in relation to service guidelines.

A range of additional reasons for not intubating during cardiac arrest were given by paramedics, which adds to existing research where little attention has been paid [to paramedics' opinions on ETI]. These included the clinical presentation of the patient, the unpredictable nature of the out-of-hospital environment, access to the 'head end' of the patient and the effective use of a laryngoscope while in confined areas. These problematic situations essentially relate to the inability to obtain a view of the airway. Practitioner related issues, a patient's clinical state and the need to transfer to a definitive care centre (hospital), were further reasons (given by paramedics) not to intubate. Some also gave these concepts as reasons to intubate. For instance, 'in an attempt to obtain a return of spontaneous circulation' (ROSC), by correcting hypoxia or 'to secure and maintain a patient's airway during a transfer' (both onto and off an ambulance and during the journey

to hospital). These explanations can again be related to guidelines, which suggest that patients should be transferred to a definitive care centre as soon as possible post-ROSC (Resuscitation Council, 2015). Alongside this, patients need to be transported to the right hospital for their care (given the suspected reason for cardiac arrest), rather than the nearest centre (Moy *et al.,* 2011), potentially lengthening journey times. Paramedics in this research also suggested that evidence of regurgitation may direct them to intubate, in order to protect the airway and increase chances of survival from cardiac arrest. Therefore, approaches that treat or prevent regurgitation (for instance the insertion of an ETT), may improve chances of survival following cardiac arrest (as supported by Benoit *et al.*, 2015; Piegeler *et al.,* 2016; Jabre *et al.*, 2018). At the same time, interventions that offer enhanced views of the airway, such as alternative intubation devices or methods, could encourage and speed up intubation in prehospital practice.

Although the question in the survey asked for reasons not to intubate, paramedics also gave considered reasons for carrying out ETI. Their reiteration of performing intubation if they deemed it necessary, during cardiac arrest, was perhaps because the question asked for reasons for not intubating during cardiac arrest and the respondents did not consider any reasons not to intubate. Alternatively, the respondents may have felt strongly about intubating, which was clear in previous questions of the survey. A further selection of respondents referred to being part of the Airways-2 trial at the time of responding to the questionnaire, indicating they would not intubate as they were allocated to the SGA group. This said, some of these respondents stated they would upgrade to an ETT if required, given the patient's condition or if the SGA was not adequate, which was in-line with the Airways-2 study protocol. This response demonstrates the application of professional judgement within a clinical situation by paramedics. The findings imply that paramedics would intubate a patient if required, supported by the findings from the earlier questions in the survey, but conflicting findings from the case note review. There is a clear disparity between actual and reported use of ETI found in this study, which additional research could explore.

To accompany professional judgement and clinical decision making, alternative intubation devices (AIDs) have been shown to help overcome some of the complications experienced by paramedics, thus ensuring intubation is more effective (Smith *et al.,* 1999; Maldini *et al.,* 2016; Ducharme *et al.,* 2017). The literature review (Section 2.3) identified gaps in the current evidence, with opportunities to provide new evidence about AIDs for use by paramedics in prehospital practice. There are a range of devices used in clinical practice, although none of them are commonly used in the out-of-hospital care environment and no one is established as more effective than another (Section 2.4). The experimental study element of the research reported in this thesis (Section 3.4) aimed to examine and

compare the ability of paramedics to effectively use alternative intubation devices, by comparing four different methods.

5.3 Examination and comparison of alternative intubation devices – effectiveness

A prospective comparative study was used to examine and compare the ability of paramedics to effectively used alternative intubating methods in an experimental setting. This research design had been used in previous research in the field (Russi *et al.*, 2008; Nasim *et al.*, 2009 and 2009b; Butchart *et al.*, 2011; Russi *et al.*, 2013; Bogdański *et al.*, 2015). Effectiveness measures included success rate, which is the most important measure of an intubation device or method, given that it is ultimately required to provide a clear airway, ventilation and oxygenation of the lungs (Cook *et al.,* 2011; Shin *et al.*, 2012; Wang *et al.,* 2012; McMullan *et al.*, 2014; Benoit *et al.,* 2015; Kang *et al.*, 2015). Time to intubate was also used as an effectiveness measure, previous research suggests time to intubate is negatively associated with out-of-hospital cardiac arrest, particularly when performed by paramedics (Kajino *et al.,* 2011; Mulder *et al.,* 2013; Henlin *et al.*, 2014).

5.3.1 Success rate

The literature review, compared a range of alternative intubation methods but did not indicate any differences in the success rates of devices, including those using mannikins. Only one study was identified which contradicted these findings and its author was the co-inventor of the VL used (Butchart *et al.*, 2011), therefore could be subject to researcher bias. In the author's research, four methods or devices were compared to establish their effectiveness when used by paramedics, which has not been carried out in previous research. In this thesis there were no statistically significant differences in the success rates of the MBL, VL and Combitube when used by paramedic participants on mannikins, which is similar to the majority of existing research that compared a VL to a SBL (Nasim *et al.,* 2009a & 2009b; Gaszynska and Gaszynski, 2014; Bogdański *et al.*, 2015; Hodnick *et al.*, 2017; Smereka *et al.*, 2017; Yildirim *et al.*, 2017) and a Combitube device to a SBL (Bollig *et al.*, 2006; Russi *et a.*, 2008). The third study that investigated the effectiveness of the Combitube (by Calkins *et al.*, 2006) carried out research on real patients and found a SBL to be superior (with no statistical significance). The author of this thesis found that the iLMA had a statistically significant lower success rate than all of the other devices, which is in disagreement with results from the study undertaken by Swanson *et al.* (2004), who found equal success rates between the iLMA and a MBL (and have so far been the only researchers to use paramedic participants and compare the iLMA to other alternative

methods). Swanson *et al*.'s study was also carried out on mannikins, though had a much smaller sample size. The higher success rate could be attributed to their participants being more familiar with the device than in this comparative study (see Section 5.4). Further reasons for the lower success rate with the iLMA in comparison to other methods used, could be attributed to the lack of view into the airway due to the blind intubation technique. However, the Combitube device is also a blind technique, though with its retroglottic nature is not inserted into the patient's trachea, whereas the ETT through the iLMA is, potentially making this technique more difficult. All the studies (including the author's) that were carried out on mannikins should be interpreted with caution, given that mannikins are not exact replicas of real patients. Complications such as airway obstructions from bodily fluids are not present in mannikin studies, which may affect success rates of each device, compared to those derived from use in real clinical situations (see Cook *et al.,* 2012; Freund *et al.*, 2012). To reduce other factors associated with mannikin use, the same mannikin was used in the author's comparative study, which reduced the variation in airways. At the same time, the muscle memory and skill to carry out intubation is observable on mannikins and findings can be applied to real patients in terms of the techniques used (Graham, 2005). Further research investigating alternative intubation devices on real patients would be a useful addition to the body of knowledge, whilst the findings would have enhanced implications for clinical practice.

In the experimental study presented in this thesis, the observed similar success rates with the MBL and Airtraq were unforeseen, given that paramedics are familiar with using a MBL and not a video-optic device. This outcome challenges previous literature findings that suggest the skill of intubation is diminishing (Deakin *et al.,* 2009). Familiarity with the MBL had the potential to influence outcomes (as discussed in Section 3.4.3), this potential training effect is recognised as a design limitation. In order to minimise and account for this, didactic explanation of each of the devices was given prior to use and paramedic participants were aware of the definition of intubation (further discussed in Section 5.3.2). At the same time, the number of years' experience a paramedic participant had was documented and associated with outcomes (see below), following findings that previous intubation experience was associated with intubation success and first pass success rate (Dyson *et al.*, 2017). Memory recall bias effect on intubation attempts was limited using random allocation of the order in which the devices were used. The results suggest that familiarity did not affect the results. Regardless of the above findings, ETI success rates identified in the case note review (stage one) were lower on real patients in cardiac arrest, compared to the success rates of intubation on mannikins in the simulated empirical study presented in this thesis.

First time success rates are important to minimise the amount of time the patient is without oxygen (Wang *et al.*, 2012). Existing studies found no differences between the first time success rates of VLs and a SBL (Bogdański *et al.,* 2015; Nasim *et al.*, 2009a and 2009b). Similarly, this empirical study identified no evidence to suggest that there are any differences between these devices in terms of the number attempts required to successfully intubate. Not finding a difference in the number of attempts required for successful intubation is likely related to the high success rates with the devices, with the exception of the iLMA, which required more attempts. In the author's study many participants did not continue on to use second and third attempts with the iLMA (a maximum of three attempts were permitted with each device) and it is noted that success rates might have improved if they had. The similar number of attempts and success rates with three of the AIDs compared in this thesis, alongside existing study findings, could have implications for practice in that either method would support effective patient care.

5.3.2 Time to intubate

When analysing all attempts, the quickest device for successful intubation was the Macintosh blade laryngoscope (MBL) (mean time=46 seconds), which is understandable as the paramedics were likely to be familiar with the MBL, whereas the other devices were new to them. This result is also similar to previously published studies, where times ranged from 8 seconds to over 90 seconds with a standard blade laryngoscope (SBL). A number of existing studies identified a SBL as the quickest method of intubation (when compared to a VL) (Nasim *et al.*, 2009a; Gaszynska and Gaszynska, 2014; Smereka *et al.*, 2017; Yousif *et al.*, 2017), though these studies had smaller sample sizes and one investigated participants wearing level C personal protective equipment (Section 2.3.1), which would have potentially slowed intubation times. A range of times to intubate were reported in these studies and, similar to the author's study, the participants were less familiar with VL devices. Guidelines suggest a maximum of 30 seconds for attempts to intubate (Difficult Airway Society, 2015), though mean times for all devices exceeded this (Airtraq; 55 seconds, the Combitube 51 seconds and iLMA 118 seconds). These times are lengthy, though comparable to previous study findings which found intubation times of greater than 30 seconds using a VL[28], Combitube (Bollig *et al.,* 2006; Russi *et al.*, 2008) and iLMA (Swanson *et al.*, 2004).

When the devices were compared to each other, there were statistically significant differences between the mean time to intubate with the iLMA and all the other devices

[28] Swanson *et al.,* 2004; Bollig *et al.,* 2006; Russi *et al.,* 2008; Wayne and McDonnell, 2010; Butchart *et al.,* 2011; Arima *et al.,* 2013; Bogdański *et al.,* 2015; Hodnick *et al.,* 2017; Yousif *et al.,* 2017.

(when all attempts were considered). This was attributed to the slower mean time to intubate with the iLMA (almost two minutes), which could be explained by the two-step process required with this intubation technique (time to intubate commenced from the insertion of the laryngeal mask airway (LMA), through which the ETT is passed). However, the study by Swanson *et al.* (2004), who compared the iLMA in an out-of-hospital practice environment on mannikins, found average intubation times of 39 seconds; three times quicker than in the author's research study. Their study sample size was 15 (nurse and paramedic participants); significantly lower than the sample in the empirical study presented in this thesis and not large enough to detect a difference (results were not statistically significant). Didactic training on the device took place in both studies, though it was noted that participants in the authors' study found the device difficult to use, despite grasping the concept of intubating over the SGA. Mean time differences presented in this thesis may be due to the high failure rate for intubation using the iLMA, which was investigated by analysing only successful attempts. However, results from the second analysis also found statistically longer times to intubate with the iLMA when compared to the other devices in this thesis. A quicker time to intubate did not necessarily lead to paramedics selecting this device as their preferred device, which was investigated in the final part of the research project.

In this comparative study, the researcher did not allow paramedics to practice with any of the devices in order to minimise memory recall bias (Sections 3.4.3 and 5.4.1). The training effect of using the devices was considered, which was shown in the literature review to have the potential to influence results (Russi *et al.,* 2013); Jarvis *et al.,* 2015; Ducharme *et al.,* 2017). In the author's study, the lack of statistically significant differences between device intubation times indicates that the familiarity of the MBL did not affect results. Further training on the alternative methods of intubation could potentially improve intubation times, improving their applicability for use in prehospital care. This said, caution should be taken with the findings from this thesis given that the empirical study was carried out on mannikins and experience with using AIDs varied. Training and user-friendliness were concepts raised by paramedics when asked for their opinions about the devices (see Section 5.4).

5.4 Examination and comparison of alternative intubation devices – paramedics' preferences

Paramedics' preference was an important component of the research; one of the initial objectives set by the researcher was to investigate the preferences of paramedics for AIDs. Each paramedic was asked to rank the devices (or methods of intubation) in order of

preference, which required conscious comparison of the devices. This data collection method has not been used in previous comparative studies - which used rating methods where participants were asked to rate devices individually (using visual analogue scales) and comparisons made at the point of data analysis. Furthermore, open responses were collected and analysed in the authors' research, which also has not been used in previous comparative studies. Reasons for ranking order of the devices was captured qualitatively and analysed using inductive thematic analysis. This method ensured that the themes were not driven by the researcher's theoretical interest in ETI and the devices, but data driven directly from the paramedic participants (after Patton, 1990). Four themes emerged; process of intubation, outcome of intubation, training and exposure to the devices and user friendliness.

The Airtraq (a video-optic device) was the preferred alternative method of intubation; over half the participants selected this device as their favourite. The reasons given for this included offering clear visualisation of the vocal cords and being the most user friendly. Previous mannikin studies also found that views of the glottis are significantly enhanced when a VL is used (Butchart *et al.,* 2011; Bogdański *et al.,* 2015; Hodnick *et al.,* 2017; Smereka *et al.,* 2017). In other studies, airway views with a VL were found to be comparable to a SBL (Truszewski *et al.,* 2016; Ducharme *et al.,* 2017). Similar statements were mentioned by paramedics in the authors' comparative study, where it was reported that the more familiar method of a MBL allowed for a good degree of capability in visualising the ETT passing through the vocal cords. Unfortunately, adverse effects such as levering on the teeth of the mannikin, excessive force in the soft palate of the upper airway and excessive head movement, were observed by the researcher through the data collection process. Existing studies also identified the issue of excessive pressure used with a SBL (Butchart *et al.*, 2011; Smereka *et al.*, 2017; Yildirim *et al.*, 2017) (see Section 2.3.3). Although in the author's research this was a small proportion (less than 10%, particularly related to older paramedics), it was not always recognised by participants. This observation is concerning as the method is currently used on real patients in practice and could have caused significant trauma and additional complications. Previous studies and researchers discovered that using a VL considerably reduced the amount of dental force exerted on patients (Butchart *et al.,* 2011; Yildirim *et al.,*2017). The lack of force required with a VL was supported by paramedic participants, who made comments about the Airtraq that suggested no pressure or force was needed on the device or by the user. Indeed, the researcher observed a good degree of adaptability when using new devices, though there was an element of manipulation when using the Airtraq device, with a temptation to 'rock' in an attempt to obtain a view. Using the device in this way could be attributed to the lack of familiarity with the device and could potentially be overcome with training interventions. With similar results in paramedic preference for VLs being found in

the current and existing studies, this could be considered when further investigating AIDs for use in practice.

Having a good view of the vocal cords is more likely to lead to a successful, timely intubation (Katz and Falk, 2001; Wang and Yealy, 2006a), though this is not a necessary element when using the blind intubation or retroglottic methods (the iLMA and the Combitube). The inability to gain an effective airway was important for paramedics and devices were not favoured if they could not intubate or ventilate first time with them. However, the Combitube had a 100% success rate and although favourable comments were made about the reliability of the device, it was not the most preferred. A reason for this could be related to paramedics being used to viewing a patient's airway and visualising the ETT passing through the vocal cords. In a previous study that investigated and compared Combitube devices, authors reported on ease of use and found the Combitube to be easier to use than performing intubation with a SBL (Russi *et al.*, 2008). The same authors found paramedics were similarly comfortable with a SBL and a Combitube. In this thesis, participants had perhaps not considered potential airway obstructions that could be present in real patients. It is necessary to be mindful of these and if applying the method to practice, practitioners may require additional equipment and interventions to clear the airway, such as suctioning of obstructive fluid or to remove foreign bodies in the airway. Research carried out on real patients (and therefore real airway management situations) to compare retroglottic and blind intubation techniques, is required to establish device effectiveness and make recommendations for practice.

