The availability of alternative devices for the management of the difficult airway in public Emergency Centres in the Western Cape

by

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Declaration

I, Willem Johannes Lodewyk Jooste, hereby declare that the work contained in this assignment is my original work and that I have not previously submitted it, in its entirety or in part, at any university for a degree.

Signature: …… **Date:** ……December 2017…….

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Abbreviations

ASA – American Society of Anesthesiologists
BVM – bag-valve-mask
cLMA – LMA Classic
CVCI – cannot ventilate, cannot intubate
DAS – Difficult Airway Society
EC – emergency centre
EGA – extraglottic airway
EMSA – Emergency Medicine Society of South Africa
ETT – endotracheal tube
GEB – gum elastic bougie
ILMA – intubating laryngeal mask airway
LMA – laryngeal mask airway
LT – laryngeal tube
LTS – Laryngeal Tube S
OTC – oesophageal-tracheal combitube
pLMA – LMA ProSeal
PTJV – percutaneous transtracheal jet ventilation
RGA – retroglottic airway
RSI – rapid sequence induction
SGA – supraglottic airway
TTI – tracheal tube introducer
uLMA – LMA Unique

Part A: Literature Review

INTRODUCTION

The ability to maintain adequate ventilation and oxygenation in a critically ill patient is of utmost importance. Although airway control rarely fails with the use of direct laryngoscopy and endotracheal tube (ETT) placement, difficult and failed airways do arise (4% and 0.3% of cases, respectively).(1) The American Society of Anesthesiologists (ASA) defines the **difficult airway** as "*the clinical situation in which a conventionally trained anaesthesiologist experiences difficulty with facemask ventilation of the upper airway, difficulty with tracheal intubation, or both*."(2) **The failed airway** can be defined as multiple unsuccessful attempts to pass an endotracheal tube via the nasal-tracheal, orotracheal or transtracheal (surgical) route. The terminology is however not consistent throughout the literature and others have defined the concept of the failed intubation as the scenario where a patient underwent successful intubation, but more than one course of intubation were required.(3)

Several alternative airway devices are available on the market to aid the physician when encountering these difficult situations. A predetermined idea of what is regarded as essential devices is thus imperative and a thorough search for and description of these devices is thus indicated.

Guidelines, as set out by respected professional bodies, are another valuable source to measure our findings against, but the actual application of these guidelines would best be gauged through comparing them with other observational studies that have been carried out before.

LITERATURE REVIEWED

The objectives of the literature review are:

- To determine what alternative devices are available to aid in the management of the difficult airway.
- To determine if there are any recommendations or guidelines as to what alternative devices should be available in an emergency centre for the management of the difficult airway.
- To explore the findings of similar studies done in different settings across the world that also explored the availability of alternative devices for the management of the difficult airway.

Search Strategy

A separate search was conducted by the principal investigator for each of the study's objectives. All searches were completed by 18 May 2013.

The PubMed electronic database was searched to determine what alternative devices for the management of the difficult airway are currently available. The search terms used were “alternative airway devices AND difficult airway”. No search restrictions were applied.

The PubMed and SCOPUS databases were searched to establish the availability of guidelines as to the availability of alternative airway devices for difficult intubation. The search terms used were “difficult airway OR alternative airway device*” (PubMed) and “difficult airway OR alternative airway device” (SCOPUS). The search was restricted to articles containing the term “guideline” in the title. The search was repeated using the general search engine Google, using the terms “South African guidelines difficult airway devices”.

A further search was conducted on PubMed and SCOPUS to search for similar studies. The search terms used for PubMed were “alternative airway device* availability OR difficult airway device* availability”. No search restrictions were applied. The terms search for on SCOPUS were “alternative airway device* AND availability OR difficult airway device* AND availability”. The search terms were applied for titles, abstracts and key words; while the search was limited by article type (article or review) and subject matter (medicine).

ALTERNATIVE DEVICES FOR THE MANAGEMENT OF THE DIFFICULT AIRWAY

If either the difficult airway or failed airway is encountered, alternative methods to direct laryngoscopy and bag mask ventilation to achieve ventilation and oxygenation are available. These are encountered in a vast, ever-growing number of different formats, many of these in slightly altered forms from different manufacturers.

These devices can be grouped according to their function (some devices fall somewhat in-between):

1. Facilitators of direct laryngoscopy
2. Alternative ventilation devices
3. Alternative intubation devices

1. Facilitators of direct laryngoscopy

These devices do not offer an alternative route or method of intubation. Instead they aid the clinician in placement of the tracheal tube via direct laryngoscopy.

i) Tracheal Tube Introducers (or Gum Elastic Bougies)

Tracheal Tube Introducers (TTIs) are also commonly known, although erroneously, as “bougies" or gum elastic bougies (GEBs). A GEB is in fact a urinary catheter used as a dilator. The original, reusable device was first introduced by Eschmann Bros. & Walsh, Ltd in 1973, and is still referred to as an Eschmann TTI. It is made of braided polyester threads covered in a resin layer.(4,5)

The bougie is indicated whenever a difficult airway is encountered and has been used with success in patients with airway oedema and in patients in spinal immobilization.(6)

Bougies are relatively inexpensive devices and the insertion technique relatively easy to master. Complications include local tissue trauma, breakage of the device and contamination. Although sometimes serious (pharyngeal perforation, oesophageal lacerations, and pneumothorax), these complications are very rare and limited to case reports.(7)

A vast array of disposable tracheal introducers has entered the market. However, concerns have been raised about their use, mainly due to the inherent risk of airway trauma (due to greater force that can be applied through these devices), as well as a lower intubation success rate.(8,9)

Comparing styletted ETT and TTI’s use, success rates were much higher using a TTI (96% vs. 66%) in simulated difficult intubations.(10) These findings have been echoed by manikin studies showing 94% vs. 77% success rate, with no significant difference in time to successful intubation when TTI assisted intubation was compared to traditional styletted endotracheal intubation.(11) This particular study evaluated the performance of a variety of emergency medicine practitioners, including paramedics and emergency physicians.(11) However, in a more recent study success rates in the EC were lower (76.9%); albeit a small sample size (n=26) and participating physicians that were relatively inexperienced with the use of the device. Also noteworthy, is that TTIs were not directly compared with styletted ETTs, but were used when there were already a median of two failed attempts with conventional endotracheal intubation. One of the six failed cases was probably due to incorrect usage of the device, while the remaining five were truly difficult intubations requiring advanced methods and expert intervention.(12)

2. Alternative ventilation devices

An alternative ventilation device offers a route other than the use of bag-valve-mask ventilation in order to facilitate ventilation. Ventilation can be achieved by either using an alternative to trans-oral ventilation or by using a percutaneous route.

i) Extraglottic Airways

Extraglottic airways (EGAs) are alternative airway devices that lie inside the oropharyngeal and/or oesophageal areas after successful placement. Among other characteristics, the ideal EGA would allow the upper airway to be bypassed efficiently to achieve ventilation, placement should be easily learned and achieved, aspiration risk should be minimal, airway morbidity should be rare and suboptimal placement should affect ventilation minimally.(13)

EGAs can be classified into supraglottic airway (SGA) devices and retroglottic airway (RGA) devices, depending on the position of the ventilation holes.(14)

a) Supraglottic Airways

The laryngeal mask airway (LMA; LMA North America, San Diego, CA)) was first introduced in 1988 and is the prototype SGA. Since then the LMA has undergone a multitude of design modifications that has led to the evolution of a plethora of different iterations of the device - as well as a score of competitive companies delivering similar devices. It consists of a semi-rigid tube attached to an inflatable mask. The mask is inserted into the hypopharynx, resting over the larynx. The cuff of the mask, when inflated, seals the glottis aperture and ventilation can ensue.

