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Improving the Quality and Safety of Airway Management

Paul Andrew Baker

A thesis submitted in fulfilment of the requirements for the degree of Doctor of Medicine, The University of Auckland, 2013.
Abstract

Any quest to improve the quality and safety of airway management must start with an understanding and recognition of the problems, before addressing the solutions. I include in this thesis case reports, audits, clinical studies and bench studies which help to define some of the problems associated with airway management. Emphasis is placed on assessment, equipment, education and documentation. The studies, combined with two review articles, provide a platform for improvement.

The successful delivery by an EXIT procedure of a newborn child with severe micrognathia was attributed to meticulous preoperative assessment of the airway, planning, provision of expertise and equipment. Preoperative airway assessment, however, has limitations. In our study of the dissemination of critical airway information, in only half of the patients with a difficult airway was this anticipated preoperatively. Poor technique in the assessment of airways is partly to blame. In a survey and meta-analysis of the thyromental distance test, ruler measurement, rather than finger breadth, increased test sensitivity three fold when predicting difficult intubation. While assessment and planning are important, the loop must be closed by robust dissemination of information concerning critical airways.

Airway management equipment should be fit for purpose; practitioners should be knowledgeable in the correct use of that equipment; manufacturers’ instructions should be followed and equipment should comply with performance standards. These fundamental requirements were examined and important data concerning performance was discovered.

An audit of airway management equipment in Auckland identified missing emergency equipment, expired and faulty equipment and poor quality control mechanisms such as inadequate checking of equipment. In this study I recommended the establishment of detailed equipment guidelines. The Australian and New Zealand College of Anaesthetists then published a guideline for equipment to manage the difficult airway during anaesthesia. The guideline was founded on principles such as standardisation, redundancy and a culture of safety.

Finally, I include a review article in which I discuss the importance of education in airway management. This review highlights key components of simulation training, both in procedural skills and human factors. In the future, the trend is likely to be towards a greater emphasis on competency in medical education. It is likely that anaesthetists will be required to demonstrate competency in the management of difficult airways, not only during training, but throughout their entire professional lives.

Improvements in the quality and safety of airway management are multifaceted. At the local level, improvements can be made by identifying problems such as faulty laryngoscopes and applying quality standards to effect change. Equally, improvements can be achieved globally by adding to the evidence that is required to establish practice guidelines. The findings presented in this thesis exemplify the impact of research on the safety of airway management.
Acknowledgements

“If I have seen further it is by standing on the Shoulders of Giants”. Isaac Newton 1676.

I have been very fortunate to have been influenced by giants in airway management. Professor Viji Patil was truly a giant and a pioneer in her field and inspired many practitioners to pursue the study of airway management and medical education. With her teaching, encouragement and generous donation of equipment I was able to establish hands-on training for airway management techniques in New Zealand in 1996. This created my enduring interest in airway management and medical education. I am also indebted to Dr John Henderson, co-author of the Difficult Airway Society guidelines, who encouraged me to research airway management.

The next mentors I wish to acknowledge are my supervisors, Dr John Thompson, Professor Brian Anderson and Professor Alan Merry, who were constant sources of encouragement and inspiration throughout this challenging but thoroughly enjoyably academic process. Despite my endless demands on their time, they never once wavered from their task as role models. I am grateful for their time, encouragement and knowledge.

I would also like to acknowledge my co-authors who contributed to the original work found in this thesis. I rapidly realised the benefit of academic cooperation in the pursuit of knowledge, especially across specialties, fields of interest and countries.

During the preparation of this thesis I was grateful to receive help and advice with formatting from Jacqui Hannam.

Finally, and most importantly, I acknowledge my wonderful wife Margot and four fantastic children who have all contributed in various ways with proof reading, advice, encouragement and moral support throughout this degree.

Further acknowledgements for each chapter appear in Appendix 1.
Included publications

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Outline of this thesis

This thesis presents research and case reports which aim to build on the current knowledge concerning the quality and safety of airway management. Key areas of interest include assessment of the airway, equipment for management of the airway, education in airway management and documentation of the difficult airway.

Chapter one is a literature review examining current research relevant to the chapters that follow. Methods of airway assessment are discussed, including a review of the techniques and their efficacy. Associated with airway assessment, there is a trend toward the identification of risk factors linked to complications in airway management. The importance of combining assessment of the airway with a plan to manage the airway is highlighted. This is followed by a review of the current status of emergency airway access and transtracheal ventilation. Equipment to manage the airway is investigated in the context of quality assurance and fitness-for-purpose. This chapter establishes the foundation for the work that follows.

Chapter two describes an audit of equipment to manage the airway. This audit arose from a hands-on airway management course which I have conducted regularly since 1996. The training room for this course is stocked with an extensive range of current devices to manage the airway. Some participants on the course commented that the range of equipment supplied was not representative of their clinical environment and that many operating rooms lack important equipment. These comments inspired the audit of airway equipment in our region. Deficiencies identified in this audit initiated the formation of an ANZCA guideline (PS56, 2012) and the background paper which is included in Chapter three of this thesis. Equipment to manage the airway is also the subject of Chapters seven to 12 which consider quality and safety issues.

Chapter three is an updated background paper which supports an ANZCA guideline (PS56, 2012) concerning equipment to manage a difficult airway. This guideline was a direct result of the audit presented in Chapter two. I presented ANZCA with the results of this audit. The Quality and Safety Committee of ANZCA subsequently agreed to adopt my recommendation and develop a regional guideline for equipment to manage the difficult airway.

Chapter four is a review article entitled Education in Airway Management. The provision of equipment to manage the difficult airway is the subject of several chapters in this thesis; however, such equipment can only be safely utilised with appropriate education and experience. Chapter four identifies deficiencies in our current medical education system and signals important developments for the future, including competency based medical education, procedural skill training with simulation and a commitment to life-long learning.

Chapter five discusses airway assessment and presents a study concerning the accuracy of thyromental measurement. The concept of thyromental distance as a predictor of difficult intubation was first described by Professor Viji Patil, who was my mentor and helped me to establish hands-on training in airway management in Australasia. Participants on the course are taught objective measurement of the thyromental distance using the Patil gauge. The subject of Chapter five is the accuracy of thyromental distance measurement.
Assessment of the airway should lead to an airway plan. Chapter six presents a case report which exemplifies the importance of detailed planning for the management of a difficult airway. The delivery of a neonate with severe micrognathia incorporated the fundamental principles of airway management: airway assessment, pre-planned strategies, maintenance of oxygenation, avoidance of trauma, and provision of equipment and expertise. This rare case highlights the clinical relevance of airway assessment which has been discussed in Chapters one and five.

Chapter seven is a randomised controlled trial which compared supraglottic airways for flexible bronchoscopy in children. This paper examined the issue of equipment being fit for purpose.

Chapter eight includes a case report of a drowning victim who was unsuccessfully ventilated with two different supraglottic airways. This is an example of equipment not being fit for purpose.

Chapter nine presents an audit of laryngoscopes and an application of a new ISO standard. Quality issues affecting airway management equipment were highlighted in this paper.

Chapter ten presents a study of visual acuity during direct laryngoscopy at different illuminance levels. Data from this study validated details of the ISO standard for laryngoscopes.

Chapter 11 presents a prospective randomised controlled trial which examined the suitability of two tracheal tube designs for percutaneous emergency airway access. This study confirmed that both tubes would be suitable for this purpose. A secondary outcome of this study was the result of a time and motion study of this procedure confirming the rapidity and success rate of the procedure by novice anaesthetists after one hour of training.

Chapter 12 details a bench study of the Enk oxygen flow modulator, adapting it for potential paediatric use. Important information concerning the correct use of this device, including potential gas flows, was derived from this study.

Chapter 13 describes a study of the dissemination of critical airway information in New Zealand. This chapter closes the loop from Chapters four and five which considered airway assessment and planning. This chapter also highlights the importance of medical education as part of the effort to improve documentation of the difficult airway.

Chapter 14 is a conclusion which summarises the findings of this thesis and discusses future directions for further study. This chapter focuses on the key areas concerned in this thesis, which are assessment of the airway, equipment to manage the airway, education in airway management and documentation of the difficult airway.
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADEPT</td>
<td>Airway Device Evaluation Project Team</td>
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<tr>
<td>AEC</td>
<td>Airway exchange catheter</td>
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<tr>
<td>AED</td>
<td>Automated external defibrillator</td>
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<tr>
<td>AIC</td>
<td>Aintree intubation catheter</td>
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<tr>
<td>ANZCA</td>
<td>Australian and New Zealand College of Anaesthetists</td>
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<tr>
<td>APLS</td>
<td>Advanced Pediatric Life Support</td>
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<tr>
<td>ASA</td>
<td>American Society of Anesthesiologists</td>
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<tr>
<td>BMI</td>
<td>Body mass index</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>CICV</td>
<td>Cannot intubate, cannot ventilate</td>
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<tr>
<td>CJD</td>
<td>Creutzfeldt-Jakob disease</td>
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<tr>
<td>CL</td>
<td>Check list</td>
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<tr>
<td>CL</td>
<td>Cormack Lehane</td>
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<td>cLMA</td>
<td>Classic laryngeal mask airway</td>
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<tr>
<td>CO₂</td>
<td>Carbon dioxide</td>
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<tr>
<td>CPR</td>
<td>Cardiopulmonary resuscitation</td>
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<td>CT</td>
<td>Computerised tomogram</td>
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<td>DAT</td>
<td>Difficult airway trolley</td>
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<td>DAS</td>
<td>Difficult Airway Society</td>
</tr>
<tr>
<td>DL</td>
<td>Difficult laryngoscopy</td>
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<tr>
<td>DMV</td>
<td>Difficult mask ventilation</td>
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<td>DTI</td>
<td>Difficult tracheal intubation</td>
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<td>ECT</td>
<td>Electroconvulsive therapy</td>
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<td>Enk OFM</td>
<td>Enk oxygen flow modulator</td>
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<td>ETT</td>
<td>Endotracheal tube</td>
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<td>EXIT</td>
<td>Ex utero Intrapartum treatment</td>
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<td>FB</td>
<td>Flexible bronchoscope</td>
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<td>FₑO₂</td>
<td>Fraction of expired oxygen concentration</td>
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<td>FOB</td>
<td>Fibreoptic bronchoscope</td>
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<td>IDAS</td>
<td>Injectable drug administration and automated anaesthetic record system</td>
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<td>ILMA</td>
<td>Intubating laryngeal mask airway</td>
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<tr>
<td>IQR</td>
<td>Inter quartile range</td>
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<td>ISO</td>
<td>International Standards Organisation</td>
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<tr>
<td>kPa</td>
<td>Kilopascal</td>
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<td>KS</td>
<td>Karl Storz</td>
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<td>KW</td>
<td>KaWe</td>
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<td>LED</td>
<td>Light emitting diode</td>
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<td>LMA</td>
<td>Laryngeal mask airway</td>
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<tr>
<td>LogMAR</td>
<td>The logarithm of the minimum angle of resolution</td>
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<td>lx</td>
<td>Lux</td>
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<tr>
<td>M &amp; M</td>
<td>Morbidity and mortality</td>
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<tr>
<td>MMP</td>
<td>Modified Mallampati test</td>
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<tr>
<td>NAP4</td>
<td>The fourth National Audit Project of the RCA and DAS</td>
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<tr>
<td>NC/TM</td>
<td>Neck circumference/thyromental distance</td>
</tr>
<tr>
<td>OR</td>
<td>Odds ratio</td>
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<td>OR</td>
<td>Operating Room</td>
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<td>PEAA</td>
<td>Percutaneous emergency airway access</td>
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<td>PEAE</td>
<td>Preoperative endoscopic airway examination</td>
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<tr>
<td>PGSLT</td>
<td>Paraglossal straight laryngoscope technique</td>
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<td>POGO</td>
<td>Percentage of glottis opening</td>
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<tr>
<td>PVC</td>
<td>Polyvinyl chloride</td>
</tr>
<tr>
<td>RHTMD</td>
<td>Ratio of height to thyromental distance</td>
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<tr>
<td>ROC</td>
<td>Receiver operating characteristic curve</td>
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<td>SD</td>
<td>Standard deviation</td>
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<td>SGA</td>
<td>Supraglottic airway</td>
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<tr>
<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>SI</td>
<td>International system</td>
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<tr>
<td>TMD</td>
<td>Thyromental distance</td>
</tr>
<tr>
<td>TT</td>
<td>Tracheal tube</td>
</tr>
<tr>
<td>TTJV</td>
<td>Trans tracheal jet ventilation</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>uLMA™</td>
<td>Laryngeal Mask Airway Unique™</td>
</tr>
<tr>
<td>USA</td>
<td>United States of America</td>
</tr>
<tr>
<td>VAR</td>
<td>Visual acuity rating</td>
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<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
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<tr>
<td>vCJD</td>
<td>Variant Creutzfeldt-Jakob disease</td>
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<td>Wt</td>
<td>Weight</td>
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Chapter 1. Literature review

Preface

Complications of airway management are leading causes of patient morbidity and mortality (1-3). Information from the Fourth National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society (NAP4) indicates that the incidence of mortality due to airway management during general anaesthesia in the United Kingdom is 1 in 180,000 general anaesthetics (95% CI 1 per 352-120,000) (3). Although this figure appears low, the authors calculate that this may only represent 25% of the real incidence, based on the assumption that not all mortality was reported during the audit.

Updated practice guidelines and the NAP4 study have led to a range of recommendations to improve patient care (3-6). Evidence to support these recommendations is of varying quality, but is often at the level of expert opinion. Much research is still needed to address many of the unanswered questions relating to airway management. This literature review addresses key aspects of airway management including assessment of the airway, planning for the difficult airway, management of the patient who cannot be intubated or ventilated, and equipment to manage the difficult airway. Education in airway management and dissemination of information concerning patients with critical airways are discussed in Chapters four and 13 respectively.

1.1. Assessment prior to airway management

Introduction

“An anaesthetist must assess the patient before anaesthesia and devise an appropriate plan of anaesthetic management” – The Good Anaesthetist, Royal College of Anaesthetists 2010 (7).

Airway assessment includes taking a history, performing a physical examination, reviewing the clinical records and performing additional tests. Based on the information gleaned from the airway assessment, a strategy should emerge to cope with each aspect of the patient’s airway. This strategy should include options to postpone the case or manage the patient’s airway awake and should provide back-up plans to deal with failure. Successful identification of physical features which are suggestive of a difficult airway should direct planning toward safe airway management. Accordingly, many national airway guidelines emphasise the importance of a thorough and skilled assessment of all patients undergoing anaesthesia (4, 5).

Since the original case series describing physical features associated with difficult direct laryngoscopy and difficult tracheal intubation (DTI) (8), several upper airway diagnostic screening tests have been proposed (9). The latest recommendations from the Canadian Airway Focus Group (CAFG) promote airway assessment at multiple levels, including, not only tracheal intubation, but also bag mask ventilation, supraglottic airway ventilation (SGA) and percutaneous emergency airway access (PEAA). The following tables have been reproduced from that group and include bedside airway tests and risk factors for airway difficulty (5).

See Appendix five for a list of devices.
Table 1.1 Predictors of difficult direct laryngoscopy (10-26).

- Limited mouth opening
- Limited mandibular protrusion
- Narrow dental arch
- Decreased thyromental distance
- Modified Mallampati class 3 or 4
- Decreased submandibular compliance
- Decreased sternomental distance
- Limited head and upper neck extension
- Increased neck circumference

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Table 1.2 Predictors of difficulty in the use of the *Glidescope®*

**Predictors of difficult *Glidescope®* use (27, 28)**

- Cormack-Lehane Grade 3 or 4 view at direct laryngoscopy
- Abnormal neck anatomy, including radiation changes, neck scar, neck pathology, and thick neck
- Limited mandibular protrusion
- Decreased sternothyroid distance

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NB Predictors of difficult Trachlight® lighted stylet use have been removed from this table because the Trachlight® is no longer commercially available. *Airway devices and manufacturers (city and country of manufacture) quoted in this thesis appear in Appendix five.

Table 1.3 Predictors of difficult face mask ventilation (29-33)

- High body mass index or weight
- Older age
- Male sex
- Limited mandibular protrusion
- Decreased thyromental distance
- Modified Mallampati 3 or 4
- Beard
- Lack of teeth
- History of snoring or obstructive sleep apnoea
- History of neck radiation

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See Appendix five for a list of devices.
### Table 1.4  Predictors of difficult supraglottic device use (34-41)

- Reduced mouth opening
- Supra- or extraglottic pathology (e.g., neck radiation, lingual tonsillar hypertrophy)
- Glottic and subglottic pathology
- Fixed cervical spine flexion deformity
- Applied cricoid pressure
- Male sex*
- Increased body mass index*
- Poor dentition*
- Rotation of surgical table during case*
- Ear, nose and throat procedures†
- Admission status†
- Prolonged surgical duration†
- Airway abnormalities†
- Patient transport†

*Some of the listed predictors are device-specific: the four predictors originate from a single study using the LMA Unique™ (40). †The last four predictors refer to failure of Laryngeal Mask AirwayUnique™ and Classic™ in the paediatric surgical patient (42)

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### Table 1.5  Predictors of difficult cricothyroidotomy (43, 44)

- Difficulty identifying the location of the cricothyroid membrane:
  - Female sex
  - Age < 8 years
  - Thick/obese neck
  - Displaced airway
  - Overlying pathology (e.g., inflammation, induration, radiation, tumour)

- Difficult access to the trachea through the anterior neck
  - Thick neck/overlying pathology
  - Fixed cervical spine flexion deformity

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See Appendix five for a list of devices.
Many of the airway tests were specifically designed to identify patients without obvious airway pathology or abnormal anatomy who might be harbouring a difficult airway. The majority of the airway tests can be performed at the bedside in seconds.

Bedside airway tests have been criticised for their poor predictive capability. This relates to the low incidence of airway difficulty. In this situation, the positive and negative predictive values will always be low for any test unless their sensitivities and specificities approach 100% (45). Other reasons for the poor test performances include a lack of standardised methodology, ill-defined end-points and reliance on subjective assessment, thereby decreasing reproducibility. Most of the tests show only fair inter-observer reliability (46). Predictive tests have also been criticised for relating their findings to the sample from which the study was derived, rather than validating the test from a separate population (15). Subsequent validation studies often find inferior predictive value (47). Several recent studies have focused on improving the predictive value of airway examination by improving test methodology or combining tests into composite scores.

Definitions and incidence of airway difficulty

One of the problems of finding reliable predictors of a difficult airway concerns a failure to standardise definitions of airway difficulty (48). Variations in definitions create problems when trying to compare studies of complications and risk factors. A current list of definitions can be found in the Canadian Airway Focus Group special article, including definitions for difficult airway, difficult face mask ventilation, difficult laryngoscopy, difficult tracheal intubation, difficult supraglottic device (SGD) use, difficult transtracheal surgical airway, failed airway and difficult extubation of the airway (5).

Bedside tests

Following a number of publications which were inconsistent and failed to describe the details of bedside airway tests, Lewis et al examined the Mallampati test and thyromental distance measurements in 213 patients using 24 different method combinations, including neutral, sniffing and full extension head positions, tongue in or out, sitting and supine body positions and presence or absence of phonation (49). Direct laryngoscopy view was then recorded according to the definition of Cormack and Lehane (50). After statistical analysis using receiver operating characteristic curves (ROC area) and logistic regression analysis, optimum testing conditions were defined. Recommendations from this study included performing tests with the patient in the sitting position, head fully extended, tongue out, with phonation and measuring the distance from the inside of the mentum to the thyroid cartilage. These results helped standardise test conditions for clinical and research purposes.

See Appendix five for a list of devices.
The original description of the modified Mallampati test (MMP) had the head in the neutral position (21). The proposal by Lewis et al to extend the head was supported by another study by Mashour et al who advocate craniocervical extension during MMP testing. This position decreases the MMP class, improves specificity and positive predictive values and maintains sensitivity (51). A study comparing the MMP test in the supine and sitting positions in regard to Cormack Lehane scores found a higher positive predictive value and true positive values in the supine position (52).

The accuracy of any test is enhanced by using objective measurements. The thyromental distance (TMD) measurement was first described by Patil who promoted objective measurement using a 6.5 cm thyromental gauge (53). Callipers measuring thyromental distance in millimetres were used by Lewis et al (49). Objective measurement of the TMD using a gauge or ruler compared to fingerbreadth measurement, can treble the sensitivity of this test from 16 to 48 per cent (54). The inaccuracy of fingerbreadth measurement for TMD testing has been reiterated in a second study (55). Despite these findings, the use of “three knuckles” (56) or “three ordinary finger breadths,” is still advocated in some guidelines (4).

**Bedside test refinement**

Modifications to bedside tests have shown improved predictive values. An example includes the ratio of height to thyromental distance (RHTMD). Schmitt et al demonstrated an increase in specificity of 91% for RHTMD compared to 73% for TMD alone. A ratio of 25 was proposed as the optimal cut-off value when predicting difficult laryngoscopy (57). This has been validated by Krobuaban et al who compared the RHTMD, Mallampati test and neck movement and found that the RHTMD had the highest odds ratio in this group (6.72 (CI 3.29-13.72%), 2.96 (1.63-5.35), and 2.73 (1.14-6.51) respectively (58).

A study of 123 obese patients requiring tracheal intubation evaluated the neck circumference to thyromental distance (NC/TM) as a predictive test of DTI (59). When comparing independent predictors of DTI in obese patients including the Mallampati test and the Wilson score, the NC/TM had the best predictive outcome.

A comparison of the modified Mallampati test (MMP), the upper-lip-bite test (ULBT) and the ratio of height to thyromental distance (RHTMD) was conducted on 603 consecutive patients with one experienced anaesthesiologist performing laryngoscopy and grading according to the Cormack Lehane classification. After detailed statistical analysis, it was found that the MMP was significantly lower than the ULBT and the RHTMD scores. There was no significant difference between the ULBT and the RHTMD score (60).

See Appendix five for a list of devices.
Several systematic reviews of upper airway diagnostic screening tests have been published. Lee et al have published a protocol pending their Cochrane review on “Airway physical examination tests for detection of difficult airway management in apparently normal patients” (61).

A meta-analysis and systematic review of six tests was performed by Shiga et al (62). This study concluded that “Currently available screening tests for difficult intubation have only poor to moderate discriminative power when used alone. Combinations of tests add some incremental diagnostic value in comparison to the value of each test alone. The clinical value of bedside screening tests for predicting difficult intubation remains limited”. This review included 25 studies and 50,760 patients. These studies were heterogeneous in terms of test methodology and the review was dominated by two studies which accounted for 28,712 patients (12, 19). In these two studies, test methodology for thyromental distance relied on fingerbreadth or was not defined. These two studies would therefore have reduced the pooled test accuracy for predicting DTI with the thyromental test.

The overall incidence of DTI in this meta-analysis was 5.8% (95% CI 4.5-7.5%). Tests included the MMP, thyromental distance, sternomental distance, mouth opening, Wilson risk score and a combination MMP/thyromental test. Each test showed poor to moderate sensitivity (20-62%) and moderate to fair specificity (82-97%).

According to the 2003 American Society of Anesthesiologists (ASA) Task force on management of the difficult airway, “…there is insufficient published evidence to evaluate the effect of a physical examination in predicting the presence of a difficult airway”. This report did not present a meta-analysis (9).

The 2013 ASA Task force stated, “…there is insufficient published evidence to evaluate the predictive value of multiple features of the airway physical examination versus single features in predicting the presence of a difficult airway”. A meta-analysis was not presented (4).

A meta-analysis and systematic review of the Mallampati tests (15, 21) were conducted by Lee et al who concluded that “…the Mallampati tests have limited accuracy for predicting the difficult airway and thus are not useful screening tests” (63).

See Appendix five for a list of devices.
A meta-analysis of 55 studies involving 177,088 patients examined the prognostic value of the modified Mallampati score (47). This study concluded that “…the modified Mallampati score is inadequate as a stand-alone test of a difficult laryngoscopy or tracheal intubation, but it may well be a part of a multivariate model for the prediction of a difficult tracheal intubation”.

**Composite scoring**

Composite multivariable risk scores have been described to improve the predictive capability of preoperative airway assessment by combining up to seven individual variables (12, 24, 25, 32, 64-66). These scoring systems tend to perform better than individual variables alone; however, a number of deficiencies in these composite scores have been identified (67). For example, the Wilson Risk Score which tests five physical variables: weight, head and neck movement, jaw movement, receding mandible and buck teeth was designed to test difficult laryngoscopy rather than DTI (24). Composite scores tend to be dichotomous. Langeron et al proposed adopting three classes of high, intermediate and low risk of difficulty, as advocated by Ray (68). This creates two cut-off points with an intermediate, grey or inconclusive zone. Each cut-off point can then be used to include or exclude with certainty. By developing a computer model that uses multiple simple variables, Langeron et al were able to accurately predict DTI and minimise the number of patients in the grey zone. This method requires further validation in various populations. It could also be used to assess other endpoints, such as a difficult mask ventilation or difficult supraglottic airway ventilation (67).