The iLMA was the least preferred device, with almost 80% of participants ranking this device fourth out of four. Analysis showed significant differences between the preference rankings for the iLMA and all other devices (with the iLMA having a lower ranking than the others). This outcome is plausible, given that the iLMA was the least successful and took the longest time to intubate. Paramedic participants found the device to be ineffective and problematic in terms of user-friendliness. This finding is different to the findings of the one identified published study that investigated the iLMA with paramedic participants (Swanson *et al.*, 2004), whose participants rated the process of using an iLMA as 'fairly easy', though more difficult than with a standard blade. In this comparative study, least preferred ranking could be attributed to the lack of training and familiarity with the iLMA; it was clear that paramedics knew what they had to do with the device, though found it difficult to execute this. The likelihood of the iLMA being accepted in to paramedic practice is low given the device was not favoured by the paramedics that participated in the study presented in this thesis and the one existing study was not large enough to identify a statistically significant preference for the iLMA.

The training effect and its potential to influence results has been discussed throughout this thesis (see Sections 3.4.3 and 5.4.1). In this research, participants referred to not being able to use some of the devices straight away whilst others suggested they would improve with practice or need to practice more. This suggestion is encouraging and suggests that paramedics are open to try new methods, or change practice, particularly if this could improve patient outcomes. The literature review revealed that many researchers have found ETI to improve patient outcomes when performed by skilled professionals (Wang and Yealy, 2006a; Wang *et al.*, 2010; Shin *et al.*, 2012; Tanabe *et al.*, 2013; Wallis *et al.*, 2013; Henlin *et al.*, 2014; Benoit *et al.*, 2015; Kang *et al.*, 2015). It was observed that paramedics were familiar with the concept of intubation and had anatomical and physiological awareness when performing intubation. Many of the participants prepared their equipment beforehand for instance by pre-filling syringes with air and or loading the Airtraq with an ETT). This preparedness in performing intubation could increase confidence and competence and thus patient care, when applied to practice effectively.

Chapter 6 Conclusion

The research presented in this thesis investigated airway management and endotracheal intubation (ETI) in the out-of-hospital care environment, along with the examination of the ability of paramedics to effectively used alternative intubation devices (AIDs) in an experimental setting. The research project included a retrospective case note review, an opinion survey and an experimental comparative study of four different intubation devices. This chapter summarises the findings in the light of the research aims and published literature (Section 6.1) and discusses the limitations and weaknesses of the research (Section 6.2). Contributions to and recommendations for further research and implications for practice, are presented in Section 6.3 of the chapter.

6.1 Summary of findings aligned with the research aims

Aim 1) Identify current practice relating to airway management and endotracheal intubation in the out-of-hospital environment.

The data from the case note review in one region of the UK show that a variety of airways were used for patients in cardiac arrest. The frequency of use of simple airway adjuncts (oropharyngeal airway and nasopharyngeal airways) was low and fewer than half of patients had a supraglottic airway (SGA) inserted. The data suggest that a step-wise approach to airway management is not routinely carried out whilst resuscitating patients in cardiac arrest. The success rates of these airway adjuncts were high, indicating good skill and technique when using these simple airway adjuncts in practice.

Paramedics could have intubated immediately, rather than use a step-wise approach. The data suggests that attempts to intubate were made in less than half the patients in cardiac arrest (42%). Twenty-three per cent of these were unsuccessful, leading to less than a third of patients in cardiac arrest being successfully intubated (32%), which could be due to the (unrecorded) level of responder to the cardiac arrest: emergency technicians and care assistants do not perform intubation.

Aim 2) Ascertain paramedics' opinions on airway management and endotracheal intubation in the out-of-hospital environment.

The airway adjuncts that the paramedics reported commonly using in cardiac arrest included simple adjuncts (oropharyngeal and nasopharyngeal airways), SGAs and endotracheal tubes (ETTs). Over 80% of respondents stated they would use a SGA, either

an iGel or a laryngeal mask airway (LMA). A similar number indicated they would commonly perform ETI in cardiac arrest (78%). A large proportion (83%) of paramedics reported that they believe ETI is gold standard airway management during cardiac arrest, implying that they would perform the skill in practice if feasible. The results from the survey conflict with findings from the case note review, which found that less than half (42%) of patients in cardiac arrest had intubation attempted. However, these two sources of data were not directly comparable as the case note review data did not contain details about the responder status and was only from one area of the UK (see Section 6.2).

The most common reason given for not performing ETI in cardiac arrest was if an alternative device was adequate to ventilate the patient. Further reasons given for not intubating or unsuccessful intubation, were a lack of available equipment, not being able to obtain a view of the vocal cords due to limited patient access, patient position or obstructions in the airway.

Aim 3) Examine and compare the ability of paramedics to effectively use alternative intubation devices

Effectiveness was determined by success rates (defined by simulated ventilation of the mannikins lungs) and time taken to successfully ventilate. Analysis of the experimental study data showed the overall success rates for the Airtraq, Combitube and Macintosh Blade Laryngoscope (MBL), were comparable (over 97% successful) when used by paramedics. Similar findings were found in recent peer reviewed literature, with no one AID found to be more successful than another (Nasim *et al.*, 2009a and 2009b; Ducharme *et al.*, 2017; Hodnick *et al.*, 2017; Smereka *et al.*, 2017; Yildirm *et al.*, 2017). In the comparative study presented in this thesis, there were statistically significant differences between the proportion of successful intubations of the iLMA and all the other devices. The iLMA was the least successful, with a success rate of 65%. This result contradicts the results from previous research, which found comparable success rates between the iLMA and a standard blade laryngoscope (SBL) (Swanson *et al*., 2004).

The quickest device for successful intubation in this research was the MBL, with a mean time of 42 seconds, followed by the Airtraq and Combitube (mean time=51 seconds for both) and the iLMA taking a mean time of 86 seconds. Time taken to intubate was measured in most of the previously published studies (see for example Nasim *et al.*, 2009a and 2009b; Gaszynska and Gaszynska, 2014; Smereka *et al.*, 2017; Yousif *et al.,* 2017), although the results were varied and conflicting; there was no one method found to facilitate quicker ventilation than another overall. There were statistically significant differences in the time taken to successful ventilation between the iLMA and all other

devices. The long intubation times with the iLMA could be attributed to the higher failure rate with this device and a lower proportion of participants using all three attempts with this device (see Section 6.2).

Aim 4) Investigate the preferences of paramedics for alternative intubation devices

Paramedic participants were asked to rank the intubation methods and devices in order of preference. In some previously published studies, paramedics' opinions on devices were gathered using visual analogue scales to establish perceived ease of use for each device (Bogdański *et al.,* 2015; Hodnick *et al.,* 2017; Wallace *et al.,* 2017 and Yousift *et al.,* 2017). The ranking rather than rating of devices in this research study was considered superior as the participants were required to explicitly compare the devices. The most frequently selected as preferred device was the Airtraq, with over half the participants selecting this device as their most favoured. The least favoured device was the iLMA, with over 79% of participants ranking this device last. When the device ranks were compared to each other, there was a statistically significant preference for the Airtraq over the Combitube, which was different to existing findings that suggested that paramedics were similarly comfortable with a SBL and Combitube device (Russi *et al.,* 2008). There was also a statistically significant difference between the iLMA and all other devices, with the iLMA being the least preferred device. Associations were investigated between the ranking of devices and the demographic data. A higher proportion of younger paramedics ranked the iLMA as the least preferred device.

These rankings were further explored by the use of free text comments which were analysed qualitatively. Reasons given for selecting the Airtraq as the preferred device predominantly related to the good view of the vocal cords the device provided. Other positive statements related to the lack of pressure required to use the device, as well as the lack of force exerted on the mannikin. This is similar to findings from previous studies, which found that VLs were superior in terms of the view the device offered, particularly when alternative situations such as chest compressions and cervical spine immobilisation were introduced (Butchart *et al.,* 2011; Bogdański *et al.,* 2015; Hodnick *et al.,* 2017; Smereka *et al.,* 2017). At the same time, VLs reduced adverse effects such as dental trauma. The MBL was reflected upon positively with statements about the 'control' one had when using the device and the familiarity of the technique. Perceptions of speed to successfully intubate were also made about all the methods, when selecting a favoured.

Reasons for ranking a method or device as least preferred predominantly related to the lack of user friendliness, in the main relating to the iLMA. A common phrase used was the 'awkwardness' of the devices, for both the iLMA and Combitube. The outcome of intubation

also featured highly with justification of least preferred devices; not being able to intubate with the device. Training and exposure to devices was mentioned; participants suggested that they would improve with practice with each of the devices (see Section 6.3).

6.2 Research limitations and weaknesses

The research design was the three-stage, mixed methods approach which was novel and offered a diverse and more comprehensive understanding of ETI by paramedics in the out-of-hospital environment. Whilst this was effective in answering the research aims and objectives, there were some limitations in the design. These have been referred to throughout the methods chapter (Chapters 3) and further challenges that emerged during the completion of the research were discussed in Chapter Five. A summary of the methodological limitations, weaknesses and challenges are offered in this section.

In order to minimise the differences between local service guidelines and practices, the research was completed in one region of the UK. Whilst this has not offered an opportunity to consider comparisons of practice across the UK, it has enabled a focus on the airway management interventions provided by paramedics to patients in cardiac arrest (see Section 3.2.1). The case note review sampled all the patients in cardiac arrest in the East Midlands region over the period of a year. This avoided the Airways-2 trial data collection period in an attempt to mitigate any risk of skewing data regarding choice of airway adjunct used in cardiac arrest. It is possible that the findings will be unique to the area, given the national guidance on cardio pulmonary resuscitation (Resuscitation Council, 2015) and national ambulance guidelines (Fisher *et al*., 2016) (see Section 3.2.1).

The data provided from EMAS for the case note review was a summary of cardiac arrests and airway management techniques used over the period of a year. An initial data sharing agreement was in place at the outset of the research, approving access to relevant raw data. Subsequent changes (in staff and guidance) challenged this, restricting the data shared (see Section 4.2). Requests were made by the researcher for the raw data, including offers to extract the data herself, though this was not possible. A weakness that was identified during data analysis was the inclusion of airway management practices from all ambulance personnel, rather than paramedics only. Despite the format of the data provided limiting data analysis[29], the data extraction method ensured no influence from the researcher on findings and the first aim of the research project (to identify current

[29] It had been intended to analyse the data by looking not only at overall summary statistics, but also by looking at possible associations with demographic professional and clinical factors including responder status.

practice relating to airway management and intubation in the out-of-hospital environment) was met.

The data from the case note review was taken from one [ambulance] Trust, from 2014-2015 and the opinion survey carried out in 2017, which included responses from paramedics from a number of different ambulance Trusts. Weaknesses have been identified in the opinion survey (see Section 3.3.1) through reflection upon the questions asked, being potentially leading and inferring researcher bias. For example, questions asked for reasons why paramedics would not intubate in practice, rather than reasons for failed intubation in practice or an open question about ETI in OHCA.

The snowball sampling method used to recruit respondents for the opinion survey did not enable a random sample of the paramedic population. Snowball sampling was carried out due to there being no centre register of paramedics available to the researcher, supporting a random sample design. The method used enabled recruitment from an otherwise hard to reach population. The resulting sample was large enough to enable the second aim of the research to be met. This aim focussed on ascertaining paramedics' opinions on airway management and intubation in the out-of-hospital environment (see Section 3.3.2). By using this sampling method, the recruitment process was taken out of the researcher's control after the initial round of direct contacts, reducing bias in terms of selection.

The recruitment method for the comparative study could also not be random, given the lack of a central register to sample from. However, the convenience sampling recruitment method was effective in ensuring a spread of demographic factors, as well as achieving the *a priori* sample size (see Section 3.4.2). The comparative study used a mannikin to measure intubation attempts, which is a recognised limitation of the research design.

One of the limitations of observational studies is not accounting for any errors during airway management, such as ETT misplacement or the duration of airway insertion attempts (Wang *et al.*, 2012) (see Section 2.2.1). Timing continued throughout all the attempts required for successful intubation and ventilation, rather than separating each attempt (Section 3.4.3). This is not truly representative of clinical practice (whereby reoxygenation would usually take place between intubation attempts) (Weingart, 2011; Jung *et al*., 2012; Higgs *et al*., 2018).

The video-optic device selected for the comparative study (the Airtraq) was selected because of its availability. Other video laryngoscopes could have been incorporated into the comparisons if they had been available. The paramedics were accustomed to using

the MBL but not the other alternative methods of intubation, which was recognised as a study design limitation (see Sections 3.4.3 and 5.4.1).

6.3 Contribution to and recommendations for practice and further research

The research adds to knowledge by offering empirical evidence on airway management techniques (including ETI), used by paramedics for patients in out-of-hospital cardiac arrest (OHCA). Furthermore, paramedics' own views on airway management have been presented, including their reasons for not performing ETI and experiences of unsuccessful ETI, during OHCA. The comparative study is the first known to the author to compare more than two alternative intubation devices or methods in one study, investigating effectiveness in terms of success rate and time to intubate. It is also the first research in the UK to compare blind intubation methods (the Combitube device and intubating laryngeal mask airway (iLMA)) using paramedic participants. To ascertain paramedics' preferred AID, participants were asked to rank the devices in order of preference, rather than obtaining ratings on individual methods. Ranking the devices in this way required conscious comparisons between the devices and was further investigated by obtaining paramedics' justifications of their decisions in their own words, which has not been carried out in existing comparative studies.

The case note review in the current research study identified airway management techniques for patients in OHCA, carried out by all ambulance personnel. Future research could investigate the airway management practices by paramedics only and compare these to ambulance technicians and care assistants. It would be useful to review the case notes of patients in a range of geographical areas, to establish local and national airway management practices. Furthermore, carrying out research using case notes and a survey simultaneously would allow for succinct comparison of results and give an enhanced overview of practice. Future studies should recruit a larger sample, through a wider range of Trusts, where resources and approvals allow.

The opinion survey offers intuitive insight into paramedics' opinions of airway management and intubation, one of the reasons given not to intubate was the lack of available equipment, another because another adjunct was adequate. A number of factors are considered by ambulance service commissioners when considering the introduction of new practices, such as equipment and processes. This is service dependent and could be further investigated by ambulance services to establish which resources are limiting paramedics performing intubation in practice and or whether this is related to new methods or changes in clinical practice guidance. Paramedics' opinions and preferences should be considered in addition to the clinical effectiveness, cost analysis, patient input and national standard review, when considering service changes. The author's research study has demonstrated that involving paramedics can offer useful insights to practice-based challenges and are valuable in determining apposite changes in practice.

The ability of alternative intubation devices to help overcome some of the reasons given by paramedics in the opinion survey for not intubating, such as difficulties in accessing patients or being unable to obtain a view of the vocal cords, was examined. Previous studies found that paramedic experience positively affects the success rate of intubation (Wang *et al*., 2010; Dyson *et al*., 2017) and should be considered when further examining the use of AIDs. The comparative study presented in this thesis acknowledged the number of years' experience and training background the paramedic participants had, which is a strength of this research. Furthermore, previous studies have not accounted for training background or paramedics opinions, this research therefore offered an alternative view on factors associated with intubation by paramedics (Sections 3.4.3 and 5.4.1).