The LMA has been shown to be a very effective back-up device when the clinician comes face-to-face with the dreaded situation where a patient has been induced for anaesthesia, but there is failure to ventilate and intubate the patient. Using the LMA as back-up device, successful ventilation can be achieved in up to 94% of patients.(15)

The technique of LMA insertion and ventilation is easier to master than ETT intubation and face mask ventilation.(16) Direct visualization of the vocal cords is not needed and placement is usually effective despite anatomic abnormalities, prone position, or cervical spine immobilization (collar or manual in-line stabilization). On the other hand, LMAs are not definitive airways and aspiration remains possible. The relatively low pharyngeal seal pressure (20-30cm H_2O) can result in air leakage when high ventilator pressures are needed, resulting in gastric distention and inadequate ventilation.(17)

The first model introduced, the LMA Classic (cLMA) is a reusable silicone-based model with its disposable counterpart, the LMA Unique (uLMA) being made of polyvinylchloride. It consists of a ventilation tube attached to an elliptically shaped mask. The mask rests above the larynx, sealing off the oropharynx. The LMA has been modified into different formats, each evolution equipping the device to make it more desirable, for example the LMA-ProSeal (pLMA) with a posterior cuff, drainage tube and an integrated bite block as well as the LMA-Supreme (sLMA) with a curved, rigid shaft and integrated drainage system.(18) The LMA-Fastrach, an intubating LMA (ILMA), was introduced in 1997. The LMA-Fastrach has a rigid, curved design and a bar to elevate the epiglottis, making it a very effective conduit through which an ETT can be introduced. It has been used with a 96.5% success rate as a conduit for blind tracheal intubation in patients with difficult airways.(19) Other companies have modified the initial design; for example Ambu Inc's AuraStraight (Ambu, Glen Burnie, MD) and AuraOnce, Smith Medical's Portex Soft Seal (Smith's Medical, Hythe, Kent, UK) and the I-Gel (Intersurgical, Wokingham, UK).

b) Retroglottic Airways

The Oesophageal-tracheal Combitube

The oesophageal-tracheal combitube (OTC; Tyco Healthcare, Mansfield, MA, USA) is a double lumen (pharyngeal and tracheal) device and the prototype retroglottic device.(20) It has a large proximal oropharyngeal cuff (sealing the upper airway) and a small distal cuff that seals either the oesophagus or trachea, depending on placement of the device.

The oesophageal-tracheal combitube was designed as an alternative to tracheal intubation by personnel unskilled in direct laryngoscopy. Its use was later extended to aid the skilled laryngoscopist when faced with the "cannot intubate, cannot ventilate" situation. It is contraindicated in a patient that has intact airway reflexes, oesophageal pathology, upper airway obstruction or who have ingested corrosive material. The insertion technique is easily learned and it may offer some advantage in patients with cervical spine immobilization, although findings have been contradictory. Cervical motion seems to be less using the Combitube, compared to standard Macintosh blades but cervical collar placement seems to significantly impair correct placement. (21,22) Disadvantages are the possibility of oesophageal and laryngeal trauma and the lack of a suctioning port. A randomized study directly comparing the OTC, the Laryngeal Tube S (LTS; VBM Medizeintechnik, Sulz, Germany), and the pLMA for the conduction of general anaesthesia in obstetric patients showed the OTC to have a longer time to successful ventilation, higher number of failed attempts, and a higher airway morbidity (dysphagia, sore thought) compared to the other two devices.(23)

The Laryngeal Tube

The laryngeal tube (LT; VBM Medizintechnik, Sulz, Germany) is a single lumen device with a single pilot tube and balloon (inflating both the proximal, larger cuff and the smaller distal cuff). There are reusable and disposable versions, covering neonates to large adults with six sizes. A further modified version (the LTS) has an additional lumen to accommodate a nasogastric tube. The device has been successfully used in a number of difficult airway cases as well as in isolated cases of cardiopulmonary resuscitation.(24)

Rüsch Easytube

The Rüsch Easytube (Teleflex Medical (Reusch), Kernen, Germany) is a doubled lumen device, similar to the OTC, but modified to improve on the OTC's shortcomings. Improvements include an open ended distal tube that allows a fibre-optic bronchoscope to be passed through. The distal lumen is also narrower; minimizing the possibility for airway trauma.(25)

Its definite role in emergency intubation has not been clarified. A case series and an observational study demonstrated its possible use in emergency situations in both the pre-hospital and in-hospital environment; but in depth studies are lacking.(26,27)

ii) Percutaneous Transtracheal Jet Ventilation

Percutaneous Transtracheal Jet Ventilation (PTJV) consists of transcutaneous placement of a catheter-over-a-needle into the trachea via the cricothyroid membrane.(28) Commercial catheter sets or angiocatheters (adults,12-16 guage; children, 16-18 gauge) can be used. The catheter is then attached to high pressure tubing, either via a Luer lock, a three way stopcock or directly into a 3ml syringe connected to the angiocatheter.(29) Flow can then be regulated via a manual on/off device, usually in a 1:4 ratio, after connecting the tubing to an oxygen flow regulator, set to 15L/min. Pressurized oxygen is thus delivered via the catheter to achieve inspiration, followed by passive expiration via the patent upper airway.

PTJV has been shown to successfully serve as a temporizing measure when faced with a desaturating patient after attempts at intubation have failed. A retrospective analysis of 29 cases indicated a 79.3% success rate to canalization and successful temporary ventilation. The major complications were pneumomediastinum and subcutaneous emphysema.(30)

PTJV is also the preferred mode of surgical airway rescue in the paediatric population as surgical cricothyroidotomy is contraindicated in the pre-pubertal child.(31)

3. Alternative intubation devices

These devices offer an alternative to direct laryngoscopy in order to achieve endotracheal intubation. Tube placement can either be achieved by the usual oral route or via a surgical route.

i) Video and Optical Laryngoscopes

Video laryngoscopy (where a camera is attached to the tip of a laryngoscope) and optical laryngoscopy (where an image is obtained through the use of lenses and fibre-optic cables) have numerous proven and theoretical advantages when compared to direct laryngoscopy.(32,33) As the laryngeal, pharyngeal and oral axis do not have to be aligned, cervical motion is lessoned. Further advantages lie in their ability to assist in training - either giving the instructor a direct view of laryngoscopy being performed by the trainee or giving a trainee the opportunity to visualise an experienced laryngoscopist at work.

Video and Optical Laryngoscopes can be divided into four subsets according to their fundamental characteristics:

i. Angulated blades (e.g. GlideScope (Verathon Inc., Bothell,WA, USA) and McGrath Series 5 (AircraftMedical Ltd, Edinburgh, UK))
ii. Standard Macintosh blades (e.g. the C-Mac (Karl Storz, Tuttlingen, Germany)
iii. Presence of a tube channel (Ambu-Pentax Airway Scope (AWS; Louisville, KY, USA) and Airtraq (Prodol Ltd, Vizcaya, Spain))
iv. Presence of a videostylet (e.g. the Clarus Video System (Clarus Medical LLC, Minneapolis, MN, USA)).

To focus the discussion, an example of each group will be discussed below.

a) The Glidescope (a video laryngoscope with an angulated blade)

The Glidescope is available in portable or stationary units; with either disposable or reusable blades. The blades have a characteristic exaggerated anterior curvature (60 degree flexure from midline) that theoretically aids in visualization of the larynx.

During EC usage, the superiority of the Glidescope over direct laryngoscopy has been demonstrated in first attempt success rates (68 vs. 78%, p=0.007) and in the management of the difficult airway. For rescue attempts success rates were similar.(34)

b) Storz C-MAC (a video laryngoscope with a standard Macintosh blade)

In their 2010 study, Brown et al compared laryngeal views from direct laryngoscopy with follow-up views using the Storz C-MAC (Karl Storz, Tuttlingen, Germany). Cormack and Lahane category I or II views were obtained 80% of the time via direct laryngoscopy and 93% of the time with the Storz C-MAC.(35)

A retrospective analysis of EC intubations performed with either a Storz C-MAC or via direct laryngoscopy using the standard Macintosh blade showed the Storz C-MAC to be more successful (97.3%; 95%CI 94.4 to 98.9% vs. 84.4%; 95%CI 81.0% to 87.5%). The Storz C-MAC was also associated with a higher ratio of successful intubations in the individuals that showed difficult airway characteristics.(36)

Direct comparison between the Glidescope and Storz C-MAC revealed no statistically significant difference regarding intubation success rates (first pass or overall).(37)

c) The Airtraq laryngoscope (an optical laryngoscope with a tube channel)

The Airtraq laryngoscope (Prodol Ltd, Vizcaya, Spain) is a disposable laryngoscope that employs optical components and a viewfinder through which the laryngoscopist views the lighted larynx. Intubation times have been shown to be shorter compared to direct laryngoscopy. A definite advantage of the device is its cost, portability and the fact that it does not need any assembly. Literature evaluating its effectiveness has been contradicting, but a systemic review and meta-analysis has shown it to shorten intubation times and to increase the rate of successful first attempts in novices.(38) Further study would be needed to clarify the role of these kind of devices in the management of the difficult or failed airway.

d) The Clarus Video System (an Video laryngoscope with a videostylet)

The Clarus Video system (also known as the Trachway (Biotronic Intrument Enterprise, Tai Chung, Taiwan, China) is a rigid, straight video stylet with a malleable tip. Fibre-optics relay the image onto a monitor attached to the handle. An ETT is loaded onto the stylet, and the malleable tip is placed into the trachea under video observation. A randomized crossover manikin simulation study showed the device to achieve similar intubation rates in both easy and difficult laryngoscopy scenarios. The Clarus

Video System provided faster (mean 20.8s versus 25.5s) and less traumatic intubations (0% vs 7% simulated dental injuries) during difficult intubations.(39)

The role that this device might play in difficult airway scenarios still needs to be investigated further.

ii) Cricothyroidotomy

Surgical airway placement is a drastic manoeuvre with serious complications and is seen as the last resort in the dire "cannot-ventilate, cannot-intubate (CVCI)" scenario. However, it is a lifesaving intervention that should not be shied away from if it is indicated. Airway securement through the cricothyroid membrane is the preferred method (compared to thyroidectomy) as it is a safer and simpler technique with less short term complications.