**Three column model**

A three column model of the airway has been proposed by Greenland in an effort to provide a reliable assessment of the airway for direct laryngoscopy and tracheal intubation (69, 70). This model integrates current methods of airway assessment and divides the airway into three columns, along with the processes of laryngoscopy and tracheal intubation. The anterior column requires evaluation of the submandibular space for laryngoscopy and includes the size of the tongue, the thyromental distance, the mandibular length, the width of the palate and the size of the maxillary teeth. The middle column focuses on the airway passage and relies on airway history and examination, supplemented by computerised tomography (CT) and magnetic resonance imaging (MRI) scans and nasopharyngoscopy. The posterior column involves positioning of the head and neck; and tests require examination of neck movement for extension and flexion. The three column model encourages the practitioner to inspect the airway as a whole. One of the stated aims for this model was to provide a reliable assessment tool to predict difficult laryngoscopy and intubation. This model requires further independent validation in different populations.

See Appendix five for a list of devices.
Risk factors

A number of studies have identified risk factors associated with management of the difficult airway. Knowledge of these could help plan management and play an important role in airway assessment. Historically, examination of the airway has focused on identification of features suggestive of a DTI, but risk factors have been investigated to identify other aspects of airway difficulty, such as bag mask ventilation, laryngeal mask insertion, video laryngoscopy and cricothyroidotomy.

Mask ventilation. At a time of little information about the incidence or risk factors for difficult mask ventilation, Langeron et al undertook a prospective study of 1,502 patients, looking for these factors. They defined difficult mask ventilation as “...the inability of an unassisted anesthesiologist to maintain the measured oxygen saturation as measured by pulse oximetry > 92%, or to prevent or reverse signs of inadequate ventilation during positive-pressure mask ventilation under general anesthesia.” In this study 75 patients had difficult mask ventilation, giving an incidence of 5% (CI 3.9-6.1%). One patient was impossible to bag mask ventilate and only 13 difficult mask ventilation patients were anticipated (17% of the total 75). Five independent risk factors for difficult mask ventilation were found using multivariate analysis, including age >55 years, body mass index (BMI) > 26 kg. m⁻², presence of a beard, lack of teeth and a history of snoring.

Using a four point scale of mask ventilation difficulty, described by Han et al (71), Kheterpal et al studied prospectively 22,660 mask ventilation attempts. A grade 3 difficult mask ventilation incidence of 1.4% was found and impossible mask ventilation was described in 37 patients (0.16%). Independent risk factors for difficult mask ventilation included advanced age >30 years, BMI >30 kg.m⁻², presence of a beard and a history of snoring. Comment was also made of the association between difficult or impossible mask ventilation and DTI, where the mandibular protrusion test was found to be a good prognostic test, and independent risk factors included a history of snoring, obstructive sleep apnoea and the presence of a thick or obese neck (30).

Kheterpal’s study of difficult mask ventilation was not big enough to identify reliable risk factors for impossible mask ventilation. A subsequent study by the same group of 53,041 mask ventilation attempts over a period of four years was published. Seventy seven cases of impossible mask ventilation were found, giving an incidence of 0.15%. Independent risk factors included a history of neck radiotherapy, male gender, obstructive sleep apnoea, Mallampati Class III or IV and the presence of a beard (31). Interestingly, when reviewing the outcome of the 77 patients with impossible mask ventilation, only one patient required an emergency cricothyroidotomy, one was woken for an emergency tracheostomy by the surgical team and two were woken for fibreoptic intubation. This gives a cricothyroidotomy incidence in this study of 1 patient in 53,041 or 0.0019%.

See Appendix five for a list of devices.
Laryngeal mask airways. Ramachandran et al have studied predictors and clinical outcomes after failed Laryngeal Mask Airway Unique™ (uLMA™) insertions from an adult surgical population of 15,795 patients. Failure occurred in 1.1% of the population and was associated with significant hypoxia, hypercapnia or airway obstruction. Forty two percent presented with inadequate ventilation related to a cuff leak. Independent risk factors for failed uLMA™ in this study were surgical table rotation, male sex, poor dentition and increased body mass index (BMI). Failed uLMA™ was also associated with a three-fold increased incidence of difficult mask ventilation (40).

Video laryngoscopes. These devices have proven high success rates for novice practitioners in patients with normal airways (72), and for experienced practitioners in patients with difficult airways (73). Yet despite the enthusiasm for their use, they are associated with failure rates and predictors of poor clinical outcome. Experience using the Glidescope®, from two centres, found a failure rate of 3% when used to intubate patients with anticipated difficult airways, and 6% when used to rescue failed direct laryngoscopy (27). In this study, the risk factors for Glidescope® failure were altered neck anatomy, presence of a surgical scar, radiation changes or the presence of a mass. These same risk factors apply to direct laryngoscopy. Further study is required to investigate other video laryngoscope designs, particularly in patients with difficult airways.

Difficult mask ventilation and difficult laryngoscopy. This clinical combination is not uncommon. A recent multi-centre study of 492,239 patients found 176,679 documented cases of both mask ventilation and direct laryngoscopy of which 698 were associated with difficulty. This resulted in an incidence of 0.4%. From this study, 12 independent risk factors were found including age ≥46 years, BMI ≥ 30 kg/m², male sex, Mallampati III and IV, neck mass or radiation, limited TMD, sleep apnoea, presence of teeth, presence of a beard, thick neck, limited cervical spine mobility and limited jaw protrusion (74).

Age. Age has also been identified as a risk factor for DTI. Moon et al compared young, middle aged and elderly adults and studied the relationship between various methods of airway assessment and the incidence and causes of DTI. The incidence of DTI was less in young adults compared to their older cohorts, and the metrics associated with DTI, such as thyromental distance, cervical spine movement, inter-incisor distance and grade of dentition decreased with age, while the Mallampati score, cervical spine rigidity and the ratio of Arne > 11 increased with age (75).

Cricothyroidotomy. Cricothyroidotomy is a rare event, and therefore there are few systematic reviews of published series. A study examining the accuracy of percutaneous identification of the cricothyroid membrane see Appendix five for a list of devices.
in female obese and non-obese patients, found that misidentification of the cricothyroid membrane was more likely in obese patients, particularly those with increased neck circumference (43).

Neuromuscular blocking agents. A study conducted between 2005 and 2007 of 103,812 patients from the Danish Anaesthesia Database examined whether avoiding neuromuscular blocking agents increases the risk of a DTI. Establishing that the incidence of DTI was 5.1% [95% confidence interval (CI): 5.0–5.3], univariate and multivariate analysis found odds ratios (OR) 1.52 (95% CI: 1.43–1.61), P < 0.0001 and 1.48 (95% CI: 1.39–1.58), P < 0.0001 respectively, suggest that avoiding neuromuscular blocking agents increases the risk of DTI. This study also found that there was a steady decrease in the use of neuromuscular blocking agents over the period of the study and yet the frequency of DTI remained relatively unchanged. It was also found by multivariate analysis that patients who received non depolarizing neuromuscular blocking agents were at greater risk of DTI than those who received depolarizing neuromuscular blocking agents. Other confounding factors may influence the interpretation of these results. The experience of the anaesthetist, and other risk factors for DTI could alter the relative importance of neuromuscular blocking agents as a risk factor for DTI (76).

Patient factors

In a qualitative review of 184 cases of major airway complications, identified in The Fourth National Audit Project of the Royal College of Anaesthetists (RCoA) and the Difficult Airway Society (DAS) (NAP4) (3), by an expert panel found that patient factors were the most frequent causal and contributory factors (77%) of airway complications. Certain patient factors have been found to be associated with difficult airway management and are, therefore, worth identifying in the preoperative airway assessment.

Cervical spine limitation. Movement of the cervical spine is an important component of direct laryngoscopy and tracheal intubation. The best position for direct laryngoscopy requires 35° neck flexion and face plane extension to 15° (77). The Mallampati test (51), thyromental distance (78) and mouth opening (79) are all impaired by cervical spine limitation, which suggests the importance of adequate neck movement when trying to predict DTI. In a retrospective review of 14,053 patients, Mashour et al found an incidence of cervical spine limitation of 8.1%. A multivariate analysis found that cervical spine limitation was associated with increased difficulty in all aspects of airway management and DTI could be expected in patients who had cervical spine limitation, where independent risk factors included patients ≥ 48 years old, thyromental distance < 6 cm and Mallampati class 3 and 4 (80).

See Appendix five for a list of devices.
**Obesity.** The association between obesity and DTI has been investigated in a number of studies, with varying conclusions concerning obesity as an independent risk factor for DTI. Some studies suggest that obesity does not increase the risk of difficult laryngoscopy (81), or DTI (10, 82). Others suggest the contrary (12, 24). A cohort study from the Danish Anaesthesia Database of 91,332 consecutive patients found that obese patients with a body mass index (BMI) of 35 kg.m\(^{-2}\) or more did predict DTI as a stand-alone test with a sensitivity of 7.5% (95% CI 7.3-7.7%) and a positive predictive value of 6.4% (95% CI 6.3-6.6%) (83). The methodology and size of this study lend credibility to this result, which shows a high BMI as a weak but statistically significant predictor of difficult and failed intubation. Examining the relative impact of weight and height in this study, a univariate analysis found that these variables were statistically significant in their association with DTI, but only weight was found as an independent risk factor for DTI.

Other aspects of airway difficulty have also been related to obesity. Kheterpal et al, in a study of 22,660 patients, identified obesity with a BMI > 30 kg.m\(^{-2}\) as a risk factor for difficult mask ventilation (30). A study of 50 morbidly obese patients with BMI > 35 kg.m\(^{-2}\) were assessed for difficult laryngoscopy using thyromental distance, mouth opening, MMP, abnormal upper teeth, neck circumference and sleep apnoea. None of these factors correlated with difficult laryngoscopy; however, patients with difficult laryngoscopy were found to have a greater neck circumference and more pretracheal soft tissue, as measured by ultrasound, and these measurements correlated with difficult direct laryngoscopy (84). Another study failed to establish increased pretracheal tissue as a predictor of difficult laryngoscopy in obese patients (85).

**Acromegaly.** Acromegaly is associated with macroglossia, enlarged and distorted laryngeal anatomy and prognathism. The incidence of DTI in patients with acromegaly is four to five times higher than people without acromegaly. In this study, only the Mallampati test had moderate predictive validity. The sensitivity and specificity to predict difficult laryngoscopy and DTI using the MMP grades 3 and 4 were 76% and 44% respectively. The MMP test was measured with the patients in the sitting position, without phonation, and the head was held in a neutral position, as described by Samsoon and Young (21), but contrary to the optimum conditions described by Lewis et al (49). In the study group of 128 patients with acromegaly, the thyromental distance was 9.5 ± 1.5cm (6-14 cm). This test was not predictive of difficult laryngoscopy. The difference between patients with or without difficult laryngoscopy was not significant (86). Similar results were also found in a study by Ali et al (87).

**Pregnancy.** Several studies have described an increase in the Mallampati class during pregnancy and during labour (88-90). Approximately one third of patients were observed to increase their Mallampati score, regardless of the use of an epidural (91). Despite these changes, a review of 2,633 intubations during pregnancy found a difficult (4.7%) and failed (0.08%) intubation rate similar to the non-pregnant general surgical

See Appendix five for a list of devices.
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population. In this study, risk factors included a maternal age ≥35 years, weight 90–99 Kg and the absence of active labour (92).

Thyroid hypertrophy. In 324 consecutive patients presenting for thyroid surgery, there was an overall incidence of DTI in 11.1% of patients, when assessed using the Intubating Difficulty Scale (IDS) (93). By comparison, the incidence of DTI in 1171 patients during routine surgery was 8% (94). Palpable goitre, endothoracic goitre, thyroid malignancy and airway deformation were not found to be specific predictors of DTI; however, MMP 3 and 4, interdental distance less than 35 mm, TMD < 6.5 cm, cervical spine limitation < 80°, short neck and retrognathia were significantly reliable predictors of DTI (95).

History of a previous DTI

A study of 103,812 patients from the Danish Anaesthesia Database assessed the diagnostic accuracy of a previous documented DTI. It was found that 24% (21-28%) of patients who had previously experienced difficulty with direct laryngoscopy and tracheal intubation also experienced difficulty with tracheal intubation on another occasion. Conversely, of the patients who experienced no difficulty with tracheal intubation, 95% (95-95%) had the same outcome during a subsequent event. A repeat experience of a failed direct laryngoscopy and tracheal intubation occurred 30% (24-36%) of the time, compared to the patients who did not experience a failed intubation, where 98% (98-98%) did not experience a subsequent failed tracheal intubation by direct laryngoscopy. Using a multivariate regression model and adjusting for other covariates, an odds ratio of 16.6 (11.9-23.2, 95% CI, p<0.0001) suggested that a previous failed tracheal intubation by direct laryngoscopy was a strong predictor for future failed intubation (96).

Other tests

Various forms of imaging, indirect visualisation and mathematical modelling have been proposed to predict the difficult airway.

Nasopharyngoscopy. Indirect visualisation of the upper airway by nasopharyngoscopy is a quick and potentially rewarding clinical examination of patients who have known or suspected upper airway pathology. Information derived from this examination can direct airway management. In a prospective study of 140 patients presenting for diagnostic or therapeutic airway procedures by Rosenblatt et al, a preoperative endoscopic airway examination (PEAE) was performed following a standard airway examination and management plan. In 26% of patients the PEAE had an influence on the original airway management plan (97).

See Appendix five for a list of devices.
Ultrasound. Ultrasonography has a limited role in predicting DTI where interpretation of the scan can be difficult (98, 99). The floor of the mouth can be seen, but the epiglottis is problematic because it is surrounded by air (100). Despite these limitations, ultrasonography can be useful evaluating the airway for subglottic tumours, assessing fasting status and diagnosing obstructive sleep apnoea (101). Identification of the cricothyroid membrane with ultrasonography can be achieved with a mean time of 24.3 seconds, which is a useful aid considering percutaneous identification of anatomical landmarks has a success rate of only 30% (44, 102). Preoperative identification of the trachea in adults and children is also possible with ultrasonography, where percutaneous palpation or radiology can fail (103, 104).

Computer analysis. A computer software analysis of facial photographs created a computer model that could objectively analyse facial anatomy to improve prediction of a difficult intubation. This analysis, which included three facial parameters, was combined with the thyromental test and used to analyse 80 male subjects who had been divided into easy and challenging intubation groups. The technique correctly classified 70 of 80 subjects, compared to an MMP/thyromental distance test combination which correctly classified 47 of 80. Sensitivity, specificity and AUC (area under the curve) for the computer modelling method were 90%, 85%, and 0.899 respectively. Interestingly, this study measured thyromental distance with finger breadths and with the patient’s head in neutral position, both of which are known to significantly decrease this test’s sensitivity compared to objective measurement of the TMD (54), and head extension (49).

Limitations of airway tests in emergency medicine, intensive care and paediatrics

Various limitations of predictive tests used in airway assessment have been identified. Patients in the emergency department, who require tracheal intubation, may be obtunded or uncooperative, rendering predictive tests inappropriate. Levitan et al found that all of the rapid sequence intubation failures and two thirds of the non-cardiac arrest emergency medicine intubations were inappropriate for predictive tests such as the Mallampati score, thyromental distance and neck mobility measurement (105). These findings were reinforced by Bair et al who questioned the feasibility of a preoperative Mallampati test in the emergency department after studying 296 adult emergency patients requiring tracheal intubation. They found only 76 patients (26%) (CI 21-31%) were able to comply with a Mallampati test, citing lack of patient cooperation and clinical instability as reasons for this low result (106).

Difficult tracheal intubation in the intensive care unit is associated with high mortality (107). An intubation score has been developed and independently validated in a multicentre trial. The score is based on patient, pathology and operator factors. Called the MACOCHA score, factors and weighted scores include Mallampati III and IV (5 points), Apnoea syndrome (obstructive) (2 points), Cervical spine limitation (1 point), Opening

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mouth less than 3 centimetres (1 point), Coma (1 point), Hypoxia (1 point) and Anesthesiologist non trained (1 point). The 12 point score has limits of zero (easy) and 12 (very difficult). The score was prospectively developed from 1000 consecutive intubations in a multicentre study, including 42 intensive care units (ICUs), and then validated with 400 consecutive intubations from a separate 18 ICUs. In the validation study, the MACOCHA score sensitivity was 73%, specificity 89%, negative predictive value 98% and positive predictive value 36%. Thirty eight percent of the 1000 cases experienced severe life-threatening events, including severe hypoxia, collapse, cardiac arrest or death. Using the MACOCHA score, a significantly higher incidence of life threatening complications was found in the difficult intubation group compared to the non-difficult intubation group (51% vs. 36%, p, 0.0001) (108).

Airway assessment in the context of retrieval medicine has not yet been described; however, management in these environments is likely to involve the same challenges as those described in emergency medicine and intensive care.

Paediatric patients, whose ages range from birth to sixteen years old, present with a broad spectrum of anatomical features which is incompatible with tests using fixed endpoints, such as the thyromental distance. Young children are often uncooperative or unable to comply with simple instructions when performing airway tests. A study of 476 infants and children examined the predictive capability of the Mallampati test for DTI. Five paediatric anaesthetists recorded a Samsoon and Young modified Mallampati test, using a tongue blade to open the mouth if necessary. They then performed direct laryngoscopy with a laryngoscope of their choice. The Mallampati test was found to have overall sensitivity of 16.2% with 9.6% in children less than 3 years of age and 22% in children over 3 years of age. The specificity and positive predictive values were not reported. This study can be criticised for non-standard application of the Mallampati test, use of a variety of laryngoscopes to achieve a laryngeal view as described by the Cormack Lehane scale, and failure to rate intubation difficulty. The sensitivity was unacceptably low indicating that the Mallampati test is inaccurate and is not a useful screening test in this age group (109).

A second paediatric study found that the Mallampati test was applicable in children 4 to 8 years old when correlated with the Cormack Lehane scale for direct laryngoscopy. This study found a sensitivity of 75.8% (CL 21.9 – 98.7%) and specificity of 96.2% (CL 89.9 – 98.9%) (110). The wide confidence intervals for sensitivity suggest that the Mallampati test may include many false positive cases. The lack of reliability of the Mallampati test to correctly predict DTI in this study is demonstrated by the positive predictive value of 42.9% (CL 11.8 – 79.8%).

A retrospective data base review of 11,910 paediatric patients anaesthetised with a laryngeal mask airway (LMA) found a failure rate of 0.86%. This compared favourably with a similar adult study which reported a failure rate of 1.1% (40). Presenting features in the paediatric study included LMA leak, obstruction and patient intolerance. Independent risk factors associated with failure included ear nose and throat surgery, non-outpatient admission status, prolonged surgical duration, congenital/acquired airway abnormality and patient transport (42).

See Appendix five for a list of devices.
In a retrospective analysis of 11,219 paediatric anaesthesia patients up to age 18 years, it was found that the incidence of difficult laryngoscopy (DL) (as defined by Cormack Lehane grade III and IV) is lower in children (1.35%) (111) than in adults (9%) (25). Infants had a higher incidence of DL than older patients (4.7% versus 0.7%). Risk factors in this study included children undergoing cardiac and oromaxillofacial surgery, ASA Physical status II and IV, Mallampati III and IV and children with a low BMI.

A review of paediatric syndromes and medical conditions identified anatomical predictors of paediatric DTI including reduced head extension, reduced mandibular space and increased anteroposterior tongue thickness (112).

**Conclusion**

The importance of assessing a patient prior to airway management is universally accepted and yet I found in a regional study that up to 32% of patients have no documented evidence of this (113). Evidence to support the practice of airway assessment is based on expert opinion. In the opinion of the expert panel involved in the NAP4, inadequate airway assessment contributed to poor patient outcome. In this national audit, common events were omission, incomplete assessment or failure to modify airway management technique in response to assessment findings. Airway assessment was considered poor in a large proportion of airway morbidity and mortality reports (114).

The techniques and measurements used to predict airway management difficulty are inaccurate. Bedside tests such as the MMP, thyromental distance measurement, sternomental distance measurement and mouth opening lack accuracy as stand-alone tests to predict DTI. Combining bedside tests and examining multiple physical features improves the chances of predicting a difficult airway, but not enough to perform as reliable predictive tests. Yet despite these imperfections, physical features revealed by simple tests, such as limited mouth opening and neck movement, can help formulate an airway strategy. If one aspect of airway management is identified as potentially difficult, assessment of alternative routes should be critically assessed and back up plans formulated in view of the increased risk of difficult bag ventilation in the presence of DTI (30).

Several studies have examined risk factors associated with airway management techniques and patient factors. This information can be useful when planning to manage a patient’s airway.

Novel approaches to airway assessment are worthy of further investigation.

See Appendix five for a list of devices.
1.2. Planning the management of a patient’s airway

Introduction

Appropriate planning and preparation is the key to safely managing a known difficult airway. Planning the airway is based on airway assessment and typically involves the organisation of equipment and personnel with relevant clinical expertise. Postoperative care includes extubation and the dissemination of information concerning the critical airway. Planning is required at each stage, from presentation to postoperative care. Back-up plans are recommended and, for extremely difficult airways, this should involve multiple options. The EXIT procedure illustrates the importance of planning in the management of the difficult airway.

The EXIT procedure

The EX utero Intrapartum Treatment (EXIT) procedure is performed by a multidisciplinary team during Caesarean section. It is indicated when the neonate’s airway is at significant risk of severe obstruction immediately after birth. The technique allows the foetus to be partially delivered and the airway to be controlled while placental perfusion is maintained. It was originally used in 1989 to deliver a foetus with a large anterior neck mass (115). It then became part of the antenatal treatment of congenital diaphragmatic hernias. In this condition, it was discovered that prenatal obstruction of the trachea using surgical clips could allow expansion and maturation of foetal lungs. The EXIT procedure allowed removal of the tracheal clips prior to delivery while the foetus remained well oxygenated on placental bypass (116). The EXIT procedure is now indicated for other foetal conditions where airway obstruction immediately after birth is a significant risk. These conditions include giant foetal neck masses, lung or mediastinal tumours, congenital high airway obstruction syndromes (CHAOS), EXIT to extra-corporeal membrane oxygenation (ECMO) for certain congenital cardiac conditions and congenital cystic adenomatoid malformation (CCAM). Recently, EXIT to airway for severe micrognathia has been added to this list (117).

Antenatal diagnosis

Antenatal diagnosis determines the severity and outcome of foetal disorders prior to other management. A maternal serum alpha-fetoprotein level may initiate further investigation. Genetic history, past history of previous congenital abnormality and a history of polyhydramnios are obtained (118).

Imaging the lesion is an essential step prior to instrumentation. 2D and 3D ultrasound, (which create volumetric sequences from two dimensional images), can locate the placenta prior to amniocentesis for karyotyping. Ultrasound combined with magnetic resonance imaging (MRI) can define the foetal anomaly (119). This provides important information about the severity of airway obstruction and may help guide the decision concerning outcome (120).

See Appendix five for a list of devices.
Multidisciplinary approach

Planning and performing an EXIT procedure is a team effort, and requires participation from multiple specialty groups. A foetal medicine panel determines the likely outcome of an EXIT procedure and communicates with the parents. Radiology provides vital information about the severity of airway obstruction and a team approach to delivery will include obstetric, anaesthetic, ear-nose and throat, paediatric and surgical subspecialties, depending on the foetal diagnosis. Surgical treatment is now possible during antenatal, intrapartum and immediate postpartum periods. These procedures require support and back up plans. These aspects of care are emphasised in a review paper by Abraham et al (121). A case report of an EXIT procedure is presented in Chapter six of this thesis.

See Appendix five for a list of devices.
1.3. Percutaneous emergency airway access

Introduction

An inability to ventilate or intubate a patient in the presence of decreasing oxygen saturation is a medical emergency requiring immediate intervention in order to avoid brain damage or death. Various terminologies now apply to this condition, including cannot intubate, cannot ventilate (CICV) and cannot intubate, cannot oxygenate (CICO). Similarly, various techniques are advocated including cricothyroidotomy and tracheotomy. A generic term for emergency tracheal access which includes cricothyroidotomy and tracheotomy is percutaneous emergency airway access (PEAA).

Many questions concerning this aspect of airway management remain unanswered and current literature is dominated by case reports, manikin studies and expert opinion. Much of the evidence supporting practice guidelines concerning CICV and PEAA is low level (122). Randomised controlled trials are typically inappropriate for human studies of emergency airway management.

Areas of research include prediction and prevention of CICV, optimal equipment and techniques to manage CICV for adults and children, training techniques and skill retention to manage CICV, behavioural aspects of CICV and emergency transtracheal ventilation for adults and children.

Incidence and success of emergency cricothyroidotomy for CICV

The crisis of CICV is a rare event. In a series of 53,041 adult patients undergoing general anaesthesia at a university hospital in the USA, four cases of impossible tracheal intubation and bag ventilation occurred (an incidence of 0.008%) resulting in one emergency cricothyroidotomy (a rate of 0.002%). In this study, 77 patients were impossible to ventilate by bag ventilation, of whom 68 were intubated by direct laryngoscopy, 5 were intubated by alternative intubation techniques and three were woken up to receive flexible bronchoscopy or tracheostomy. This was an observational study which offered no practice guidance (31). This incidence of cricothyroidotomy is equivalent to the findings of the NAP4 study where 58 cases of PEAA were reported from a population of 2.9 million people. This equates to one PEAA in 50,000 anaesthetics. The authors of the NAP4 study comment that under-reporting in their study could mean that only 25% of cases were reported (3). The incidence of cricothyroidotomy in other environments is much higher. Trauma admissions to emergency departments from two large series report surgical cricothyroidotomy rates of 0.32% (123) and 0.36% (124). Airway establishment was successful in 94% and 89% respectively. Military figures reported by Mabry et al from the battlefield in Iraq and Afghanistan report a cricothyroidotomy rate of 0.62% (125). These cricothyroidotomies were performed by medics (62%) or physicians (38%) with success rates of 67% and 85% respectively. The NAP4 reported 133 cases of serious complications associated with anaesthesia. Cricothyroidotomy or urgent tracheostomy was attempted in 58 of these patients (43%). Percutaneous emergency airway access was performed by surgeons in 33 of these patients, and by anaesthetists for the other
Chapter 1. Literature review

25. Anaesthetists were successful in only nine of these 25 attempts (36%). All emergency tracheostomies were successful as judged by tracheal tube placement in the trachea. Only seven of the 19 cannula cricothyroidotomies performed by anaesthetists were successful. Four out of seven wide bore cannula cricothyroidotomy succeeded and all three surgical cricothyroidotomies were successful (3). All of the failed cannula cricothyroidotomies were rescued by surgical tracheostomies [7], surgical cricothyroidotomy [2], wide-bore cannula [1] and tracheal intubation [2].