The impact on patient care has been referred to throughout this thesis and a device that offers the best outcome for patients is desired. The comparable success rate of the Airtraq, Combitube and MBL in this thesis suggests that all would be suitable in practice. However, with this being a mannikin study, it is impossible to state whether airway obstructions present in real patients would have hindered the use of each of these devices or methods. Time to intubate was also similar between the MBL, Airtraq and Combitube, although using each of these devices took longer than 30 seconds to successfully ventilate and so other factors need to be considered when making recommendations for the most effective device for use in prehospital practice. The intubating laryngeal mask airway (iLMA), had poor success rates and lengthy time to intubate (on average 86 seconds), which is not conducive to effective patient care during cardiorespiratory resuscitation. The results showed that the iLMA was the least effective of the devices used in this study. It is likely that it would also not be effective for patient care in prehospital practice. However, the methodological limitations in this research including paramedic participants having prior experience in using a MBL in practice and the use of a mannikin to examine the AIDs, it is not appropriate to recommend a particular method of intubation in the clinical situation.

Accompanying the findings of the equivalent success rate and time to ventilate that the Airtraq, Combitube and MBL had, it was determined that paramedics' preferred device was the Airtraq video-optic device. This preference ranking separates this device from the others; the enhanced views of the airway and diminished adverse effects the VL offered. This finding has implications for practice in that a VL could offer superior intubations and the author suggests further research to determine whether a VL would be suitable for use in paramedic practice. Further training may improve intubation times and enhance patient care with all of the devices and methods compared. The educational preparedness of paramedics is likely to positively affect the ability to provide effective care, alongside availability of appropriate equipment. To maintain the skill with whichever method of

intubation is used in practice, a comprehensive training programme and a predetermined skill maintenance plan is recommended.

The methodological limitations of this research require that more robust experimental studies are undertaken to fully explore the use of ETI and alternative intubation devices or methods in clinical practice.

References

Abbott, P. and Sapsford, R. (1998) *Research methods for nurses and the caring professions.* 2nd ed. Buckingham: Open Univesity Press.

American College of Surgeons (2011) *Prehospital Trauma Life Support.* 7th ed. Philadelphia: Elsevier.

American Heart Association (2012) ACLS Provider Manual Supplementary Material. American Heart Association [online]. Available from: http://ahainstructornetwork.americanheart.org/idc/groups/ahaecc-public/@wcm/@ecc/documents/downloadable/ucm_425488.pdf [Last Accessed January 2018].

Arima, T., Nagata, O., Miura, T., Ikeda, K., Mizushima, T., Takahashi, A. and Sakaida, K. (2014) Comparative analysis of airway scope and Macintosh laryngoscope for intubation primarily for cardiac arrest in prehospital setting. *The American Journal of Emergency Medicine.* **32**(1), pp.40-43.

Arslan Hanif, M., Kaji, A. H., & Niemann, J. T. (2010). Advanced airway management does not improve outcome of out-of-hospital cardiac arrest. *Academic Emergency Medicine*. **17**(9), pp.926-931.

Asai, T. (2012) Complications with Supraglottic Airways Something to Worry About or Much Ado About Nothing? *Anesthesiology.* **116**(6), pp.1183-1185.

Association of Anaesthetists of Great Britain and Ireland (2017) Safer pre-hospital anaesthesia 2017. *Anaesthesia.* **72**, pp.379-390.

Aufderheide, T.P., Nichol, G., Rea, T.D., Brown, S.P., Leroux, B.G., Pepe, P.E., Kudenchuk, P.J., Christenson, J., Daya, M.R., Dorian, P., Callaway, C.Q., Idris, A.H., Andrusiek, D., Stephens, S.W., Hostler, D., Davis, D.P., Dunford, J.V., Pirrallo, R.G., Stiell, I.G., Clement, C.M., Craig, A., Van Ottingham, L., Schmidt, T.A., Wang, H.E., Weisfeldt, M.L., Ornato, J.P. and Sopko, G. (2011) A trial of an Impedance Threshold Device in Out-of-Hospital Cardiac Arrest. *New England Journal of Medicine.* **365**, pp.798-806.

Aziz, M. (2013) Use of Video-assisted Intubation Devices in the Management of Patients with Trauma. *Anesthesiology Clinics.* **31**(1), pp.57-166.

Bell, J. and Waters, S. (2014) *Doing your research project a guide for first-time researchers. 6th ed.* Berkshire: Open University Press.

Benger, J., Coates, A., Davies, S., Greenwood, R., Nolan, J., Rhys, M., Thomas, M. and Voss, S. (2016) Randomised comparison of the effectiveness of the laryngeal mask airway supreme, i-gel and current practice in the initial airway management of out of hospital cardiac arrest: a feasibility study. *British Journal of Anaesthesia.* **116**(2), pp.262-268.

Benoit, J.L., Gerecht, R.B., Steuerwald, M.T. and McMullan, J.T. (2015) Endotracheal intubation versus supraglottic airway placement in out-of-hospital cardiac arrest: A meta-analysis. *Resuscitation.* **93**, pp.20-26.

Benumof, J.L. (1999) Preoxygenation: Best method for both efficicacy and efficiency. *Anaesthesiology*. **91**(3), pp.603-605.

Berg, M.D., Nadkami, V.M., Suercher, M. and Berg, R.A. (2008) In-hospital pediatric cardiac arrest. *Pediatric Clinics of North America.* **55**(3), pp.589-604.

Biggs, H (2010) *Healthcare Research Ethics and Law. Regulation, Review and Responsibility.* Oxon: Routledge-Cavendish

Bingham, R.M. and Proctor, L.T. (2008) Airway Management. *Pediatric Clinics of North America*. **55**(4), pp. 873-876.

Blaber, A. (2012) Foundations for paramedic practice. 2nd ed. Berkshire: Open University Press.

Bobrow, B.J. and Spaite, D.W. (2009) Do not pardon the interruption. *Annals of Emergency Medicine.* **54**(5), pp.653-655.

Bogdański, Ł., Truszewski, Z., Kurowski, A., Czyżewski, Ł., Zaśko, P., Adamczyk, P. and Szarpak, Ł. (2015) Simulated endotracheal intubation of a patient with cervical spine immobilization during resuscitation: a randomized comparison of the Pentax AWS, the Airtraq, and the McCoy Laryngoscopes. *The American Journal of Emergency Medicine.* **33**(12), pp.1814-1817.

Bollig, G., Løvhaug, S., Sagen, Ø., Svendsen, M., Steen, P. and Wik, L. (2006) Airway management by paramedics using endotracheal intubation with a laryngoscope versus the oesophageal tracheal Combitube™ and EasyTube™ on mannikins: A randomised experimental trial. *Resuscitation.* **71**(1), pp.107-111.

Booth, A., Sutton, A. and Papaioannou, D. (2016) *Systematic approaches to a successful literature review.* 2nd ed. London: Sage.

Bowling, A. (2014) *Research Methods in Health. Investigating health and health services.* Berkshire: Open University Press.

Braun, V. and Clarke, V. (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology.* **3**(2), pp. 77-101.

Braun, V. and Clarke, V. (2013) *Successful Qualitative Research a practical guide for beginners.* London: Sage Publications Ltd.

Bristol Online Survey (BOS) (2015) BOS Online Survey Tool [online]. Available from: https://www.onlinesurveys.ac.uk/ [Last Accessed October 2017].

Brown, C.A., Sakles, J.C. and Mick, N.W. (2017) *Manual of Emergency Airway Management*, 5th edition. Philadelphia: Lippincott, Williams and Wilkins.

Brown, S.N., Kumar, D., Millins, M. and Mark, J. (Eds) (2016) *UK Ambulance Services Clinical Practice Guidelines.* Bridgwater: Class Professional.

Burns, N. and Groves, S.K. (1987) *The practice of Nursing Research: Conduct critique and Utilisation.* Philadelphia: W.B. Saunders Company.

Butchart, A.G., Tjen, C., Garg, A. and Young, P. (2011) Paramedic Laryngoscopy in the Simulated Difficult Airway: Comparison of the Venner A.P. Advance and GlideScope Ranger Video Laryngoscopes. *Academic Emergency Medicine.* **18**(7), pp.692-698.

Byhahn, C., Meininger, D., Walcher, F., Hofstetter, C. and Zwissler, B. (2007) Prehospital emergency endotracheal intubation using the Bonfils intubation fiberscope. *European Journal of Emergency Medicine.* **14**(1), pp.43-46.

Calkins, T., Miller, K. and Langdorf, M. (2006) Success and Complication Rates with Prehospital Placement of an Esophageal-Tracheal Combitube as a Rescue Airway. *Prehospital and Disaster Medicine.* **21**(2), pp.97-100.

Carter, Y., Shaw, S. and Thomas, C. (Eds) (2000) *The use and design of questionnaires.* London: The Royal College of General Practitioners

Cohen, J. (1988) *Statistical Power Analysis for the Behavioral Sciences.* 2nd ed. Hillsdale: Lawrence Erlbaum.

College of Paramedics (2018) Consensus statement. A framework for safe and effective intubation by paramedics. London: College of Paramedics.

Colombage, D. (2014) I-Gel supraglottic airway. *Premier Healthcare & Hygiene Ltd* [online]. Available from: https://www.premierhh.co.uk/i-gel-supraglottic-airway.html [Last Accessed August 2018].

Comstock, G. (2016) *Research Ethics. A philosophical guide to the responsible conduct of research.* Cambridge: Cambridge University Press.

Cook, T. and Howes, B. (2011) Supraglottic airway devices: recent advances. *Continuing Education in Anaesthesia Critical Care & Pain.* **11**(2), pp.56-61.

Cook, T., Behringer, E.C. and Benger, J. (2012) *Airway Management outside the operating room: hazardous and incompletely studied.* Current Opinion Anaesthesiology. **25**(4), pp.461-9.

Cook, T.M. Woodall, N. Frerk, C. (2011) Fourth National Audit Project. Major complications of airway management in the UK: results of the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society. Part 1: Anaesthesia. British Journal of Anaesthesia. **106**, pp.617-31.

Cormack, R.S. and Lehane, J. (1984) Difficult tracheal intubation in obstetrics. *Anaesthesia.* **39**(11), pp.1105–11.

Creswell, J.W. (2009) *Research Design. Qualitative, Quantitative, and Mixed Methods Approaches.* 3rd ed. London: Sage Publications Ltd.

Creswell, J.W. (2013) *Qualitative Inquiry and Research Design. Choosing among five approaches.* 3rd ed. London: Sage Publications Ltd.

Creswell, J.W. and Plano Clark, V.L. (2011) *Designing and conducting mixed methods research.* 2nd ed. London: Sage Publications Ltd.

Crowe, S., Cresswell, K., Robertson, A., Huby, G., Avery, A. and Sheikh, A. (2011) *The case study approach.* BMC Medical Research Methodology. **11**(100).

De Vaus, D. (2002) *Surveys in Social Research.* 5th ed. London: Routledge.

Deakin, C. D., Clarke, T., Nolan, J., Zideman, D. A., Gwinnutt, C., Moore, F., Ward, M., Keeble, C. Blancke, W. (2010). A critical reassessment of ambulance service airway management in prehospital care: Joint Royal Colleges Ambulance Liaison Committee Airway Working Group, June 2008. *Emergency Medicine Journal.* **27**(3), pp.226-233.

Deakin, C.D., King, P. and Thompson, F. (2009) *Prehospital advanced airway management by ambulance technicians and paramedics: is clinical practice sufficient to maintain skills?* Emergency Medicine Journal. **26**(12), pp. 888-891.

Denscombe, M. (1998) The Good Research Guide. Buckingham: Open University Press.

Department of Health (DOH) (2005) *Research Governance Framework for Health and Social Care.* 2nd ed. London: Department of Health.

DePoy, E. and Gitlin, L. (2011) *Introduction to Research. Understanding and Applying Multiple Strategies.* 4th ed. Missouri: Elsevier.

Difficult Airway Society (DAS) (2015) DAS guidelines for management of unanticipated difficult intubation. DAS [online]. Available from: https://www.das.uk.com/ [Accessed January 2018].

Difficult Airway Society (DAS) (2018) What is airway management? [online] Available from: https://das.uk.com/content/patient_info/what_is_airway_management [Last Accessed January 2019].

Doherty, R.F. and Purtilo, R.B. (2016) *Ethical Dimensions in the Health Professions.* 6th ed. Missouri: Elsevier.

Dorges, V., Knacke, P. and Gerlach, K. (2003) Comparison of different airway management strategies to ventilate apneic, nonpreoxygenated pateitns. Critical Care Medicine. **31**, pp.800-804.

Ducharme, S., Kramer, B., Gelbart, D., Colleran, C., Risavi, B. and Carlson, J. (2017) A pilot, prospective, randomized trial of video versus direct laryngoscopy for paramedic endotracheal intubation. *Resuscitation.* **114**, pp.121-126.

Dyson, K., Bray, J.E., Smith, K., Bernard, S., Straney, L., Nair, R. and Finn, J. (2017) Paramedic Intubation Experience Is Associated with Successful Tube Placement but Not Cardiac Arrest Survival. *Annals of Emergency Medicine.* **70**(3), pp.382-390.

East Midlands Ambulance Service (EMAS) (2018) Airway Management Policy. EMAS.

East Midlands Ambulance Service (EMAS) (2019) Dispatch Protocols. EMAS.

East Midlands Ambulance Service (EMAS) --@emas.nhs.uk (2017) *Doctoral study information.* [email]. Message to: Sarah Cross. --@authoremail.com. 7th July. 11:02.

Eastern Association for The Surgery of Trauma (EAST) (2002) *Guidelines for Emergency Tracheal Intubation Immediately Following Traumatic Injury.* Ohio: EAST.

Egly,J., Custodio, D., Bishop, N., Prescott, M., Lucia, V., Jackson, R.E. and Swor, R. (2010) Assessing the impact of prehospital intubation on survival in out-of-hospital cardiac arrest. *Prehospital Emergency Care*. **15**(1), pp.44–49.

Fawzy, E., Sadana, N., Khan, M., Dasan, J. and Desai, N. (2012) Use of supraglottic airway devices by the non-anaesthetists. *British Journal of Anaesthesia.* **108**(1), pp. 131.

FOIA.gov. (2000) Freedom of Information Act. [online] Available from: https://www.foia.gov/ [Last Accessed January 2018].

Foregger, R. (1966) Manufacturer of anesthesia equipment. Anesthesiology. **84**, pp.190-200.

Franek, M., Pokorna, M. and Sukupova, P. (2010) Pre-hospital cardiac arrest in Prague, Czech Republic – The Utstein-style report. *Resuscitation.* **81**(7), pp.831-835.

Freund, Y., Duchateau, F.X., Devaud, M.L., Ricard-Hibon, A., Juvin, P. and Mantz, J. (2012) Factors associated with difficult intubation in prehospital emergency medicine. *European Journal of Emergency Medicine*. **19**(5), pp.304–308.

Garza, A.G., Gratton, M.C., Coontz, D., Noble, E. and John, O. (2003) Effect of paramedic experience on orotracheal intubation success rates. *Journal of Emergency Medicine*. **25**(3), pp.251-256.

Gaszynska, E. and Gaszynski, T. (2014) Truview EVO2 and Standard Macintosh Laryngoscope for Tracheal Intubation During Cardiopulmonary Resuscitation. *Medicine*, **93**(14), p.e78.

Gatward, J.J., Thomas, M.J., Nolan, J.P. and Cook, T.M. (2008) Effect of chest compressions on the time taken to insert airway devices in a mannikin. British Journal of Anaesthesia. **100**(3), pp.351–356.

George, J., Smith, J. and Moore, F. (2012) *Airway management in UK ambulance services: where are we now?* Emergency Medicine Journal. **29**(6), pp.516

Goldman, K. and Ferson, D.Z. (2005) *Education and training in airway management.* Best Practice and Research Clinical Anaesthesiology. **19**(4), Pp. 717-732.

Gorard, S. and Taylor, C. (2004) *Combining Methods in Educational and Social Research*. Berkshire: Open University Press.

Gough, D., Oliver, S. and Thomas, J. (2012) *An introduction to systematic reviews.* London: Sage.

Gov.UK. (2018). Data protection act. GOV.UK. [online] Available from: https://www.gov.uk/data-protection/the-data-protection-act [Accessed January 2018].