Cricothyroidotomy involves creating a surgical opening into the trachea at the level of the cricothyroid membrane. EC cricothyroidotomies account for 1% of all intubations preformed and can be accomplished using two techniques, namely surgical and puncture.(40)

a) Surgical Technique

The conventional technique involves surgical preparation of the site, proper identification of the anatomical landmarks, and immobilization of the larynx, vertical skin incision, blunt dissection up to the membrane, incision of the membrane, followed by placement of the endotracheal tube.

b) Puncture Techniques

A number of commercial sets are available that allow access through the cricothyroid membrane either using the Seldinger technique or a stylet technique. The latter involves a tube that is secured over a sharp stylet. After the skin is incised the stylet is advanced into the trachea through the cricothyroid membrane. The tube is then advanced into the trachea and the stylet removed. The Seldinger technique involves the initial placement of a guide wire via a needle. After an introducer is passed over the guide wire, enlarging the passage, a cricothyroidotomy tube is advanced over the guide-wire into the trachea.

RECOMMENDATIONS/GUIDELINES

Most guidelines regarding the management of the difficult airway have been drafted to aid anaesthetists. This group of patients are also encountered in the emergency medicine setting; often with less time available to plan the intubation. Still, emergency medicine registrars achieve a 94% success rate by their third post-graduate year and a 98% success rate when qualifying.(41) It is clear that guidelines regarding the difficult airway is applicable in both environments, with a few logical adaptions indicated.

1. International Guidelines Regarding the Difficult Airway

i) American Society of Anesthesiologists

The American Society of Anesthesiologists (ASA) guidelines, updated February 2013, emphasize the need for a pre-planned strategy for ventilation and intubation of the difficult airway, including alternative methods should the primary method fail.(3) Their algorithmic approach prompts the clinician to choose between primary and secondary intubation strategies based on a pre-intubation estimation of the likelihood of difficult intubation, ventilation and surgical airway access. This subsequently guides the clinician in his/her choice of a primary and alternative airway strategy.

In many aspects the ASA algorithm fails as a useful, prompt guide to the physician in time-constrained situations. Many of the pathways allow for a wide range of techniques to be used, instead of clear, directed guidelines. In terms of choice of alternative airway equipment the guidelines are non-directive, accept for the use of the SGA as airway device and video-assisted laryngoscopy as possible alternative to primary intubation.

ii) Difficult Airway Society (DAS) Guidelines

In the United Kingdom, the Difficult Airway Society (DAS) has devised their own set of guidelines with more direct directives at each decision making stage.(42) An primary as well as secondary intubation plan is addressed, as well as the CICV situation. Of note is that these guidelines specifically address the unexpected difficult tracheal intubation during RSI – the intubation technique performed in the majority of EC cases.(43) The guidelines are much more specific in their recommendations with regard to the use of equipment when compared to the ASA guidelines, e.g. the gum elastic bougie and different laryngoscope blades are advocated as alternative techniques to aid in initial tracheal intubation.

The DAS guidelines offer a more useful algorithmic approach for use at the bed side compared to the ASA guidelines. Unfortunately, the guidelines have not been updated since 2004 (it only briefly mentions video and optical laryngoscopy, a technique that gained a lot of ground in the last couple of years). Although outdated, the DAS guidelines (specifically Scenario 1 and 2) provide useful, easily remembered and easy to implement algorithms.

2. South African Guidelines

The South African setting has many unique aspects differentiating it from international settings where the above mentioned guidelines were generated. Comparatively, the South African government health sector operates in a far more resource limited environment with resource acquisition being governed heavily by monitory implications.

i) The South African Society of Anaesthesiologists (SASA) Guidelines

The SASA guidelines were published in 2008.(45) The guidelines, compared to the ASA and DAS guidelines, do not provide a basic approach to the assessment and management of the difficult airway, but specifically list what equipment should be available to manage the difficult airway.

The authors based their equipment guidelines on three airway scenarios:

- Equipment used routinely during an uncomplicated endotracheal intubation with no difficulty foreseen (stylets and bougies are listed as standard equipment, albeit as additional devices).
- Equipment used after a difficult airway has been identified pre-anaesthetically or when laryngoscopy with additional equipment (e.g. stylets, bougies) remains difficult when mask ventilation remains possible.
- Equipment used where laryngeal visualization and mask ventilation is difficult (the CICV scenario).

The SASA guidelines are concise but non-directive; with a substantial number of alternative devices listed. The guidelines are also generalizable to the South African context as they address different needs as dictated by level of care expected. Regrettably the evidence-based nature of these guidelines should be questioned as there is no mention of the process by which these guidelines have been formulated or reviewed.

ii) The Emergency Medicine Society of South Africa (EMSSA)

The only guidelines specifically taking the emergency medicine perspective into account are those formulated by EMSSA. There are two relevant documents:

1) *The Emergency Centre Equipment Guideline* (Practice Guidelines EM004) - a comprehensive equipment list that should be available (as a minimum) in South African ECs. A specific difficult intubation list is also available.(46)

2) *The RSI Guidelines* (Practice Guidelines EM015), addresses difficult airway management through the use of a step wise algorithm.(47) The rational and evidence behind the guidelines is described separately (*Rapid Sequence Intubation: Supporting Materials* (Practice Guidelines EM015B)).(48) The EMSSA guidelines advocated the use of an alternative intubation strategy from the start when difficult BVM ventilation is expected. The early use of TTIs is encouraged; with SGAs and GEBs described as being pivotal to achieve successful intubation.

The guidelines are evidence based as indicated by the supporting material and clear referencing. A possible improvement would be to elaborate these guidelines to include consensus statements about possible ambiguous matters such as the use of different classes of SGAs.

FINDINGS BY SIMILAR STUDIES ELSEWHERE

The literature search identified two studies that examined the availability of alternative airway devices to aid in the management of the difficult airway.

In 1997, Levitan et al conducted a survey looking at the availability of alternative airway devices in American ECs where emergency medicine residency programs were run.(49) They divided the alternative devices into those that aid ventilation and those that aid intubation (devices that aid direct intubation, like directional stylets and GEBs were not included.) Their results indicated that 79% of ECs (n=75) had some form of alternative intubation device, 49% (n=47) had more than one alternative intubation device (flexible fibre-optic bronchoscope, rigid fibre-optic device, lighted stylet or retrograde intubation kit) and 21% (n=20) had none. Surprisingly, 64% (n=61) had a flexible fibre-optic bronchoscope available. This equipment is expensive and in the South African setting usually only available in theatres. A possible explanation for this could be that, at the time of the study, fibre-optic nasal intubation was part of the core curriculum for American emergency medicine residency programs. Retrograde intubation kits were found in 45% (n=43) of the responding ECs. Lighted stylets were available in 33% (n=31) of the ECs. Thirty one centres (33%) had more than one alternative ventilation device; 20 centres (21%) had none. Alternative ventilation devices included a PTJV system, the OTC or a LMA. A relatively high percentage of ECs (67%, n=64) stocked a PTJV system (also part of the

core residency curriculum). In contrast to this, both OTCs and LMAs were only stocked in 25 centres (26%).

The second study, conducted in 1999 by Morton et al, surveyed all English adult ECs that evaluates more than 20 000 new patients per year.(50) They included the availability of tracheal tube stylets, straight and curved blades as well as GEBs in their survey. Alternative ventilation devices included in their standard pro forma questionnaire were LMAs, OTCs and pre-assembled needle cricothyroidotomy sets. Alternative intubation devices included fibre-optic bronchoscopes, ILMAs, lighted stylets as well as retrograde intubation kits and percutaneous tracheostomy or cricothyroidotomy kits. Twenty-one of the 197 surveyed centres (11%) did not have alternative ventilation devices; this was 10% less than the American study two years earlier. The remaining 176 ECS (89%) had at least one form of alternative ventilation device. Laryngeal masks were available in 128 (65%) ECs, needle cricothyroidotomy sets in 124 (63%) and the OTC in 35(18%). The OTC was thus less frequently available and LMAs substantially more frequently stocked, compared to the American study.