Risk factors for CICV

Kheterpal et al found that one quarter of patients who were impossible to bag ventilate were also difficult to intubate and, therefore, risk factors for impossible bag ventilation should also be considered risk factors for CICV. These risk factors include neck radiation changes, male sex, sleep apnoea, Mallampati III and IV and the presence of a beard (31). Obesity with increased neck circumference is associated with decreased accuracy identifying the cricothyroid membrane (43). Laryngeal disease is associated with CICV. Head and neck disease was found in 43 of the 58 NAP4 patients requiring PEAA. Tonsil hypertrophy is associated with airway obstruction and CICV (126). Multiple intubation attempts are known to increase the risk of CICV (127) and functional airway obstruction can occur with cricoid pressure and laryngospasm.

Avoiding CICV

A retrospective review of institutional changes concerning airway management by Berkow et al used the rate of cricothyroidotomy as a marker of improvement before and after change (128). This study examined the impact of a number of changes: standardising the airway cart, educating support staff who manage airway cart supplies, adding difficult airway information to the electronic record, formalising the airway education programme, standardising the preanaesthesia airway examination, introducing simulation airway training, upgrading airway technology and providing a 24 hour a day difficult airway response team (DART). These changes coincided with a significant drop in the annual cricothyroidotomy rate from 6.5 per year to 2.2 per year (p<0.0001). This drop was sustained for 11 years despite an absolute increase in patient numbers over that time. The study lacked a control group and therefore the result is temporal in nature. Although it is impossible to say which of these changes or combination of changes was responsible for the reduction in cricothyroidotomy rate, the authors ascribe teamwork, training, oversight and patient education to this improvement and prevention of cricothyroidotomy.

See Appendix five for a list of devices.
Chapter 1. Literature review

Optimal equipment and techniques to manage CICV in adults and children

Since the first description of tracheostomy around 2000 BC many procedures and techniques have been described, lost and re-invented (129). Despite this long history, the ideal technique for PEAA has not been developed. Smith and Dejoy discuss the requirements for an ideal PEAA including a high success rate and low complication rate, easy to master, involving only a few steps, providing protection against aspiration and allowing adequate ventilation, regardless of upper airway obstruction (130). There is currently no technique which satisfies these criteria.

PEAA can be achieved by one of three techniques: surgical incision with a scalpel, narrow cannula-over-needle or large bore cannula (usually ≥ 4 mm) over a wire or trocar. Surgical tracheotomy was the norm until Toye and Weinstein described needle cricothyroidotomy and catheter ventilation in 1969 (131). This technique was promoted as being faster and safer than surgical dissection.

Hamaekers and Henderson reviewed 21 randomised controlled trials concerning cricothyroidotomy and divided them into human cadaver, non-human material (manikins or animal models) and ventilation studies. They concluded that there is no consensus on the best technique or device to treat CICV (132). In a recent systematic review of 24 studies concerning emergency cricothyroidotomy, the authors concluded that there was insufficient evidence to conclude that any one technique was better than another, due to the low, or very low, quality of the evidence in many of the studies (133).

An algorithm for CICV proposed by Heard et al promotes cannula cricothyroidotomy or tracheotomy as first-line treatment (134). The notion that a cannula is less invasive than a scalpel, is familiar to all anaesthetists and is readily available, is appealing to many practitioners. It is also believed that anaesthetists are more likely to pick up a needle than a scalpel. Further support for this argument comes from a national survey in 2005 of Canadian anaesthetists in which 51% favoured cricothyroidotomy by IV catheter (135). This audit was repeated in 2013 and the preference for cannula cricothyroidotomy is now reduced to 28% (personal communication Dr David Wong).

Cannula cricothyroidotomy may not be the best option. Two studies suggest that percutaneous identification of landmarks for cricothyroidotomy by anaesthetists is poor (43, 44). In the NAP4 audit, 15 out of 29 (52%) cannula cricothyroidotomies performed by anaesthetists failed compared to surgical cricothyroidotomy or tracheotomy performed by surgeons with a success rate of 100%. There may have been a reporting bias in NAP4 in favour of unfavourable outcomes and therefore successful cannula cricothyroidotomy might not have been reported. Failure could be attributed to patient factors affecting the identification of anatomical landmarks, such as neck positioning or obesity (43), or to equipment issues, poor insertion techniques, incorrect cannula ventilation methods and inadequate training. These outcomes have resulted in a reconsideration of optimum PEAA technique. Most current guidelines recommend that practitioners involved in airway management should be proficient in surgical and cannula cricothyroidotomy (3, 4). The Canadian Airway Focus Group guidelines now limit treatment options to large bore cannula or scalpel techniques for cricothyroidotomy (5).

See Appendix five for a list of devices.
Paediatric CICV

Management of CICV in children has received recent attention. A management protocol and algorithm proposed by Weiss and Engelhardt suggests surgical cricothyroidotomy for all ages, cannula cricothyroidotomy for patients over eight years and surgical tracheostomy and rigid bronchoscopy if expertise and equipment is available (136). These suggestions are expert opinions. Very little clinical evidence exists to support these recommendations. In a recent review of the literature, only six cases of paediatric emergency transtracheal cannula ventilation were reported since 1950 (137). A seventh case of an eleven month old child with CICV following a foreign body aspiration has since been reported. This infant was saved by needle cricothyroidotomy and transtracheal ventilation using a resuscitation bag attached to the cannula (138). The Association of Paediatric Anaesthetists of Great Britain and Ireland in conjunction with the Difficult Airway Society released three consensus documents, one of which considered CICV in a paralysed child aged 1 to 8 years (139). This algorithm recommends surgical tracheostomy or rigid bronchoscopy if ear nose and throat surgeons are available or, if not, cannula cricothyroidotomy with pressure regulated transtracheal jet ventilation (TTJV). If this fails, surgical cricothyroidotomy with low pressure ventilation through an endotracheal or tracheostomy tube is recommended.

Recent experimental studies have examined paediatric PEAA. An animal study used piglets and compared needle cricothyroidotomy and surgical tracheotomy following a training session with anaesthetists. This study found a significantly higher success rate for surgical tracheotomy (140). The same group in a randomised trial compared transtracheal catheter and needle cricothyroidotomy to surgical tracheotomy in piglets. Success rates were 65, 68 and 97% respectively, with a higher complication rate for the needle procedures (141). Similar success and complication rates were found in a study using rabbits, with 60% cannula tracheotomy success rate and 0% success with the Quicktrach Child™ device (142).

Emergency transtracheal ventilation

Most literature concerning CICV focuses on rescue intubation, rather than ventilation; however, poor ventilation methods or techniques can result in serious morbidity and mortality, even in the presence of successful tracheal access. Flint et al conducted a bench study comparing ventilation methods for cannula cricothyroidotomy. They concluded that they were unable to deliver minute volumes greater than 2 litres when using any of the following low-pressure devices: the Enk oxygen flow modulator, the resuscitation bag, oxygen flush from an anaesthetic machine, or oxygen from a wall-mounted flow meter with a three-way tap connection. These experiments were conducted through cannulae of diameter 20, 16, 14, and 13 G into an artificial lung. Based on their results, the authors recommend a high pressure ventilation device, such as the Manujet III™, which is manually operated and includes pressure control (143). This paper reported that the Enk oxygen flow modulator (Enk OFM), which was connected to a high pressure piped oxygen supply of 4 bar, was unable to generate a measurable minute volume of gas flow through 20G and 16G cannulae and only 0.39

See Appendix five for a list of devices.
and 1.14 litre min$^{-1}$ through 14G and 13G respectively. It is not clear whether these authors completely occluded all five holes of the Enk OFM during inflation, because in our study, using complete hole occlusion with a pressure gas source of 4 bar and a flow meter setting of 15 L. min$^{-1}$, the Enk OFM can deliver 250 ml. s$^{-1}$ and minute ventilation of 5 L as described in Chapter 12 of this thesis (144). Our findings were published as an e-letter in response to Flint’s paper (145). Animal studies have shown equivalent ventilation conditions after transtracheal ventilation comparing the Enk OFM and pressure regulated jet ventilation (146, 147). Our study highlights the importance of correct use according to manufacturer’s instructions. As a result of our research, Cook® has inserted specific instructions concerning occlusion of all holes for inflation. The three-way tap has been criticized because it is unable to release forward gas flow during expiration (148).

Transtracheal jet ventilation (TTJV) is associated with a high complication rate. In a closed claims study from the USA of 179 claims of difficult airway management, needle cricothyroidotomy was performed in 26 cases and all had a poor outcome. When TTJV was used, 89% were associated with severe morbidity such as pneumothorax, pneumomediastinum and subcutaneous emphysema (127).

In a national survey in the United Kingdom of high pressure source ventilation (HPSV), Cook and Alexander examined injector and jet ventilation during elective laryngeal surgery (149). Reports from 229 centres over a five year period included major complications and three deaths. All deaths occurred in departments without high frequency jet ventilators (HFJV), where manual devices were in use. Manually operated high pressure source ventilators are advocated for ventilation following emergency cannula cricothyroidotomy (150). In Cook’s survey, manual devices were in widespread use and only 17% of centres used a high frequency jet ventilator (HFJV). Morbidity using manual injectors involved 65 events in 36 patients over the five year period. In comparison, 12 complications in 9 patients occurred with HFJV over the same period. Clinical practice varied widely in this survey. Practices such as initiating ventilation with pressures > 2 atmospheres were reported by two thirds of respondents.

There are currently no evidence-based or consensus guidelines for best practice to use high pressure source ventilation. Cook et al point out that TTJV is rarely performed and, therefore, it should be avoided if possible. TTJV is associated with serious complications and should be used with extreme care while adhering to best practice. Cook et al have published their own recommendations, which are worthy of consideration in the absence of agreed guidelines. These recommendations apply to elective cases, but many of these principles apply equally well to emergency use, such as TTJV following emergency cricothyroidotomy (149).

The Ventrain (Dolphys Medical, Eindhoven, The Netherlands) is a single-use, manually operated, small lumen ventilation device which functions on the Bernoulli principle. It uses a controllable oxygen source, such as a pressure-compensated flow meter (151-153). The Ventrain is capable of oxygen insufflation and expiratory ventilation assistance (EVA). The latter occurs when the bypass channel in the Ventrain is occluded. This creates a subatmospheric pressure (up to -217 cm H$_2$O) at the side port. Active expiration can then occur through the narrow bore cannula. A case report describes the successful use of the Ventrain in a patient with near total upper airway obstruction from an exophytic glottis tumour (154). This device may have an...
application as an emergency ventilation device but negative pressures are only achievable clinically if total proximal airway obstruction exists. Use during partial airway obstruction may be limited unless the upper airway can be artificially obstructed. This was described in a case report in the British Journal of Anaesthesia e-letter by Mir et al where the Ventrain was used, with only limited success, in a patient with a laryngeal tumour and a partially obstructed airway (155).

**Education for PEAA**

Many anaesthetists are poorly prepared for CICV and lack the skills and knowledge to competently perform PEAA. This leads to patient morbidity and mortality (3, 135). As I have stated in the paper, *Accuracy of surface landmark identification for cannula cricothyroidotomy* (44), the main source of cricothyroidotomy failure is lack of clinical experience. Only 4 of the 18 participants in this study had previously performed a cricothyroidotomy; over a combined total of 159 years’ clinical experience in anaesthesia, this equates to one cricothyroidotomy every 40 years, or once in a professional lifetime. The infrequent requirement for cricothyroidotomy necessitates regular practice in order to maintain the skill. Once the correct diagnosis of CICV is established, and the vital decision to proceed with a cricothyroidotomy has been made, the ultimate success of the procedure depends on understanding both the anatomy and the required equipment (156). A thorough description of relevant anatomy is available in standard anatomy texts and reviews (157). Clinical application of this anatomy can be achieved by examining the human neck on a regular basis. Skill improves with clinical examination. Transtracheal catheterisation under flexible bronchoscope guidance for elective surgery further increases experience and skill (158).

The frequency of training and the rate of skill decay have been the subjects of a number of studies. One study suggests training on manikins requires at least five attempts to achieve success within 40 seconds (159). This procedural time does not include other important components of PEAA: the selection and preparation of equipment, the allocation of tasks, the optimization of ventilation and the management of a stressful environment. A study by Scerbo *et al* measured subjects’ performance while completing a cricothyroidotomy on a high fidelity simulator in a fully immersive battle situation, with virtual sniper fire, using both day time and night time conditions. Performance improved between the first and second attempts, while the time of day had no impact on performance (160). In an effort to minimize procedural errors during cricothyroidotomy in the battlefield, Bennett *et al* identified key training issues, including limited frequency of use, unfamiliarity with the procedure and limited knowledge of anatomical landmarks (161). Kuduvalli *et al* found that simulation based training significantly increased performance for up to eight weeks, and should be repeated at six month intervals (162). In contrast to this, a study by Boet *et al*, using a high fidelity simulator to train cricothyroidotomy, found that skills were retained for at least a year, if training was supported by practice and feedback (163). The importance of suitable training for PEAA, incorporating procedural skill and human factor training, has been stressed by Greenland *et al* (164).

See Appendix five for a list of devices.
Outside the clinical environment, cricothyroidotomy can be practised on manikins, animals and cadavers. It is important to choose an accurate anatomical model. Animal models provide better tissue fidelity than manikins, but large differences in species anatomy lead to significantly different outcomes when compared to human cadavers (165). Schebesta et al demonstrated that the airway dimensions of some high fidelity airway manikins and airway trainers differ significantly from human anatomy (166). A study by Biron et al supported the concept of multisensory teaching, including vodcast, cadaver demonstrations and cadaver hands-on experience, which improved knowledge, skill and confidence in medical student subjects (167). There is no evidence to support one teaching method ahead of others (156); however, Friedman et al found that objectively rated skill improvement for Seldinger large cannula cricothyroidotomy (Melker) was the same whether training had been on a simple inexpensive model or an expensive simulator. Performance was measured on cadavers two weeks after training, using checklists (CL) and global rating scale, (GRS) with excellent reliability by two raters (CL: \( r = 0.90 \), GRS: \( r = 0.89 \)) both \( p < 0.05 \) (168).

### 1.4. Equipment to manage a difficult airway

One important component of safe airway management is the availability of suitable equipment. This section of the literature review relates to Chapters seven to twelve. A number of important issues are discussed concerning the safety and reliability of equipment to manage the airway: re-usable versus single use devices (Chapter seven), use of equipment outside their specified indications (Chapter eight and eleven), introduction of new devices into clinical use (Chapter eight and twelve), routine maintenance (Chapter nine) and the adoption of equipment standards (Chapter nine and ten).

An audit of airway management equipment is the subject of Chapter two in this thesis (169). This audit led to an Australian and New Zealand College of Anaesthetists professional document PS56 (2012) which I co-authored. This background paper is presented in an updated form in Chapter three (150). In an editorial, I discussed the principles used to select equipment for a difficult airway container (170). Those principles included standardisation, redundancy and a culture of safety.

Several subsequent publications have reviewed the provision of equipment for airway management. To investigate the availability of equipment to manage the difficult airway, Ely et al conducted a postal survey of practitioners in rural Queensland, Australia (171). Eighty two percent of practitioners had access to suitable equipment and this was unrelated to the remoteness of their location. The type of equipment was very variable and the authors recommended standardisation of equipment and the promotion of equipment workshops for education. The same group surveyed urban anaesthetists in Queensland with a postal survey, including a questionnaire about five airway scenarios. They found that a difficult airway container was available to 98% of respondents and that direct laryngoscopy and flexible bronchoscopy were the preferred techniques to manage difficult airways (172). Both of these studies were postal surveys with response rates of 44% and 55%.

See Appendix five for a list of devices.
Chapter 1. Literature review

respectively. An online survey of rural general practitioners, engaged in anaesthesia in Australia, found that only 53% of respondents had access to a difficult airway container; a need for training was identified (173).

An international survey by Calder et al of difficult airway trolleys (DAT) for paediatric anaesthesia found that training with, and recent use of, the DAT increased anaesthetists’ confidence with the DAT. This survey also identified problems with quality control and deficiencies in knowledge concerning the location, content and use of airway equipment. Of note, 54% of respondents thought that a surgical cricothyroidotomy kit was essential, but only 16% indicated that they were confident with its use. Similarly, 50% thought that a transtracheal ventilation device was essential, but only 39% were confident in its use; and 82% thought that a flexible bronchoscope was essential and 69% were confident in its use (174). These findings emphasise important concerns regarding education in airway management and the selection of TTJV with cannula cricothyroidotomy.

Single use or re-usable? The disposable debate

Traditionally, hospitals have relied on equipment that could be cleaned and sterilized for re-use. Approximately two decades ago, original equipment manufacturers (OEMs) in the USA started changing the labels on certain medical devices from “reusable” to “single-use”.

Many of the reasons used to support single-use anaesthetic equipment are debatable: the risk of cross infection, the cost of cleaning and sterilization, and the cost of damage and repairs to permanent items (175, 176). Despite this, patients and anaesthetists prefer to use single-use items (177).

In 2002, the Royal College of Anaesthetists and Association of Anaesthetists of Great Britain and Ireland (AAGBI) recommended the use of single-use devices where possible to minimize infection risk in response to concerns about the risk of spongiform encephalopathy (CJD) (178). Between 1990 and February 2011, 64 cases of iatrogenic CJD were reported, none of them variant CJD (179). The risk of CJD transmission from reusable airway equipment is unknown, but it is likely to be extremely small.

Other transmissible diseases can also affect airway equipment. The ECRI Institute, (formerly the "Emergency Care Research Institute") which establishes best practices in healthcare through scientific research (180), lists the top ten health technology hazards. Cross contamination from flexible endoscopes, for example, was fourth on the list in 2012. Bacteria, such as mycobacterium and pseudomonas, can be found in suction/biopsy channels of endoscopes and can survive the decontamination process. A literature review of articles concerning endoscopy-related infections between 1966 and 2005 identified 70 infection outbreaks reported in 64 papers, with bronchoscopy accounting for half of all outbreaks (181). Despite this, the estimated incidence of endoscopy-related infection is 1:1.8 million procedures (182). Although this rate is low, improper decontamination is still prevalent due to numerous inconsistencies that exist among reprocessing guidelines and manufacturers’ recommended practices. It was estimated that 91% of outbreaks are preventable by improving

See Appendix five for a list of devices.
quality control systems (183). Disposable alternatives to reusable flexible bronchoscopes in anaesthesia include the single use Ambu® aScope™ (184) and the Vision Sciences EndoSheath® (Vision-Sciences, Inc. Orangeburg, New York, USA) (185).

Laryngoscope handles and blades can also be a source of infection, requiring appropriate cleaning after use (186). Laryngoscopes are now available as disposable items and their performance in terms of illumination, flexibility and breaking limits have been defined by the ISO (187). Some disposable metal or plastic blades perform well (188), while others are prone to decreased success rates (189), fractures of the blades (190, 191) and greater peak force; they are also associated with prolonged duration of laryngoscopy (190). It is suggested that conventional laryngoscopes should be kept for difficult intubations (192) and the ANZCA PS56 “Guideline for equipment to manage a difficult airway” recommends reusable laryngoscopes that comply with ISO Standards (150).

The debate surrounding re-usable equipment raises a number of questions. What are the environmental implications of single-use versus reusable medical equipment? Does single-use equipment make economic sense? Are single-use airway devices equivalent in performance to reusable versions, and what standards are in place to ensure that new disposable devices are fit for purpose?

A review of single-use endotracheal introducers stated that, ‘many anaesthetists feel obliged to use single-use equipment; however, they must ensure that the risk-exposure is not increased as a result of using equipment that is not fit for purpose (193).’ This manikin study highlights the inferiority of new Portex and Pro-breathe introducers when compared to the gold standard single-use Frova and multi-use Eschmann. Despite being gold standard single-use, Frova still increases the risk of airway trauma over the multi-use option (193).

In an editorial concerning the relative risks of vCJD infection and disposable anaesthetic equipment, Blunt concludes that even a small deterioration in safety, as a result of using a single-use device of poorer quality in place of a reusable device, would increase the overall risk to patients and be in conflict with the recommendations of the Spongiform Encephalopathy Advisory Committee (194). In the current climate of ‘evidenced-based practice’, as proposed by the DAS Airway Device Evaluation Project Team (ADEPT) (195), it is surprising that there is such enthusiasm for some single-use equipment with limited safety and efficacy research to support it, when there is a clinically well-validated re-usable option.

The appropriate clinical use of airway equipment

Drowning. The concept of being fit for purpose is important for airway equipment when that equipment is applied for uses beyond the scope of the manufacturer’s recommendations. One example is the application of supraglottic airway devices for resuscitation of the drowning victim. In a review of ventilation adjuncts during in-water-resuscitation, Winkler et al suggest that the Laryngeal tube (VBM Medizintechnik, Sulz, Germany) might be useful during in-water-resuscitation by improving the efficacy of ventilation during in-water-

See Appendix five for a list of devices.
resuscitation (196). No evidence is provided to support this assertion. This randomised cross over trial examined no-ventilation, mouth to mouth ventilation, bag mask ventilation and laryngeal tube ventilation using volunteer lifeguards and a Laerdal Resusci Anne in an inland lake. This study did not appreciate the subtleties of lung pathophysiology during drowning with aspiration. Supraglottic airway devices are unfit for this purpose (197). The difficulties of initial ventilation following drowning and water aspiration are reiterated in a review of drowning (198).

Paediatric supraglottic airways. Several studies have examined the use of supraglottic airways as a conduit for tracheal intubation in paediatrics. This technique is now recommended in paediatric airway management guidelines and has been described as either a blind intubation technique through the Cookgas® Air-Q™, or as a conduit for flexible bronchoscopy (199, 200). A case series of children at risk of gastric reflux and aspiration describes a modified rapid sequence induction technique following awake insertion of the Cookgas® Air-Q™. Anaesthesia is induced with Propofol or Ketamine and suxamethonium, and intubation aided by flexible bronchoscopy (201).

Separate published review articles appear in Chapters three and four which consider equipment to manage a difficult airway during anaesthesia and education in airway management.

**Conclusions from the literature review**

Assessment of the airway is an important component of preparing the patient for safe airway management. Improving the prediction of difficult airways can be achieved by adopting objective assessment, as discussed in Chapter five of my thesis. Review of the literature suggests that bedside airway tests are very poor predictors of airway difficulty. Improvements can be achieved, however, by adopting combined tests or by using indices, such as the ratio of height to thyromental distance. Knowledge of risk factors associated with particular clinical conditions may also assist in the planning of safe airway management.

Rigorous research is needed to elucidate many issues surrounding percutaneous emergency airway access. I have examined the scalpel bougie technique in Chapter 11 and the use of the Enk oxygen flow modulator in Chapter 12, but further work is required to understand optimal equipment and techniques to manage this crisis in adults and children. Methods to improve procedural skill and behavioural aspects of this emergency should be established.

Questions remain about the appropriate use of airway equipment. Numerous surveys have identified deficiencies in the content and quality of equipment to manage the airway. A common theme is requests for standardisation of equipment and for access to hands-on education about equipment. The trend towards single-use items highlights the importance of fitness-for-purpose and compliance with manufacturers’ recommendations.

See Appendix five for a list of devices.
There are still important gaps in our knowledge, including optimum assessment of the airway, management of CICV and provision of suitable airway equipment. I have addressed a number of these issues in my thesis.

See Appendix five for a list of devices.
Chapter 2. An audit of airway management equipment in a metropolitan region


Preface

The findings from this study highlight deficiencies in content, quality and practice surrounding the availability of emergency airway management equipment in the Auckland region. The ready availability of appropriate, functioning equipment is essential for safe airway management. This audit was conducted following concerns raised, in our airway management course, regarding deficiencies in airway management equipment in our region. As lead author of this study, I designed the audit, collected data, analysed the results, researched the subject, wrote the first draft of the paper and supervised all subsequent revisions, prior to publication.

Abstract

Difficult airway containers are commonly found in operating rooms, but the availability of airway equipment beyond that environment is unknown. Using the Difficult Airway Society (UK) and American Society of Anesthesiologists’ guidelines we conducted an inspection audit of airway equipment at all anaesthetic sites in our region. Staff knowledge about the equipment was assessed and feedback was provided to each site.