Graham, C.A. (2005) Emergency Department Airway Management in the UK. *Journal of the Royal Society of Medicine.* **98**(3), pp.107-110.

Green, J. and Thorogood, N. (2009) Qualitative methods for health research. London: Sage.

Green, J. and Thorogood, N. (2013) *Qualitative methods for health research.* 3rd ed. London: Sage.

Gregory, P. and Mursell, I. (2010) *Manual of clinical paramedic procedures*. Oxford: Wiley-Blackwell.

Guyette, F.X., Greenwood, M.J., Neubecker, D., Roth, R. and Wang, H.E. (2007) Alternate airways in the prehospital setting. *Prehospital Emergency Care*. The Journal of the American Medical Association. **11**(1), pp.56–61.

Hansen, M.L., Lin, A., Eriksson, C., Daya, M.R., McNally, B., Fu, R., Yanez, N., Zive, D. and Newgard, C. (2017) A comparison of pediatric airway management techniques during out-of-hospital cardiac arrest using the CARES database. *Resuscitation.* **120**, pp.51-56.

Hasegawa, K., Hiraide, A., Chang, Y. and Brown, D.F. (2013) Association of prehospital advanced airway management with neurologic outcome and survival in patients with out-of-hospital cardiac arrest. The Journal of the American Medical Association. **309**, pp.257–66.

Häske, D. Schempf, B., Gaieretal, G. (2013) Performance of the i-gel during pre-hospital cardiopulmonary resuscitation. *Resuscitation.* **84**(9), pp.1229-1232.

Health and Care Professions Council (2012) *Standards of Continuing Professional Development.* London: HCPC

Health Education England (2013) PEEP report. Health Education England. [online] Available from: http://www.councilofdeans.org.uk/wp-content/uploads/2014/01/15102015-Paramedic-PEEP-project.pdf [Accessed January 2018].

Heckathorn, D.D. (2011) Comment: Snowball versus Respondent-Driven Sampling. *Sociological Methodology.* **41**(1), pp.355-356.

Henlin, T., Michalek, P., Tyll, T., Hinds, J.D. and Dobias, M. (2014) Oxygenation, Ventilation, and Airway Management in Out-of-Hospital Cardiac Arrest: A Review. *Biomedical Research International* [online]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3958787/ [Last accessed January 2019].

Higgs, A., McGrath, B.A., Goddard, C., Rangasami, J., Suntharalingam, G., Gale, R., Cook, T.M. and on behalf of Difficult Airway Society, Intensive Care Society, Faculty of Intensive Care Medicine, Royal College of Anaesthetists. (2018) Guidelines for the management of tracheal intubation in critically ill adults. *British Journal of Anaesthesia*. **120**(2), pp.323-352.

Hodnick, R., Zitek, T., Galster, K., Johnson, S., Bledsoe, B. and Ebbs, D. (2017). A Comparison of Paramedic First Pass Endotracheal Intubation Success Rate of the VividTrac VT-A 100, GlideScope Ranger, and Direct Laryngoscopy Under Simulated Prehospital Cervical Spinal Immobilization Conditions in a Cadaveric Model. *Prehospital and Disaster Medicine*. **32**(6), pp.621-624.

Hubble, M.W., Brown, L., Wilfong, D.A., Hertelendy, A., Benner, R.W. and Richards, M.E. (2010) A meta-analysis of prehospital airway control techniques part I: orotracheal and nasotracheal intubation success rates. *Prehospital Emergency Care*. **14**(3), pp.377-401.

Hutchinson, A., Coster, J.E., Cooper, K.L., McIntosh, A, Walters, S.J., Bath, P.A., Pearson, M., Young, T.T., Rantell, K., Campbell, M.J. and Ratcliffe, J. (2010) Comparison of case note review methods for evaluating quality and safety in health care. *Health Technology Assessment.* **14**(10), pp.1-170.

Idris, A., Becker, L., Banner, M. and Orban, D. (1995) Does hypoxia or hypercarbia independently affect resuscitation from cardiac arrest? *Chest*. **108**(2), pp.522–528.

Jabre, P., Penaloza, A., Pinero, D., Duchateau, F., Borron, S., Javaudin, F., Richard, O., de Longueville, D., Bouilleau, G., Devaud, M., Heidet, M., Lejeune, C., Fauroux, S., Greingor, J., Manara, A., Hubert, J., Guihard, B., Vermylen, O., Lievens, P., Auffret, Y., Maisondieu, C., Huet, S., Claessens, B., Lapostolle, F., Javaud, N., Reuter, P., Baker, E., Vicaut, E. and Adnet, F. (2018) Effect of Bag-Mask Ventilation vs Endotracheal Intubation During Cardiopulmonary Resuscitation on Neurological Outcome After Out-of-Hospital Cardiorespiratory Arrest. *The Journal of American Medical Association.* **19**(8), pp.779.

Jarvis, J.L., McClure, S.F. and Johns, D. (2015) EMS Intubation Improves with King Vision Video Laryngoscopy. *Prehospital Emergency Care.* **19**(4), pp.482-489.

Jensen, J.L., Cheung, K.W., Tallon, J.M. ad Travers, A.H. (2010) Comparison of tracheal intubation and alternative airway techniques performed in the prehospital setting by paramedics: a systematic review. *Canadian Journal of Emergency Medicine.* **12**(2), pp.135-140.

Jones, H., Wilmshurst, S.L. and Graydon, C. (2017) Aetiology and outcome of paediatric cardiopulmonary arrest. *Anaesthesia & Intensive Care Medicine.* **18**(11), pp.537-540.

Jung, B., Azuelos, I., Chanques, G. and Jaber, S. (2012) How to improve preoxygenation before intubation in patients at risk. *Trends in Anasaesthesia and Critical Care.* **2**(1), pp.20-24.

Kajino, K., Iwami, T., Kitamura, T., Daya, M., Eng Hock Ong, M., Nishiuchi, T., Hayashi, Y., Sakai, T., Shimazu, T., Hiraide, A., Kishi, M. and Yamayoshi, S. (2011) Comparison of supraglottic airway versus endotracheal intubation for the prehospital treatment of out-of-hospital cardiac arrest. *Critical Care*. **15**(5), pp.1-8.

Latto, I.P., Stacey, M., Mecklenburgh, J. and Vaughan, R.S. (2002) Survey of the use of the gum elastic bougie in clinical practice. *Anaesthesia.* **57**(4), pp.379-384.

Laurin, E.G. and Murphy, M.F. (2016) Extraglottic Devices. Emergency Medicine. [online] Available from: https://aneskey.com/extraglottic-devices/ [Accessed September 2017].

Le May, A. and Holmes, S. (2012) Introdcution to nursing research: developing research awareness. London: Hodder Arnold.

Levitan, R.M., Mechem, C., Ochroch, E.E., Schofer, F.S. and Hollander, J.E. (2003) Head-elevated laryngoscopy position: Improving laryngeal during laryngoscopy by increasing head elevation. Annals of Emergency Medicine. **41**(3), pp.322-330.

Lockey, D.J., Avery, P., Harris, T., Davies, G.E. and Lossius, H.M. (2013) A prospective study of physician prehospital anaesthesia in trauma patients: oesophageal intubation, gross airway contamination and the 'quick look' airway assessment. *BMC Anaesthesiology.* **13**(1).

London Ambulance Service (LAS) (2010) *The future direction of airway management in the London Ambulance Service.* [letter]. 8th June. Available from: https://www.whatdotheyknow.com/request/135585/response/330261/attach/html/4/1137%20medical%20bulletin%2008jun10.pdf.html [Accessed March 2018].

London Ambulance Service (LAS) (2018) Annual Report 2016-17. *LAS* [online]. Available from: https://www.londonambulance.nhs.uk/document-search/annual-report-2016-17/ [Last Accessed August 2018].

Long, T. and Johnson, M. (2007) *Research Ethics in the Real World. Issues and solutions for health and social care.* London: Churchill Livingstone Elsevier.

Lossius, H., Sollid, S., Rehn, M. and Lockey, D. (2011) Revisiting the value of prehospital tracheal intubation: an all time systematic literature review extracting the Utstein airway core variables. *Critical Care.* **15**(1), pp.R26.

Lowe, D. (1993) *Planning for Medical Research: A practical guide to research methods*. Congleton: Astroglobe.

Lyon, R.M., Ferris, J.D., Young, D.M., McKeown, D.W., Oglesby, A.J. and Robertson, C. (2010) Field intubation of cardiac arrest patients: a dying art? *Emergency Medicine Journal.* **27**(4), pp.321-323.

Macintosh, R.R. (1949) An aid to oral intubation. British Medical Journal. **1**(28).

Maldini, B., Hodzovic, I. and Goranovic, T. (2016) Alternative devices in airway visualization. *Acta Clinica Croatica.* **55**(Supp 1), pp. 76-84.

Mantzoukas, S. (2005) The inclusion of bias in reflective and reflexive research: A necessary prerequisite for securing validity. *Journal of Research in Nursing.* **10**(3), pp.279-265.

Maxwell, J. A. and Loomis, D. M. (2003). Mixed methods design: An alternative approach. In Tashakkori, A. and Teddlie, C. (eds.) Handbook of mixed methods in social & behavioral research (pp.241–271). Thousand Oaks, California: Sage.

McMullan, J., Gerecht, R., Bonomo, J., Robb, R., McNally, B., Donnelly, J. and Wang, H. (2014) Airway management and out-of-hospital cardiac arrest outcome in the CARES registry. *Resuscitation.* **85**(5), pp.617-622.

McNally, B., Robb, R., Mehta, M., Vellano, K., Valderrama, A.L., Yoon, P.W., Sasson, C., Crouch, A., Bray Perez, A., Merritt, R. and Kellermann, A. (2011) Out-of-Hospital Caridac Arrest Surveillance. Cardiac Arrest Registry to Enhance Survival (CARES), United States, October 1, 2005 – December 31, 2010. *Surveillance Summaries.* **60**(SS08), pp.1-19.

McNeil, P. and Chapman, S. (2005) *Research methods*. 3rd ed. Oxon: Routledge.

MD Nexus (2018) Airway Management. [online] Available from: http://mdnxs.com/topics-2/pulmonary-and-critical-care/airway-management/ [Accessed March 2018].

Medical Research Council (MRC) (2017) Research. MRC. [online] Available from: https://www.mrc.ac.uk/research/ [Accessed December 2017].

Moher, D., Liberati, A., Tetzlaff, J. and Altman, D.G. 'The PRISMA Group' (2009) Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med* [online]. Available from: https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000097 [Last accessed January 2019].

Morrison, E.F. (1991) *as cited in* Cutcliffe, J.R. and Ward, M. (2007) *Critiquing Nursing Research.* 2nd ed. Wiltshire: MA Healthcare.

Morse, J. M. and Niehaus, L. (2009) *Mixed methods design: Principles and procedures.* Walnut Creek, California: Left Coast Press

Morton, G., Chileshe,B., Baxter, P. (2002) Gum elastic bougie in the hole technique. *Anaesthesia*. **57**, pp.1028-1044.

Moy, R., Han, K., Smith, G.D. and Henning, J. (2011) Trauma systems: the potential impact of a trauma diver policy on a regional ambulance service. *Emergency Medical Journal.* **5**(29), pp. 404-408.

Mulder, P.J., Oetomol, S.B., Vloet, L.C.M., De Vries, P.H. and Hoogerwerf, N. (2013) Comparison in Effectiveness and Safety Between a Supraglottic Airway Device and Endotracheal Intubation in Out-of-Hospital Cardiac Arrest in The Netherlands. *Annals of Emergency Medicine*. **62**(4), Supplement p.45.

Murad, M.H., Asi, N., Alsawas, M. and Alahdab, F. (2016) New evidence pyramid. *Evidence Based Medicine.* **21**(4), pp.125-127.

Muzzi, D.A., Losasso, T.J. and Cucchiara, R.F. (1991) Complication from a nasopharyngeal airway in a patient with a basilar skull fracture. Anesthesiology. **74**, pp.366-368.

Nasim, S., Maharaj, C., Butt, I., Malik, M., O' Donnell, J., Higgins, B., Harte, B. and Laffey, J. (2009a) Comparison of the Airtraq and Truview laryngoscopes to the Macintosh laryngoscope for use by Advanced Paramedics in easy and simulated difficult intubation in mannikins. *BMC Emergency Medicine.* **9**(2).

Nasim, S., Maharaj, C., Malik, M., O' Donnell, J., Higgins, B. and Laffey, J. (2009b) Comparison of the Glidescope and Pentax AWS laryngoscopes to the Macintosh laryngoscope for use by Advanced Paramedics in easy and simulated difficult intubation. *BMC Emergency Medicine.* **9**(9).

NHS Health Research Authority (2017) *Do I need NHS REC approval?* NHS HRA REC. [online] Available from: http://www.hra-decisiontools.org.uk/ethics/EngresultN1.html [Accessed January 2018].

Nicholson, A., Cook, T.M., Smith, A.F., Lewis, S.R. and Reed, S.S. (2013) Supraglottic airway devices versus tracheal intubation fo r airway management during general anaesthesia in obese patients. *Cochrane Database of Systematic Reviews* [online] Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD010105.pub2/full [Last accessed January 2019].

Nitta, M., Iwami, T., Kitamura, T., Nadkarni, V.M., Berg, R.A., Shimizu, N., Ohta, K., Nishiuchi, T., Hayashi, Y., Hiraide, A., Tamai, H., Kobayashi, M., Morita, H. Utstein Osaka Project. (2011) Age-specific differences in outcomes after out-of-hospital cardiac arrests. *Pediatrics.* 128(4), pp.e812-820.

Nolan, J. P. and Soar, J. (2008) Airway techniques and ventilation strategies. *Current Opinion in Critical Care*. **14**(3), pp.279–86.

North West Ambulance Service (NWAS) (2017) Resuscitation Procedure. *NWAS* [online]. Available from https://www.nwas.nhs.uk/media/1446026/nwas-resuscitation-dod-v081-1.pdf [Last accessed October 2018].

Nursing and Midwifery Council (NMC) (2018) *The Code.* London: Nursing Midwifery Council.

O'Connor, D., Green, S. and Higgins, J.P.T. (2011) *Defining the review question and developing criteria for including studies.* Cochrane Handbook for Systematic Reviews of Interventions. [online]. Available from: http://handbook-5-1.cochrane.org/ [Last Accessed December 2017].

Ollerton, J.E., Parr, M.J., Harrison, K., Hanrahan, B. and Sugrue, M. (2006) Potential cervical spine injury and difficult airway management for emergency intubation of trauma adults in the emergency department – a systematic review. *Emergency Medicine Journal*. **23**(1), pp.3-11.

Panditt, J.J., Duncan, T. and Robbins, P.A. (2003) Total oxygen uptake with two maximal breathing techniques and the tidal volume breathing technique: a physiologic study of preoxygenation. Anaesthesiology. **99**, pp. 841-846.

Patton, M. Q. (1990) *Qualitative evaluation and research methods.* 2nd ed. Newbury Park, California: Sage.

Peate, I. (2015) Scope of practice: considering how the role of the paramedic continues to change. Paramedic Practice. **7**(7), pp. 330-331.

Perkins, G.D. and Cooke, M.W. (2012) Variability in cardiac arrest survival: the NHS Ambulance Service Quality Indicators. **29**(1), pp.3-5.

Perry, M. and Morris, C. (2008) Advanced trauma life support (ATLS) and facial trauma: can one size fit all? Part 2: ATLS, maxillofacial injuries and airway management dilemmas*. International journal of Oral Maxillofacial Surgery*. **37**(4), pp. 309-320.

Piegler, T., Roessler, B., Goliasch, G., Fischer, H., Schlaepfer, M., Lang, S. and Ruetzler, K. (2016) Evaluation of six different airway devices regarding regurgitation and pulmonary aspiration during cardio-pulmonary resuscitation (CPR) – A human cadaver pilot study. *Resuscitation.* **102**, pp.70-74.