Surgical airway devices (percutaneous tracheostomy or cricothyroidotomy kits) were found in most centres (98%, n=193), but other alternative intubation devices were all very rare (bronchoscopes 10%, n=20; retrograde intubation kits 8%, n=16; ILMA 7%, n=14; and lighted stylet 2%, n=4). GEBs were found in all but one centre (99%).

These studies give us snapshots of alternative airway devices available in two different first world countries a mere two years apart, but more than a decade ago. It would be expected that time has changed the scene dramatically, but we do gain a sense of the vast inter-centre as well as inter-continental variance in the availability of alternative airway devices. This variance might well be explained by the relative paucity of literature to back the use of one device over another (a situation that has recently changed) or that devices that were part of residency curricula were more frequently stocked. Another factor could be financial restraint as one of the governing principles during equipment procurement; British ECs had a relative scarcity of alternative intubation equipment (lighted stylet, bronchoscopes, ILMAs and retrograde intubation kits), all relatively expensive pieces of equipment.

A common thread in both studies, however, is the vast amount of first world ECs that have no alternative airway devices available. Twenty one present of the American centres had no alternative intubation device and 21% no alternative ventilation device (surgical airway was not included in the study as alternative intubation method). The British ECs did better with regard to alternative ventilation methods (11%) with LMAs accounting for most of the difference (10%). Alternative intubation devices, if surgical airway equipment is not taken into account, were however very scarce (available in 2-8% of the centres).

CONCLUSION

The difficult airway is an entity that physicians working in an EC will rarely encounter. It is, however, a life threatening situation that could potentially be managed effectively, given that the right equipment is available. The current literature search elucidated a number of essential pieces of equipment that must be available in all ECs as well as a number of potentially helpful devices against which findings in a South African EC could be tested. Thorough guidelines are available for South African ECs from EMSSA, on par with national as well as international guidelines, with the added benefit of being tailored for the South African emergency care setting. Previous studies in affluent first world countries have shown substantial variance between different ECs as well as between countries as to what alternative devices are available, with an alarming percentage of ECs that have no alternative devices available.

How South African EC's compare in light of available equipment, current guidelines as well as compared to other world regions have not been tested. A thorough understanding of the current situation will aid in optimizing difficult airway management in South African EC's.

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Part B: Proposal

The availability of alternative airway devices in public Emergency Centres in the Western Cape

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INTRODUCTION

Background

Airway management is an important aspect of the management of all patients in the emergency setting. The goals of airway management are to ensure airway patency, prevent aspiration and promote gas exchange.(1) The majority of patients seen in our emergency centres can maintain their own airway and some might just need some supplemental oxygen to aid adequate gas exchange. Emergency personnel only need to intervene and secure an artificial airway when airway patency is threatened or ventilation is needed.

Over the years a number of alternative airway devices and adjuncts to intubation with an endotracheal tube have become available. Levitan *et al* and Boet *et al* summarise the history of the development of these devices: from Miller and Macintosh blades developed in the 1940s, to the more recent laryngeal mask airways and video laryngoscopy.(2-3) The skills required to use these devices are usually mastered quickly and easily by doctors and other emergency personnel. It is often the availability of such equipment in the work environment that hinders mastery of the skills.

In most cases a threatened airway can easily be managed by physicians in emergency centres using direct laryngoscopy; therefore alternative devices are not often used in these centres. However, a number of patients can be classified as having a "difficult airway". Crosby *et al* defines a difficult intubation as "when an experienced laryngoscopist, using direct laryngoscopy, requires: 1) more than two attempts with the same blade or 2) a change in the blade or an adjunct to a direct laryngoscope (i.e. bougie) or 3) use of an alternative device or technique following failed intubation with direct laryngoscopy".(4) It is in these situations where alternative or adjunct airway devices are necessary.

In 1993 the American Society of Anesthesiologists developed a difficult airway algorithm that was recently updated.(5-6) It was recognised that anaesthetists, being seen as experts in airway management, frequently deal with difficult airways. Subsequently the use of difficult airway devices has become standard in operating theatres. More recently a cohort study was done where a difficult airway algorithm which incorporated gum elastic bougie and fibre optic devices, was used.(7) All patients were intubated successfully.(7) Recommendations were made by the American Society of Anesthesiologists regarding the assessment and management of an airway for peri-operative patients. One of the recommendations are to have a portable storage unit in the operating theatre, containing all the specialised equipment needed to manage a difficult airway.(6) There are no such recommendations for emergency centres, even though that is very often where difficult airways are encountered. To have an alternative airway box in all emergency centres, like those kept for example at Boston children's Hospital or at the Medical College of Georgia, seems like an excellent idea.(8)

There have been relatively little studies on the availability of alternative airway devices in emergency centres worldwide. In England a survey of all the emergency centres revealed that very few (11%) had no alternative ventilation devices, but only 10% had some form of alternative intubation device.(9) The study suggests that at least one alternative device for both ventilation and intubation should be available in the emergency centre. A similar survey in the United States showed somewhat better results, but still a tenth of centres did not have devices for either intubation or ventilation.(10) There have been no such studies done in South African emergency centres.

Motivation

Airway control is a vital procedure for any doctor, even more so in the specialty of Emergency Medicine. Although endotracheal intubation is the preferred method to obtain a definitive airway, several devices have been developed to help physicians handle a difficult or failed intubation. We can surmise from literature that there should be at least one alternative device for ventilation and one for intubation. We don't know what the current availability of such devices in the Western Cape is. Recommendations for improvement can only be made once this is known.

Research question

What alternative airway devices are available in public Emergency Centres in the Western Cape?

Aim

- To determine which alternative airway devices are available in public Emergency Centres in the Western Cape

METHODOLOGY

Study design

A cross-sectional study design will be used.

Study setting

The study will take place within the Western Cape Province of South Africa. The Western Cape covers an area of 129 370 km², with approximately 5.2 million people living in the province (65% of the population resides around Cape Town).(11-12) There are eight secondary level hospitals and three tertiary level hospitals which are managed by the Western Cape Provincial Department of Health Services.(13)

Study population

The 11 study hospitals include all the secondary and tertiary hospitals within the Western Cape (Table 1). These hospitals provide care for patients with the highest illness acuity and subsequently perform endotracheal intubations at regular intervals. It is thus vitally important that these hospitals should have adequate equipment to manage compromised airways.

Table 1. Study hospitals

Hospital	**Location**	**Hospital level**
George Hospital	George, Eden	Secondary
G.F. Jooste Hospital	Mannenberg, Cape Town	Secondary
Groote Schuur Hospital	Observatory, Cape town	Tertiary
Helderberg Hospital	Somerset West, Stellenbosch	Secondary
Karl Bremer Hospital	Bellville, Cape Town	Secondary
Paarl Hospital	Paarl, Drakenstein	Secondary
Red Cross War Memorial Children's Hospital	Rondebosch, Cape Town	Tertiary
Somerset Hospital	Green Point, Cape Town	Secondary
Tygerberg Hospital	Bellville, Cape Town	Tertiary
Victoria Hospital	Wynberg, Cape Town	Secondary
Worcester Hospital	Worcester, Breede Valley	Secondary

Data collection and management

A single data collector will visit each emergency area at every study hospital once during the study period. The tertiary hospitals have separate emergency centres (e.g. trauma and medical emergencies); these centres will all be included. Data will be collected on a standardised data collection sheet (Appendix 1).

The investigators will insert the data into an electronic spreadsheet (Microsoft Excel®, Microsoft Corporation, Redmond, WA). The electronic spreadsheet will be password protected to ensure the integrity of the data. All data collection sheets will be destroyed after data extraction – a paper shredder will be used for this purpose.

The validity of the study findings will be ensured in a couple of ways:

– A single data collector with knowledge regarding alternative airway devices will collect the data

- A standardised data collection sheet will be used
- The data collector will take a digital photograph of any piece of equipment possibly related to alternative airway devices. The photograph will be evaluated by a person with extensive knowledge of alternative airway devices to try to identify it.

Statistical analysis

The primary aim of this analysis is to determine which alternative airway devices are available in public Emergency Centres in the Western Cape. Summary statistics will be used to describe all variables. Distributions of variables will be presented with histograms and or frequency tables.