Eighteen of the forty-two sites had an airway container. Equipment for an unexpected difficult intubation, according to the guidelines, was deficient at all sites. Equipment to detect oesophageal intubation was inadequate. Locations remote from the operating suite lacked emergency invasive airway equipment and were, on average, 4.3 min walk from the nearest appropriate equipment. Two clinics had no emergency invasive airway equipment. Half of the airway containers with check lists had items missing. One third of the items with an expiry date were expired. Quality control and implementation of airway guidelines could rectify these deficiencies. Anaesthesia organisations should be encouraged to publish detailed equipment guidelines.

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Chapter 2. An audit of airway management equipment in a metropolitan region

Introduction

International efforts to improve management of the difficult airway have resulted in practice guidelines from national professional societies in Great Britain, USA, France, Canada, Italy and Germany (202-209). These guidelines recommend techniques and equipment, based on literature reviews and consensus. The availability of a difficult airway container is advocated in all of these guidelines. Several of these groups also specify equipment.

The type of airway equipment in a difficult airway container, designed to manage an unexpected difficult intubation, should reflect the requirements of the anaesthetic site. These requirements depend on patient characteristics, age groups, specialty needs, individual preference and the skills of the practitioners. Equipment use reflects national and regional preferences (135, 210). Irrespective of these conditions, the presence of certain devices is recommended wherever anaesthesia is performed. These devices include a range of oral airways, nasal airways and laryngeal mask airways (LMA™) for ventilation. Requirements for oral or nasal intubation include rigid laryngoscope blades of different lengths and shapes, with spare handles, a range of standard and specialized endotracheal tubes, a malleable short stylet, tracheal introducers, and Magill forceps. For emergency invasive airway ventilation, the difficult airway container should include either a non-kink cricothyroidotomy cannula with a high pressure ventilation system, or a percutaneous cricothyroidotomy set, or a surgical cricothyroidotomy set. A method to detect oesophageal intubation such as a capnograph, a colorimetric CO₂ detector, an oesophageal bulb or an oesophageal syringe should also be included. This list was compiled from a review of multiple airway management guidelines (202-209) and represents basic requirements. The Difficult Airway Society UK (DAS) equipment list (Appendix) expands on these basic requirements to allow secondary intubation attempts using alternative techniques of proven efficacy (202). The presence and performance of this equipment then needs to be regularly checked.

Few studies have focused on the organization and provision of airway management equipment (211), yet it is understood that the implementation of practice guidelines can only be fully effective when equipment and training have been made available (202). Survey questionnaires of airway management equipment have been reported (210, 212, 213), but we have found no previous inspection audits. Our aim in this audit was to identify the current practices relating to the provision of airway equipment in a metropolitan region.

Methods

We inspected sites where anaesthesia is administered in the Auckland region, having previously obtained institutional permission. This metropolitan region covers 16,104 km² with a population of 1.2 million people. Approximately 106,000 anaesthetics are administered within the region annually. The medical system comprises both publicly and privately funded health care in separate institutions. The ratio of public to private anaesthesia is 1.62: 1.

See Appendix five for a list of devices.
To minimize the risk of a Hawthorne effect (214) biasing the results, staff did not receive prior warning of the audit, but, when necessary, accompanied investigators to assist in the location of equipment.

An audit tool was utilised based on recommendations from the DAS website www.das.uk.com/ and the American Society of Anesthesiologists (ASA) guidelines (203) because both are used for teaching in a local airway management course.

All airway equipment was recorded at each site. Quality control was assessed, including the presence and use of check lists, expiry dates, container seals, sterility information and performance of equipment. The availability and separation of paediatric equipment was also recorded. Location of the airway equipment, with travel time and distance from the site of use, were measured. Travel distance was recorded in metres using a Roto-sure® measuring wheel and time was recorded in seconds.

At each site a staff member was questioned about their orientation process and knowledge of the location and content of the airway equipment. On completion of the audit a confidential report was supplied to each hospital with recommendations based on chosen guidelines.

**Results**

Forty two sites were inspected in locations where anaesthesia was administered. Twenty two were private hospitals and the remaining twenty were associated with public hospitals. Twenty two difficult airway containers were found. One site had three containers (two adult and one paediatric for eleven operating rooms). Another site had three containers, including two portable briefcases for off-the-floor procedures.

Of the twenty four sites without a difficult airway container, fifteen relied on nearby equipment to manage an unexpected difficult intubation and these included locations outside of the operating suite, such as Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Electroconvulsive Therapy (ECT), Radiotherapy, Angiography and Cardiac investigation rooms. The average distance to equipment from these sites without a difficult airway container (n=15) was 240.4 m (range 56.4-551.3 m) and average one-way walking travel time was 257 sec (range 95-450 sec). Four of these locations outside the operating room were in privately funded facilities.

In the remaining nine sites without a difficult airway container, equipment from lists 1 and 2 was incomplete, disorganized, dispersed and often difficult to locate. Two sites lacked emergency invasive airway equipment. All these sites were in stand-alone private hospitals.

Equipment found in the airway containers varied. No container satisfied the DAS or ASA guidelines completely. Every container provided an alternative to bag mask ventilation, and the most common device in this category was the laryngeal mask airway (LMA™) in a range of sizes. An alternative to the Macintosh...
laryngoscope blade was found in every container and the intubating laryngeal mask airway (ILMA™) was found in 20 out of 22 containers.

Equipment to detect oesophageal intubation was rare. Only one difficult airway container had a colorimetric CO₂ detector. There were no self-inflating bulbs, capnographs or oesophageal intubation detector syringes in the airway containers. Although all operating rooms were equipped with capnography, only one of twenty seven postanaesthetic care units surveyed was equipped with capnography.

Seventeen of the forty two sites inspected did not have any emergency invasive airway equipment immediately available (cricothyroid cannula with any form of jet ventilation, large bore cricothyroidotomy cannula or surgical cricothyroidotomy equipment.). This included all off the floor sites. Trans-tracheal jet ventilation equipment was provided in 19 of 22 containers, but only 15 containers had a non-kink needle. Twenty one out of 22 containers had a cricothyroidotomy device, and 3 sites had a scalpel, dilator and tracheal hook. Airway guidelines were found on only 1 airway container (DAS). Of the 22 containers found, none had seals, 14 had contents lists, but only 8 of these were signed and showed signs of being checked. In the 14 containers with a check list, the contents corresponded with the list in 7 containers. Eighteen of the containers were labelled and 10 had a relocation mechanism. Twenty eight items with expiry dates were found and, of these, 10 were expired. Seventeen sites with airway containers administered paediatric anaesthesia, but only 3 of these sites had separate paediatric difficult airway containers, and only 1 of those containers had a full range of paediatric airway equipment as recommended by the ASA Society of Pediatric Anesthesia (215). Two stand-alone private hospital sites without an airway container provided paediatric anaesthesia services without any emergency airway equipment or equipment to manage a difficult paediatric airway.

See Appendix five for a list of devices.
Table 2.1 lists the equipment and frequency found in the 22 difficult airway containers. Basic airway equipment, including bag and mask, oral airways, LMA™, a size three Macintosh laryngoscope and endotracheal tubes, was also found at all forty two sites where anaesthesia was administered. Specialized endotracheal tubes, including reinforced tubes in 9 of 22 containers, microlaryngoscopy tubes in 3 of 22 containers and Parker tubes in 2 containers were also noted. Fibreoptic bronchoscopes (FOBs) were provided at 18 of the 42 anaesthetic sites audited and were associated with 20 of the 22 airway containers. At the time of the audit, two sites had their FOBs removed for sterilizing. The 24 sites without FOBs encompassed 15 locations outside the operating suite and 9 stand-alone private hospitals. Twelve of the eighteen FOBs had evidence of quality control such as sterilization details. In our audit five FOBs were stored incorrectly.
Table 2.2 shows FOB ancillary equipment found in the airway containers.

The majority of staff interviewed had correct knowledge of the difficult airway container location, but approximately 20% of staff had never been orientated to the container and did not know the contents (Table 2.3).

The results of our audit were conveyed back to the hospitals with recommendations for improvement.

**Discussion**

As the first complete assessment of airway management equipment from anaesthetic sites in a Metropolitan region, this study highlights deficiencies, particularly in locations outside the operating suite. There are currently no national or regional practice guidelines for airway management in New Zealand, however, Health and Disability Sector Standards from Standards New Zealand apply to all hospitals and clinics (216). This standard requires emergency equipment to be accessible, stored correctly, not expired and stocked to a level appropriate to the service setting. In the Australian Incident Monitoring Study (AIMS) an analysis of difficult intubation reports concluded that there was a need for a greater emphasis on ensuring that the necessary equipment is available (217).

Recommendations for the proximity of emergency airway management equipment to anaesthetic locations are poorly defined. The DAS guidelines (202) suggest that an equipped airway cart should be located “no more than a couple of minutes” from every location where anaesthesia is administered. Patients anaesthetised at sites remote from the operating suite could be compromised during a cannot-intubate-cannot ventilate (CICV) event because of a 4 minute delay retrieving equipment. The clinical relevance of this delay has yet to be defined, but a lung model study showed an average haemoglobin desaturation from $\text{SaO}_2$ 90 to 40% occurred at 33% min$^{-1}$ with an obstructed airway and 26% min$^{-1}$ with an open airway (218). Since any delay in such a crisis could be deleterious, we believe appropriate emergency equipment should be kept immediately available at every anaesthetic location.

A requirement in practice guidelines (202-209) is the provision of at least one device suitable for emergency non-invasive ventilation and equipment for emergency invasive airway ventilation. Only two sites in our audit provided an Enk™ oxygen flow modulator set in each operating room, but seventeen sites lacked immediate access to invasive airway equipment. Absence of such reliable equipment in an emergency promotes desperate innovative techniques of dubious efficacy (219). These measures may lead to delays in treatment and poor outcome (220).

The Australian Incident Monitoring Study (AIMS) (217) documents 85 of the first 2000 incidents reported (4%) had difficulties with intubation. Oesophageal intubation (18 cases) was the commonest complication reported. In a recent review of the American Society of Anesthesiologists (ASA) Closed Claims database from 1993 to 1999 (127), difficult airways were encountered throughout the perioperative period. Seven percent of

See Appendix five for a list of devices.
the perioperative claims occurred in the recovery period and 67% of these resulted in death or brain death. Only one recovery room was equipped with capnography and only one difficult airway container had a method to detect oesophageal intubation in the current audit. Outside locations were the site for 13% of claims for difficult airway management problems in the ASA database (127). This data suggests that a significant proportion of airway complications can occur away from the operating room, and therefore emergency airway containers should be equipped to detect oesophageal intubation.

Specialist areas such as paediatrics and obstetrics are not included in the DAS guidelines. The ASA Task force on Obstetric Anesthesia published recommendations for the contents of a portable unit for difficult airway management for Caesarean Section anaesthesia locations (221). This list includes the same items as the DAS and ASA lists from our audit. A recent review of airway problems in the obstetric patient examines other techniques and equipment (222). Recommendations from the ASA Task Force on Pediatric Anesthesia (215) suggests provision of airway equipment for all ages of paediatric patients. This includes specialised equipment for management of the difficult paediatric airway by a variety of techniques for airway control, intubation and ventilation, including, but not limited to, fiberoptic bronchoscopy and emergency cricothyroidotomy.

A recent questionnaire of New Zealand anaesthetists suggested that access to fiberoptic equipment was high in public hospitals, and 92% of respondents performed fiberoptic intubation (223). Our current audit confirmed the availability of FOBs in public hospitals. Procedures for correct cleaning, disinfecting and sterilizing of FOBs are defined in New Zealand Standards (202). These standards recommend that records shall be kept concerning details of the patient, instrument, disinfectant and sterilizing. To optimize FOB use, and to minimize infection and damage, manufacturers recommend that FOBs should be stored dry, clean, well ventilated and at a normal temperature. The carry case is inappropriate for storage. Ideally the FOB should be hung straight.

Despite preoperative examination, at least 10-30% of the difficult airways are undetected before anaesthesia (207). The unexpected difficult airway requires immediate access to emergency airway equipment which should be available at each anaesthetic site (207). A successful outcome will rely on efficient and skilful use of appropriate equipment that is reliable and immediately available. It is important to adopt simple quality control measures such as inventory lists, regular equipment checks, container seals to avoid scavenging, relocation mechanisms and staff orientation with training.

In the AIMS study (217) five of the fourteen contributing factors that were identified in the 85 difficult intubation reports were equipment deficiencies mainly due to “failure to check”. Our audit revealed several examples of poor quality control including expired, absent or faulty equipment. We found laryngoscope blades that would not fit handles, a difficult intubation trolley with a stuck drawer and noted one cricothyroidotomy set appearing on a check list but missing from the container. Our audit found a 50% incidence of check lists not corresponding with contents indicating scavenging and inadequate checking. We also found staff unfamiliar with the location and contents of the difficult airway containers. There has been debate about the necessity for airway management guidelines and the wisdom of retaining cricothyroidotomy as a “core skill” (224).

See Appendix five for a list of devices.
This audit was conducted in a region where no local airway management guidelines applied and there were no uniform guidelines for airway management equipment in Australasia. In many other respects, anaesthesia training, equipment and standards are similar throughout Australia and New Zealand, mainly attributable to the efforts of the Australian and New Zealand College of Anaesthetists, and therefore we doubt that our findings were unique. The inconsistencies and deficiencies revealed in our results may be rectified if guidelines, such as those applied in this audit, were adopted and implemented. Formal checking could then maintain a high standard of airway management equipment.

We advocate that guidelines describing the equipment necessary for the management of difficult airways and its storage and maintenance be established within our community. Anaesthesia organisations should be actively involved in the establishment, promulgation and implementation of such guidelines.

See Appendix five for a list of devices.
### Table 2.1 Difficult airway container contents and frequency (n=22)

<table>
<thead>
<tr>
<th>Item</th>
<th>Occasions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bag/masks</td>
<td>8</td>
</tr>
<tr>
<td>Oropharyngeal airways, 3 sizes</td>
<td>11</td>
</tr>
<tr>
<td>Nasopharyngeal airways, 3 sizes</td>
<td>19</td>
</tr>
<tr>
<td>Laryngeal mask airways (LMA’s™), range of sizes</td>
<td>12</td>
</tr>
<tr>
<td>A second spare handle for laryngoscope</td>
<td>15</td>
</tr>
<tr>
<td>Size 3 and 4 Macintosh laryngoscope blades</td>
<td>19</td>
</tr>
<tr>
<td>Bougie</td>
<td>21</td>
</tr>
<tr>
<td>Stylet</td>
<td>19</td>
</tr>
<tr>
<td>Magill forceps</td>
<td>16</td>
</tr>
<tr>
<td>Straight laryngoscope blade</td>
<td>21</td>
</tr>
<tr>
<td>Other laryngoscope blade (e.g. McCoy)</td>
<td>19</td>
</tr>
<tr>
<td>Intubating laryngeal mask airways (ILMA™), 3 sizes</td>
<td>20</td>
</tr>
<tr>
<td>Endotracheal tubes</td>
<td>18</td>
</tr>
<tr>
<td>ProSeals™, range of sizes</td>
<td>4</td>
</tr>
<tr>
<td>Bullard™ laryngoscope</td>
<td>1</td>
</tr>
<tr>
<td>Light wand</td>
<td>8</td>
</tr>
<tr>
<td>Aintree™ introducer</td>
<td>0</td>
</tr>
<tr>
<td>Combitube™</td>
<td>5</td>
</tr>
<tr>
<td>Non-kink jet ventilation needle (Patil or Ravussin)</td>
<td>15</td>
</tr>
<tr>
<td>Jet ventilator (regulated, non-regulated or Enk™ disposable)</td>
<td>19</td>
</tr>
</tbody>
</table>

See Appendix five for a list of devices.
Chapter 2. An audit of airway management equipment in a metropolitan region

See Appendix five for a list of devices.

### Table 2.2 Fibreoptic ancillary equipment (n=18).

<table>
<thead>
<tr>
<th>Item</th>
<th>Occasions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endoscopy airways (various sizes)</td>
<td>17</td>
</tr>
<tr>
<td>Nasal airways (various sizes)</td>
<td>17</td>
</tr>
<tr>
<td>Local anaesthetic</td>
<td>17</td>
</tr>
<tr>
<td>Lubrication</td>
<td>16</td>
</tr>
<tr>
<td>Tongue depressor</td>
<td>14</td>
</tr>
<tr>
<td>Endoscopy masks (various sizes)</td>
<td>10</td>
</tr>
<tr>
<td>Antifog</td>
<td>10</td>
</tr>
<tr>
<td>Swivel connector</td>
<td>8</td>
</tr>
<tr>
<td>Wire (145cm, 0.038inch)</td>
<td>8</td>
</tr>
<tr>
<td>Bite block</td>
<td>5</td>
</tr>
<tr>
<td>Vasoconstrictor</td>
<td>4</td>
</tr>
</tbody>
</table>

### Table 2.3 Staff interview at each site (n=22)

<table>
<thead>
<tr>
<th>Subject Matter</th>
<th>Occasions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correct knowledge of difficult airway container location</td>
<td>21</td>
</tr>
<tr>
<td>Correct knowledge of difficult airway container contents</td>
<td>17</td>
</tr>
<tr>
<td>Orientated to difficult airway container by senior staff</td>
<td>18</td>
</tr>
<tr>
<td>Staff allocated as “keeper” of the difficult airway container</td>
<td>16</td>
</tr>
</tbody>
</table>
Appendix 1

According to DAS guidelines the following is a list of equipment which should be immediately available where anaesthesia is administered. (Guidelines for non-obstetric adult patients without upper airway obstruction).

List 1

Recommended equipment for routine airway management.

Facemasks

Oropharyngeal airways: three sizes

Nasopharyngeal airways: three sizes

Laryngeal masks: range of sizes (3, 4 & 5)

Tracheal tubes in a range of sizes (6 to 8)

Two working laryngoscope handles

Macintosh blades: sizes 3 & 4

Tracheal tube introducer (“gum elastic” bougie or Frova™ bougie)

Malleable stylet

Magill forceps

Tooth guard (not included in the guidelines, but considered useful)

Recommended equipment for management of unanticipated difficult intubation.

- Difficult airway society guidelines algorithm flowchart.
- Equipment list for re-stocking (to be checked regularly)

At least one alternative blade (e.g. straight Miller 3, McCoy 3)

Intubating Laryngeal Mask Airway (ILMA™) set (size 3, 4, 5 with dedicated tubes and pusher)

Tracheal tubes – reinforced and Microlaryngoscopy size 5 & 6 mm.

Flexible fibreoptic laryngoscopy (with portable/battery light source)

(If you have a fibreoptic, see list 3)

See Appendix five for a list of devices.
Chapter 2. An audit of airway management equipment in a metropolitan region

ProSeal™ laryngeal mask airway (ProSeal LMA™) sizes 3, 4 & 5.

Cricothyroidotomy cannula (e.g. Ravussin or Patil) with High pressure jet ventilation system (e.g. Manujet™ or Enk™ oxygen flow modulator set. (not specified in the DAS list) or

Large bore Cricothyroidotomy cannula (e.g. cuffed Melker™)

Surgical Cricothyroidotomy kit (Scalpel with no.20 blade, tracheal hook, Trousseau dilator, 6/7 mm tracheal and tracheostomy tubes)

For oesophageal intubation detection, a colorimetric CO2 detector or an oesophageal bulb or syringe, or a Capnograph (ASA guidelines).

List 2

Additional equipment of value

Combitube™ SA

Trachlight™

Aintree™ Intubation Catheter

Bullard™ laryngoscope

A tube changer/jet stylet (ASA guidelines)

Retrograde intubation set (ASA guidelines)

List 3 (compiled by authors - not DAS or ASA)

Fibreoptic equipment

Spare battery or light source.

Intubating airways (e.g. Berman – 3 sizes)

Endoscopy masks (3 sizes.)

Swivel connectors.

Wire (0.038 inch, 145 cm.)

Antifog

See Appendix five for a list of devices.
Local anaesthetic (sprays, jelly, atomizers)

Nasal vasoconstrictor

Bite block.

Evidence of quality control (sterilization).

Appropriate storage. (Clean, dry, well ventilated, with the insertion tube as straight as possible. To avoid the risk of infection, do not use the carrying case for storage).

Storage

- Equipment should be contained in a labelled, portable, immediately available, dedicated “Difficult Airway Container”.
- Each container should have an inventory attached, which is checked weekly for contents’ readiness, expiry dates, and sterility. Items should be immediately replaced after use. Ideally the container should have plastic locks to prevent scavenging, and containers with broken locks should be immediately restocked.
- The container should be located close enough to allow immediate use. A relocation mechanism should be in place.

Staff

- A “keeper of the container” should be appointed, to be responsible for checking and maintaining the “Difficult Airway Container”.
- New staff should be orientated to the “Difficult Airway Container”.
- All staff should be familiar with the location and contents of the “Difficult Airway Container”.

Paediatric equipment

If paediatric patients are being anaesthetized, special airway equipment in appropriate sizes is required.

Lists 1, 2 & 3 need to be modified appropriately. This equipment should be contained separately from the adult equipment.

Obstetric and other specialized areas

See Appendix five for a list of devices.
Special laryngoscope blades such as Polio or Kessel, and rigid fibreoptic blades such as the Bullard™ or optical stylets may prove useful in these patients.

**Remote “satellite” sites**

Items in list 1 need to be **immediately** available. Consideration should be given to a portable airway box or permanent equipment on site at every location.

**Postscript**

This audit was a catalyst for change in Australasia. The problems highlighted by this study were brought to the attention of the Quality and Safety Committee of the Australian and New Zealand College of Anaesthetists (ANZCA) and resulted in a new college guideline concerning *Equipment to manage a difficult airway during anaesthesia* (PS56, 2012). Other audits have since been conducted by other groups in Australia and anecdotal reports suggest that there has been a significant improvement in the standard of airway management equipment in the region. Future studies could confirm this belief with a follow-up audit in the same units. The background document for this guideline has been updated for the purpose of this thesis and appears in Chapter three. This update needs to be formally undertaken within five years of publication. It is remarkable how rapidly equipment and attitudes have changed since the instigation of this audit.

See Appendix five for a list of devices.
Chapter 3. Equipment to manage a difficult airway during anaesthesia


Preface

In 2007, I undertook an audit of airway equipment which was published and appears in Chapter two of this thesis. This audit identified a number of important clinical problems, including missing or faulty equipment, inadequate equipment and a failure to implement quality control. Consequently, the Australian and New Zealand College of Anaesthetists (ANZCA) undertook a review of equipment used to manage a difficult airway during anaesthesia. I researched and wrote the first draft of the College guideline and I was the primary author of the paper that emerged from that work. In this chapter, I have updated the background paper which supports the Australian and New Zealand College of Anaesthetists (ANZCA) guideline PS56, 2012.

Abstract

Airway complications are a leading cause of morbidity and mortality in anaesthesia (3, 225). Effective management of a difficult airway requires the timely availability of suitable airway equipment. The Australian and New Zealand College of Anaesthetists has developed a guideline for the minimum set of equipment needed for the effective management of an unexpected difficult airway (226). PS56,2012 is based on expert consensus, underpinned by wide consultation and an extensive review of the available evidence which is summarised in a Background Paper which was published in Anaesthesia and Intensive Care in 2011 (150). The guideline was published in its original form in 2010 as TG4 on the ANZCA website. It was resolved that it would be reviewed at the end of one year and, thereafter, every five years or more frequently if necessary. In 2012 the guideline name was changed on-line to PS56.

See Appendix five for a list of devices.
Chapter 3: Equipment to manage a difficult airway during anaesthesia

Introduction

Airway complications are a leading cause of morbidity and mortality in anaesthesia (3, 225). Effective management of a difficult airway is a core skill for anaesthetists, and depends on the timely availability of suitable airway equipment.

Case reports reported to Australian Coroners’ involving “cannot intubate, cannot ventilate” (CICV) scenarios with tragic outcomes have highlighted the need for better management of airway emergencies (227, 228). Deficiencies in equipment have been identified in Coroners’ reports. One Coroner noted that “the importance of appropriately functioning equipment in an emergency does not just rest in the fact of the equipment itself, but also in the psychological support it provides to those dealing with the emergency” (227). In the Australian Incident Monitoring Study (AIMS), equipment deficiencies, which were mainly due to “failure to check”, contributed to five of the 14 factors that were identified in the 85 difficult intubation reports (217). The 1000 anaesthesia incidents reported to this study from 2002-2006 showed an appreciable increase in difficult and failed intubations compared with the first 2000 reports (229). A review from the American Society of Anesthesiologists (ASA) Closed Claims database comparing claims for difficult airway management from two time periods, 1985 – 1992 and 1993-1999, showed improvement in death/brain death categories from difficult airway management during induction of anaesthesia, but not during other phases of anaesthesia (127).

The Australian and New Zealand College of Anaesthetists (ANZCA) has defined the minimum requirement for basic airway equipment in operating suites and other anaesthetising locations in its Professional Document T1 Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations (2008) (230). This document states that in every anaesthetising location equipment for managing difficult intubations must be readily available in all locations where endotracheal intubation is electively performed. There is, however, no document specifying the items and conditions required to manage a difficult airway.

A number of professional societies have developed guidelines for equipment and techniques for managing difficult airways on the basis of literature reviews and expert consensus (9, 202, 205-207, 209, 231, 232). All of these guidelines recommend a dedicated airway cart. Despite this, a recent audit in New Zealand identified inconsistencies and deficiencies in the airway equipment available in a major metropolitan area. Alarmingly, some sites lacked any emergency airway equipment (169).