Ramachandran, S.K. and Kumar, A.M. (2014) Supraglottic Airway Devices. *Respiratory Care.* **59**(6), pp.920-932.

Resuscitation Council (2015) Prehospital Resuscitation. [online]. Available from: https://www.resus.org.uk/resuscitation-guidelines/prehospital-resuscitation/ [Last accessed August 2018].

Resuscitation Council (UK) (2014) Consensus Paper on Out-of-Hospital Cardiac Arrest in England. NHS England, British Heart Foundation. [online]. Available from: https://www.bhf.org.uk/research/heart-statistics [Last accessed August 2018].

Royal College of Anaesthetists (2013) Guidelines for intubation in ICU and the ED. [online] Available from: http://www.rcoa.ac.uk/clinical-standards-quality [Last accessed December 2017].

Russi, C., Miller, L. and Hartley, M. (2008) A Comparison of the King-LT to Endotracheal Intubation and Combitube in a Simulated Difficult Airway. *Prehospital Emergency Care.* **12**(1), pp.35-41.

Russi, C., Myers, L., Kolb, L., Goodman, B. and Berns, K. (2013) The Airtraq Optical Laryngoscope in Helicopter Emergency Medical Services: A Pilot Trial. *Air Medical Journal*, **32**(2), pp.88-92.

Sánchez, L. (2010) Positionality. In: Warf, B. (ed) *Encyclopedia of Geography.* Sage: USA. pp. 2258-2259.

Sapsford, R. and Jupp, V. (Eds) (2006) *Data Collection and Analysis.* 2nd ed. London: Sage.

Schade, K., Borzote, A. and Michaels, A. (2000) Intracranial malpostition of nasopharyngeal airway. *Journal of Trauma*. **29**, pp. 967-968.

Shanks, G. and Parr, A. (2003) Positivist, single case study research in information systems: A critical analysis. Proceedings of the European Conference on Information Systems. Naples. [online] Available from: https://pdfs.semanticscholar.org/15c4/0bfeed971290c3f7d98a1734604cdc204e80.ppd [Accessed December 2017].

Shin, S.D., Ahn, K.O., Song, K.J., Park, C.B. and Lee, E.J. (2012) Out of-hospital airway management and cardiac arrest outcomes: a propensity score matched analysis. *Resuscitation.* **83**(3), pp.313-319.

Simons, R.W., Rea, T.D., Becker, L.J. and Eisenberg, M.S. (2007) The incidence and significance of emesis associated with out-of-hospital cardiac arrest. *Resuscitation.* **74**(3), pp.427-31.

Smally, A.J., Ross, M.J. and Huot, C.P. (2002) Gastric rupture following bag-valve mask ventilation. *Journal of Emergency Medicine*. **22**(1), pp.27-29.

Smereka, J., Ladny, J., Naylor, A., Ruetzler, K. and Szarpak, L. (2017) C-MAC compared with direct laryngoscopy for intubation in patients with cervical spine immobilization: A mannikin trial. *The American Journal of Emergency Medicine*, **35**(8), pp.1142-1146.

Smith, A. (2003) Informed consent does not exist. The 2003 Ethics Forum Debate. *Clinical Research Focus.* **14**(5), pp.18-22.

Smith, C.E., Sidhu, T.S., Lever, J. and Pinchak, A.B. (1999) The complexity of tracheal intubation using rigid fiberoptic laryngoscopy (WuScope). Anesthesia Analgesia. **89**(1), pp.236-9.

Smith, J. and Noble, H. (2014) Bias in research. Evidence-Based Nursing. 17. Pp.100-101.

Soar, J. (2013) Which airway for cardiac arrest? Do supraglottic airways devices have a role? *Resuscitation.* **84**(9), pp.1163–1164.

Sowers, N. and Kovacs, G. (2016) Use of a Flexible Intubating Scope in Combination with a Channeled Video Laryngoscope for Managing a Difficult Airway in the Emergency Department. *The Journal of Emergency Medicine.* **50**(2), pp.315-319.

Steel, A. (2005) The intubating laryngeal mask airway. *Emergency Medicine Journal.* **22**(1), pp. 47-49.

Stiell, I.G., Nichol, G., Leroux, B.G., Rea, T.D., Ornato, J.P., Powell, J., Christenson, J., Callaway, C.W., Kudenchuk, P.J., Aufderheide, T.P., Idris, A.H., Daya, M.R., Wang, H.E, Morrison, L.J., Davis, D., Andrusiek, D., Stephens, S., Cheskes, S., Schmicker,

R.H., Fowler, R., Vaillancourt, C., Hostler, D., Zive, D., Pirrallo, R.G., Vilke, G.M., Sopko, G. and Weisfeldt, M. (2011) Early versus Later Rhythm Analysis in Patients with Out-of-Hospital Cardiac Arrest. *New England Journal of Medicine.* **365**, pp.787-797.

Streeton, R., Cooke, M. and Campbell, J. (2004) Researching the researchers: using a snowball technique. *Nurse Researcher.* **12**(1), pp.35-46.

Strote, J., Roth, R., Cone, D. and Wang, H. (2009) Prehospital endotracheal intubation: the controversy continues. *The American Journal of Emergency Medicine.* **27**(9), pp.1142-1147.

Swanson, E., Fosnocht, D., Matthews, K. and Barton, E. (2004) Comparison of the intubating laryngeal mask airway versus laryngoscopy in the Bell 206-L3 EMS helicopter. *Air Medical Journal*, **23**(1), pp.36-39.

Tanabe, S., Ogawa, T., Akahane, M., Koike, S., Horiguchi, H., Yasunaga, H., Mizoguchi, T., Hatanka, T., Yokota, H. and Imamura, T. (2013) Comparison of neurological outcome between tracheal intubation and supraglottic airway device insertion of out-of-hospital cardiac arrest patients: a nationwide, population-based, observational study. Journal of Emergency Medicine. **44**(2), pp.389–397.

Taylor, J., Black, S., Brett, S., Kirby, K., Nolan, J.P., Reeves, B.C, Robinson, M., Rogers, C., Scott, L.J., South, A., Stokes, E.A., Thomas, M., Voss, S., Wordsworth, S. and Benger, J.R. (2016) Design and implementation of the AIRWAYS-2 trial: A multi-centre cluster randomised controlled trial of the clinical and cost effectiveness of the i-gel supraglottic airway device versus tracheal intubation in the initial airway management of out of hospital cardiac arrest. *Resuscitation*. **109**, pp. 25-32.

Teddlie, C. and Yu, F. (2007) Mixed Methods Sampling: A Typology with Examples. *Journal of Mixed Methods Research.* **1**(1), pp.77.

The University of Warwick (2018) Out of Hospital Cardiac Arrest Outcomes (OHCAO) Registry. [online]. Available from: https://aace.org.uk/wp-content/uploads/2018/05/Out-of-Hospital-Cardiac-Arrest-Outcomes-OHCAO-Registry-57904-CTU-Report-final.pdf [Last accessed August 2018].

Truszewski, Z., Czyzewski, L., Smereka, J., Krajewski, P., Fudalej, M., Madziala, M. and Szarpak, L. (2016) Ability of paramedics to perform endotracheal intubation during continuous chest compressions: a randomized cadaver study comparing Pentax AWS and Macintosh laryngoscopes. *The American Journal of Emergency Medicine*, **34**(9), pp.1835-1839.

Wallace, M., Britton, S., Meek, R., Walsh-Hart, S., Carter, C. and Lisco, S. (2017) Comparison of five video-assisted intubation devices by novice and expert laryngoscopists for use in the aeromedical evacuation environment. *Military Medical Research*, **4**(1).

Walls, R.M., Brown, C.A., Blair, A.E. and Pallin, D.J. (2011) Emergency airway management: a multi-center report of Emergency Department intubations. *Journal of Emergency Medicine.* **41**(4), pp.347-354.

Wang, H. and Yealy, D. (2013) Managing the Airway During Cardiac Arrest. *The Journal of the American Medical Association.* **309**(3), p.285.

Wang, H., Cook, L., Chang, C., Yealy, D. and Lave, J. (2009a) Outcomes after out-of-hospital endotracheal intubation errors. *Resuscitation.* **80**(1), pp.50-55.

Wang, H., Kupas, D., Hostler, D., Cooney, R., Yealy, D. and Lave, J. (2005a) Procedural experience with out-of-hospital endotracheal intubation. *Critical Care Medicine.* **33**(8), pp.1718-1721.

Wang, H., Szydlo, D., Stouffer, J., Lin, S., Carlson, J., Vaillancourt, C., Sears, G., Verbeek, R., Fowler, R., Idris, A., Koenig, K., Christenson, J., Minokadeh, A., Brandt, J. and Rea, T. (2012) Endotracheal intubation versus supraglottic airway insertion in out-of-hospital cardiac arrest. *Resuscitation.* **83**(9), pp.1061-1066.

Wang, H.E. and Yealy, D.M. (2006a) How many attempts are required to accomplish out-of-hospital endotracheal intubation? *Academic Emergency Medicine.* **13**(4), pp.372-377.

Wang, H.E. and Yealy, D.M. (2006b) Out-of-Hospital Endotracheal Intubation: Where Are We? *Annals of Emergency Medicine*. **47**(6), pp.532-541.

Wang, H.E., Kupas, D.F., Paris, P.M., Bates, R.R. and Yealy, D.M. (2003) Preliminary experience with a prospective, multi-centred evaluation of out-of-hospital endotracheal intubation. *Resuscitation.* **58**(1), pp.49-58.

Wang, H.E., Mann, N.C., Mears, G., Jacobson, K. and Yealy, D.M. (2011) Out-of-hospital airway management in the United States. *Resuscitation.* **82**(4), pp.378-385.

Wang, H.E., Seitz, S.R., Hostler, D. and Yealy, D.M. (2005b) Defining the learning curve for paramedic student endotracheal intubation. *Prehospital Emergency Care.* **9**(2), pp.156-162.

Wang, H.E., Simeone, S.J., Weaver, M.D. and Callaway, C.W. (2009b) Interruptions in cardiopulmonary resuscitation from paramedic endotracheal intubation. *Annals of Emergency Medicine.* **54**(5), pp.645-652.

Wang,.H.E., Balasubramani, G.K., Cook, L.J., Lave, J.R. and Yealy, D.M. (2010) Out-of-Hospital Endotracheal Intubation Experience and Patient Outcomes. *Annals of Emergency Medicine*. **55**(6), pp.527-537.

Warner, K.J., Sharar, S.R., Copass, M.K., Bulger, E.M. (2009) Prehospital management of the difficult airway: a prospective cohort study. Journal of Emergency Medicine. **36**(3), pp.257-265.

Wayne, M.A. and McDonnell, M. (2010) Comparison of Traditional versus Video Laryngoscopy in Out-of-Hospital Tracheal Intubation. *Prehospital Emergency Care.* **14**(2), pp.278-282.

Webb, C. and Roe, B. (Eds) (2007) *Reviewing Research Evidence for Nursing Practice. Systematic Reviews.* Oxford: Blackwell Publishing Ltd.

Weingart, S.D. (2011) Preoxygenation, Reoxygenation, and Delayed Sequence Intubation in the Emergency Department. *The Journal of Emergency Medicine*. **40**(6), pp.661-667.

Weinger, M.B., Slagle, J., Jain, S. and Ordonez, N. (2003) Retrospective data collection and analytical techniques for patient safety studies. *Journal of Biomedical Informatics.* **36**(1-2), pp.106-119.

Williams, A.L., Anderson, R.M. and Nasir, M.A. (2013) The i-gel and cardiopulmonary resuscitation, in Michalek, P. and Donaldson, W. (eds) *The I-gel supraglottic Airway.* pp.151-162. New York: Nova Science Publishers.

Xanthos, T., Bassiakou, E., Koudouna, E., Stroumpoulis, K., Vlachos, I., Johnson, E.O., Vasileious, P., Papalois, A. and Lacovidou, N. (2012) Inexperienced nurses and doctors are equally efficient in managing the airway in a mannikin model. *Heart Lung.* **41**(2), pp.161-166.

Yildirim, A., Kiraz, H.A., Ağaoğlu, İ. And Akdur, O. (2017) Comparison of Macintosh, McCoy and C-MAC D-Blade video laryngoscope intubation by prehospital emergency health workers: a simulation study. *International Emergency Medicine.* **12**(1), pp.91-97.

Yin, R.K. (2009) *Case study research, design and method.* London: Sage.

Yousif, S., Machan, J.T., Alaska, Y. and Suner, S. (2017) Airway Management in Disaster Response: A Mannikin Study Comparing Direct and Video Laryngoscopy for Endotracheal Intubation by Prehospital Providers in Level C Personal Protective Equipment. *Prehospital and Disaster Medicine.* **32**(3), pp.1-5.

Yu, S.H. and Beirne, O.R. (2010) Laryngeal mask airways have a lower risk of airway complications compared with endotracheal intubation: a systematic review. *Journal of Oral and Maxillofacial Surgery.* **68**(10), pp.2359-2376.

Appendices

i. Types of alternative intubation devices

Blades
Mackintosh blade laryngoscope 
McCoy blade laryngoscope 
Miller blade laryngoscope 

Retroglottic tubes
Endotracheal Combitube (ETC) 
King LT Airway 
Easytube 

Video Laryngoscopes	
Airtraq 	GlideScope 
King Vision 	C-MAC 
Pentax Airway scope (AWS) 	Coopdech VLP-100 
Truview PCD 	Truview EVO2 
Vivid Trac (VT-A100) 	Venner AP Advance 

Intubating Laryngeal Mask Airway
LMA Fastrach 

Fibreoptic
Bonfils intubation fiberscope 

ii. Literature review method: Endotracheal intubation or supraglottic airway devices

Data bases used

Five data bases were selected that were considered appropriate for study in professional healthcare practice (see below):

- Medline
- AMED
- CINAHL with Full Text
- Computers and Applied Sciences Complete
- Education Research Complete

Search terms used to identify studies for literature review

A selection of terms were used to search for and select articles; endotracheal intubation and supraglottic airway, these were then combined with cardiac arrest. Boolean operators were employed with the search terms to exhaust the literature of all relevant research (Table 1).

Search Terms

Endotracheal Intubation	Supraglottic Airway	Cardiac Arrest
Advanced airway management	Laryngeal mask airway	"Cardiac arrest"
Endotracheal intubat*	iGel	Resus*
Tracheal intubation	Supraglottic	CPR
Airway management	Extraglottic	Cardio pulmonary resuscitation
Protected airway	SGA device	"heart arrest"
Laryngoscopy	Supraglottic airway	Cardio pulmonary arrest
Intubat*	SAD	
Endo tracheal airway		**Pre-hospital**
Difficult intubation		"Out of hospital"
		Pre?hospital
		EMS
		"Critical Care"
		"Urgent Care"
		"Emergency Care"

Table 8: Boolean operators employed to search for relevant articles for the initial literature review

Inclusion and exclusion criteria

Inclusion and exclusion criteria for study selection were developed (Figure 1). Studies from across the globe were sought to explore airway management techniques used in cardiac arrest. Studies focussing on all medical disciplines were included, though a focus remained cardiac arrest and comparisons of intubation and supraglottic airways. Studies

from the previous 10 years were included to offer the most recent findings from practice. Comparative studies were included explore the literary findings about recommendations for airway management during prehospital cardiac arrest. With this in mind, studies offering patient outcomes were included.