Time schedule

The study will be completed within 5 months after approval from the Stellenbosch University Human Research Ethics Committee and the Western Cape Health Research Committee.

Task	**Month 1**	**Month 2**	**Month 3**	**Month 4**	**Month 5**
Data collection	x	x			
Data management		x	x		
Statistical analysis / Reporting of results			x		
Writing				x	
Preparing and submit for publication					x

ETHICAL AND LEGAL CONSIDERATIONS

The study doesn't involve human subjects. It only describes the availability of equipment at the study hospitals' emergency centres.

We therefore request a waiver of informed consent under the following conditions:

- This is a low risk descriptive study
- No personal or identifying information will be collected
- The findings of the study will provide valuable information that is likely to influence emergency care within the Western Cape. Hospitals with inadequate equipment can be identified and recommendations made to properly stock these units.

Data collected will be entered into an electronic spreadsheet (Microsoft Excel®, Microsoft Corporation, Redmond, WA). The electronic spreadsheet will only be accessible on a password protected work computer situated in the offices of the Division of Emergency Medicine, Faculty of Medicine and

Health Sciences, Stellenbosch University. Access to this information will be restricted to members of the research team. All data collection sheets will be destroyed after data extraction by means of a paper shredder.

Approval for this study will also be obtained from the Western Cape Health Research Committee.

Limitations

The study will only describe the availability of alternative airway devices in emergency centres of secondary and tertiary level hospitals within the Western Cape. Follow-up studies need to determine the actual knowledge and practical skills of healthcare personnel regarding these devices. Secondly, other regional hospitals, district hospitals and community health clinics also need to manage patients' airways (although less commonly) and might have similar equipment needs. A separate study will look at these health facilities.

Reporting and implementation of results

The investigators will be able to determine the current availability of alternative airway devices within public emergency centres in the Western Cape. Hospitals with inadequate equipment can be identified and recommendations made to properly stock these EC's. The recommendations can also be extended to include district hospitals and community health clinics. The study results will be reported in a peer reviewed journal.

RESOURCES

Available resources

The Harry Crossley Foundation at Stellenbosch University will be approached for funding.

Budget and budget motivation

The budget for this study is: R 5710.55. A detailed budget is available (Appendix 2).

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Appendices

1. Data collection sheet
2. Detailed Budget

Appendix 1 – Data collection sheet

Hospital:	**Date:**

Intubating guides	**Types / Names / Similar**	**Available sizes***	**Working condition (Y/N)**
Stylets (malleable introducers)	• •		
Tracheal Tube Introducers • Eschmann Tracheal Tube Introducer (Gum elastic bougie) • The Flex-Guide • Flextrach ETTube Guide	• • • •		

Intubating stylets	**Types / Names / Similar**	**Available sizes***	**Working condition**
Directional Stylets • Shroeder Directional Stylets	• • •		
Lighted stylets/wands • Trachlight	• • •		

Fibre-optic Endoscopy Aids	**Types / Names / Similar**	**Available sizes***	**Working condition**
Fibre-optic stylets (semi-rigid) • Shikani Optical Stylet • Levitan/FPS Scope	• • •		
Fibre-optic stylets (rigid) • Bonfils Retromolar Intubating Fiberscope • Airway RIFL • Bullard laryngoscope • UpsherScope • WuScope	• • •		
Flexible fibre-optic bronchoscope	• •		
Extra-glottic devices	**Types / Names / Similar**	**Available sizes***	**Working condition**
Supra-glottic class: • Laryngeal mask airways • Disposable LMA-type designs (e.g. Ambu LMA) • Cookgas ILA & Air Q • CobraPLA • Pharyngeal Airway Express (PAXpress)	• • • •		
Infra(retro)-glottic class: • Esophageal Obturator Airway • Esophageal Tracheal Combitube • King LT airway (Laryngeal Tube Airway) • Rusch Easy Tube	• • •		

Scopes	**Types / Names / Similar**	**Available sizes***	**Working condition**
Video laryngoscope • GlideScope • Karl Storz videoscope • McGrath videoscope • Pentax Airway Scope • Res-Q-Scope II	• •		
Optical laryngoscope • Airtraq • TruView EVO	• •		

Surgical airway devices	**Commercial set:**	**Self assembled (√ if present):**
Needle cricothyriodotomy (with percutaneous jet ventilation)	Types / Names: • •	Equipment: • IV catheter (12-16 G) • 20-ml syringe • High pressure O_2 source • High pressure O_2 tubing • Regulator • On-off valve • Luer lock / adaptor • Other:
Surgical cricothyriodotomy	Types / Names: • • Direct airway placement devices (e.g. Nu-Trake, Pertrach): •	Equipment: • Trousseau dilator • Tracheal Hook • Scalpel with no 11 blade • Cuffed, non-fenestrated no 4 tracheostomy tube • Gauze • Two small haemostats • Surgical drapes • Other:

*** Use N/A when not available**

Appendix 2 – Detailed budget

Personnel Compensation		R 0
Consulting services		R 0
Statistical services (@ R175 per hour)	R 0	
Travel		R 5 091.41
Transport[1]	R 4 641.41	
Accommodation in George[2]	R 450	
Equipment & Furniture		R 0
Stationary		R 100
Telephone / Internet		R 0
Total direct cost		**R 5 191.41**
Inflation (10%)		R 519.14
Total costs		**R 5 710.55**

[1] Transport

Hospital	Return distance from SUN (km)	Cost (@R3.16/km)
George Hospital	850	R 2 686.00
G.F. Jooste Hospital	26	R 82.16
Grootte Schuur Hospital	50	R 158.00
Helderberg Hospital	77	R 244.58
Karl Bremer Hospital	9	R 28.44
Paarl Hospital	102	R 322.32
Red Cross War Memorial Children's Hospital	46	R 145.36
Somerset Hospital	52	R 164.32
Tygerberg Hospital	0	R 0.00
Victoria Hospital	66	R 207.93
Worcester Hospital	191	R 602.30
Total	1469	R 4 641.41

[2] Accommodation: One night in B&B for single person

Part C: Manuscript in Article Format
(South African Medical Journal)

The availability of alternative devices for the management of the difficult airway in public Emergency Centres in the Western Cape

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ABSTRACT

Background
The failed or difficult airway is a rare, but life-threatening situation. Alternative airway devices to direct laryngoscopy are essential aids to manage these scenarios successfully.

Objective
To determine which alternative airway devices are currently available in public emergency centres in the Western Cape Province, South Africa.

Methods
A cross sectional study was conducted in 15 emergency centres. Data regarding the availability of different classes of alternative airway devices was documented on a standardised data collection sheet by a single investigator via direct observation. Incomplete or non-functional equipment was classified as 'unavailable'. Summary statistics were used to describe the data.

Results
Twenty-six different types of alternative airway devices were documented. Three centres (20%) had no alternative airway device. Five centres (33.3%) stocked only one device, three centres (20%) had two devices and four centres (26.7%) had more than two devices. Most centres (n=12, 80%) stocked supraglottic airways (only one centre (6.7%) had paediatric sizes). Tracheal tube introducers were available in five centres (33.3%). Four centres (26.7%) had video-laryngoscopes, but none had optical laryngoscopes. Retroglottic devices and needle cricothyroidotomy equipment were available in two centres (13.3%). Although surgical cricothyroidotomy equipment was available, the equipment was widely dispersed and only three centres (20%) had pre-packed sets available. None of the specialised paediatric centres had needle cricothyroidotomy equipment readily available.

Conclusion
The study demonstrated that Western Cape public emergency centres are currently inadequately stocked with regards to alternative airway devices. A guideline regarding the procurement and implementation of these devices is needed.

INTRODUCTION

Advanced airway management is indicated when a patient fails to protect his or her own airway. Failure to secure a threatened airway can have devastating consequences, leading to permanent neurological damage or even death. However, managing the threatened airway isn't always a straight-forward procedure. About 4% of patients will not be amenable to timely intubation via direct laryngoscopy due to the presence of a difficult airway, while 0.3% will have a failed airway.[1] Although a universal definition of the difficult airway is not used in published literature, it has been defined by the American Society of Anesthesiologists (ASA) as "*the clinical situation in which a conventionally trained anaesthesiologist experiences difficulty with facemask ventilation of the upper airway, difficulty with tracheal intubation, or both*".[2] The concept of the failed airway is also included here and is defined by the ASA as the failure of endotracheal tube placement after multiple attempts.[2]

In these situations, alternative devices to the endotracheal tube and laryngoscope to achieve intubation, as well as equipment other than the bag-valve-mask to ventilate the patient, become paramount in an attempt to avoid the dreaded "cannot ventilate, cannot intubate" situation. A vast number of alternative devices, many in a plethora of subtly altered incarnations, are currently available. They act as facilitators of direct laryngoscopy, as alternative ventilation devices or as alternative intubation devices.