The Health and Disability Sector Standards from Standards New Zealand require emergency equipment to be accessible, stored correctly, not expired, and stocked to a level appropriate to the service setting (233). In Australia, the regulation of medical devices is overseen by the Therapeutic Goods Administration (TGA). Published and draft International Organization for Standardization (ISO) documents also apply to airway management equipment (ISO 7376:2009 (E), ISO 11712:2009) (187). It is likely, however, that these standards are not as well known or accessible to anaesthetists as those published by ANZCA.

See Appendix five for a list of devices.
Chapter 3: Equipment to manage a difficult airway during anaesthesia

It was therefore apparent that a new Professional Document from ANZCA was needed to specify the equipment required to manage a difficult airway, the locations in which it should be kept, and the quality assurance measures that should be implemented to ensure that it is always available and in good working condition. The process of developing such documents has recently been revised (234, 235), and includes the development of a Background Paper outlining the basis for the recommendations in the document. Here I describe the development of the Background Paper for the ANZCA document, PS56, 2012, and report its contents.

Methods

The aim was to develop expert consensus, supported by published evidence where available, and then to consult with ANZCA national and regional committees and other experts (234). Expert Workshops were held at ANZCA Headquarters, Melbourne, on April 6th and July 12th 2008, to develop preliminary consensus on the equipment needed to manage a patient with a difficult airway. People known to have an interest in airway management, or who expressed an interest in contributing were invited to participate (see Table 3.1). Contributors were asked to identify all relevant publications, both from their existing databases, and from the references within these articles. Searches were also undertaken of Medline and Pubmed, using the following terms: Airtraq, Bonfils, Bullard, C Trach, Combitube, cricothyroidotomy, Easytube, endotracheal intubation confirmation, endotracheal tube introducers, extubation, fibreoptic intubation, Henderson laryngoscope, Light wand, laryngeal mask airway (LMA), LMA Fastrach, LMA Proseal, McCoy laryngoscope, Miller laryngoscope, Optical stylet, retrograde intubation, Transtracheal jet ventilation, Truview, video laryngoscopy, Viewmax, equipment, airway management, difficult intubation, Ambu aScope, C-Mac, McGrath, Pentax AWS, King Vision, Glidescope, Airtraq, Ventrain, Sugammadex.

See Appendix five for a list of devices.
Table 3.1 Participants in the Difficult Airway Management Workshops, 2008-2010.

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<thead>
<tr>
<th>Name</th>
<th>Comment</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Dr Paul Baker, FANZCA</td>
<td>Lead author</td>
<td>All</td>
</tr>
<tr>
<td>Prof. Alan Merry, FANZCA, FFPMANZCA, FRCA</td>
<td>Primary Facilitator</td>
<td>All</td>
</tr>
<tr>
<td>A/Prof. Brendan Flanagan, FANZCA</td>
<td></td>
<td>All</td>
</tr>
<tr>
<td>Dr Keith Greenland, FANZCA</td>
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<td>J,T</td>
</tr>
<tr>
<td>Dr Richard Morris, FANZCA</td>
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<tr>
<td>Prof. Harry Owen, FANZCA</td>
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<td>Prof. Bill Runciman, FANZCA, FJFICM</td>
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<td>Dr Margie Cowling, FANZCA</td>
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Administration:

Pauline Berryman Quality and Safety Officer, All ANZCA

John Biviano Director, Policy, Quality and Accreditation, ANZCA

See Appendix five for a list of devices.
Chapter 3: Equipment to manage a difficult airway during anaesthesia

At the workshops selected participants provided brief presentations on aspects of airway management, supported by the references identified above; these were followed by in depth discussion, with the aim of reaching consensus on the issues canvassed. Consideration was given to rating supporting evidence according to the GRADE system (236, 237) as high, moderate, low and very low, and to grading recommendations as strong or weak. The proceedings were recorded in summary form.

Following the workshop lead participants (PAB, AFM) collated the information. I prepared the first draft of the paper. This was then reviewed by AFM and then the other members of the group. It was then subjected to an iterative process of reviewing and editing. The first iteration involved the other participants of the workshop and members of the Airway Management Special Interest Group (Australian and New Zealand College of Anaesthetists, Australian Society of Anaesthetists and New Zealand Society of Anaesthetists) and resulted in a document entitled “Preliminary Draft”. The second iteration involved ANZCA’s established consultation process for Professional Document development, overseen by its Council, through its Quality and Safety Committee, and involving its Regional Committees and New Zealand National Committee (see Table 3.2). Feedback from this consultation was then incorporated into the Background Paper and Professional Document by members of the Expert Working Party, and submitted to Council through the Quality and Safety Committee for approval. These documents were promulgated with pilot status for approximately one year, during which further feedback was sought, with a view to producing definitive versions in 2011. These will be subject to review every five years, or more frequently if appropriate.

See Appendix five for a list of devices.
Table 3.2 Consulted individuals and organisations

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<tr>
<td>ANZCA Regional Committees</td>
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<td>ANZCA NZ National Committee</td>
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<td>ANZCA Quality and Safety Committee</td>
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<tr>
<td>Airway Management Special Interest Group*</td>
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<td>Obstetric Anaesthesia Special Interest Group*</td>
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<td>Dr Kym Osborn</td>
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<td>SPANZA Dr Peter Kemphorne, Dr Patrick Farrell, Dr Tom Watson, Dr Niall Wilton, Dr Elizabeth Prentice.</td>
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ANZCA: Australian and New Zealand College of Anaesthetists

SPANZA: The Society of Paediatric Anaesthetists in New Zealand and Australia

* Australian and New Zealand College of Anaesthetists, Australian Society of Anaesthetists and New Zealand Society of Anaesthetists

See Appendix five for a list of devices.
Results

A list of airway devices, manufacturers and the manufacturers’ city and country of origin are listed in Appendix 5. References identified and deemed relevant are included in the list of references.

Few of these studies evaluated devices in comparison with a contemporary “gold standard” in patients with difficult airways. Furthermore, relevant evidence concerning equipment is difficult to obtain in a prospective randomised manner. Many of the published case series are heterogeneous or apply to patients with normal airways. Overall, we identified few large prospective randomised trials or meta-analyses to guide decisions on airway management or equipment (238, 239). It follows that the published evidence supporting many points in PS56, 2012 is typically moderate to very low (209). On the basis of common sense (240) and clinical experience, the key recommendation that an adequate selection of appropriate equipment should be readily available soon enough to avoid the onset of irreversible brain damage in an unexpected CICV scenario was graded “strong”, but recommendations favouring one device over another similar device were in general graded as “weak”. The agreed recommendations we incorporated into PS56, Equipment to Manage a Difficult Airway During Anaesthesia (2012) (226).
Discussion

Principles related to the management of a difficult airway

Successful management of the difficult airway requires technical skill (241) and appropriate equipment. PS56, 2012 provides generic advice to anaesthetic practitioners and departments. It is not intended to be an exhaustive list of available equipment, but rather to provide guidance to essential categories of equipment from which items can be chosen. Selection of equipment should be based on evidence and decided on the principles of standardisation, redundancy and a culture of safety (170). Standardisation avoids unwanted duplication and facilitates familiarity with carefully selected equipment. Familiarity and confidence with the chosen equipment are key factors contributing to a successful outcome. Redundancy provides backup when first line ventilation or intubation equipment fails. It is important to recognise that every device and technique is associated with a failure rate, and therefore backup plans and equipment are essential. Patient safety should come ahead of considerations of convenience or economy.

Many difficult intubations are unpredicted (207), so emergency airway equipment should be immediately available wherever airways are managed. This equipment should be of high quality (242, 243). There are important differences between some brands of airway equipment in terms of quality and function (242, 243). For this reason, a number of brands have been identified in PS56, 2012 when such data are available or data to support an alternative are lacking. Furthermore, there are examples of differences in performance between disposable and reusable items even within the same brand (242).

Equipment should be kept in a dedicated container with clear labelling to streamline use in an emergency (169). All staff working within operating suites and other anaesthetising locations should be familiarised with the container’s location and contents (169). Removal of airway equipment from airway containers is very common (169). Airway containers are required to be completely stocked and a method such as breakable seals and regular checking should be implemented. In addition, the quality of this airway equipment should be regularly checked and meet recognised standards (244). Oesophageal intubation can be difficult to diagnose clinically (245), so equipment to diagnose oesophageal intubation should be immediately available wherever airways are managed (9). Remote operating sites are sometimes poorly equipped (169), but require the same standards of airway equipment for safe airway management. One way of achieving this cost-effectively is by use of a “grab-bag”. A grab-bag is a dedicated portable container including essential emergency airway management equipment. A pre-formulated strategy is recommended for extubation of the difficult airway, and a plan to manage possible post-extubation hypoventilation (9, 205, 246).

The effective use of airway equipment in an emergency requires that it is presented in an orderly manner, that users are familiar with it, and that they have the skills to use it. Therefore, airway equipment should be prioritised and the contents of the emergency container kept to a minimum. Changes to the contents should be evidence-based, or at least guided by expert advice; where possible any new equipment should be evaluated against the known “gold standard” (244).

See Appendix five for a list of devices.
A difficult airway may be recognised and managed electively, or unrecognised and managed in an emergency. The emphasis in management shifts from intubation with a predicted difficult airway to ventilation and oxygenation with an unpredicted difficult airway. The airway difficulty may arise with ventilation or intubation and a surgical airway may be required. A review of algorithms for difficult airway management highlights the evolution of and inconsistencies between different documents caused by a lack of evidence to support many statements (48). This leads to considerable variation in definitions for “airway”, “ventilation”, “laryngoscopy” and “intubation”. The evolution of these definitions is discussed elsewhere (48).

Priorities when managing a difficult airway include the maintenance of oxygenation and ventilation and the avoidance of trauma (202, 247). Selection of airway equipment should reflect these priorities. Ancillary equipment or devices which facilitate the maintenance of oxygenation and ventilation and improve intubation success should be given priority.

Any anaesthetist who may be called upon to manage a paediatric emergency, however infrequently, will need at least basic skills in managing paediatric airways, and to be familiar with at least one device for a difficult paediatric airway. Paediatric airway equipment should be stored separately from adult equipment and should be available in a suitable range of sizes. Where obstetric patients are managed, additional equipment may prove useful (221, 222).

**Ventilation devices**

The “gold standard” basic equipment for controlled ventilation is a self-inflating bag and mask for bag-mask ventilation (BMV), supplemented by oropharyngeal or nasal airways. This equipment is required by ANZCA Professional Document T1 *Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations* (2008) (230).

Airway devices that include a ventilation orifice above the glottis are commonly referred to as “supraglottic” (e.g. classic laryngeal mask airway or cLMA™, Combitube™) and those designed to deliver gas below the vocal cords are “infraglottic” airways (e.g. endotracheal tube, cricothyroidotomy device). The term “extraglottic” was suggested by Brimacombe (248), who argues that some devices have components in the hypopharynx or upper oesophagus and are therefore anatomically infraglottic. Classifications have been proposed to describe the increasing variety of ventilation devices (248, 249). One simple classification divides airways into first and second generation depending upon the use of mechanisms to protect against gastric aspiration (250). Further classification might include single or reusable devices.

All the current international airway algorithms include extraglottic devices in airway carts. In the presence of a difficult airway, an extraglottic airway can be used for ventilation throughout surgery, as a conduit for intubation, or as a secondary rescue device and ventilation/oxygenation bridge. There is now a wide group of devices in this category. Selection of an extraglottic airway as a rescue ventilation device and/or a conduit for

See Appendix five for a list of devices.
endotracheal intubation, should be determined after considering the relative contraindications which include limited mouth opening, obstruction of the airway at or above the glottis, disrupted airway and high lung compliance. Risk factors for failed Laryngeal Mask Airway Unique™ (uLMA™) include surgical table rotation, male sex, poor dentition and increased body mass index and failed uLMA™ was associated with a three-fold increase of difficult mask ventilation (40).

The cLMA™ and its variants have been investigated by various groups as airway rescue devices (251-255). Safe and effective use of the cLMA™ as a rescue device in non-fasted patients following failed tracheal intubation in general surgery and in obstetric surgery have also been reported (256). The use of the cLMA™ and its variants as airway rescue devices in the difficult airway and in the CICV situation has been recommended by the American Society of Anesthesiologists, the Canadian Airway Focus Group (4, 5) and the Difficult Airway Society (UK) (202). The cLMA™ is considered a useful device in neonatal resuscitation and is included in the 2005 European Resuscitation Council Guidelines for neonatal resuscitation (257). Case studies suggest that the cLMA™ can provide suitable ventilation when BMV and endotracheal intubation fails, but a Cochrane review found no eligible studies comparing LMA with BMV in neonatal resuscitation (239).

The cLMA™ has the advantage of being readily available. It is also easy and safe to use as a ventilation device, and can function as a conduit for endotracheal intubation. However, limitations of the cLMA™ as a conduit for endotracheal tube insertion include its relatively long length, narrowness and aperture bars (202). Endotracheal intubation with a flexible bronchoscope through a cLMA™ requires either an appropriately long tracheal tube such as a Mallinckrodt® reinforced tube (31 cm long, size 6.0mm or 6.5mm for size 4 or 5 LMA respectively) (258), a nasal RAE™ (Ring Adair Elwyn) tube, a microlaryngoscopy tube, or a two stage procedure with an Aintree™ catheter.

A large number of laryngeal masks from different manufacturers are now available commercially. Only a few of these products have been evaluated in clinical trials (244). Laryngeal masks should comply with the ISO Standard, which concerns supralaryngeal airways and connectors (259). This Standard assists the operator by requiring dimensional disclosure to match the appropriate size flexible bronchoscope or endotracheal tube with the laryngeal mask. The efficacy of many disposable extraglottic devices as a conduit for endotracheal intubation is unproven. Extraglottic ventilation devices which have proven function as conduits for endotracheal intubation or flexible bronchoscopy are desirable for management of a difficult airway. Any new product should also perform at least as well as a recognised “gold standard”.

The LMA-Fastrach™ or ILMA™ is a device designed for use in both anticipated and unexpected difficult intubations, and for ventilation and intubation after failed intubation with other techniques. It can be used for awake intubation (254), in cardiopulmonary resuscitation (260), and as a rescue and primary airway management device (261). It has been used prehospital, in the emergency department and operating rooms (255) (262). Use by inexperienced operators (263) and in patients with unstable cervical spine with neck immobilisation, and the lateral position (264) has been reported. In a group of 111 patients with Cormack Lehane grade 4 views and failed rigid laryngoscopy and/or intubation, insertion of the ILMA™ and ventilation

See Appendix five for a list of devices.
Chapter 3: Equipment to manage a difficult airway during anaesthesia

was successful. First pass intubation attempt with the ILMA™ was then only 65.2% successful. This reached 92% within five attempts. In a study of 254 patients with varying pathology, the ILMA™ was successfully inserted in all patients with three or fewer attempts (254). The number of intubation attempts can be reduced by applying the Chandy manoeuvre. This involves aligning the internal aperture of the ILMA™ and the glottic opening by finding the optimum degree of sagittal rotation in order to maximise ventilation. This is followed by a slight anterior lift of the ILMA™ handle in order to move the ILMA™ away from the posterior pharyngeal wall prior to insertion of the endotracheal tube (ETT) (254). Both fibreoptic bronchoscope guidance (254) and light wand guidance (265) through the ILMA™ can also reduce the number of insertion attempts required. The ILMA™ also minimises the risk of aspiration (266). Intubation through the ILMA™ on the first attempt is not always reliable, and this uncertainty could limit its use. The ILMA™ is an established supraglottic airway device, which enables ventilation and intubation in both anticipated and unexpected difficult airway situations (254). The ILMA™ has first-attempt and overall success rates from 73% and 90% (267).

The ProSeal™ with its oesophageal access port and ability to provide higher seal pressures is particularly suitable for cases needing positive pressure ventilation, and also where access to the gastrointestinal tract is desirable (268). This device is suitable for spontaneous and positive pressure ventilation in routine and emergency anaesthetic procedures (269). The ProSeal™ serves as a rescue device for failed intubation (252) in known or unexpected difficult airways. It is also useful for establishing an airway during resuscitation in profoundly unconscious patients with absent glossohypopharyngeal and laryngeal reflexes when tracheal intubation is not possible. The ProSeal™ can be used with the Aintree catheter and flexible bronchoscope as a conduit for endotracheal intubation in adults (270), but the disposable version of the ProSeal™, the Supreme LMA™, is not reliably compatible with the Aintree catheter (271). The ProSeal™ is suitable for adult and paediatric patients (272, 273). Protection against large volume regurgitation with the ProSeal™ has been reported (274). Careful technique is required when inserting the ProSeal™ in order to avoid malposition and failure of the device in adults (275) and children (276). Even with correct placement, airway obstruction can occur as a result of the ventral cuff of the ProSeal™ causing compression of the glottis or supraglottis (277). Reported incidence of airway obstruction with the ProSeal™ varies with the size of the mask (0.4% (278) in adults, 6.6% with the size 2.5 (279) and 10% with the size 1.5 (272)). In a randomised series of 46 consecutive neonates and infants, the size 1.0 ProSeal™ (which lacks a dorsal cuff and bite block) formed a more effective seal than the cLMA™, suggesting that the size 1.0 ProSeal™ might have a benefit in newborn infants requiring high airway pressures for ventilation (280). In summary, the ProSeal™ allows higher airway leak pressure and separates the respiratory and digestive tracts. These features may provide better conditions for controlled ventilation in children than the cLMA™, but further evidence is required (281).

The i-gel™ airway is a second generation extraglottic airway with an integrated gastric drainage tube and a bite block. It is made of a medical grade thermoplastic elastomer and features a non-inflatable anatomical periglottic seal. It has a shorter stem than an equivalent size cLMA™ and is available in multiple sizes, for adult and paediatric patients. This device is suitable also for rescue ventilation (282, 283), and also functions as a conduit for flexible bronchoscopy guided endotracheal intubation (284, 285).

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Chapter 3: Equipment to manage a difficult airway during anaesthesia

The Cookgas® Air-Q™ intubating laryngeal airway is an extraglottic airway designed as a conduit for endotracheal intubation with a standard endotracheal tube (ETT). This is possible with or without the assistance of a flexible bronchoscope, in adults and children (286, 287). The Air-Q™, in a pilot study of 59 patients, was successfully inserted and used as a ventilation device in all patients, but of 19 intubated patients, only 58% were successfully intubated on the first attempt, and 74% were intubated overall, using a blind intubation technique (288).

The Combitube™ is a valuable emergency airway device which combines the function of an oesophageal obturator airway and a conventional endotracheal tube. It has a role as a ventilation/oxygenation bridge and secondary rescue device (289). The Combitube™ has demonstrated superiority over other supraglottic ventilation devices in resuscitation in relation to ease of ventilation and insertion (290, 291). The device has advantages in patients with massive bleeding, regurgitation and limited mouth opening (292). It also minimises the risk of aspiration (266). Complications are rare (293, 294) but include piriform sinus perforation, oesophageal laceration and tongue engorgement. These complications can be minimised by avoiding Combitube™ use with oesophageal pathology, ensuring loss of gag reflex before insertion, using minimum cuff inflation volumes, using the small adult size (SA – 37F), applying the “Urtubia manoeuvre” (295) (bend tip up before insertion) and using a laryngoscope.

The EasyTube® is a relatively new variant of the Combitube™ which has a non-latex cuff, an airway suitable for flexible bronchoscope insertion, and a single lumen distal tube. It is available in two sizes, a large size of 41 French for patients >130cm height and a small 28 French for patients 90-130cm. Bronchoscopy is possible through the EasyTube® with a 3.7 mm endoscope for the 41Fr and a 2.8mm endoscope for the 28Fr. However, literature concerning this device is limited (266, 296-301).

In summary, review of the literature supports using the cLMA™ or ProSeal™ for ventilation and oxygenation, the LMA-Fastrach™ as a rescue ventilation/intubation device and the Combitube™ as an emergency airway. There is growing evidence to support recommendations in relation to other extraglottic airways such as the i-gel™ and the Cookgas® Air-Q™.

Direct laryngoscopy

Direct laryngoscopy and intubation with the Macintosh laryngoscope is the first line approach when managing the difficult airway including impossible bag and mask ventilation (31). The Macintosh laryngoscope is regarded as the “gold standard” for direct laryngoscopy. A number of variants in design exist (302) including the American (A-Mac) and the English (E-Mac). The E-Mac has better illumination than the A-Mac (303). In unexpectedly difficult laryngoscopy the E-Mac provided a better glottic view than the A-Mac (304). Laryngoscopes with a high proximal flange, such as the A-Mac, might cause more trauma to the maxillary incisors (305).

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Macintosh modified the laryngoscope blade to allow the tip to “fit into the angle made by the epiglottis and the base of the tongue” (306). Tension by the tip of the Macintosh blade on the hyoepiglottic ligament in the vallecula, combined with upward tension on the base of the tongue and displacement of the tongue to the left, provides the view of the larynx (307, 308). To optimise this mechanism in different sized adult patients, a range of laryngoscope sizes is required, including sizes 2, 3 and 4. Adult patients, with micrognathia and a short thyromental distance of 5 cm, benefit from a size 2 Macintosh laryngoscope (309).

The levering or McCoy laryngoscope is a modification of the Macintosh laryngoscope with a levering tip. However, subtle differences in the design of the tip may alter its performance compared to the Macintosh laryngoscope (310). Less force is applied during laryngoscopy with the McCoy and hence the stress response is reduced (311). Poor visualisation of the larynx may be improved by lifting the epiglottis, especially in necks fixed in the neutral position (312). The McCoy lifts the relaxed epiglottis and expands the collapse of soft tissues around the laryngeal aperture (313). A reduction in the anterior-posterior forces across the cervical region during tracheal intubation occurs with the McCoy (314). The McCoy blade, when activated, provides a better view of the glottis in approximately 20% of patients with manual in-line stabilisation than the Macintosh blade (315). However, in a small proportion of laryngoscopies, the McCoy blade can make the view of the larynx worse (316). With the head in the neutral position, the McCoy is associated with poorer views than the Macintosh blade (310), which is thought to be due to downward movement of the middle portion of the blade into the line of sight (317). A straight McCoy blade based on the Seward blade is available in size 1 for paediatric use. The tip of this blade was designed to be placed in the valleculae (318). A prospective randomised trial of normal infants found that the straight McCoy offered no advantage over the size 1 Miller blade, when the tip of the blade was placed beyond and posterior to the epiglottis (319).

Use of a straight blade, such as the Miller, with the paraglossal straight laryngoscope technique (PGSLT) was originally described by Magill (320) and more recently by Henderson (180). This technique is useful for buck teeth, over-riding teeth, large tongue, large floppy epiglottis, and failed Macintosh laryngoscopy. Failure occurs in 1- 3% of Macintosh laryngoscopies (205, 321) and is associated with a 44% straight blade success rate (322). The straight blade should be of sufficient length to trap and support the epiglottis. A prospective randomised trial of 161 patients compared the laryngoscopy view of the Miller and Macintosh blades. A much better view of the larynx was achieved in the majority of patients with the Miller blade using a paraglossal approach (323). The straight blade using PGSLT has been successfully used to intubate difficult paediatric patients (324). (325). There is a variety of paediatric laryngoscope blades, including the paediatric straight McCoy size 1 (based on the Seward straight blade), Anderson-Magill, Robertshaw, Seward, Wis-Hipple, Henderson, Dörges and Flagg. Selection will therefore depend on individual experience and preference.

Poor illumination by the laryngoscope may compromise tracheal intubation (303). The optimum level of laryngoscope illumination has been established at 700 lux with no improvement in visual acuity during laryngoscopy up to 2000 lux (326, 327). As a minimum standard, the ISO suggest illumination should exceed 500 lux at a distance of 20 mm from the tip of the blade for at least 10 minutes (187). Illumination from the

See Appendix five for a list of devices.
reusable Macintosh blade is decreased by placing a protective cover over the blade (328). Light emitting diodes (LEDs) produce a cooler (blue-white) and brighter light than conventional bulbs. (329).

Laryngoscope blades and handles can be a source of infection, and proper cleaning procedures should be followed (186). Disposable plastic laryngoscope blades are associated with a decreased success rate of tracheal intubation (189) and increased laryngoscopic forces can cause fracture to these blades (190, 191). Flexibility and breaking limits for laryngoscope blades have been specified by the ISO (330). Some disposable metal blades performed poorly, and others reasonably well, when compared to the “standard” reusable Macintosh (243). One argument for using disposable blades is based on the possibility that certain pathogens might be resistant to disinfection or even sterilisation, but Blunt and Burchett concluded that the risk to the patient of using poorly functioning airway equipment may be greater than the risk of acquiring transmissible spongiform encephalopathies (194). Galinski et al suggest that conventional laryngoscopes be kept in reserve for difficult intubations (192). For these reasons PS56, 2012 recommends reusable laryngoscopes that comply with ISO Standards.

**Intubation guides and stylets**

Early use of intubation guides and stylets is recommended for difficult laryngoscopy. However, persistent use of these devices can be traumatic, particularly in patients with difficult laryngoscopy presenting with Cormack Lehane views 3b and 4.

A large range of intubation guides and stylets is commercially available. These devices should be carefully selected on the basis of proven efficacy and safety. Large variability in performance can be found between different products (193). This discussion will focus on devices of proven effectiveness and safety.