- all countries
- all medical / clinical disciplines
- cardiac arrest patients
- out-of-hospital environment
- real patient studies
- comparative studies (including prospective and retrospective)
- not alternative intubation devices
- previous 10 years
- not patient outcomes (such as survival rates)

Figure 17: Inclusion and exclusion criteria used to select articles for review

The titles and abstracts of the studies were read and cross-referenced with the inclusion and exclusion criteria. Following deletion of duplications, a total of 21 articles were identified for review, which were organised in tabular format, for further cross-reference with the inclusion criteria, as well as to establish the nature of articles. The reference lists of the articles were scrutinised to identify any additional studies relevant to the field of practice, two additional articles were found for review. Upon reading the articles, six studies were discounted due to not meeting inclusion criteria (one was not a comparison, one a Cochrane review and four editorials or opinion articles). A total of 13 studies were identified using the search parameters, to provide an insight to the research question; 'is ETI superior to a SGA in OHCA.

iii. Table of articles used in the initial systematic review of the literature: The most effective method of airway management in out-of-hospital cardiac arrest

Authors	Year	Country	Method	Sample size	Themes	Findings
Dyson *et al.*	2017	Australia	Retrospective	14,857	Paramedic experience Successful tube placement CA survival	Success rate 95%, first pass success rate 80%. Previous intubation experience was associated with intubation success and first pass success rate though not with patient survival.
Jeong *et al.*	2016	Korea	Meta-analysis	1452 studies 17, 380 ETI, 67,525 BVM patients	OHCA survival Neurological recovery	Study findings suggest a decreased survival for OHCA patients treated with AAM. However, the effect of prehospital AAM on neurological recovery, especially that of ETI, is still unclear.
Benoit *et al.*	2015	United States America	Meta-analysis	34,533 and 41,116 patients	Survival from OHCA (ROSC) Survival to hospital admission Neurological status Survival to hospital discharge	Patients who received ETI had statistically significant higher odds of ROSC, survival to hospital admission and neurologically intact survival compared to SGA. Survival to hospital discharge was not statistically different.
Kang *et al.*	2015	Korea	Retrospective case note review	32,513 29684 BVM 1634 SGA 1195 ETI	Neurologically favourable survival to discharge	The odds of neurologically favourable survival to discharge was significantly higher in the ETI group compared to the BVM and SGA groups.

Authors	Year	Country	Method	Sample size	Themes	Findings
McMullan *et al.*	2014	United States America	Meta-analysis	10,691 5,591 ETI 3,110 SGA 1,929 no a/w	Sustained ROSC, Survival to hospital admission Survival to hospital discharge Neurologically-intact survival to hospital discharge	In CARES, survival was higher among OHCA receiving ETI than those receiving SGA and for patients who received no advanced airway than those receiving ETI or SGA.
Mulder *et al.*	2013	Netherlands	Prospective RCT	188	Placement success, placement time, hands off time, return of spontaneous circulation (ROSC) and complications	It appears that when a SGA is placed by EMS paramedics that it is faster, safer and thus more effective than ETI in the out-of-hospital setting. The number of alternative placements was lower in the SGA group than with the ETI group. ROSC was higher in the SGA group than in the ETI group. Placement of a SGA is preferable to the ETI in OHCA in the out-of-hospital setting.
Tanabe *et al.*	2013	Japan	Retrospective	318,141 patients	Neurological outcome of patients	Both SADs were associated with significantly worse neurological outcome than tracheal intubation.
Wang *et al.*	2012	United States America	Meta-analysis	10,455 patients	Survival to hospital discharge (with satisfactory functional status) ROSC 24 hour survival Major airway or pulmonary complications	Successful tracheal intubation was associated with better early survival and higher hospital discharge rates when compared to insertion of a SGA during OHCA.

Authors	Year	Country	Method	Sample size	Themes	Findings
Shin *et al.*	2012	Korea	Comparative study	5,278	Survival to hospital admission Reduced survival to discharge	Lowest rates of survival to hospital admission and also reduced survival to discharge from hospital with LMA.
Kajino *et al.*	2011	Japan	Prospective cohort base	5,377	Neurological outcome Time to intubate One month survival	There were no differences either in survival or incidence of good neurological outcome between devices, although tracheal intubation took a significantly longer time.
Frascone *et al.*	2011	United States America	Prospective RCT	204	Placement success Time to ventilation	Therefore in this study no differences in placement success rate or time to insertion were detected between the extra glottic and ETI.
Wang *et al.*	2010	United States America	Retrospective	62,586 patients	EMS personnel experience Hospital discharge Death data	Adjusted odds of survival was higher for patients intubated by rescuers with very high ETI experience. Rescuer procedural experience is associated with improved patient survival after OHCA with ETI.
Egly *et al.*	2010	United States America	Retrospective analysis	1,515	Survival of OHCA	Patients with ventricular fibrillation or ventricular tachycardia who were intubated showed lower survival rate to discharge while, in the whole cohort, there was no difference found between intubated and non-intubated subjects.

iv. Literature review method: Alternative intubation devices for use by paramedics in the out-of-hospital environment

Data bases used

Five data bases were selected that were considered appropriate for study in professional healthcare practice, similar to the initial literature review (see Appendix-ii).

Search terms used to identify studies for literature review

A selection of terms were used to search for and select articles; alternative intubation devices, paramedics and prehospital. The term cardiac arrest was also considered, due to the nature of intubation and the urgent care environment, though was used alongside other terms, given the inclusion of studies carried out on mannikins and patients with traumatic injuries (not necessarily in cardiac arrest). Boolean operators were employed with the search terms to exhaust the literature of all relevant research (Table 2).

Search Terms

Alternative intubation devices	**Paramedics**	**Pre-hospital**
Advanced airway management	Professionals	"Out of hospital"
Endotracheal intubat*	Best practice	Pre?hospital
Tracheal intubation	Ambulance	EMS
Airway management	Ambulance service	"Critical Care"
Protected airway	HCPC registered	"Urgent Care"
Laryngoscopy	Emergency Care Practitioners	"Emergency Care"
	EMT (Emergency Medical Technician)	
Intubat*	Nurse	**Cardiac Arrest**
Assist* intubation device	Doctor	"Cardiac arrest"
Video assist*	Physician	Resus*
Fibreoptic		CPR
Difficult intubation		Cardio pulmonary resuscitation
Endo tracheal airway		"heart arrest"
?sophageal?tracheal Combitube		Cardio pulmonary arrest
Difficult airway		
intratracheal		
Intubating LMA		
LMA protector		

Table 9: Boolean operators employed to search for relevant articles for the literature review

Inclusion and exclusion criteria

Inclusion and exclusion criteria for study selection were developed (Figure 2). Initially studies solely from the UK were sought, though research relating to paramedics using alternative intubation devices (AIDs) in the UK is extremely limited, with just one study found that was set in England and two in Northern Ireland. The criteria were therefore expanded to include worldwide literature, to reflect the use of AIDS in the pre-hospital environment in other countries. Studies focussing on paramedics, rather than other medical disciplines were included; as paramedic practice is unique, in terms of the application of knowledge and skills to the practice environment. It is important to note that paramedic practice varies country to country, though the expected skill level to carrying out intubation and airway management remains equivalent in each country, as well as the nature of an uncontrolled out-of-hospital emergency care environment.

- all countries
- one group of professionals - paramedics / prehospital / OOH workers
- out of hospital environment (i.e. not patients about to undergo surgery)
- cardiac arrest patients
- patients with traumatic injuries requiring intubation
- mannikin studies included
- not solely paediatrics / children
- not supraglottic comparison
- comparison of alternative intubation methods
- all years
- not tube comparison (specifically endotracheal tube variations)
- no secondary research
- not patient outcomes (such as survival rates)

Figure 18: Inclusion and exclusion criteria used to select articles for review

Existing research studies in the out-of-hospital environment have focussed on the use of AIDs by paramedics in practice using both real patients and mannikins, both methods are included in the literature review. The studies on real patients included patients in cardiac arrest in the out-of-hospital environment only, rather than patients' pre-procedure or in a hospital environment.

The titles and abstracts of the studies were read and cross-referenced with the inclusion and exclusion criteria. Following deletion of duplications, a total of 24 articles were identified for review, which were organised in tabular format, for further cross-reference with the inclusion criteria, as well as to establish the nature of articles. The reference lists

of the articles were scrutinised to identify any additional studies relevant to the field of practice, though no additional articles were found for review. Upon reading the articles, three studies were discounted due to not meeting inclusion criteria (one used physicians in the out of hospital environment, another emergency technicians not paramedics and the third studied patients' pre-surgery). A total of 21 studies were identified using the search parameters, to provide an insight to the research question; 'which is the most effective and preferred alternative intubation device, for use by paramedics'.

v. Table of articles used in the systematic review of the literature: Alternative intubation devices used by paramedics in the out-of-hospital environment

Authors	Year	Country	Method	Mannikin or real patients	Sample size	Statistical significance	Devices	Additional measures / scenarios
Yousif *et al.*	2017	Saudi Arabia	Prospective, randomised, crossover study	Mannikin	20	Various	VL (GlideScope ranger) SBL (MBL)	
Wallace *et al.*	2017	United States America	Comparative study	Mannikin	40	Various	VL (Airtraq AWS C-MAC Coopdech VLP-100 GlideScope Ranger)	
Smereka *et al.*	2017	United States America	Prospective, randomised, crossover trial	Mannikin	70	Yes	VL (C-MAC) SBL (MBL)	Scenarios: normal MILS CCILS
Ducharme *et al.*	2017	United States America	Prospective, randomised trial	Real patients	82	Various	VL (King vision laryngoscope) SBL (not stated)	
Hodnick *et al.*	2017	United States America	Non-randomised, group-controlled trial	Cadavers	281 intubation attempts	Various	VL (GlideScope Ranger, VividTrac) SBL (Miller, Macintosh)	
Yildirim *et al.*	2017	Turkey	Randomised crossover study	Mannikin	40	Yes	VL (C-MAC) SBL (MBL & McCoy)	Scenarios: normal MILS CCILS
Truszewski *et al.*	2016	Poland	Randomised crossover trial	Cadavers	35	Various	VL (Pentax AWS) SBL (MBL)	

Authors	Year	Country	Method	Mannikin or real patients	Sample size	Statistical significance	Devices	Additional measures / scenarios
Bogdański *et al.*	2015	Poland	Randomised comparative study	Mannikin	67	Various	VL (Airtraq and Pentax AWS) SBL (McCoy)	C-spine immobilised patients only
Jarvis *et al.*	2015	United States America	Comparative, observational study, Retrospective case note analysis	Real patients	514	Yes	VL (King Vision) SBL (unknown type)	
Gaszynska and Gaszynski	2014	Poland	Randomised comparative crossover study	Mannikin	30	Various	VL (Truview EVO2) SBL (MBL)	Scenarios with and without CPR
Arima *et al.*	2013	Japan	Comparative study	Real patients	109	No	VL (Pentax AWS) SBL (MBL)	
Russi *et al.*	2013	United States America	Prospective observational trial.	Real patients	50	Not reported	VL (Airtraq) SBL (MBL)	
Butchart *et al.*	2011	England	Simulated comparative study	Mannikin	30	Various	VL (GlideScope Ranger, Venner Advanced VL) SBL (not stated)	
Nasim *et al.*	2009a	Northern Ireland	Comparative study	Mannikin	21	Various	VL (Airtraq and Truview) SBL (MBL)	Scenarios: Normal CCILS
Nasim *et al.*	2009b	Northern Ireland	Comparative study	Mannikin	25	Various	VL (GlideScope Ranger and Pentax AWS) SBL (MBL)	Scenarios: Normal CCILS
Russi *et al.*	2008	United States America	Simulated comparative study.	Mannikin	69	Yes	Combitube, King LT SBL (MBL or Miller)	

Authors	Year	Country	Method	Mannikin or real patients	Sample size	Statistical significance	Devices	Additional measures / scenarios
Byhahn *et al.*	2007	Germany	Observational study.	Real patients	15	Not reported	Fibre scope (Bonfils intubation fibre scope) SBL (MBL)	
Bollig *et al.*	2006	Norway	Randomised experimental trial	Mannikin	26	Various	Combitube	
Calkins *et al.*	2006	United States America	Retrospective case note review	Real patients	162 + 128	No	Combitube (Oesophageal-Tracheal Combitube) SBL (type not stated)	
Wayne and McDonnell	2005	United States America	Comparative study	Real patients	615 (including paeds)	Various	VL (GlideScope Ranger) SBL (not specified)	
Swanson *et al.*	2004	United States America	Prospective randomised crossover trial	Mannikin	15/45	No	iLMA SBLs (not stated)	Scenarios: Helicopter

Key:

VL – video laryngoscope

SBL – standard blade laryngoscope

MBL – Macintosh blade laryngoscope

iLMA – intubating laryngeal mask airway

MILS – manual inline stabilisation (of the cervical spine)

CCILS – cervical collar inline stabilisation (of the cervical spine)

vi. Cadaver studies used in the systematic literature review

The Cadaver studies used in the systematic literature review were carried out by Hodnick *et al.* (2017) and Truszewski *et al.* (2016) and met the inclusion criteria for review. These studies have remained in the literature review due to the value they add in terms of the methods used (both sets of authors carried out RCTs). Both studies compared video-laryngoscopes to standard blade laryngoscopes and the findings in the studies correspond to both mannikin and real patient study findings. Furthermore, the study by Hodnick *et al.* explored paramedics opinions, which were measured by just two-thirds of the studies reviewed.

It is recognised that using cadavers may not be appropriate with the availability of high-fidelity mannikins, however, they can be valuable in more adequately simulating interventional approaches.

vii. Information about the National Airways-2 Trial

Design and implementation of the AIRWAYS-2 trial: A multi-centre cluster randomised controlled trial of the clinical and cost effectiveness of the i-gel supraglottic airway device versus tracheal intubation in the initial airway management of out of hospital cardiac arrest☆

Jodi Taylor[a], Sarah Black[b], Stephen J. Brett[c], Kim Kirby[b], Jerry P. Nolan[d,e], Barnaby C. Reeves[a], Maria Robinson[b], Chris A. Rogers[a], Lauren J. Scott[a], Adrian South[b], Elizabeth A. Stokes[f], Matthew Thomas[g], Sarah Voss[h], Sarah Wordsworth[f], Jonathan R. Benger[h,i,*]

[a] Clinical Trials and Evaluation Unit, School of Clinical Sciences, University of Bristol, Bristol, UK
[b] South Western Ambulance Service NHS Foundation Trust, Exeter, UK
[c] Centre for Perioperative Medicine and Critical Care Research, Imperial College Healthcare NHS Trust, London, UK
[d] School of Clinical Sciences, University of Bristol, Bristol, UK
[e] Department of Anaesthesia, Royal United Hospital Bath NHS Trust, Bath, UK
[f] Health Economics Research Centre, Nuffield Department of Population Health, University of Oxford, Oxford, UK
[g] Intensive Care Unit, University Hospitals Bristol NHS Foundation Trust, Bristol, UK
[h] Faculty of Health and Applied Sciences, University of the West of England, Bristol, UK
[i] Academic Department of Emergency Care, The University Hospitals NHS Foundation Trust, Bristol, UK

Abstract:

Health outcomes after out of hospital cardiac arrest (OHCA) are extremely poor, with only 7–9% of patients in the United Kingdom (UK) surviving to hospital discharge. Currently emergency medical services (EMS) use either tracheal intubation or newer supraglottic airway devices (SGAs) to provide advanced airway management during OHCA. Equipoise between the two techniques has led to calls for a well-designed randomised controlled trial.

The primary objective of the AIRWAYS-2 trial is to assess whether the clinical effectiveness of the i-gel, a second-generation SGA, is superior to tracheal intubation in the initial airway management of OHCA patients in the UK. Paramedics recruited to the AIRWAYS-2 trial are randomised to use either tracheal intubation or i-gel as their first advanced airway intervention. Adults who have had a non-traumatic OHCA and are attended by an AIRWAYS-2 paramedic are retrospectively assessed against eligibility criteria for inclusion.

The primary outcome is the modified Rankin Scale score at hospital discharge. Secondary objectives are to: (i) estimate differences between groups in outcome measures relating to airway management, hospital stay and recovery at 3 and 6 months; (ii) estimate the cost effectiveness of the i-gel compared to tracheal intubation. Because OHCA patient needs immediate treatment there are several unusual features and challenges to the design and implementation of this trial; these include level of randomisation, the automatic enrolment model, enrolment of patients that lack capacity and minimisation of bias.