The Emergency Medicine Society of South Africa (EMSSA) offers guidance to the management of the difficult airway through their published guidelines on rapid sequence intubation.[3]According to these guidelines at least one alternative device for ventilation (Laryngeal Mask Airway (LMA) or Laryngeal Tube (LT)) should be available as rescue airway. Furthermore, equipment to establish a surgical airway (cricothyroidotomy set or percutaneous tracheostomy set) as definitive alternative intubation technique is mandatory equipment. Other alternative intubation techniques (video laryngoscopy, fibre-optic laryngoscopy, intubating LMAs and lighted stylets) are advocated if they are suited for the clinical scenario and the expertise are available. The availability of such devices in a South African setting has not yet been studied. It is only through the establishment of the *status quo* that a potential shortage of alternative devices to aid in the management of the difficult airway can be illuminated. The need for intervention can subsequently be assessed and suitable recommendations can be made. This study aimed to determine the availability of alternative airway devices in public emergency centres in the Western Cape, South Africa.

METHODS

Study Design

A cross-sectional study was completed over a 12-day period (19 June to 30 June 2013). This study was approved by the Stellenbosch University Health Research Ethics Committee (S12/08/233).

Setting and Population

The Western Cape Province covers an area of 129 370 km^2 and is home to approximately 5.3 million people; 78% relying on state health services.[4] The City of Cape Town houses the biggest proportion of these inhabitants with an approximate citizenship of 3.5 million people.[4] Health services in the public domain are provided by the Western Cape Provincial Department of Health and include 479 Primary Health Care facilities, 12 district hospitals, 5 regional hospitals and 3 central hospitals.[4, 5] The central hospitals (Groote Schuur Hospital, Tygerberg Hospital and Red Cross War Memorial Children's Hospital) offer general as well as highly

specialised services, the regional hospitals render services at a general specialist level, while the district hospitals function as specialist supported entities.[4]

Fifteen emergency centres (EC's) in 11 hospitals in the Western Cape Province were sampled. The study included all three central hospitals, four regional hospitals and four district hospitals (Table 1). One regional hospital (Mowbray Maternity Hospital) was excluded as it is a specialised Maternity and Neonatal hospital and does not have a general emergency centre. The four district hospitals were included as these centres evaluate a high percentage of relatively ill patients and subsequently perform more endotracheal intubations compared to smaller district hospitals. Khayalitsha District Hospital, as well as Mitchell's Plain District Hospital, opened after the study was commenced and were excluded. The tertiary hospitals have separate EC's handling paediatric, surgical and medical emergencies. One of the tertiary hospitals (Red Cross War Memorial Children's Hospital) was a paediatrics only facility, with separate medical and surgical emergency centres. The centres were all analysed individually.

Table 1 Study hospitals

Hospital	**Location**	**Hospital level**
Groote Schuur Hospital	Observatory, Cape town	Central
Red Cross War Memorial Children's Hospital	Rondebosch, Cape Town	Central
Tygerberg Hospital	Bellville, Cape Town	Central
George Hospital	George, Eden	Regional
Paarl Hospital	Paarl, Drakenstein	Regional
New Somerset Hospital	Green Point, Cape Town	Regional
Worcester Hospital	Worcester, Breede Valley	Regional
G.F. Jooste Hospital	Mannenberg, Cape Town	District
Helderberg Hospital	Somerset West, Stellenbosch	District
Karl Bremer Hospital	Bellville, Cape Town	District
Victoria Hospital	Wynberg, Cape Town	District

Data Collection

A single data collector with knowledge regarding alternative airway devices collected all the data on a standardised data collection sheet. (web appendix 1). Devices were categorized into 1) Adjuncts to difficult intubation, 2) Alternative ventilation equipment, and 3) Alternative intubation equipment.

Equipment that wasn't in a working condition or had missing parts was categorised as 'unavailable'. Equipment that was used inappropriately, for example disposable tracheal tube introducers (TTIs) that were reused, were also classified as 'unavailable'. Data were transferred to a password protected electronic spreadsheet (Microsoft Excel®, Microsoft Corporation, Redmond, WA).

Statistical Analysis

Data were analysed by the principal investigator using Microsoft Excel® (Microsoft Corporation, Redmond, WA.) and summary statistics are presented.

RESULTS

Twenty-six different types of alternative airway devices were documented. Five ECs (19.2%) had one type of alternative airway devise available, 7 (26.9%) stocked at least two devices, whilst four centres (26.7%) had more than two devices available. Three centres (20%), all situated in central hospitals, had no alternative airway device available, while the best stocked centre (a regional hospital) had five different types of devices. The availability of the different types of alternative airways is depicted in Table 2.

Table 2. The availability of different types of alternative devices for management of the difficult airway in Western Cape emergency centres.

	All (n, %)	Central hospitals:* (n, %)	Regional hospitals† (n, %)	District hospitals‡ (n, %)
Adjuncts to Difficult Intubation:				
Tracheal Tube Introducers	5 (33%)	0(0%)	2(50%)	3(75%)
Alternative ventilation devices				
Supraglottic airways	12 (80%)	5 (71.4 %)	3(75%)	4(100%)
Retroglottic airways	2 (13%)	0 (0%)	1(25%)	1(25%)
Needle cricothyriodotomy equipment §	2 (13%)	0 (0%)	2(50%)	0 (0%)
Alternative intubation devices				
Video laryngoscope	4 (27%)	1 (14.2 %)	3(75%)	0 (0%)
Surgical cricothyroidotomy equipment §	3 (20%)	0(0%)	2(50%)	1(25%)
Intubating LMA	2(13%)	0 (0%)	2(50%)	0 (0%)
Optical laryngoscopy	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Lighted stylets/wands	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Fibre-optic endoscopic aids	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*N=7; † N=4; ‡ N=4; § Only complete, pre-assembled sets included

TTI's were available in 33% (*n*=5) of the studied ECs. District hospitals had the highest percentage (75%, *n*=3); whilst two of the central hospitals' units did have introducers, they were of the disposable type and not meant for reuse.

Eighty percent (*n*=12%) had at least one alternative ventilation device. Twenty percent of the centres (*n*=3) had a second or third alternative ventilation device available. Supraglottic airways were the most frequently available device (80%, *n*=12). Paediatric supraglottic airways were only available in one of the dedicated paediatric units (6.67%). Retroglottic airways and needle cricothyroidotomy equipment were rare (both 13%, *n*=2). Needle cricothyroidotomy equipment was not available in any of the dedicated paediatric units.

Alternative intubation devices (not taking surgical airways into account), were available in 27% (*n*=4) of the ECs and 13.3% (*n*=2) had a second device available. Video laryngoscopes were most frequently available (overall 27%, *n*=4; regional hospitals 75%, *n*=3; central hospitals 14%, *n*=1). Intubating LMAs were available in 13% (*n*=2) of the centres; both in regional hospitals. Lighted stylets/wands and fibre-optic endoscopic aids were not found in any of the centres.

Complete surgical cricothyroidotomy sets were available in three (20%) ECs. Two of these were regional hospitals and the other was accessible in a district hospital. No complete sets were readily available in central hospitals.

DISCUSSION

The study indicated that the majority of ECs in the Western Cape had at least one alternative form of equipment available to manage a difficult airway. This is similar to a previous international study where 89% of the ECs held some form of alternative airway equipment.[6] However, effective management of a difficult airway dictates that alternative modes for ventilation as well as intubation should be readily available. It is thus of vital importance to assess the availability of aids to intubation, alternative ventilation devices and alternative intubation devices separately.

Aids to Intubation

TTI's (also commonly known as "bougies" or gum elastic bougies) were not found in large numbers (33%). This stands in stark comparison to tracheal tube introducers being available in 99% of English ECs studied earlier.[7] In EMSSA's rapid sequence intubation guidelines, TTI's play a critical role - not only is its use indicated during a second attempt, but emphasis is also placed on it being an optional adjunct during the first attempt at intubation.[3] Directly comparing styletted endotracheal tubes to assisted intubation with TTIs, the latter showed significantly higher success rates (94% vs. 77%).[8]

Alternative Ventilation Devices

Supraglottic airways (e.g. LMAs) have a substantial body of evidence to back their use in the EC. They form an integral part of the difficult airway management protocols proposed by the recently updated ASA guidelines for difficult airway management as well as the local EMSSA guideline.[2,3] Using the LMA as back-up device, successful ventilation can be achieved in up to 94% of patients.[9] The relatively high availability of LMAs (80%) is thus reassuring.