The Eschmann endotracheal tube introducer (EETI) is 60 cm long, allowing ETT exchange. The distal 2.5cm has a 35° Coudé tip which allows hooking under the epiglottis, steering around obstacles, tactile identification of tracheal rings and “hold-up” at the carina (203). This multiple-use bougie is associated with a very low complication rate (216, 331). The introducer should not be held near the tip or introduced with forceps since this increases applied force and the risk of trauma. First pass success rate on simulated Cormack and Lehane (CL) Grade 3 mannequin studies was 85% for the multiple-use EETI and 15% for the single-use bougie (Portex Tracheal Tube Introducer, SIMS Portex) (242). Concerns about cross-infection due to re-used Eschmann endotracheal tube introducers, has led to single use only items being introduced. An example of such a single use item with a satisfactory first pass success rate is the Frova intubating introducer™. The adult Frova introducer™ is blue, has a curved 35° tip and a central lumen with removable Rapi-Fit® adapters permitting ventilation during its use and confirmation of endotracheal intubation by carbon dioxide detection or oesophageal detection device (332). Success rates of the Frova introducer™ on mannequin studies are equivalent to the reusable Eschmann endotracheal tube introducer, and significantly better than other single use devices including the Portex™ introducer (193, 333). A prospective clinical study showed that the Frova

See Appendix five for a list of devices.
introducer™ had a high success rate for tracheal placement but a potential to produce tracheal trauma (334). Correct use of the Frova introducer™ avoids shaping and elicitation of “hold-up” and click when passing the laryngeal inlet, thereby minimising trauma (335). Extreme caution should be observed when insufflating oxygen through the Frova introducer™ because of the risk of barotrauma. Precautions include providing a patent upper airway, ensuring the catheter does not pass the carina, securing the catheter and limiting gas flow to 2 L/min (336, 337).

The Aintree Intubation Catheter™ (AIC) is 19 French, 56 cm long with an internal diameter of 4.7 mm. This allows a tight fit over a 4mm fibreoptic bronchoscope leaving the distal 3cm of the FOB exposed and free to flex and extend. The AIC is suitable to replace an ETT with a 7mm inner diameter or larger. This device was specifically designed for intubation through the cLMA™, but is also suitable for use through the ProSeal LMA™ and in situations where the cLMA™ may not be suitable (270). The AIC is not always compatible with the Supreme LMA™ (271). A longer version of 83cm is available to exchange endobronchial tubes. These catheters are supplied with removable Rapi-Fit® adapters which permit ventilation during the exchange procedure.

Malleable metal stylets aid intubation by improving placement of the ETT. The potential for trauma to the pharynx, larynx, trachea or oesophagus, caused by the stylet, can be reduced by ensuring that the stylet is positioned at least 2 cm from the tip of the ETT (338). Intubation is enhanced by a “straight to cuff” configuration with a distal bend of 35° (339).

**Light wand**

Intubation of the trachea under direct vision using a lighted introducer was first described by Macintosh and Richards in 1957 (340). Transillumination for nasotracheal intubation was described by Berman in 1959 (341). These techniques rely on transillumination of the anterior neck to identify the location of the tip of the endotracheal tube. Using the glow from the wand, the device can be manoeuvred into the midline and down the trachea. This technique can be applied with a range of equipment including lighted stylets that are rigid and flexible, reusable and disposable, adult and paediatric. Interest in the light stylet technique increased with the introduction of the Trachlight™ (342-344), however this device was withdrawn by Laerdal (Laerdal Medical, Wappingers Falls, NY, USA) in 2009.

See Appendix five for a list of devices.
Retrograde intubation

Retrograde intubation has been used successfully in patients with anticipated and unanticipated difficult airways. It has also been used as a rescue technique following failed direct laryngoscopy, failed blind nasal intubation, failed bougie attempt, cLMA™ failure and failed flexible bronchoscopy. Indications include urgent airway establishment in the presence of blood and secretions, failed direct laryngoscopy, failed LMA, failed flexible bronchoscopy, unstable cervical spine and maxillofacial trauma (345). A modified rapid retrograde technique has been described (346). This has been used on three emergency patients with an average time of 10 seconds, however, retrograde intubation is not recommended as an emergency technique to manage failed oxygenation and CICV situations because the procedure generally takes longer to perform than a cricothyroidotony (5). The techniques and equipment required for this procedure have recently been reviewed (347). Equipment includes a needle and saline filled syringe for cricothyroid puncture, a retrograde guide wire of 0.889-0.965 mm diameter which is at least 70 cm in length and a long anterograde airway exchange catheter. Smaller catheters and wires are used for paediatrics. The anterograde guide which is inserted over the retrograde guide provides rigidity for the advancing endotracheal tube. The anterograde guide can be an airway exchange catheter. A custom made retrograde intubation set includes all of these components (Cook Critical Care, Bloomington, IN, USA).

Extubation and endotracheal tube changing

Data from the American Society of Anesthesiologists (ASA) Closed Claims Analysis from 1993-1999 showed 12% of difficult airway claims occurred at extubation (127). This is consistent with results from the NAP4 study which found that 16% of adverse events occurred during anaesthetic emergence and 14% occurred in the recovery phase (3).

Recent airway management guidelines recommend a pre-formulated extubation strategy for difficult airways (4, 6, 9, 348). This strategy might include the use of an airway exchange catheter (AEC) for tube changing or protected extubation. Despite associated complications and the limited evidence supporting these devices (349), their availability and appropriate use is recommended by the task force, however, the use of supplementary oxygen down the lumen of the AEC is associated with a significant risk of barotrauma. There is no evidence suggesting that oxygen administered by either TTJV of passive insufflation is associated with increased benefit compared to standard oxygen therapy and therefore oxygen administration down an AEC is not recommended (350).

Changing a paediatric cLMA to an ETT is possible with a guidewire and airway exchange catheters (Size 1 cLMA to a size 3.0 mm ETT with an 8 Fr Cook airway exchange catheter, size 1.5 cLMA to a 4mm ETT with an 11 Fr catheter, size 2.5 cLMA to a 5.5 mm ETT with a 14 Fr catheter and size 4 cLMA to a 7.0 mm ETT with a 19 Fr catheter) (351). The pilot balloon of a cuffed ETT will not pass through a cLMA smaller than size 3.

See Appendix five for a list of devices.
**Specialised endotracheal tubes**

Specialised endotracheal tubes may be beneficial for difficult endotracheal intubation, particularly during fibreoptic intubation. Wire reinforced spiral tubes have been associated with less laryngeal impingement than standard polyvinyl chloride (PVC) tubes (352), but impingement can still occur (353, 354). The flexible tip of the Parker Flex-Tip™ tube provided greater initial success of fibreoptic intubation compared with a standard PVC tube (355) and less pain and trauma following nasotracheal intubation compared with a standard PVC tube (356) and success during a scalpel bougie surgical airway (337). The ILMA™ reusable silicone endotracheal tube compares favourably to both the standard PVC tube and the reinforced flexometallic tubes for nasotracheal intubation under general anaesthesia (354). In the absence of an Aintree catheter, tubes suitable to intubate through a cLMA™ include the long flexometallic (258, 357), nasal RAETM (358) and the microlaryngoscopy tube (359-361). Inadvertent intralaryngeal tracheal cuff placement and damage has been reported with standard length (362) and reinforced ETTs (363).

The pros and cons of cuffed ETTs in paediatrics deserve careful consideration (364), and issues such as the outer diameter of ETTs, cuff design and cuff placement are important when choosing an appropriate paediatric ETT and avoiding trauma (365). A prospective randomised controlled multi-centre trial of cuffed or uncuffed endotracheal tubes (ETT) in small children undergoing general anaesthesia found that cuffed ETTs do not increase the risk of post extubation stridor compared with uncuffed ETTs, reliably seal the airway at cuff pressures of ≤ 20 cm H₂O and reduce the need for ETT exchanges (366).

**Flexible bronchoscopy**

Flexible bronchoscopy is primarily indicated for the elective management of the anticipated difficult airway. This includes a history of previous difficult intubation or predicted difficult bag-mask ventilation or predicted difficult intubation. Flexible bronchoscopy is also useful for unanticipated difficult intubation following failed direct laryngoscopy (367, 368), and hence is recommended as a second line strategy in this situation. Flexible bronchoscopy is contraindicated for emergency airway management where immediate control of the airway is required, especially in the presence of deteriorating ventilation. On this basis, the flexible bronchoscope is not a mandatory device to be immediately available, but its availability is considered highly desirable, particularly in the hands of an experienced practitioner and combined with other airway equipment which facilitates oxygenation and ventilation during the procedure. The availability of a flexible bronchoscope within five minutes of each site where airways are managed is recommended and should be integrated with the difficult airway container or stored on a dedicated mobile tower.

Numerous case studies support flexible bronchoscopy for a broad range of clinical applications. These include airway management for patients with potential cervical spine instability (369), trauma (370), aspiration risk

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Chapter 3: Equipment to manage a difficult airway during anaesthesia

(371) and potential for dental damage (372) (373). Relative contraindications of flexible bronchoscopy include uncooperative patients for awake intubation, airway bleeding, tissue disruption and laryngeal obstruction with stridor. In a survey of New Zealand anaesthetists, the majority of respondents considered fibreoptic intubation to be the “gold standard” for expected difficult airways (223). Flexible bronchosopes should be accompanied by ancillary equipment including light sources, bronchoscopy swivel connectors, endoscopy masks, intubating airways, wires, and equipment to apply local anaesthetic to the patient’s airway (169).

Flexible bronchosopes are available in a range of sizes and are designed for different applications. For example, ultra-thin or neonatal bronchoscopes (2.2mm diameter) allow a size 3.0mm ETT, but lack a working channel. Detailed specifications are available from manufacturers.

Flexible bronchosopes should be stored according to manufacturer’s instructions to avoid damage, malformation and infection. Storage should be dry, clean, well ventilated and at normal temperature. This precludes storage of endoscopes curled up in portable containers. Ideally the endoscope should be hung straight. Care is needed to avoid infection, including the use of a sterile surface, sterile gloves, single use items such as airways, bronchoscopy elbows and endoscopy masks, and leak tested endoscopes (374). Sterilisation of endoscopes should comply with ANZCA Professional Documents PS28 Guidelines on Infection Control in Anaesthesia (2005) (375) and T1 Recommendations on Minimum Facilities for Safe Administration of Anaesthesia in Operating Suites and Other Anaesthetising Locations (2008) (230) as well as Australian and New Zealand Standards (376). The Ambu® aScope™ is a single use flexible bronchoscope which offers potential benefits including reduced patient-to-patient cross contamination. This device has undergone significant design improvements and a third generation device was released commercially in 2013. This model is available in two diameters. The Ambu® aScope™ 3, 5.0mm insertion tube with a 2.2mm working channel and the Ambu® aScope™ 3 Slim, 3.8mm insertion tube with a 1.2mm working channel. The suggested benefits of these devices include immediate sterility, immediate availability and cost efficiency. Studies on patients with difficult airways comparing the Ambu® aScope™ and re-usable flexible bronchoscopes show satisfactory intubating conditions but increased time to intubated with the Ambu® aScope™ (377, 378). Two studies have performed cost comparisons and found re-usable bronchoscopes to be more cost efficient (176, 379).

Non-standard laryngoscopes and rigid fibreoptic intubation aids

Rigid fibreoptic intubation systems can be classified into three groups:

1. Devices based on conventional laryngoscopes with a blade. This group includes modified blades for direct laryngoscopy such as the Flexiblade™, McCoy and McMorrow. Another group in this category includes the Bullard®, WuScope, Upsherscope and more recently the Viewmax™ and Truview™ which feature light-bending blades for indirect laryngoscopy. The McGrath™, Berci-Kaplan™, C-

See Appendix five for a list of devices.
MAC™ and Glidescope™ are video laryngoscopes which allow indirect laryngoscopy and then require independent endotracheal tube and stylet for intubation.

2. Fibreoptic optical stylets placed within the endotracheal tube including the Bonfils®, Shikani™, Levitan™ and Foley®.

3. Devices for indirect laryngoscopy with an optical blade and a conduit for the endotracheal tube including the Pentax-AWS®, King Vision™, VividTrac® and the Airtraq®.

A number of large case series and prospective randomised trials involving patients with difficult airways have been reported concerning new intubation devices with favourable results when compared to Macintosh direct laryngoscopy (73, 238, 380-385). Evidence is still lacking to support the replacement of standard laryngoscopes with non-standard devices for routine or difficult intubations and the results of large multicentre clinical trials of new airway devices are required (386). When selecting non-standard laryngoscopes and rigid fibreoptic intubation aids, consideration should be given to the indications and application of each device, particularly the ability to maintain oxygenation and ventilation during use. Each device offers different features such as ETT guidance systems, working channels, disposability and a range of sizes, which may determine their clinical suitability (170).

The rigid ventilating bronchoscope is a valuable device for failed ventilation, particularly in the presence of foreign bodies, vomit, blood, or airway tumours, such as mediastinal masses. Unlike the flexible bronchoscope, the rigid bronchoscope can be used to ventilate a patient.

**Confirmation of tracheal intubation**

Unrecognised oesophageal intubation remains a leading cause of death and brain damage in anaesthesia and emergency medicine. This problem can occur with experienced, skilled anaesthetists as well as junior staff. Endobronchial intubation and inadvertent extubation are also common adverse events in adults and children.

The Australian Incident Monitoring Study (AIMS) (217) documents that 85 of the first 2000 incidents reported (4%) had difficulties with intubation. Oesophageal intubation (18 cases) was the commonest complication reported. In a recent review of the ASA Closed Claims database from 1993 to 1999 (127), difficult airways were encountered throughout the perioperative period. Seven percent of the perioperative claims occurred in the recovery period and 67% of these resulted in death or brain death. Outside locations were the site for 13% of claims for difficult airway management problems in the ASA database (127). Recovery rooms, off-the-floor locations and difficult intubation containers are often poorly equipped to detect oesophageal intubation (169). Other contributing factors include suboptimal conditions, poor technique and inexperienced staff. Confirmation of correct tracheal intubation should occur with every case. Techniques and equipment for this important

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diagnostic step should allow the practitioner to rapidly and confidently confirm endotracheal intubation, even in the presence of cardiac arrest. Unfortunately there is no ideal test for correct endotracheal tube placement.

The only reliable methods of confirming tracheal intubation are visualisation of tracheal rings and carina with a flexible bronchoscope, and visualisation of the endotracheal tube passing through the vocal cords. Confirmation of tube placement with a range of tests including CO₂ monitoring with capnography, oesophageal detection devices such as the self-inflating bulb and syringe, and colorimetric CO₂ detection devices may be useful, but can all yield false results (387). Capnography is required in all operating rooms and is the standard for identification of endotracheal tube placement; however, it is associated with false positive and false negative results and capnographs are not always present in non-operating room environments (169). Oesophageal detector devices, such as the oesophageal syringe and self-inflating bulb, are inexpensive, disposable, small devices which are quick and easy to deploy and are more accurate than carbon dioxide detection methods in the presence of cardiac arrest. These devices can complement carbon dioxide detection and are examples of equipment redundancy, which is valuable when capnography results are negative or equivocal (388). The self-inflating bulb is appropriate for adults and children (389, 390).

**Cricothyroidotomy**

Equipment for emergency tracheal access is mandatory and should be immediately available at every operating site. This equipment is required whenever acceptable levels of oxygenation cannot be maintained using ventilation by face mask or extraglottic device, or endotracheal intubation.

Cricothyroidotomy is the technique of choice for adult emergency surgical airway access because of its speed, simplicity and safety. Supporting literature for various cricothyroidotomy techniques is very limited and consists of heterogeneous case series, mannequin studies, animal studies and expert opinion. There is no strong evidence to support one technique over another.

In adults there are three methods to achieve oxygenation and ventilation via the cricothyroid membrane (391).

1. Surgical airway allowing a large lumen endotracheal or tracheostomy tube. Preferably this tube should be cuffed, allowing low pressure ventilation. For an adult cricothyroidotomy, the outer diameter of the endotracheal tube should not exceed 8mm (6mm ID) (157).
2. Large cannula (>4mm) cricothyroidotomy set, often inserted using a Seldinger technique, enables ventilation with low pressures, results in little entrainment and requires a cuffed tube or obstructed upper airway for optimum ventilation with low lung compliance (392).
3. Small cannula (2-3mm), requires high pressure gas source, relies on a patent upper airway and entrainment may augment the inspiratory flow.

See Appendix five for a list of devices.
Expert opinion regards surgical cricothyroidotomy as the “gold standard” with the advantages of a cuffed tracheal tube allowing a high minute volume with low pressure ventilation using readily available inexpensive equipment (393).

Large cannula cricothyroidotomy is favoured by some anaesthetists who prefer percutaneous needle access with a Seldinger technique (156).

Small cannula cricothyroidotomy was favoured by 51% of respondents in a Canadian survey (135). However this survey was repeated in 2013 with a decrease in support for cannula cricothyroidotomy to 28% (personal communication Dr David Wong); specialised cannulae with a low tendency to kink should be used (394) and a high pressure gas source that is pressure regulated (i.e. Manujet III), or flow regulated (Enk oxygen flow modulator) is needed. Flow adjusted volume ventilation can be achieved with the Enk oxygen flow modulator (OFM), and ventilation comparable to the Manujet III has been achieved in animal studies (146, 147). There are no human data supporting the use of the Enk oxygen flow modulator. The Enk OFM has the advantage of being a small, light-weight, disposable item suitable for a portable equipment container; however, it requires a pressurised oxygen source and flow meter.

One CICV algorithm emphasises early oxygenation by cannula cricothyroidotomy or cannula tracheotomy and jet ventilation. Failure of this technique should lead to either surgical cricothyroidotomy if airway anatomy is palpable, or, if not, a scalpel incision and blunt finger dissection leading to cannula cricothyroidotomy and jet ventilation. Subsequent ventilation options then include either a cuffed large cannula cricothyroidotomy tube or a size 6.0 mm cuffed endotracheal tube (134).

There is currently no robust evidence supporting the use of cannula cricothyroidotomy. Similarly, there is no robust evidence suggesting that large cannula commercially available kits are better than a surgical technique (133). Two recent systematic reviews found no evidence to support one cricothyroidotomy technique over another (132, 133); however, many studies reviewed were small or had very low quality evidence. A meta-analysis of prehospital cricothyroidotomy techniques found a much higher success rate for surgical cricothyroidotomy (90.5%) than cannula cricothyroidotomy (65.8%). The NAP4 study reported a very low success rate for cannula cricothyroidotomy (37%) performed by anaesthetists (n=19) compared to emergency surgical airway performed by surgeons (n=33) with 100% success. This result may reflect reporting which was bias toward unsuccessful outcomes, but, the magnitude of this result is concerning.

A cricothyroidotomy should be instituted early in the management of CICV in order to achieve a successful outcome (127). This requires clinical expertise and rapid deployment of appropriate equipment.

See Appendix five for a list of devices.
Paediatric CICV

When selecting an appropriate paediatric emergency invasive airway technique, consideration should be given to both the practicality and safety of the surgical procedure as well as the appropriate form of ventilation. The SIAARI Study Group, published a detailed evidence-based “recommendations for airway control and difficult airway management in paediatric patients”, which states that “It is mandatory to perform rapid tracheal access or transtracheal jet ventilation in emergency situations, whenever oxygenation cannot be granted with other devices”. Supporting evidence are at level D & E on the Delphi list (209).

Current opinion suggests that the techniques of choice for paediatric CICV are either transtracheal needle ventilation or tracheostomy (209, 395-397). Some authors suggest specific techniques are age-related, with cricothyroid needle and bag ventilation from birth to 5 years of age, cricothyroid needle and jet ventilation from 5 to 10 years of age, and open cricothyroidotomy over 10 years of age (398). Unfortunately, many aspects of these recommendations are as yet unsupported by evidence.

Insertion of a needle through the cricothyroid membrane in a child under the age of five is technically difficult because surface landmarks in children are more difficult to palpate and identify. In the neonatal age group, the cricothyroid membrane is small and the larynx is prone to cartilaginous damage during paediatric cricothyroidotomy (399). The paediatric airway is malleable and prone to injury of the laryngeal mucosa, posterior perforation and subglottic stenosis (157).

The successful use of paediatric transtracheal ventilation, below the cricothyroid membrane has been reported (400, 401). Successful transtracheal cannula ventilation with a bag has not been validated in children. A lung model study using 10 L/min of oxygen through a Mapleson C circuit and a 13 G Ravussen needle, failed to generate a minute volume of more than 3 L/min, with a range of upper airway resistances (402).

A high pressure gas source is required to overcome high resistance found in transtracheal cannulae. Suggested ventilation devices include a pressure regulated injector, such as the Manujet III, and a flow regulated injector such as the Enk OFM. Pressure regulated devices, in the presence of small lung volumes, can deliver high tidal volumes with potentially dangerous airway pressures (402). Devices such as the Manujet III provide pressure ranges on the regulator for different age groups (baby 0-1 bar (0-14.5 psi or 0-100 kPa), infant 1-2.5 bar (14.5-36.3 psi or 100 – 250 kPa), adult 2.5-4 bar (36.3-58 psi or 250-400 kPa)). Transtracheal jet ventilation following emergency cannula cricothyroidotomy was associated with barotrauma in 89% of claims from the ASA closed claim study of 179 claims of difficult airway management including 26 cases of needle cricothyroidotomy. All of these cases had a poor outcome (127).

Self-made devices using oxygen tubing and a three way tap (403) have been criticised because of wasted assembly time (219), legal implications and inadequate capability as a bidirectional airway leading to potentially dangerous continuous gas flow (148, 404, 405), and are therefore not recommended.

See Appendix five for a list of devices.
In the presence of significant upper airway obstruction adequate lung deflation is of critical importance, in order to avoid severe morbidity (391). Exhalation of 500ml of gas through a 14 G cannula can take 30 seconds (219).

The Ventrain (Dolphys Medical, Eindhoven, The Netherlands) is a single-use, manually operated, small lumen ventilation device which functions on the Bernoulli principle utilizing a controllable oxygen source such as a pressure-compensated flow meter (151-153). The Ventrain is capable of oxygen insufflation and expiratory ventilation assistance (EVA). The latter occurs when the bypass channel in the Ventrain is occluded. This creates a subatmospheric pressure (up to -217 cm H₂O) at the side port. Active expiration can then occur through the narrow bore cannula. A case report describes the successful use of the Ventrain in a patient with near total upper airway obstruction from an exophytic glottis tumour. This device may have an application as an emergency ventilation device but negative pressures are only achievable clinically if total proximal airway obstruction exists. Use during partial airway obstruction may be limited unless the upper airway can be artificially obstructed.

The Advanced Paediatric Life Support (APLS) guidelines (406) recommend setting oxygen flow at 1 L/min/year of age through a Y-connector. An I:E ratio of 1:4 is then recommended with a respiratory rate of 12 bpm. These flows have been experimentally validated using an Enk OFM and adjusting the formula to 1L/min/year for a tidal volume of 7 ml/kg (144). Flows above 15 L/min could be potentially dangerous with the Enk OFM which then fails to perform as an on-off device.

Cricothyroidotomy sets, such as the small Melker (3.5 mm ID, 3.8 cm length) (Cook® Medical Inc, Bloomington, USA), are commercially available, but this device is too large and potentially traumatic to laryngeal cartilages for children under five years of age. Product information states that use with paediatric patients should be determined by the attending physician.

A study by McLaughlin et al (407) describes a technique of emergency paediatric percutaneous tracheostomy. This technique uses a needle to locate the trachea first. Toye presented cases using a similar technique (131).

Paediatric transtracheal and cricothyroidotomy airway devices have recently been reviewed and paediatric airway practice guidelines from the Association of Paediatric Anaesthetists of Great Britain and Ireland (APAGBI) have been published (139, 397).

**Sugammadex**

Sugammadex antagonises profound neuromuscular block produced by aminosteroid neuromuscular blocking agents (rocuronium and vecuronium) (408, 409). Sugammadex is ineffective in antagonising succinylcholine and benzylisoquinolinium neuromuscular blockers, such as mivacurium, atracurium, and cisatracurium(410).

See Appendix five for a list of devices.
Sugammadex will facilitate the safe use of rocuronium for rapid sequence induction of anaesthesia by providing a faster onset-offset profile than that seen with 1.0 mg/kg succinylcholine. However, rapid reversal of profound neuromuscular blockade is only one aspect of the management of a CICV scenario. Oxygenation of the patient remains the priority in this situation and the administration of sugammadex should not delay this urgent requirement. One should also be mindful that reversal of neuromuscular blockade could make ventilation, intubation (411), or a surgical airway more difficult, and a delay in the management of oxygenation could have a detrimental effect, as seen when waiting for succinylcholine to wear off (412). There are now case reports where the administration of sugammadex failed to adequately restore spontaneous ventilation in a timely manner during a CICV situation (413, 414). The reversal of other administered drugs such as intravenous induction agents, narcotics and volatile agents should also be considered.

Thus the use of sugammadex should not unduly delay performing an emergency surgical airway or carrying out other life-saving procedures as indicated.

**Conclusions**

When confronted with an unexpected difficult airway, a carefully selected range of equipment is essential for successful and safe patient outcomes. This equipment needs to be checked, in good working order and readily available to hand. There is no magical device or technique that will be suitable for all airway problems, so a range of equipment is required. Appropriate airway equipment must be matched with procedural skill. Ideally, equipment should be chosen that has proven efficacy and is familiar to the practitioner. PS56, 2012 provides guidance on the minimum equipment needed for managing unexpected difficult airways, based on expert consensus underpinned by the best available evidence.