Reference: Taylor, J., Black, S., Brett, S., Kirby, K., Nolan, J.P., Reeves, B.C, Robinson, M., Rogers, C., Scott, L.J., South, A., Stokes, E.A., Thomas, M., Voss, S., Wordsworth, S. and Benger, J.R. (2016) Design and implementation of the AIRWAYS-2 trial: A multi-centre cluster randomised controlled trial of the clinical and cost effectiveness of the i-gel supraglottic airway device versus tracheal intubation in the initial airway management of out of hospital cardiac arrest. Resuscitation. **109** pp. 25-32.

viii. Agreement from East Midlands Ambulance Service to proceed with the study methods (including data sharing)

Dear Sarah

Project Title: Endotracheal intubation by paramedics in the urgent and emergency care environment

I am pleased to inform you that East Midlands Ambulance Service has granted approval for the above named project on the basis of the information provided in the application.

The following documents were reviewed:

Document Title	Version Number	Date
Project proposal		February 2016
Information/briefing sheet		
CV		
RDB (University of Northampton)		8th March 2016
REC approval (University of Northampton)		27th May 2016

Permission is granted subject to the following conditions:

- Please confirm that you accept the comments made to the current project proposal attached.

Legislation - You are reminded of your obligation to collect, use, store and protect all data in accordance with the Data Protection Act 1998, the Human Rights Act 1998 and all other legislation that applies to your project.

Amendments - You should inform the Clinical Governance, Audit and Research office of any changes to the protocol, membership of the project team or changes to the project status before implementing the changes locally. You should do this by forwarding details of the amendment to the Governance & Research Analyst.

Monitoring and Auditing
Please note that the EMAS is required to monitor all project activity to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of projects. You are required to comply with the Trust's monitoring arrangements. You should also ensure that you send copies of any interim and final reports to the Research Department.

EMAS Supervision - Your East Midlands Ambulance Service supervisor is Tanya Payne. The supervisor responsible for the day to day supervision of the project and should be contacted in the first instance should you require any advice or assistance.

Please find attached your letter of access and the requested data for your project. Can I advise that you liaise with station administrators to make the necessary arrangements prior to attending EMAS premises to undertake the simulation exercises.

Finally, we would like to wish you every success with the project and look forward to seeing the results.

Yours sincerely

Tanya

Tanya Payne BSc (Hons) RGN
Research Manager

Telephone: 01522 832640
Mobile: 07773 240078
Email: Tanya.payne@emas.nhs.uk

East Midlands Ambulance Service NHS Trust
Lincolnshire Divisional Headquarters
Cross O'Cliff Court
Bracebridge Heath
Lincoln LN4 2HL
www.emas.nhs.uk

NHS
East Midlands
Ambulance Service
NHS Trust

@EMAS_Research

NIHR CRN East Midlands 'Exceptional Research Delivery' award winners 2016/17

Emergency care | Urgent care | We care

Dear Tanya,

Thank you ever so much for your email confirming approval for my doctoral study. I can confirm that:

Regarding comment 1 – the survey will be advertised externally of EMAS, there will be no request for advertisement through EMAS internal media.

Regarding comment 2 – consent for the comparative study, I can confirm that a participant briefing sheet will be used, though consent will be verbal and implied to participate. There will be no written consent.

I can assure you that I will follow research legislation throughout the project and if any project team members or significant project status' change I will follow appropriate action. A final report will be sent to you as my EMAS research supervisor and I thank you for your time and energies with my studies. If and when accessing EMAS properties I will make prior appointments with relevant personnel on stations / in trust and have the letter of access you sent me.

Thank you also for the data you sent, I will be able to use this for stage 1 of my research project. If there is any data extracted in its pure / raw form giving case by case information I would be grateful to use it. This would allow me to make deeper analysis about current practices thus underpinning the final stage of primary data collection in my study.

Yours Sincerely

Sarah

Sarah Cross

ix. Planning potential relationships within survey data

A list of variables and measures of influencing factors were used to plan potential relationships within the survey responses, these are outlined below.

Q1 - ambulance service
Q2 – training route
Q3 – age
Q4 – gender
Q5 – time as a registered paramedic
Q6 – airway devices used during cardiac arrest
Q7 – ETI gold standard?
Q8 – reasons for not intubating

Questions to ask of the data:

Questions 1 to 5 = demographic data; report frequencies
Questions 6 to 8 = opinions; report frequencies
Question 8 = free text responses; content analysis

Correlate Q2 and Q3
Correlate Q2 and Q5
Correlate Q3 and Q5
Correlate Q6 and Q1
Correlate Q6 and Q2
Correlate Q6 and Q3
Correlate Q6 and Q4
Correlate Q6 and Q5
Correlate Q6 and Q7
Correlate Q6 and Q8
Correlate Q7 and Q1
Correlate Q7 and Q2
Correlate Q7 and Q3
Correlate Q7 and Q5
Correlate Q7 and Q8
Correlate Q8 and Q1
Correlate Q8 and Q2
Correlate Q8 and Q3
Correlate Q8 and Q5

x. Data collection template used for comparative study

Data Collection for assisted intubation device study

Participa	IHCD = 0 University = 1 IHCD then Uni 2	0-10 years = 1 11-15 years = 2 16-20 years = 3 >21 years = 4	18-25 = 0 26-30 = 1 31-35 = 2 36-40 = 3 41-45 = 4	Female = 0 Male = 1	A=Airtraq			B=LMA Fastrach			C=Combitube			D=Laryngoscopy			Preference Ranking				Prefered Reason	Least Prefered Reason	
	Training background	No. of years experience	Age Group	Gender	Order	Time	No. of attempts	Order	Time	No. of attempts	Order	Time	No. of attempts	Order	Time	No. of attempts	A	B	C	D			Comments
	1	0	1	1	3	0.43	1	1.00	4.08	3u	2	0.31	1	4	3.22	2	1.00	4.00	2.00	3.00			
1																							
2																							
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7																							
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9																							
10																							
11																							

xi. Permission of access from East Midlands Ambulance Service

East Midlands Ambulance Service NHS
NHS Trust

Lincolnshire Divisional Headquarters
Cross O'Cliff Court
Bracebridge Heath
Lincoln
LN4 2HL

Telephone: 01522 832611

Sarah Cross
17 Thenford Street
Northampton
NN1 5QT

26 July 2017

Dear Sarah

Re: Letter of access for research

As an existing NHS employee you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is responsible for ensuring such checks as are necessary have been carried out. This letter confirms your right of access to conduct research through East Midlands Ambulance Service NHS Trust (EMAS) for the purpose and on the terms and conditions set out below. This right of access commences on **26th July 2017** and ends on **31st October 2017** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to EMAS premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through EMAS you will remain accountable to your employer **Northampton General Hospitals NHS Trust** but you are required to follow the reasonable instructions of your nominated manager **Gemma Marsden** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with EMAS policies and procedures, which are available to you upon request, and the Research Governance Framework.

East Midlands Ambulance Service NHS
NHS Trust

You are required to co-operate with EMAS in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on EMAS premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

EMAS will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

pp Tanya

Anne Spaight
Head of Clinical Governance, Audit and Research

cc: HR Department at substantive employer

xii. Information / Briefing sheet for participants for intubation study

There are new methods on the market that are said to improve the efficiency of intubation, enabling practitioners to perform successful, swift intubation in potentially uncontrolled environments. The aim of the research is to identify which of these methods is the most efficient with regard to success rate, time taken to intubate and professional user opinion.

You are invited to take part in this research study, which involves practical simulation and a survey and in order to consent to participation you are asked to read this information sheet.

You will be asked to perform endotracheal intubation using 4 different techniques in a simulated environment, using a mannequin. Each attempt will be monitored for time taken to successfully intubate and first time success rate. You will be asked to rate the devices in order of preference as well giving your opinion on the methods.

The whole process is hoped to take no longer than 15 minutes, though explanation of the devices if not known may take a little longer. The results of both the simulated study and questionnaire will be analysed and published in the aim of informing out-of-hospital endotracheal intubation practice.

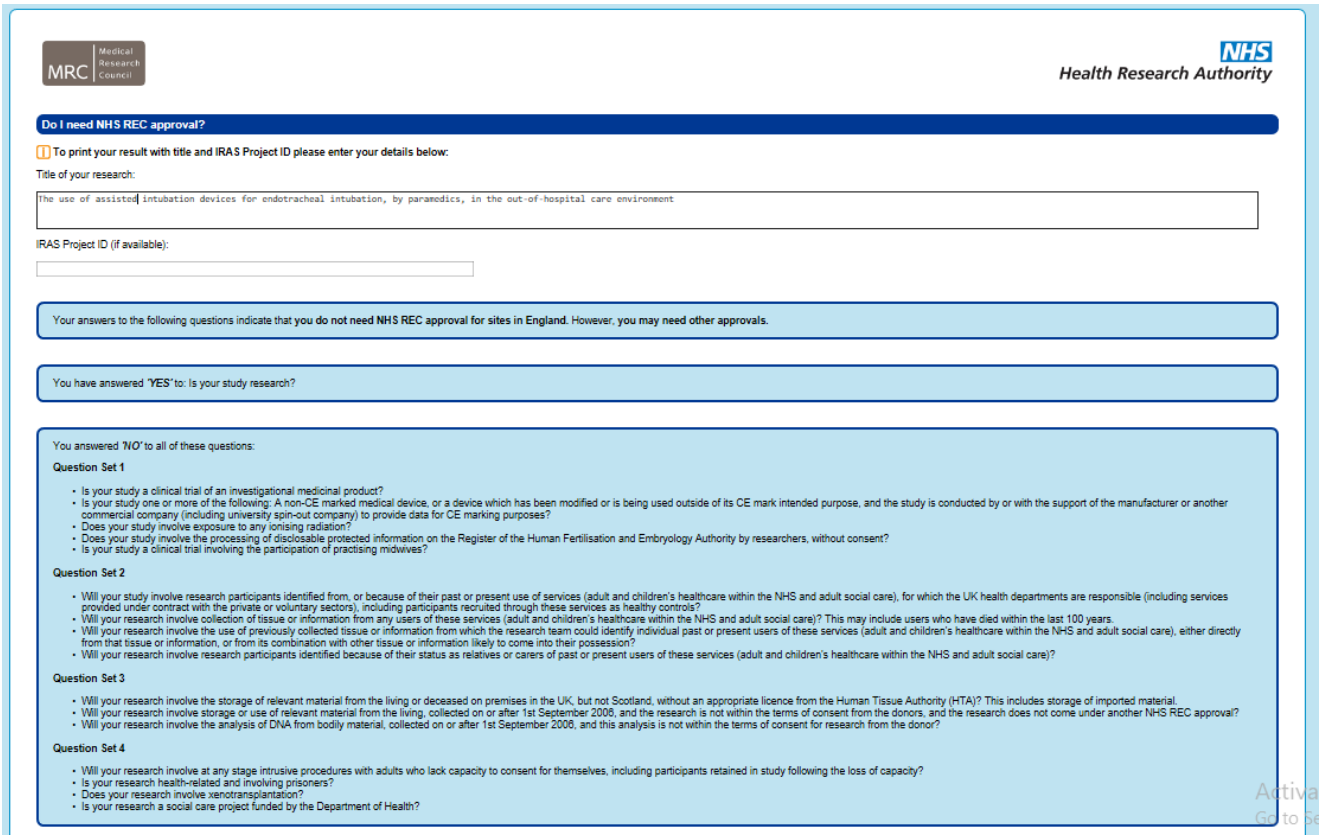
Important considerations

- No personal identifiable data will be collected, though some demographic information will be collected
- Taking part in the study will not harm you in any way
- Any practice considered dangerous will be reported to the head of training and development at EMAS
- Your professional opinion will be reflected in the questionnaire
- You will not be rewarded for completing the study
- The study does not directly involve patients or service users
- You can withdraw from the study at any time (without reason) though data that has already been collected will still be included in the study

Your time taken to participate in the study is very much appreciated. If you still feel able to contribute I would like to arrange a convenient time / place to meet and carry out the simulation and survey. This might be on your ambulance station, the local hospital or University for example. If you have any questions or can suggest a time and place to meet please respond by email or in person. Thank you, Sarah Cross.

sarah.cross07@my.northampton.ac.uk

xiii. Confirmation to negate the need for National Health Service Health Research Authority Research Ethics Committee approval for the research study



MRC Medical Research Council

NHS Health Research Authority

Do I need NHS REC approval?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

The use of assisted intubation devices for endotracheal intubation, by paramedics, in the out-of-hospital care environment

IRAS Project ID (if available):

Your answers to the following questions indicate that **you do not need NHS REC approval for sites in England**. However, **you may need other approvals.**

You have answered *'YES'* to: Is your study research?

You answered *'NO'* to all of these questions:

Question Set 1

- Is your study a clinical trial of an investigational medicinal product?
- Is your study one or more of the following: A non-CE marked medical device, or a device which has been modified or is being used outside of its CE mark intended purpose, and the study is conducted by or with the support of the manufacturer or another commercial company (including university spin-out company) to provide data for CE marking purposes?
- Does your study involve exposure to any ionising radiation?
- Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent?
- Is your study a clinical trial involving the participation of practising midwives?

Question Set 2

- Will your study involve research participants identified from, or because of their past or present use of services (adult and children's healthcare within the NHS and adult social care), for which the UK health departments are responsible (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls?
- Will your research involve collection of tissue or information from any users of these services (adult and children's healthcare within the NHS and adult social care)? This may include users who have died within the last 100 years.
- Will your research involve the use of previously collected tissue or information from which the research team could identify individual past or present users of these services (adult and children's healthcare within the NHS and adult social care), either directly from that tissue or information, or from its combination with other tissue or information likely to come into their possession?
- Will your research involve research participants identified because of their status as relatives or carers of past or present users of these services (adult and children's healthcare within the NHS and adult social care)?

Question Set 3

- Will your research involve the storage of relevant material from the living or deceased on premises in the UK, but not Scotland, without an appropriate licence from the Human Tissue Authority (HTA)? This includes storage of imported material.
- Will your research involve storage or use of relevant material from the living, collected on or after 1st September 2006, and the research is not within the terms of consent from the donors, and the research does not come under another NHS REC approval?
- Will your research involve the analysis of DNA from bodily material, collected on or after 1st September 2006, and this analysis is not within the terms of consent for research from the donor?