Of concern is that paediatric-sized supraglottic airways were only found in one of the dedicated paediatric ECs, whilst eight of the sampled ECs also treat paediatric emergency cases (two centres being exclusive specialist paediatric ECs). Failed intubation via direct laryngoscopy and failed face-mask ventilation are very rare in the paediatric population (0.42% and <0.02%, respectively).[10] However, failure of both is a devastating situation that has been addressed by the Difficult Airway Society in their management of the difficult paediatric airway guidelines, in which they advocate for the use of LMAs as rescue device if oxygenation via bag-valve-mask ventilation fails.[11]

Retroglottic airways (e.g. the oesophageal-tracheal combitube) are alternatives to supraglottic airways. The retroglottic airway devices available in the sampled ECs included the LT (VBM Medizintechnik, Sulz, Germany) and the Rüsch Easytube (Teleflex Medical (Reusch), Kernen, Germany.) The LT is a single lumen device whilst the Rüsch Easytube has a double lumen, similar to the esophageal-tracheal combitube (Tyco-Healthcare-Nellcor, Pleasanton,

California). Although a number of cases have been reported of these devices being successfully used in the management of the difficult airway and in the emergency situation, in-depth studies are lacking and their definite role in emergency intubation has not been clarified.[12,13] Wide implementation of its use cannot be advocated at this moment.

Percutaneous Transtracheal Jet Ventilation (PTJV) is the preferred mode of surgical airway rescue in the paediatric population.[11] It is thus of grave concern that needle cricothyroidotomy equipment was not freely available in the specialist paediatric units. Needle cricothyroidotomy sets were available in only two emergency centres, both as self-assembled kits. Although most of the needed equipment is freely available in most emergency centres, the assembly of kits should be done in advance. The last thing a physician needs is to waste precious time in the event of an emergency.

Alternative Intubation Devices

Alternative intubation devices are, generally, advised on a case-by-case bases and familiarity with its use.[3] Few of the studied centres had video laryngoscopes available, mostly in centres run by emergency physicians. During EC usage, the superiority that the video laryngoscopy has over direct laryngoscopy for first attempt success rate (68 vs. 78%, p=0.007), as well as overall success rate (97.3% vs. 84.4%), has been shown. Video laryngoscopy are also advantageous in the management of the difficult airway with better laryngeal views obtained more often (93% vs. 80%).[14,15] Due to the devices having an external display they also have an obvious benefit as a teaching aid. Compared to other alternative devices, video laryngoscopy is still relatively new and expensive. However, it is mentioned in the ASA guidelines as an alternative device for intubation, but advocating for more wide-spread use and implementation of the device would not be prudent. It might play a bigger part in the near future.

The EMSSA as well as the ASA guidelines both mandate the use of surgical cricothyroidotomy as the last option in case of a failed airway; it is also found on EMMSA's mandatory equipment list.[2,3] Despite this, only 20% of the ECs had formal surgical airway kits available. This situation is worrying, as a surgical airway might be the only option left in some circumstances.

LIMITATIONS

The study only evaluated ECs in the Western Cape, therefore the findings might not be generalizable to the rest of South Africa or other countries. The study only included relatively large emergency centres and the findings can thus not be taken as to represent smaller centres that might also have equipment needs.

The exclusion of Khayalitsha as well as Mitchell's Plain District Hospitals are unfortunate, as the inclusion of their ECs could have served to paint a clearer picture of the current situation. Being new units one could expect that newer trends in equipment acquisition could have been followed and a better-equipped centre might have ensued.

The study only assesses availability and does not address the clinical utilisation of these devices – the actual practical skills and knowledge that health care workers need to use the alternative airways would have to be assessed in future studies.

CONCLUSION

Airway management is a vital component in the care of the critically ill patient, but at the time of the study the included ECs did not have all the devices available to aid in the optimal management of the difficult/failed airway. Such a situation can lead to unnecessary morbidity

and mortality and should be addressed as soon as possible. We recommend that guidelines should be implemented that include TTIs as aid to intubation as well as supraglottic airways as rescue ventilation devices. Pre-prepared surgical airway equipment as definitive alternative intubation route should be available in all centres where adult airway emergencies could arise. Other alternative methods of intubation should be available where the necessary expertise to utilize them are available. In ECs managing paediatric patients it is paramount that needle cricothyroidotomy sets as well as paediatric supraglottic airways should be included.

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Web Appendix 1 – Data collection sheet

Hospital:	**Date:**

Intubating guides	**Types / Names / Similar**	**Available sizes***	**Working condition (Y/N)**
Stylets (malleable introducers)	• •		
Tracheal Tube Introducers • Eschmann Tracheal Tube Introducer (Gum elastic bougie) • The Flex-Guide • Flextrach ETTube Guide	• • • •		

Intubating stylets	**Types / Names / Similar**	**Available sizes***	**Working condition**
Directional Stylets • Shroeder Directional Stylets	• • •		
Lighted stylets/wands • Trachlight	• • •		

Fibre-optic Endoscopy Aids	**Types / Names / Similar**	**Available sizes***	**Working condition**
Fibre-optic stylets (semi-rigid) • Shikani Optical Stylet • Levitan/FPS Scope	• • •		
Fibre-optic stylets (rigid) • Bonfils Retromolar Intubating Fiberscope • Airway RIFL • Bullard laryngoscope • UpsherScope • WuScope	• • •		
Flexible fibre-optic bronchoscope	• •		
Extra-glottic devices	**Types / Names / Similar**	**Available sizes***	**Working condition**
Supra-glottic class: • Laryngeal mask airways • Disposable LMA-type designs (e.g. Ambu LMA) • Cookgas ILA & Air Q • CobraPLA • Pharyngeal Airway Express (PAXpress)	• • • •		
Infra(retro)-glottic class: • Esophageal Obturator Airway • Esophageal Tracheal Combitube • King LT airway (Laryngeal Tube Airway) • Rusch Easy Tube	• • •		

Scopes	**Types / Names / Similar**	**Available sizes***	**Working condition**
Video laryngoscope • GlideScope • Karl Storz videoscope • McGrath videoscope • Pentax Airway Scope • Res-Q-Scope II	• •		
Optical laryngoscope • Airtraq • TruView EVO	• •		

Surgical airway devices	**Commercial set:**	**Self assembled (√ if present):**
Needle cricothyriodotomy (with percutaneous jet ventilation)	Types / Names: • •	Equipment: • IV catheter (12-16 G) • 20-ml syringe • High pressure O_2 source • High pressure O_2 tubing • Regulator • On-off valve • Luer lock / adaptor • Other:
Surgical cricothyriodotomy	Types / Names: • • Direct airway placement devices (e.g. Nu-Trake, Pertrach): •	Equipment: • Trousseau dilator • Tracheal Hook • Scalpel with no 11 blade • Cuffed, non-fenestrated no 4 tracheostomy tube • Gauze • Two small haemostats • Surgical drapes • Other:

*** Use N/A when not available**

Part D: Supporting Documentation

SAMJ Author Guidelines[1]

Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, and will delay publication.

AUTHORSHIP

Named authors must consent to publication. Authorship should be based on: (i) substantial contribution to conception, design, analysis and interpretation of data; (ii) drafting or critical revision for important intellectual content; or (iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to **www.icmje.org**).

CONFLICT OF INTEREST

Authors must declare all sources of support for the research and any association with a product or subject that may constitute conflict of interest.

RESEARCH ETHICS COMMITTEE APPROVAL

Provide evidence of Research Ethics Committee approval of the research where relevant.

PROTECTION OF PATIENT'S RIGHTS TO PRIVACY

Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives informed written consent for publication. The patient should be shown the manuscript to be published. Refer to **www.icmje.org**.

ETHNIC CLASSIFICATION

References to ethnic classification must indicate the rationale for this.

MANUSCRIPTS

Shorter items are more likely to be accepted for publication, owing to space constraints and reader preferences.

Research articles (previously 'Original articles') not exceeding 3 000 words, with up to 6 tables or illustrations, are usually observations or research of relevance to clinical medicine and related fields. *References should be limited to no more than 15.* Please provide a structured abstract not exceeding 250 words, with the following recommended headings:*Background, Objectives, Methods, Results,* and *Conclusion.*

[1] Available from http://www.samj.org.za/index.php/samj/about/submissions#authorGuidelines. Accessed 18 June 2013

Scientific letters will be considered for publication as shorter ***Research articles***.