**Postscript**

This background paper was first published in 2011 in *Anaesthesia and Intensive Care* and, since then, has remained the most viewed article in that journal (150).

In the last two years, significant changes have occurred with equipment to manage airways. Most notable have been the proliferation of video laryngoscopes and supr glottic airways and the steady trend toward single-use items, such as laryngeal masks and the Ambu® aScope™. With the increasing popularity of these products, other devices, such as the flexible bronchoscope, have become less popular (415). Some products, such as the Trachlight™, the LMA CTrach™ and the Berman airway, have been withdrawn, while other equipment, such as the Bullard® laryngoscope, is steadily becoming redundant.

The relatively rapid change in airway equipment over the last two years suggests that airway management equipment should be regularly reviewed and evaluated. New products need to be assessed and compared with

See Appendix five for a list of devices.
“gold standards” in the context for which they are designed. New equipment should be carefully considered before purchase to ensure that it is fit for purpose and that it satisfies minimum standards, as outlined in the Difficult Airway Society (DAS) Airway Device Evaluation Project Team (ADEPT) study (195). The content of difficult airway containers and grab bags needs to be checked to ensure that equipment is up to the standards described in PS56, 2012.

Practice guidelines need to be revised at regular intervals to ensure that they are offering advice that is appropriate, evidence-based and up-to-date. These revisions should occur within five years of publication (416).

It would be informative to assess the impact of the PS56, 2012 on clinical practice. This could be done by re-auditing the airway management equipment in our region. Such an audit might also confirm trends in device usage.

See Appendix five for a list of devices.
Chapter 4. Education in airway management


Preface

This chapter was a review article in a special edition of Anaesthesia in 2011 devoted to airway management (417). The review relied on a detailed summary of current literature; however, this was not a systematic review. The timing of this publication coincided with the release of the The Fourth National Audit Project of the Royal College of Anaesthetists (RCoA) and the Difficult Airway Society (DAS) (NAP4) which concluded that deficiencies in education and training were major contributory factors to significant patient morbidity and mortality. As lead author of this review article I researched the subject, wrote the first draft of the paper and supervised all subsequent revisions prior to publication.

Abstract

Poor judgment, education and training are leading causes of patient morbidity and mortality associated with airway management. The traditional model of medical education, which relies on experiential learning in the clinical environment, is inconsistent and often inadequate.

Curriculum change is under way in many medical organisations in an effort to correct these problems and management of the airway is likely to be explicitly addressed as a clinical fundamental within the new anaesthetic curriculum. Competency based medical education with regular assessment of clinical ability is likely to be introduced for all anaesthetists engaged in airway management.

Essential clinical competencies need to be defined and improvements in training techniques can be expected based on medical education research. Practitioners need to understand their equipment and diversify their airway skills to cope with a variety of clinical presentations. Expertise stems from deliberate practice and a desire to constantly improve performance. Expert airway management by anaesthetists requires a career-long commitment to education and should include knowledge, skill and human factor training.

See Appendix five for a list of devices.
Introduction

Inadequate skill and poor judgement in airway management continues to lead to avoidable brain damage and death in occasional patients (3). The expert panel that reviewed 184 cases of major airway complications in The Fourth National Audit Project of the Royal College of Anaesthetists (RCoA) and the Difficult Airway Society (DAS) (NAP4) (3), concluded that poor judgement (59%) and education/training (49%) were the second and third most frequent causal and contributory factors (after patient factors; 77%). Difficult or delayed intubation, failed intubation and ‘cannot intubate, cannot ventilate’ (CICV) situations accounted for 39% of events during anaesthesia. Deficiencies in airway assessment, under-utilization of awake intubation, inappropriate use of supraglottic airway devices (SGAs) and evidence of poor airway management planning were also noted. In a review of litigation related to anaesthesia in National Health Service (NHS) Hospitals in the UK from 1995 to 2007, airway and respiratory related events accounted for 12% of all anaesthesia claims, 53% of deaths and 27% of cost, and were involved in 10 of the 50 most expensive claims (418).

These studies contain important messages which should help direct training in airway management towards improved patient care. Our aim in this review is to assess current training practice and discuss proposals to improve education in airway management in the future.

Traditional approach to learning airway management

“We now accept the fact that learning is a lifelong process of keeping abreast of change. And the most pressing task is to teach people how to learn”.

Peter F. Drucker (419).

The traditional apprenticeship model of medical education, based on experiential learning in the clinical environment, is more than 100 years old (420). The operating room (OR) environment can provide opportunities for safe and deliberate practice of airway technique in patients with varied anatomy, pathology and physiology (421). This has been, and remains, the most common form of training in airway management skills in anaesthesia. Apprenticeship training, however, is ad hoc, with varying and unpredictable exposure to appropriate cases, and consequent safety and ethical issues. Furthermore, opportunities to learn advanced airway skills are diminishing through increased use of the laryngeal mask airway, regional techniques, reduced training hours and pressures on clinical placements (422-424). Care for the patient can be compromised during training in the operating room (OR). The workload of the instructing anaesthetist is increased during teaching, and vigilance may decrease (425). Some exercises devised for OR airway training can, in fact, increase risk and may be considered unethical. These include choosing to place a tracheal tube, when an SGA would otherwise have been selected, to increase learning opportunities; or deliberately limiting the laryngoscopic view to practice more difficult intubations (426-429). Potential for patient harm during this early part of the learning

See Appendix five for a list of devices.
curve, and the question of whether consent from patients is needed, raise important practical and ethical issues (430). Intubation via direct laryngoscopy, for example, is a complex technical skill (431): its success rate is only 50% in novices (432) and a rate of 90% cannot be expected until 50 attempts have been made. Moreover, 18% of trainees still require assistance after 80 attempts (433). The limitations outlined in teaching laryngoscopy affect the time it takes for trainees to achieve an acceptable level of safe, unsupervised practice.

The challenges associated with developing and maintaining airway skills are not restricted to trainees. Many senior anaesthetists will have honed their airway skills on the job, through trial and error. Many are self-taught and have adopted flexible bronchoscopy and the use of SGAs or rigid indirect intubation devices without any formal instruction (223). As senior practitioners, they are assumed to be experts on the basis of their many years of practice. In reality, the quality of technical care tends to deteriorate over years unless regular deliberate practice is maintained (434). In one study, younger anaesthetists out-performed their older colleagues on all categories of measurement when performing cricothyroidotomy (435). Knowledge and skills decay over time, but this decay can be arrested by practice (436, 437). In a national survey of 386 anaesthetists, the average number of fibreoptic intubations performed per year was three for consultants and four for registrars. A paucity of appropriate clinical cases and, therefore, of opportunities for practice, was considered the primary barrier to development of this complex skill (223).

Anaesthetists need to be skilled in a variety of techniques in order to manage a range of clinical presentations (438), but there is a tendency to limit skills to a few core techniques. Several surveys reveal a limited use of intubation techniques other than direct laryngoscopy, and inexperience with awake fibreoptic intubation and cricothyroidotomy (439-441). It is encouraging that the number of techniques and devices available for managing difficult airways has increased dramatically over the last three decades, but this has also made it more difficult to acquire and maintain the broad range of airway skills that might reasonably be expected of an anaesthetist today. Inadequate knowledge contributes to the problem: for example, the ability to identify the cricothyroid membrane (44) or properly understand the Cormack Lehane classification (442).

While standardization of equipment is associated with improved performance and patient outcomes (443), it is infrequently done. New airway devices are often adopted without formal teaching and without practitioners reading instructions (444). Practitioners teach themselves, often without applying best practice (223). This can lead to poor techniques and harm to patients (445, 446). Educators need to improve training in airway management while practitioners’ skills need to be diversified to an adequate level of expertise without harming patients.

**Developing expertise in airway management**

Anaesthetists claim to be airway experts, but is this justified? Ericsson argues that while experience is part of being an expert, experience alone does not guarantee expertise. Ericsson has identified consistent behaviours which shape expertise and superior performance in non-medical domains such as sport and music (447). See Appendix five for a list of devices.
Deliberate practice, immediate feedback, problem-solving and evaluation with the chance to repeat performance and modify behaviour are essential ingredients in the attainment of expert performance (448). These concepts apply equally to the development of airway skills. The learning curve for most airway devices is biphasic: reasonable competence can be achieved within 30 cases, but performance continues to improve even after 100 cases (449). It is during this early phase of learning that individuals pass through the cognitive and associative phases where development is enhanced by teachers, trial-and-error and problem solving. Eventually performance plateaus, procedures become effortless and a state of automaticity is reached. Ericsson cautions that this automaticity can lead to arrested development rather than continuing enhancement of expertise. The danger is that, once a behaviour has become automatic, it is difficult to modify: Ericsson cites the tying of shoelaces as one such automated behaviour. If direct laryngoscopy becomes automated, it may be difficult to modify one’s technique to cope with a rare or unexpected situation. A patient with a difficult airway demands an anaesthetist who has the ability to modify his or her technique as necessary. The risk is that, without deliberate practice, many practitioners will not advance beyond the stage of automaticity, and will perform at a mediocre level for the rest of their careers (Figure 4.1).

Advanced expertise requires increased control over performance. Experts counter arrested development by deliberately and regularly seeking challenges outside their comfort zone as opportunities for deliberate practice. Such practice should be distributed at regular intervals over a prolonged period of time (450). Deliberate practice may be integrated into clinical practice but it can perhaps be more readily obtained in skills laboratories which provide the opportunity to accelerate learning through simulation. For anaesthetists to retain the mantle of airway experts, they need to be constantly striving to improve performance.

See Appendix five for a list of devices.
Chapter 4. Education in airway management

Figure 4.1  Illustration of the qualitative difference between the course of improvement of expert performance and of everyday activities.

The goal for everyday activities is to reach as rapidly as possible a satisfactory level that is stable and “autonomous”. After individuals pass through the “cognitive” and “associative” phases, they can generate their performances virtually automatically with a minimal amount of effort (see the grey/-white plateau at the bottom of the graph). In contrast, expert performers counteract automaticity by developing increasingly complex mental representations to attain higher levels of control of their performance and will therefore remain within the cognitive and associative phases. Some experts will at some point in their career give up their commitment to seeking excellence and thus terminate regular engagement in deliberate practice to further improve performance, which results in premature automation of their performance (adapted from Ericsson (451)).

With kind permission from Professor K.A. Ericsson, and the publishers.

Defining the Airway Curriculum

Many organisations involved in training doctors in general, and anaesthetists in particular, have engaged in reviewing their curricula over recent years. Notably, the Australian and New Zealand College of Anaesthetists (ANZCA) is currently undertaking a comprehensive curriculum review (ANZCA Curriculum Redesign Project) (452). A key feature of the revised curriculum of this College is likely to be the identification of clinical fundamentals for anaesthetists, of which airway management is one. The intent is to ensure that anaesthetists achieve and formally demonstrate appropriate levels of competence in a defined set of learning outcomes within these clinical fundamentals at each stage of their training before advancing to the next stage. Airway management will be explicitly addressed within the curriculum, and expected competencies at different stages of training will be defined (Table 4.1), with a series of assessments to ensure these are attained. Initiatives are also being considered by ANZCA to ensure that these essential competencies in airway management are not

See Appendix five for a list of devices.
only acquired in training, but also maintained after graduation as a specialist. Comparable developments have occurred within the Royal College of Anaesthetists.

Table 4.1 An example of a minimal skill set to be acquired by a trainee during an airway rotation.

<table>
<thead>
<tr>
<th>Skill Set</th>
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<tbody>
<tr>
<td>Optimal bag-mask ventilation technique.</td>
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<tr>
<td>Optimal direct laryngoscopy and intubation with a range of laryngoscopes</td>
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<tr>
<td>and intubation aids.</td>
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<tr>
<td>The use of supraglottic airways.</td>
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<tr>
<td>The use of rigid optical devices including video laryngoscopes and</td>
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<tr>
<td>optical stylets.</td>
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<tr>
<td>The use of flexible bronchoscopes</td>
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<tr>
<td>Cricothyroidotomy.</td>
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**A staged approach to developing airway expertise**

With the advent of airway management as a clinical fundamental within the curriculum, more airway training programmes will be required. Formal programmes in airway management have already been in existence for many years. The number of airway residency programmes in the US and Canada has increased over the last 16 years, and their content and modes of teaching have evolved (453). A graduated system of training which reinforces and expands participants’ existing knowledge and skills is ideal. Course content should follow a syllabus reflecting guidelines and best practices (Table 4.2).

See Appendix five for a list of devices.
Table 4.2 Topics that might be included in an airway management programme.

- Airway anatomy and physiology.
- Assessment of the airway.
- The maintenance of oxygenation and ventilation.
- Avoidance of trauma during airway management.
- Use of pre-planned strategies.
- The importance of calling for help and when to do this.
- Airway algorithms.
- Management of known and unexpected difficult airways.
- Establishment and confirmation of an open airway.
- Awake intubation.
- Rapid sequence induction.
- Intubation via a supraglottic airway
- Retrograde intubation.
- Emergency techniques for cannot ventilate cannot oxygenate situations.
- Extubation strategies.
- Dissemination of information concerning the critical airway.
- Human factor training in relation to airway management.

Numerous airway guidelines have been published internationally with varying emphasis and content, and these have been recently reviewed (48, 416). It is important that guidelines are regularly updated, are based on good evidence and are developed in accordance with methodological standards (235), especially if these guidelines are to be used to evaluate a doctor’s practice (454). Courses should include background reading material (which can be provided electronically) to support course content and provide core information. Airway training programmes often depend on institutional support and funding. It is helpful for institutions to appoint coordinators to act as champions for these programmes (455, 456).

A best practice approach should be adopted when teaching skills (180, 457). Techniques and equipment to be included in the training program should comply with guidelines (458) and be reflected in the practices and equipment held in local hospitals. Teaching should take into account the level of expertise of the learner. In an ideal setting novices should start their training on part task trainers in an airway training room, then progress through more sophisticated modalities, perhaps using cadavers or anaesthetised animals, or animal tissue preparations (134, 459-462). They should then progress to clinical training under supervision once they have achieved competence using simulation. Each of these approaches has advantages and disadvantages including cost, the requirement for ethics committee approval and potential morbidity. Awake fibreoptic intubation can be practised on volunteers (463), but we have reservations about subjecting trainees to procedures with a risk of

See Appendix five for a list of devices.
morbidity, even with their permission (374). A comprehensive review of teaching techniques has been provided by Stringer (464).

Understanding the function and limitations of airway equipment is fundamental to safe airway management. The tendency to pick up new devices and work out how to use them from first principles can lead to patient harm. Coroner’s cases have been reported where anaesthetists were unable to assemble emergency equipment (465). Use of improvised emergency equipment can lead to delays in patient care or poor outcomes (219, 405). Guidelines have been published which emphasize standardization of equipment, whilst still providing a range of alternative devices to cope with unusual circumstances, and quality control measures to promote a culture of safety (458). Suggestions have been made to 'sign off' practitioners to use new equipment only after they have demonstrated competence in its use (466). Parallels can be found in other clinical areas – for example, approval to perform percutaneous carotid artery stenting is now dependent on relevant simulation-based training by physicians (467).

Video can enhance training, and in particular can help to demystify direct laryngoscopy (468) and fibreoptic intubation. One example of this is the Airway Cam™ Direct Laryngoscopy Video System (Airway Cam Technologies, Inc, Wayne PA USA) which consists of a head mounted camera designed to display the laryngoscopist’s view on a screen for trainees or supervisors to see (469). Airway Cam™ images have been recorded for training digital versatile discs (DVDs) and for hands-on instruction (432, 468). Video can also facilitate assessment with global rating scores (470). A number of studies describe the benefit of imaging the larynx with video laryngoscopes to assist instruction during training in laryngoscopy (471-474).

Advancement of airway skills beyond the proficiency needed for routine anaesthetic practice requires opportunities for dealing with patients whose airways are more challenging. Airway fellowships provide such opportunities and also allow senior trainees to engage in relevant research, teaching and the development of advanced clinical skills. Graduates from such fellowships serve as a resource to promote and provide education in airway management (455). Airway workshops have been in existence for decades (475) and vary in content. They are usually run by enthusiasts and often focus on techniques such as flexible bronchoscopy, cricothyroidotomy or direct laryngoscopy (134, 432, 463). Participants at such workshops report improvements in accuracy and confidence with airway evaluation, adoption of previously unfamiliar airway devices and changes in practice related to managing patients with difficult airways (476). However, unless the learner follows the workshop with ongoing deliberate practice the benefits may be short-lived; providing airway laboratories in the workplace may be an effective way of facilitating this. There is considerable interest in taking simulation to the clinical environment (477).

See Appendix five for a list of devices.
The potential for simulation to enhance learning

Simulation provides a way of teaching and evaluating technical and cognitive skills (including skills related to human factors) outside the operating room, without risk to patients and away from the pressures of clinical work.

The range of simulators for use in anaesthesia is wide. As indicated above, certain basic skills can be acquired using very simple simulators (478) while more sophisticated simulators offer opportunities to achieve advanced educational objectives (479). Although part-task trainers can be useful to teach airway techniques such as SGA insertion, direct laryngoscopy and other procedures described in airway algorithms (480, 481), educators should be careful when choosing models and manikins, to ensure that they have adequate fidelity and are fit for purpose. Some manikins have been criticised as unrealistic with poor laryngeal anatomy, rigid structures and inability to simulate reversible airway obstruction (481, 482). There is unequal performance for different types of manikins using various SGAs (483). Training conditions provided by manikins are not necessarily the same as in patients, and the use of some SGAs by novices is more difficult in patients than manikins (484). Careful analysis of training needs should be applied before acquiring appropriate simulators. In order to effectively teach each step of the DAS guidelines, for example, more than one type of airway training model is required (481, 485). An advantage of using a variety of manikins is the finding that trainees tend to adapt their skill to a particular manikin, and therefore providing them with variety of manikins can lead to a broader range of skills (486).

Simulation can compensate for inadequate clinical experience by providing the opportunity to perform multiple repetitions of a procedure over a short period of time. In a study using the Accutouch® flexible bronchoscopy simulator, novice residents performed an average of 17 oral fibreoptic intubations in 39 minutes, and demonstrated significant improvement in clinical dexterity with the flexible bronchoscope after this relatively brief period of training (487). Simulators allow trainees to advance at their own rate and training can be tailored to specific tasks and procedures (433, 488). Simulation may have a role in identifying deficiencies in practitioners and contributing to their retraining (489).

In general, simulation in anaesthesia has high face validity and participants tend to enjoy simulation-based education, but improvement in patient outcome consequent to its use in training is not well established. Simulation is usually expensive, and its cost-effectiveness in relation to alternative educational methods has not been well established, although the advantages outlined above may lead to financial savings: for example, training using simulators can reduce repair costs for fibreoptic equipment by up to 84% (490). Standards in relation to simulators and simulation facilities have been slow in coming (491).

See Appendix five for a list of devices.
**Human factors, systems and team: impact on airway management**

Sound knowledge and skills are not enough to ensure safe management of the airway. Training in human factors is also important. Human error is implicated in as many as 80% of anaesthetic incidents (492). In the Australian Incident Monitoring System (AIMS) study, data from anonymous incident reporting was analysed and categorized. Human failures which included error of judgment, failure to check, fault of technique, other equipment problems, inattention, haste, inexperience, and communication problems were found in 83% of reports (493). Poor communication and teamwork were amongst the factors contributing to airway misadventures in the NAP4 study (3). Effective teamwork is important in airway management, and so is the ability to make appropriate decisions in good time; there is evidence that even experienced practitioners may feel considerable reluctance to progress to a surgical airway in an emergency, and more work is needed to find effective ways to address this reluctance (127, 494).

In recognition of the importance of human factors in the management of anaesthetic crises, the Australian and New Zealand College of Anaesthetists commissioned the development of a course, the Effective Management of Anaesthetic Crises (EMAC). This 2½ day, simulation-based course includes a strong theme of human factors and teamwork training. A half-day of this course is dedicated to management of airway crises, and includes skills stations, airway drills, and instruction on human error and decision making. This is reinforced in immersion simulations of critical events, using a whole-body computerized manikin, followed by debriefing and facilitated reflective learning. (495). The aim is to ensure anaesthetists are ready, willing and able to intervene effectively in airway crises, and in fact to recognise potential problems to avoid adverse events. While EMAC is now a compulsory component of training, and recognised for continuing professional development, consideration could be given to regular, compulsory training for anaesthetists in airway management similar to the requirements of aviation pilots.

One of the key steps in managing a difficult airway is to call for help. Trained anaesthetic assistants have been shown to improve safe management of simulated anaesthesia crises (496) and their help may be particularly useful provided they understand their role in the management of difficult airways. Anaesthetists and their assistants need to be familiar with their environment, and particularly with the required equipment and its whereabouts in their own institution. It is therefore worrying that an audit of airway management equipment in a metropolitan region in New Zealand found that 20% of anaesthetic and non-medical staff had never been orientated to the difficult airway container and did not know the contents (169). It is likely such deficiencies exist in many other countries.

It is useful to consider techniques used by the airline and other industry to mitigate the risk of human error. Standard operating procedures and checklists are an integral part of safe practice in many high reliability organisations, internationally (497). Relevant checklists for anaesthesia and surgery include the “Crisis Management Manual” from the Australian Patient Safety Foundation (498), a new crisis checklist from Gawande’s group at the Harvard School of Public Health (499) and the World Health Organisation’s Safe Surgery Checklist, which includes an airway component (500). NAP4 also recommended use of checklists and

See Appendix five for a list of devices.
standard operating procedures for a number of circumstances such as intubation outside the operating theatre and rescue of the inadvertently dislodged airway in ICU [1]

**Assessment of airway competence**

An essential element of any airway curriculum is assessment. Practitioners have a personal, professional and ethical responsibility to maintain their own competence, and the discharge of this responsibility has traditionally emphasised self-regulation (501). Unfortunately, doctors are not good at assessing their own performance (502). They tend to overestimate their own ability, and this tendency is often strongest in those individuals with the lowest competence (503). Some training programmes require trainees to record their experience in log books, but self-reported log books are unreliable and their validity as a tool for assessing competence has not been well established (504). Direct observation of performance using validated assessment tools, incorporating checklists or rating scales, is more reliable (505), but more work is needed to validate approaches to the summative measurement of anaesthetists' performance, including work on faculty development (506).

Periodic assessment and re-certification of competency, using validated workplace evaluation tools (507), are reasonable expectations in competency-based approaches to training and the maintenance of skills (454, 508). Participation by anaesthetists in approved continuing professional development programmes is now required in many countries, but few of these programmes appear to mandate demonstration of competence in managing difficult airways. Mandatory competency-based difficult airway management training at the University of Pittsburgh is linked to practising privileges (509). Whether demonstration of such skills will form a part of re-validation for anaesthetists in the UK is yet to be determined. However simulation can be expected to have an increasingly important role in assessment in the near future. Hesitancy to adopt simulation in this way has been grounded in concerns that assessment of this type needs to be reliable, valid, feasible, and cost-effective (505).

It is worth comparing the situation in anaesthesia with that in the airline industry. Commercial airline pilots are required to pass assessments integrated into their regular, competence-based training in flight simulators in order to retain their license to fly. If they fail, they are taken off flying, but in the first instance, intensive remedial training usually follows with the aim of reinstating the license as soon as possible. This is an important philosophical point – the aim is not to remove their ability to work; rather it is to ensure that they are competent to do so safely. This is, therefore, less draconian than at first it might appear, and provides a model that has much to offer in anaesthesia (and more broadly in medicine). It could be argued that simulation-based evaluation used in this way would add value in supplementing current methods of assessing competence.

See Appendix five for a list of devices.
Conclusion

Education in airway management is undergoing a much-needed change. The introduction of Competency Based Medical Education and the explicit definition of airway management in the curriculum as a clinical fundamental should lead to greater formalization of airway training programmes. We can anticipate improvements in training techniques as a result of research into medical education. Trainees can expect the assessment of their competence in airway management to become much more rigorous in the near future. Regular reassessment of this competence is likely to become the norm for both trainees and qualified practitioners.

These changes will affect all anaesthetists. A career-long commitment to relevant education and maintenance of skills is clearly integral to the credibility of anaesthetists’ claim to being experts in airway management.

Postscript

Since the publication of this review article, ANZCA have released their new curriculum. Specific requirements for training have been defined. The curriculum is designed to develop airway management skills in a graduated fashion throughout registrar training. The introduction of competency-based medical education requires valid, reliable and practical methods of assessment.

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Chapter 5. Thyromental distance measurement – fingers don’t rule


Preface

Assessment of the airway is the first step toward safe airway management. The thyromental distance measurement was first described by Patil in 1983, which was the same year Mallampati described a bedside test for difficult intubation. These tests are now used widely, despite their low predictive value. Poor technique contributes to this poor predictive value and, in the case of the thyromental distance, inaccurate methods of measurement, using fingers, are still being advocated in practice guidelines. I examine the application of this bedside test for difficult intubation and report my findings in this chapter. As lead author, I conceived and designed this study, collected data, assisted in analysis of the results, researched the subject, wrote the first draft of the paper and supervised all subsequent revisions prior to publication.