Question Set 4

- Will your research involve at any stage intrusive procedures with adults who lack capacity to consent for themselves, including participants retained in study following the loss of capacity?
- Is your research health-related and involving prisoners?
- Does your research involve xenotransplantation?
- Is your research a social care project funded by the Department of Health?

xiv. Key principles for data management, posed in the Data Protection Act

The Data Protection Act (1998) incorporates eight principles, which require that all information must be:

- Processed fairly and lawfully
- obtained for specific and lawful purposes and not processed in a manner incompatible with those purposes
- adequate, relevant and not excessive
- Accurate and up to date
- Kept no longer than necessary
- Processed in accordance with subjects rights
- protected by appropriate security
- not transferred without adequate protection

The Data Protection Act (1998)

xv. Supraglottic airway device use; findings from the case note review

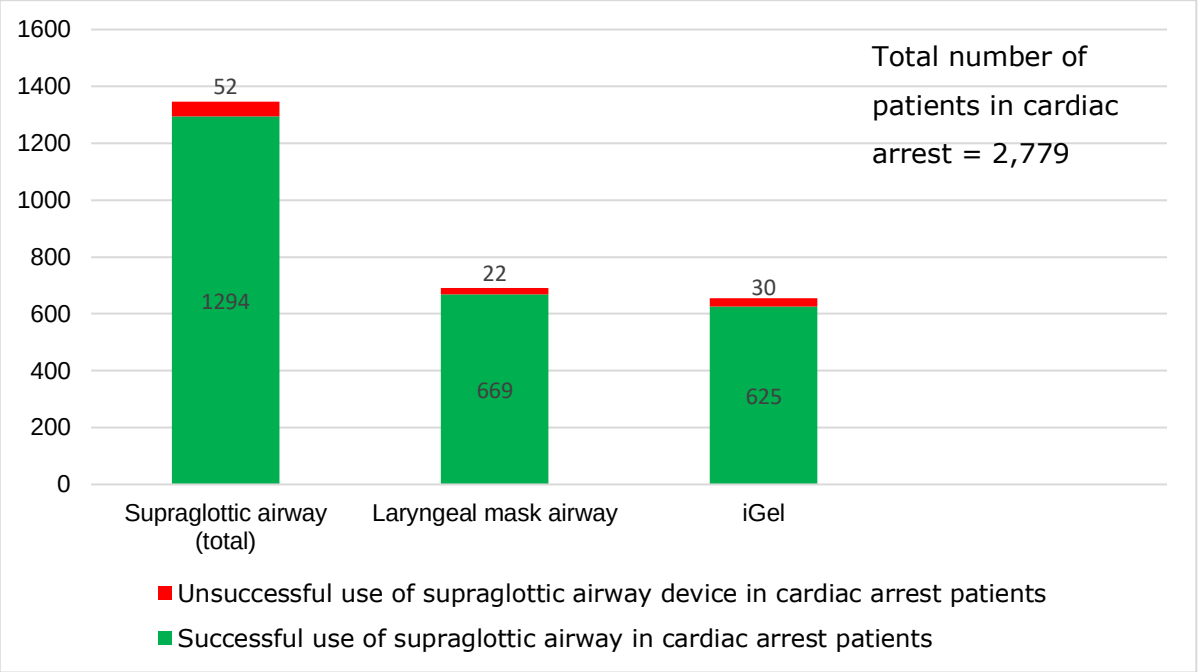


Figure 19: The graph shows the use and success rates of supraglottic airways, for patients in cardiac arrest over the period of a year, by East Midlands Ambulance Service personnel.

xvi. Ambulance services represented in the opinion survey data

The opinion survey questionnaire was distributed online using a convenience sample initial, then a snowballing sampling technique with respondents passing the survey link on to paramedic colleagues. The ambulance trusts represented through the respondents are illustrated below (Figure 20).

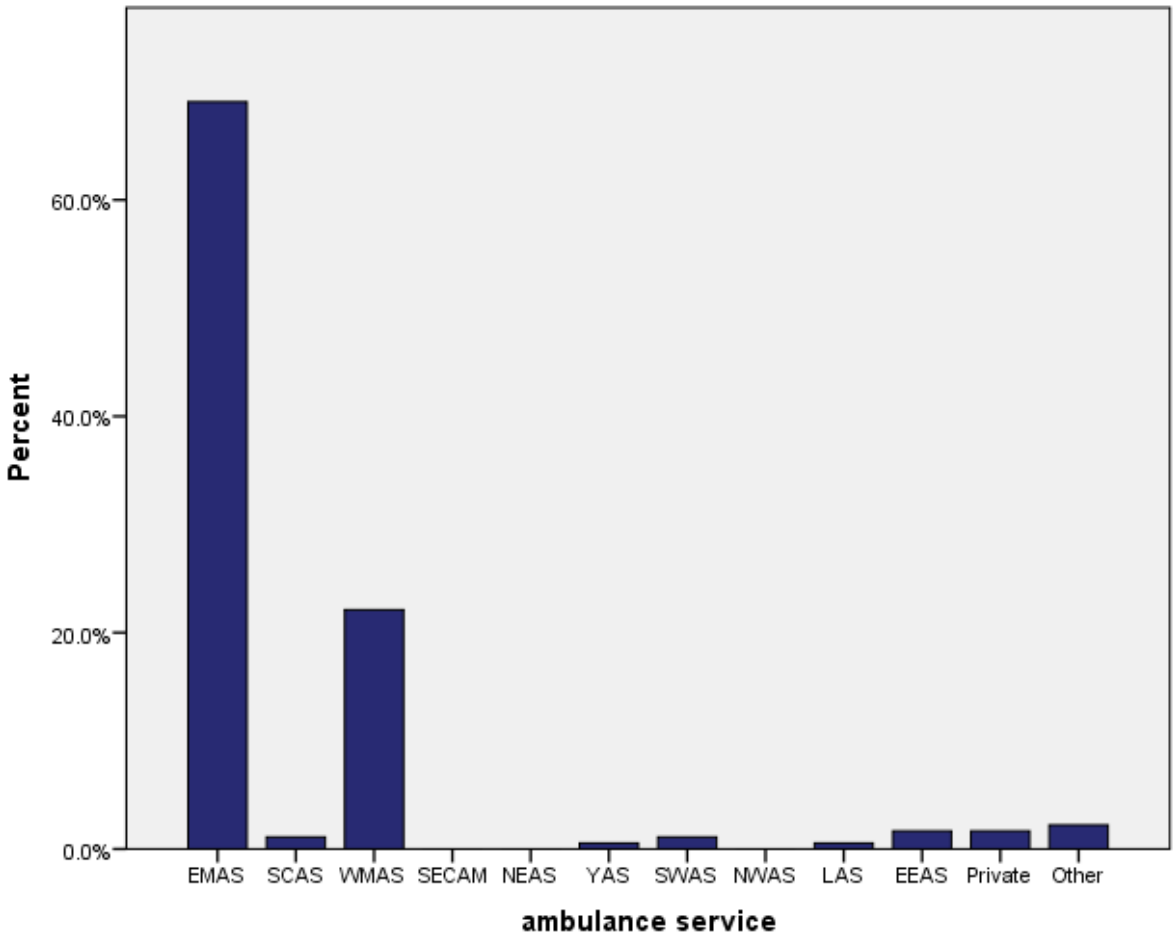


Figure 20: Ambulance services represented in the opinion survey responses

The predominant service was East Midlands Ambulance Service, which is attributed to the sampling technique used. The other services represent paramedic colleagues based in a hospital setting or working with helicopter emergency response charities.

xvii. Training background of opinion survey respondents

From the opinion survey data, it can be seen that there was a fairly even distribution for the training route undertaken by the paramedic respondents; 53.6% trained at University and 46.4% trained in-service (with the institute of health care development (IHCD) curriculum) (n=84). Of these, 51 had gone on to support their professional training with an academic qualification at University. A total of 33 respondents (18.2%) completed their initial training with no further study or training. These results are illustrated in Figure 21.

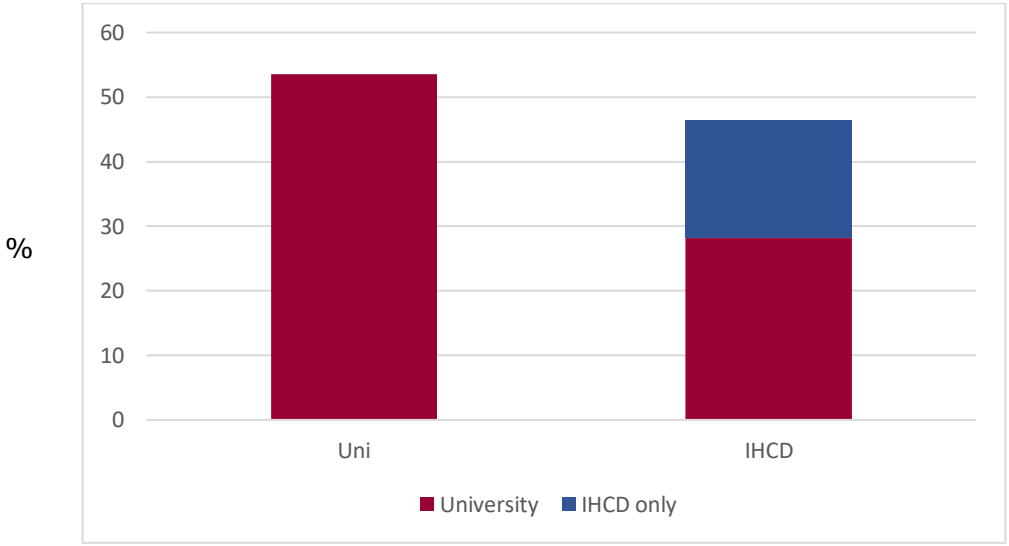


Figure 21: Training backgrounds of the respondents in the opinion survey (IHCD= institute of health care development, which refers to the in-service training route).

xviii. Health and Care Professions Council (HCPC) data on the gender and ages of UK paramedic registrants, in comparison to opinion survey and comparative study gender and age data

Demographic information was collected to give an overview of the sample of participants. A total of 44 (61%) males and 28 (39%) females took part in the comparative study, similar to the gender of paramedic registrants (male = 62%, female = 38%) (HCPC, 2018) (see Figure 5). This demographic information comparison offers reassurance that the sample was representative of the paramedic population in terms of gender.

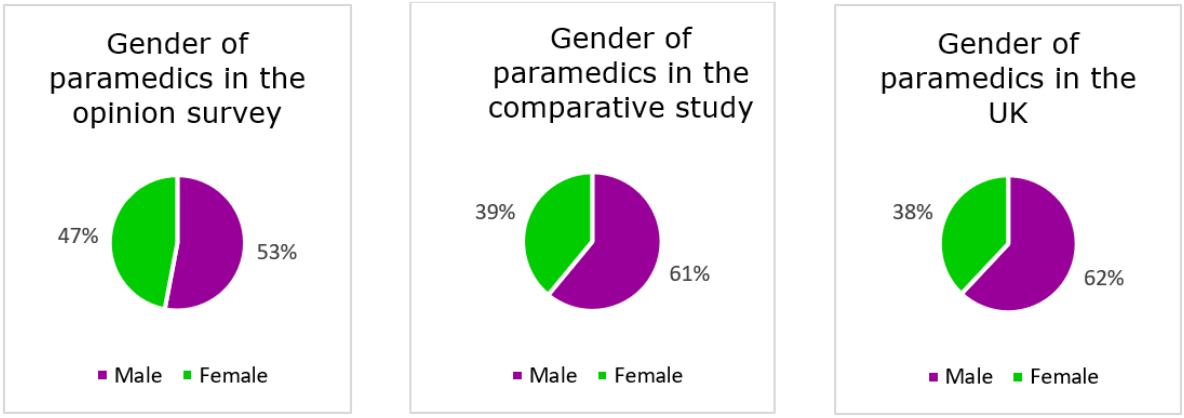


Figure 22: The gender groups of paramedics in this study compared to all paramedics in the UK

In the UK, a higher proportion of paramedics are older, whereas in the study a higher proportion of paramedics were younger (see 6). This is attributed to the sampling techniques used for the opinion survey and comparative study.

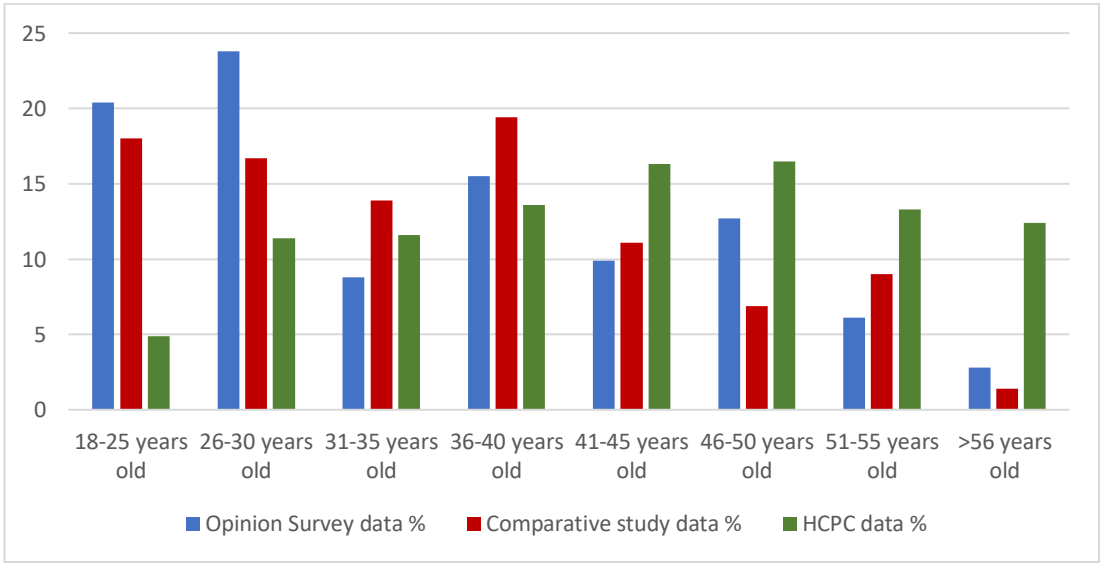


Figure 23: Age distribution of participants in the study and UK registered paramedics

xix. Demonstration of the random order the alternative intubation devices were used in (comparative study)

The alternative intubation devices were used in a random order, using the closed envelope technique, with participants selecting the order of which to use the devices. This is demonstrated in Figure 24.

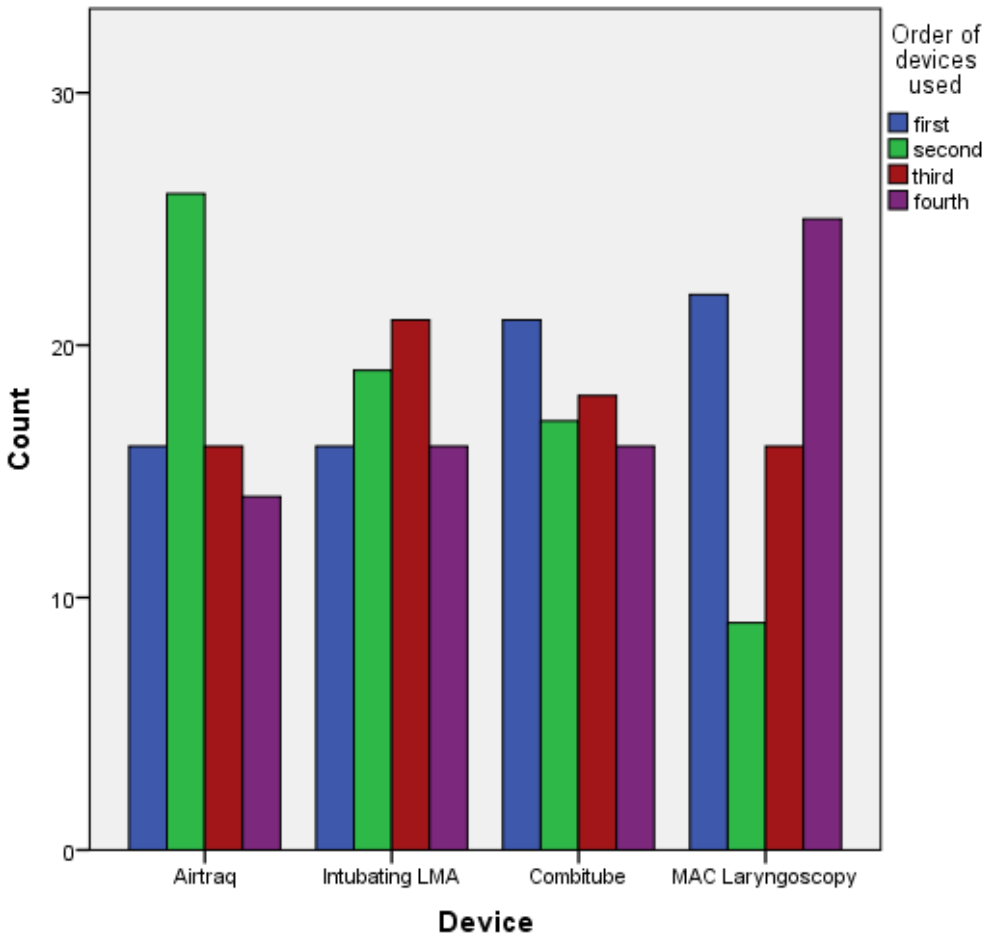


Figure 24: Random order of alternative intubation device use in the comparative study