Editorials, Opinions, etc. should be about 1000 words and are welcome, but unless invited, will be subjected to the *SAMJ*peer review process.

Review articles are rarely accepted unless invited.

Letters to the editor, for publication, should be about 400 words with only one illustration or table, and must include a correspondence address.

Forum articles must be accompanied by a short description (50 words) of the affiliation details/interests of the author(s). Refer to recent forum articles for guidance. Please provide an accompanying abstract not exceeding 150 words.

Book reviews should be about 400 words and must be accompanied by the publication details of the book.

Obituaries should be about 400 words and may be accompanied by a photograph.

Guidelines must be endorsed by an appropriate body prior to consideration and all conflicts of interest expressed. A structured abstract not exceeding 250 words (recommended sub-headings: *Background, Recommendations, Conclusion*) is required. Sections and sub-sections must be numbered consecutively (e.g. 1. Introduction; 1.1 Definitions; 2. etc.) and summarised in a Table of Contents. References, appendices, figures and tables must be kept to a minumum.

Guidelines exceeding 8 000 words will only be considered for publication as a supplement to the SAMJ*; the costs of which must be covered by sponsorship or advertising. The Editor reserves the right to determine the scheduling of supplements. Understandably, a delay in publication must be anticipated dependent upon editorial workflow.*

MANUSCRIPT PREPARATION

Refer to articles in recent issues for the presentation of headings and subheadings. If in doubt, refer to 'uniform requirements' - **www.icmje.org**. Manuscripts must be provided in **UK English**.

Qualification, affiliation and contact details of ALL authors must be provided in the manuscript and in the online submission process.

Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dl). Litres is denoted with a lowercase 'l' e.g. 'ml' for millilitres). Units should be preceded by a space (except for %), e.g. '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and 40 years of age'. The same applies to ± and º, i.e. '35±6' and '19ºC'.

Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160...

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...'
Round **brackets** (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

General formatting The manuscript must be in Microsoft Word or RTF document format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes, with the exception of Tables).

ILLUSTRATIONS AND TABLES

If tables or illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.

Tables may be embedded in the manuscript file or provided as '**supplementary files**'. They must be numbered in Arabic numerals (1,2,3...) and referred to consecutively in the text (e.g. 'Table 1'). Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged. Tables must be cell-based (i.e. not constructed with text boxes or tabs), and accompanied by a concise title and column headings. Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'. Figure legends: Fig. 1. 'Title...' All illustrations/figures/graphs must be of **high resolution/quality**: 300 dpi or more is preferable, but images must not be resized to increase resolution. Unformatted and uncompressed images must be attached individually as '**supplementary files**' upon submission (not solely embedded in the accompanying manuscript). TIFF and PNG formats are preferable; JPEG and PDF formats are accepted, but authors must be wary of image compression. Illustrations and graphs prepared in Microsoft Powerpoint or Excel must be accompanied by the original workbook.

REFERENCES

References must be kept to a maximum of 15. Authors must verify references from original sources. *Only complete, correctly formatted reference lists will be accepted.* Reference lists must be generated manually and **not** with the use of reference manager software. Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6] All references should be listed at the end of the article in numerical order of appearance in the **Vancouver style** (not alphabetical order). Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus. Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al. First and last page, volume and issue numbers should be given.

Wherever possible, references must be accompanied by a digital object identifier (DOI) link and PubMed ID (PMID)/PubMed Central ID (PMCID). Authors are encouraged to use the DOI lookup service offered by **CrossRef**.

Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. [http://dx.doi.org/10.1000/hgjr.182] [PMID: 2764753]

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Other references (e.g. reports) should follow the same format: Author(s). Title. Publisher place: publisher name, year; pages. Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'. Unpublished observations and personal communications in the text must not appear in the reference list. The full name of the source person

must be provided for personal communications e.g. '...(Prof. Michael Jones, personal communication)'.

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A PDF proof of an article may be sent to the corresponding author before publication to resolve remaining queries. At that stage, **only** typographical changes are permitted; the corresponding author is required, having conferred with his/her co-authors, to reply within 2 working days in order for the article to be published in the issue for which it has been scheduled.

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Approval Notice

New Application

23-Oct-2012
HOMAN, Roucille

Ethics Refernce #: S12/08/233

Title: The availability of alternative airway devices in public Emergency Centres in the Western Cape

Dear Dr Roucille HOMAN,

The **New Application** received on **29-Aug-2012**, was reviewed by members of **Health Research Ethics Committee 1** via Expedited review procedures on **23Oct-2012** and was approved.
Please note the following information about your approved research protocol:

Protocol Approval Period: **23-Oct-2012 -23-Oct-2012**

Please remember to use your **protocol number** (**S12/08/233**) on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:
Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary).
Annually a number of projects may be selected randomly for an external audit.
Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372
Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of
Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.
For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at 0219389657.

Included Documents:
Application Form
Protocol
Waiver of Consent
Declaration
Synopsis
Checklist
CVs
Letter
Appendix

Sincerely,

Franklin Weber
HREC Coordinator
Health Research Ethics Committee 1

Investigator Responsibilities

Protection of Human Research Participants

Some of the responsibilities investigators have when conducting research involving human participants are listed below:

1.Conducting the Research. You are responsible for making sure that the research is conducted according to the HREC approved research protocol. You are also responsible for the actions of all your co-investigators and research staff involved with this research.

2.Participant Enrolment. You may not recruit or enrol participants prior to the HREC approval date or after the expiration date of HREC approval. All recruitment materials for any form of media must be approved by the HREC prior to their use. If you need to recruit more participants than was noted in your HREC approval letter, you must submit an amendment requesting an increase in the number of participants.

3.Informed Consent. You are responsible for obtaining and documenting effective informed consent using **only** the HREC-approved consent documents, and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Please give all participants copies of the signed informed consent documents. Keep the originals in your secured research files for at least fifteen (15) years.

4.Continuing Review. The HREC must review and approve all HREC-approved research protocols at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period.** Prior to the date on which the HREC approval of the research expires, **it is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in HREC approval does not occur.** If HREC approval of your research lapses, you must stop new participant enrolment, and contact the HREC office immediately.

5.Amendments and Changes. If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of participants, participant population, informed consent document, instruments, surveys or recruiting material), you must submit the amendment to the HREC for review using the current Amendment Form. You **may not initiate** any amendments or changes to your research without first obtaining written HREC review and approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to participants and the HREC should be immediately informed of this necessity.

6.Adverse or Unanticipated Events. Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research related injuries, occurring at this institution or at other performance sites must be reported to the HREC within **five (5) days** of discovery of the incident. You must also report any instances of serious or continuing problems, or non-compliance with the HRECs requirements for protecting human research participants. The only exception to this policy is that the death of a research participant must be reported in accordance with the Stellenbosch Universtiy Health
Research Ethics Committee Standard Operating Procedures
www.sun025.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/Application_package All reportable events should be submitted to the HREC using the Serious Adverse Event Report Form.

7.Research Record Keeping. You must keep the following research related records, at a minimum, in a secure location for a minimum of fifteen years: the HREC approved research protocol and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence from the HREC

8.Reports to the MCC and Sponsor. When you submit the required annual report to the MCC or you submit required reports to your sponsor, you must provide a copy of that report to the HREC. You may submit the report at the time of continuing HREC review.

9.Provision of Emergency Medical Care. When a physician provides emergency medical care to a participant without prior HREC review and approval, to the extent permitted by law, such activities will not be recognised as research nor will the data obtained by any such activities should it be used in support of research.

10.Final reports. When you have completed (no further participant enrolment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Final Report to the HREC.

11.On-Site Evaluations, MCC Inspections, or Audits. If you are notified that your research will be reviewed or audited by the MCC, the sponsor, any other external agency or any internal group, you must inform the HREC immediately of the impending audit/evaluation.

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Ethics Letter

20-Mar-2013

Ethics Reference #: S12/08/233
Title: The availability of alternative airway devices in public Emergency Centres in the Western Cape

Dear Doctor Daniel Van Hoving,

Your letter dated 5 March 2013 refers.

The Chairperson of the Health Research Ethics Committee approved the amended documentation in accordance with the authority given to him by the Committee.

The following amendments were approved:
Dr N Hoving is now the principle investigator.

If you have any queries or need further help, please contact the REC Office .

Sincerely,

REC Coordinator

Health Research Ethics Committee 2