Abstract

Thyromental distance (TMD) measurement is commonly used to predict difficult intubation. We surveyed anaesthetists to determine how this test was being performed. Comparative accuracy of measurement by ruler and other forms of measurement were also assessed in a meta-analysis of published literature. Of respondents, 72% used fingers for TMD measurement and also considered three finger widths the minimum acceptable TMD. In terms of distance, the minimum acceptable TMD was felt to be 6.5 cm by 55% of respondents. However, the mean (range) of the width of three fingers was 5.9 (4.6 - 7.0) cm, with significant differences between genders and between proximal and distal interphalangeal joints. The meta-analysis showed measurement by ruler increased test sensitivity (48% (95% CI 43-53) vs. 16% (95% CI 14-19) without a ruler), when predicting difficult intubation.

See Appendix five for a list of devices.
Introduction

Failure to predict a difficult airway is the most important factor leading to a failed tracheal intubation (510). A range of bedside screening tests are available to help predict a ‘difficult airway’ but unfortunately these are rather unreliable (45): the incidence of unexpected difficult intubation can be as high as 30% (207). Anaesthetists should, therefore, be prepared to manage every patient as if they possessed a potentially difficult airway (511).

Among the tests commonly used is measurement of the thyromental distance (TMD). Patil originally proposed a specially designed intubation gauge of 6.5 cm (53) but other measures include a ruler (512), radiological measurement (513), or three large finger breadths (514). The accuracy of this test has been subjected to previous scrutiny and some authors have concluded that the diagnostic value of this test to predict a difficult intubation is of little value statistically (23, 62, 515).

I wished to ascertain how this test was being applied. I also wished to measure the finger widths of anaesthetists to assess how close these came to the threshold of 6.5 cm. Finally, I conducted a meta-analysis of the literature to assess the accuracy of TMD as an indicator of difficult intubation, especially when measured with a ruler as opposed to other measurement techniques.

Methods

We surveyed 118 trainee and consultant anaesthetists in New Zealand by questionnaire during an ANZCA (Australian and New Zealand College of Anaesthetists) Annual Scientific Meeting of 1200 participants. We asked how they usually measure the thyromental distance, what is the minimum acceptable thyromental distance in an adult (in cm) and, if finger measurement is used, what is the minimum acceptable finger width. Anaesthetists also marked their index, middle and ring finger widths at the proximal and distal interphalangeal joint on a ruler. The survey conformed to the audit requirements of the Northern Regional Ethics Committee who did not require informed signed consent.

We conducted a search of two Ovid databases (Medline plus Medline-in-process and Embase) (1980 to December 2008) and the Cochrane Central Register of Controlled Trials (2008, issue 4) for studies and trials relating to the accuracy of TMD as a predictive test for difficult intubation. Our key words included ‘thyromental’, ‘thyroid’, TMD, airway, intubation, laryngoscope and combinations thereof. No language limit was applied. For inclusion, studies needed to be prospective and to present test specificity and sensitivity or raw data from which these statistics could be derived and tracheal intubation had to be performed with a standard laryngoscope. We excluded studies where patients had anatomically abnormal airways.
Chapter 5. Thyromental distance measurement – fingers don’t rule

Statistical analysis. Chi-square analysis was used to test categorical variables for differences between groups, and continuous variables were analysed using 2-sided t-tests (SAS v 9.1 for Windows, SAS Institute, Cary, NC, USA). A p value of <0.05 was considered significant. The meta-analysis was carried out using the program Meta-DiSc (http://www.hrc.es/investigacion/metadisc.html). The results of the various studies and the sensitivities and specificities were pooled using the Mantel-Haenszel method and weightings were assigned using the inverse variance method.

Results

Survey. There were 118 anaesthetists surveyed (24 trainees, 91 consultants; 74 males, 41 females. Three respondents did not reply with status or gender). The commonest TMD measure was finger width (72%), and 24% simply used visual inspection to assess thyromental distance. Only one respondent used a ruler and four used a thyromental gauge. Half of the respondents (55%) considered 6.5 cm as the minimum acceptable TMD, although 42% regarded a lesser distance as acceptable. Three finger widths was considered the minimum acceptable TMD in an adult by the majority (71%) and four finger widths by 21%. The ruler measurements of three finger widths revealed that the majority (84.4%) were less than 6.5 cm. The mean measurement of three finger widths in the sample was 5.81 cm (s.d=0.62). The actual measurement of three finger widths for the same group of respondents revealed that the majority (84%) were <6.5 cm. The mean three finger width was less in females than males (5.38 cm vs. 5.91 cm, t(105)=5.27, p<0.0001). The mean difference between three male finger widths at the proximal and distal interphalangeal joints was 0.99 cm (n=37, p<0.0001). In females the mean difference was 0.86 cm (n=37, p<0.0001).

Meta-analysis. The meta-analysis included 24 studies (12, 22, 23, 25, 57, 58, 81, 515-531) with 23,146 patients where the accuracy of thyromental distance measurement was assessed as a predictor of difficult intubation. Fourteen of these studies (22, 23, 57, 515-517, 519, 523-525, 527-529, 531), including 6,066 patients, placed in Group A (Table 5.1), used a ruler for thyromental distance measurement and produced a sensitivity of 48% (95% CI 43-53) and specificity of 79% (95% CI 78-80). Ten studies (12, 25, 58, 81, 518, 520-522, 526, 530), with a total of 17,080 patients, did not specify use of a ruler to measure thyromental distance. This Group B (Table 5.2) produced a sensitivity of 16% (95% CI 14-19) and specificity of 94% (95% CI 94-95). One study in the ruler group used a different TMD cut off point for men and women (8 cm and 7 cm respectively) and results were calculated separately according to gender (529).

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Chapter 5. Thyromental distance measurement – fingers don’t rule

Discussion

This study shows that using three fingers as a gauge was the most common method in our participants of measuring thyromental distance, but this correlated poorly with the commonly accepted cut-off point of 6.5 cm and using three finger widths to judge this distance overestimated the true measure. This overestimation was greater in females than in males. Measurement of three finger width at the proximal interphalangeal joint in our population revealed a wide range from 4.6 to 7.0 cm (mean 5.92 cm). We found finger width varied between proximal and distal interphalangeal joints, as did the width between genders. Although three large finger widths (514) could be interpreted as the proximal interphalangeal joint, other texts demonstrate the use of the distal interphalangeal joint (532) and we found these to differ by ~0.9 – 1 cm. We showed a three-fold increase in sensitivity when ruler TMD measurements rather than non-ruler measurements were used.

The studies selected for this meta-analysis were heterogeneous. Cut off points for TMD ranged from 6.0 to 8.0 cm. Patient lower age limit ranged from 15 to 18 years allowing anatomical immaturity to be a variable. Two studies in the non-ruler group applied objective measurement in the form of a thread (522) or a pencil (518). The remaining eight studies in this group used unspecified methods of TMD measurement. Previously identified sources of TMD measurement error include excessive adipose tissue on the mentum, a thick mandible, incorrect use of the cricoid instead of the thyroid cartilage as a landmark for measurement, measurement while the patient’s mouth is open or the neck is not fully extended (533), and digit preference where measurements are rounded off to the nearest whole number. Even under optimal standardized testing conditions with two trained researchers, only moderate inter-observer reliability was found. This variability was possibly caused by patient inability to maintain a correct position (13).

Shiga conducted a meta-analysis of bedside tests for prediction of a difficult intubation in apparently normal patients (62). This meta-analysis included thyromental distance measurement in over 20,000 patients from 17 studies with a variety of test thresholds ranging from 4.0 to 7.0 cm. Measurement of the thyromental distance in this meta-analysis suffered from a wide range of test sensitivity 20% (95% CI 11-29), moderate specificity 94% (95% CI 89-99) and low positive likelihood ratio 3.4 (95% CI 2.3-4.9), however, Shiga did not differentiate in the study on the basis of thyromental distance measurement technique. The majority of patients in Shiga’s thyromental distance meta-analysis came from one study (19) where assessment was made by multiple individuals of unspecified gender using three finger widths as a cut-off point and measure of thyromental distance. The sensitivity in this study was the lowest found in the meta-analysis (15%, 95% CI 11-21). Our meta-analysis of 24 studies included 15 studies which were also used by Shiga. We excluded two studies from Shiga’s analysis because we were unable to extract specificity, sensitivity or raw data from which these statistics could be derived. Our meta-analysis of 23,146 patients had a sensitivity of 25% (95% CI 23-28) and specificity 90.2% (95% CI 90-91) which are similar to those found by Shiga, however, dividing our patients into ruler and non-ruler measurement groups revealed two diverse subgroups with a three-fold difference in sensitivity (Table 5.1 and Table 5.2). In another study of 1500 obstetric patients where three fingers were used

See Appendix five for a list of devices.
to measure TMD, the relative risk of experiencing a difficult intubation compared to a Class I Mallampati airway assessment was 9.71% (95% CI 1.91-49.32) (18).

Thyromental distance varies with patient size (57), and applying the ratio of height to TMD (RHTMD) improves the accuracy of predicting difficult laryngoscopy compared with TMD alone (sensitivity 83% and 67% respectively) (528). When evaluating the predictive value of RHTMD versus mouth opening, TMD, neck movement and oropharyngeal view (modified Mallampati), RHTMD had the highest sensitivity, positive predictive value and fewer false negatives than the other variables (58). In these studies TMD was measured objectively in a standardized method (49).

The choice of a suitable cut-off point for TMD involves a balance between positive and negative likelihood ratios. Decreasing the cut-off point of the TMD to 4.0 cm results in positive and negative likelihood ratios of 9.4 and 0.03 respectively (516). Patil originally suggested that in a normal adult, the thyromental distance is greater than 6.5 cm and this cut-off point is now commonly applied. In two studies receiver operating characteristic curves were used to identify the optimal cut-off point for measuring thyromental distance which were 6.5cm (sensitivity 52%, specificity 71%) (58) and 6.5 cm (sensitivity 67%, specificity 68%) (528). Shiga et al using pooled data with a cut-off of 6.0 cm or less for TMD, found slightly improved prediction of difficult laryngoscopy compared to a larger threshold (62). Standard anaesthesia textbooks (514) suggest the TMD should be at least 5.0 cm or three large finger breadths. Our survey showed that three finger breadths is the most common form of TMD measurement and is also used as a cut-off point. Racial difference also influences TMD as a predictor of difficult laryngoscopy. In Chinese women, high sensitivity and specificity (71.4% and 92.1% respectively) were found with a TMD ≤5.5 cm (523).

Objective measurement of the TMD improves test sensitivity. This, in turn, leads to a lower false negative rate which has clinical implications by reducing the chance of missing a difficult intubation (58). We recommend that accurate TMD measurement requires the use of a ruler or a thyromental gauge. It should be noted that although measurement of TMD with a ruler improves the sensitivity of predicting a difficult intubation compared to other methods, sensitivity still remains relatively poor.

See Appendix five for a list of devices.
### Table 5.1 Summary of studies in the meta-analysis, Group A (ruler measurement), including sensitivity and specificity with 95% confidence intervals

<table>
<thead>
<tr>
<th>Study (n=14)</th>
<th>No. patients</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ayoub et al (516)</td>
<td>160</td>
<td>0.95 (0.76-0.99)</td>
<td>0.89 (0.84-0.94)</td>
</tr>
<tr>
<td>Bilgin et al (531)</td>
<td>500</td>
<td>0.35 (0.21-0.52)</td>
<td>0.95 (0.93-0.97)</td>
</tr>
<tr>
<td>Butler et al (515)</td>
<td>250</td>
<td>0.56 (0.31-0.78)</td>
<td>0.75 (0.69-0.80)</td>
</tr>
<tr>
<td>Descoin et al (517)</td>
<td>295</td>
<td>0.24 (0.12-0.40)</td>
<td>0.92 (0.88-0.95)</td>
</tr>
<tr>
<td>Iohom et al (519)</td>
<td>212</td>
<td>0.45 (0.23-0.68)</td>
<td>0.95 (0.91-0.97)</td>
</tr>
<tr>
<td>Krishna et al (525)</td>
<td>200</td>
<td>0.76 (0.50-0.93)</td>
<td>0.77 (0.70-0.81)</td>
</tr>
<tr>
<td>Krobbuaban et al (528)</td>
<td>382</td>
<td>0.67 (0.50-0.80)</td>
<td>0.69 (0.64-0.74)</td>
</tr>
<tr>
<td>Lasinska-Kowara et al (529)-Male</td>
<td>206</td>
<td>1.00 (0.73-1.00)</td>
<td>0.46 (0.39-0.54)</td>
</tr>
<tr>
<td>Lasinska-Kowara et al (529)-Female</td>
<td>305</td>
<td>0.87 (0.62-0.98)</td>
<td>0.63 (0.57-0.68)</td>
</tr>
<tr>
<td>Merah et al (527)</td>
<td>380</td>
<td>0.15 (0.02-0.45)</td>
<td>0.98 (0.96-0.99)</td>
</tr>
<tr>
<td>Savva (22)</td>
<td>350</td>
<td>0.59 (0.33-0.82)</td>
<td>0.79 (0.74-0.83)</td>
</tr>
<tr>
<td>Schmitt et al (57)</td>
<td>270</td>
<td>0.81 (0.54-0.96)</td>
<td>0.73 (0.67-0.78)</td>
</tr>
<tr>
<td>Tse et al (23)</td>
<td>471</td>
<td>0.32 (0.21-0.45)</td>
<td>0.80 (0.76-0.84)</td>
</tr>
<tr>
<td>Wong et al (523)</td>
<td>411</td>
<td>0.86 (0.42-0.99)</td>
<td>0.24 (0.20-0.28)</td>
</tr>
<tr>
<td>Yildiz et al (524)</td>
<td>1674</td>
<td>0.29 (0.19-0.40)</td>
<td>0.89 (0.87-0.90)</td>
</tr>
<tr>
<td><strong>Pooled Data</strong></td>
<td><strong>6066</strong></td>
<td><strong>0.48 (0.43-0.53)</strong></td>
<td><strong>0.79 (0.78-0.80)</strong></td>
</tr>
</tbody>
</table>

See Appendix five for a list of devices.
Chapter 5. Thyromental distance measurement – fingers don’t rule

Table 5.2 Summary of studies in the meta-analysis, Group B (non-ruler measurement), including sensitivity and specificity with 95% confidence intervals.

<table>
<thead>
<tr>
<th>Study (n=10)</th>
<th>No. patients</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arne et al (25)</td>
<td>1200</td>
<td>0.16 (0.07-0.29)</td>
<td>0.95 (0.93-0.96)</td>
</tr>
<tr>
<td>El-Ganzouri et al (12)</td>
<td>10507</td>
<td>0.07 (0.05-0.09)</td>
<td>0.99 (0.97-0.99)</td>
</tr>
<tr>
<td>Ezri et al (81)</td>
<td>1472</td>
<td>0.30 (0.22-0.37)</td>
<td>0.86 (0.84-0.88)</td>
</tr>
<tr>
<td>Frerk et al (518)</td>
<td>244</td>
<td>0.82 (0.48-0.98)</td>
<td>0.81 (0.75-0.86)</td>
</tr>
<tr>
<td>Koh et al (520)</td>
<td>605</td>
<td>0.38 (0.18-0.62)</td>
<td>0.88 (0.85-0.90)</td>
</tr>
<tr>
<td>Krobbuaban et al (58)</td>
<td>550</td>
<td>0.52 (0.40-0.64)</td>
<td>0.72 (0.67-0.76)</td>
</tr>
<tr>
<td>Merah et al (530)</td>
<td>80</td>
<td>0.62 (0.24-0.91)</td>
<td>0.93 (0.84-0.98)</td>
</tr>
<tr>
<td>Noorizad et al (526)</td>
<td>379</td>
<td>0.17 (0.05-0.36)</td>
<td>0.87 (0.83-0.90)</td>
</tr>
<tr>
<td>Ulrich et al (521)</td>
<td>1993</td>
<td>0.16 (0.10-0.25)</td>
<td>0.86 (0.84-0.87)</td>
</tr>
<tr>
<td>Vani et al (522)</td>
<td>50</td>
<td>0.25 (0.03-0.65)</td>
<td>0.93 (0.80-0.98)</td>
</tr>
<tr>
<td><strong>Pooled Data</strong></td>
<td><strong>17080</strong></td>
<td><strong>0.16 (0.14-0.19)</strong></td>
<td><strong>0.94 (0.94-0.95)</strong></td>
</tr>
</tbody>
</table>

Postscript

This study contributes to a better understanding of how to improve the predictive value of this commonly used bedside screening test. Application of the thyromental distance test to ratios, such as the ratio of height to thyromental distance (RHTMD), and neck circumference to thyromental distance (NC/TM), has also shown improved predictive values. This concept could be applied to paediatric airway assessment. Thyromental distance measurement may also help with laryngoscope blade selection. In the absence of a thyromental gauge or a ruler, accurate pre-measurement of finger width is a compromise.

See Appendix five for a list of devices.
Chapter 6. Airway management during an EXIT procedure for a foetus with dysgnathia complex


Preface

In the previous chapter, I focused on airway assessment and, specifically, a bedside test to identify difficult tracheal intubation. Planning is an important component of airway management (Chapter 1.2). I now take airway assessment to the next step, where a detailed plan is developed to manage the airway, based on information derived from an antenatal airway assessment. This case study illustrates some of the challenges associated with airway assessment in a particularly difficult clinical case.

This case report describes the first use of an EXIT procedure to safely deliver a neonate with severe micrognathia. This is now a recognised indication for this presentation. The technique of using a paediatric flexible bronchoscope to access the foetal airway in utero was also novel.

As the anaesthetist responsible for the airway management of this child, I promoted and coordinated an EXIT procedure for her delivery. I then researched the subject and wrote the first draft of this paper, and supervised all subsequent revisions prior to publication.

Abstract

Nonsyndromal dysgnathia is a rare disorder with a probable genetic basis characterized by a hypoplastic or absent mandible (agnathia), microstomia, microglossia, and ear anomalies secondary to a defect in the ventral portion of the first branchial arch caused by defective neural crest migration or proliferation. Dysgnathic newborn infants often suffer fatal respiratory failure from airway obstruction. Nineteen children with isolated dysgnathia complex are described in the literature – six were stillborn, eight died shortly after birth, and only five survived infancy. All survivors required tracheostomy to maintain an airway. It is difficult to intubate the trachea of these children and early airway management planning is important. We report a neonate who presented with a prenatal ultrasound diagnosis of severe micrognathia, polyhydramnios and a family history of severe micrognathia. Airway management was achieved with fibreoptic intubation through a laryngeal mask airway (LMATM) during an ex utero intrapartum treatment procedure. Fibreoptic intubation was hampered by copious amounts of amniotic fluid. This child and her sibling are the first two siblings with isolated dysgnathia complex to have survived infancy and provide further support for a genetic basis to this condition.

See Appendix five for a list of devices.
Chapter 6. Airway management during an EXIT procedure for a fetus with dysgnathia complex

Introduction

Dysgnathia is a rare condition which is thought to result from a defect in the embryonic development of the first branchial arch. A recent report of transmission of the dysgnathia complex from mother to daughter raised the possibility of a genetic basis for the anomaly and suggested an autosomal dominant transmission (534). This supposition is supported by data on animals (535-538). This condition can occur in isolation, with hypoplastic or absent mandible (agnathia), microstomia, microglossia and ear anomalies including characteristic non-contiguous lobules that are dorsal to the rest of the auricle.

Dysgnathia can also be associated as a syndrome with holoprosencephaly, situs inversus and also absent pituitary and adrenals, kidney anomalies, cardiac anomalies and ocular malformations. The dysgnathia syndrome is more common than isolated dysgnathia complex. Only 19 cases of nonsyndromal dysgnathia complex have been published since 1961 (534, 539-553), and only five of these have survived infancy (534, 548-550). All survivors required tracheostomy. The remaining children were stillborn or suffered respiratory arrest during the neonatal period. We present a neonate diagnosed antenatally. Early intubation of the trachea, secured during an ex utero intrapartum treatment (EXIT) procedure, made survival tenable.

Case report

A 33-year-old woman (62.9 kg, height 1.56 m) presented with antenatal ultrasound scans showing a foetus with severe micrognathia, ear abnormalities and polyhydramnios. The parents were nonconsanguineous and had no ear or mandibular anomalies. The mother’s past obstetric history included two previous pregnancies. The first resulted in a live male delivered by Caesarean section at 38 weeks with severe micrognathia and microstomia, a bifid uvula and ear abnormalities. This sibling required a tracheostomy for respiratory obstruction at 17 months, and he subsequently underwent multiple plastic surgical procedures including mandibular distraction. The second pregnancy, 4 years later involved a normal male who died at 32 weeks from a placental abruption. After 2 years a third pregnancy occurred. Concern over potential airway complications secondary to severe micrognathia, and the past history of placental abruption, led to a decision to use an EXIT procedure at 37 weeks gestation. Written informed consent was obtained from the mother. The neonate’s airway management was coordinated between anaesthesia and ENT, and a cascade of alternatives was planned, starting with direct laryngoscopy, followed by rigid bronchoscopy, fibreoptic laryngoscopy, retrograde intubation, and finally tracheostomy. Anaesthesia for the Caesarean section included a rapid sequence induction using thiopentone 6 mg.kg\(^{-1}\), succinylcholine 1.6 mg.kg\(^{-1}\), and cricoid pressure. Anaesthesia was maintained with sevoflurane end tidal concentration 2.1 volumes %, FiO\(_2\) 0.4 plus intermittent boluses of fentanyl 1 µg.kg\(^{-1}\) up to 300 µg. Induction of anaesthesia to skin incision time was 9 min. Then a further 15 min elapsed before commencing the EXIT procedure and delivering the foetal head. After the EXIT procedure the mother was given syntocinon 10 IU, sevoflurane was stopped and propofol 300 mg by intermittent infusion was given until the end of the Caesarean section. Atracurium 30 mg was given for neuromuscular blockade. Maternal arterial pressure was

See Appendix five for a list of devices.
maintained during anaesthesia with intermittent ephedrine 5 mg boluses. Maternal systolic blood pressure and pulse were above 100 mmHg and 98, respectively, throughout the Caesarean section and blood loss was estimated to be 500 ml. The mother’s postoperative recovery was uneventful.

A warm balanced electrolyte infusion was commenced to maintain normal amniotic fluid volume, uterine temperature and prevent cord compression after hysterotomy. The foetus was given no drugs other than those from placental transfer. Upon delivery of the foetal head and shoulders through a low transverse hysterotomy, suction and direct laryngoscopy with a Seward No. 1 blade revealed severe microstomia, cleft palate and a grossly hypoplastic tongue of only the posterior one-third. This hypoplastic tongue occupied the cleft palate, creating oropharyngeal obstruction and obscuring a direct view of the larynx. Attempts at direct laryngoscopy with a 2.5 mm 0° rigid bronchoscope (John Stortz & Son, Philadelphia, PA, USA) were similarly unsuccessful and failed to expose any anatomy beyond the tongue. Laryngoscopy was complicated by copious amniotic fluid that required further suctioning.

The foetal airway was then maintained using a laryngeal mask airway (LMA\textsuperscript{TM}). This occupied the space created by the cleft palate. An ultrathin fibreoptic bronchoscope (Olympus Optical Co, Tokyo, Japan), with two 3.0 mm internal diameter tracheal tubes mounted, was then advanced through the LMA (554). Bilateral equal air entry was confirmed immediately after intubation and fibreoptic view and capnography confirmed correct positioning of the tracheal tube. The Apgar scores were 8 at 1 min and 8 at 5 min and the neonate weighed 2075 g. The foetus was successfully intubated 20 min after commencement of the EXIT procedure. The foetus remained motionless and did not attempt to breathe prior to intubation but remained well perfused throughout the procedure. A tracheostomy was performed electively 4 h after delivery to achieve a definitive airway. The neonate had severe micrognathia with jaw opening of 4 mm. A 3D reformatted CT scan showed abnormal temporomandibular joints with rudimentary mandibular condyles articulating with the skull base. The mandible was severely hypoplastic with short and vertical rami and a linear configuration of the body of the mandible (Figure 6.1 and Figure 6.2).

See Appendix five for a list of devices.
Chapter 6. An audit of airway management equipment in a metropolitan region

Figure 6.1  A 3D reformatted CT scan showing abnormal temperomandibular joints with rudimentary mandibular condyles articulating with the skull base

Figure 6.2  A 3D reformatted CT scan showing a severely hypoplastic mandible with short and vertical rami and a linear configuration of the body of the mandible

Ear abnormalities included malformation of the external auricles with non-contiguous lobules dorsal to the rest of the auricle, an abnormality unique to this condition (Figure 6.3). Brainstem response audiometry was within normal limits. Zygomatic arches, eyes and brain were all normal. There were no other physical abnormalities.

See Appendix five for a list of devices.
Discussion

The prevalence of syndromal dysgnathia with isolated dysgnathia complex is less than 1/70,000 newborn infants (555). The incidence of isolated dysgnathia complex alone is unknown. There are 21 reports of isolated dysgnathia complex in the literature since 1961, including our current case and her older sibling. Six were stillborn (540-544, 553), eight died shortly after birth (539, 545-549) and only seven have survived infancy (534, 550-552). Respiratory distress occurred in all reported live births, except in this current report where an EXIT procedure was used. Seven of the eight neonates that died after birth suffered a respiratory arrest within 60 min of birth and the eighth died at 5 weeks of respiratory arrest. All the survivors required a tracheostomy. Consequently, we believe a prepared delivery and early airway management are essential.

Isolated dysgnathia complex has been considered a lethal condition because of this high incidence of respiratory complications. Prenatal planning was possible in our patient because of an antenatal diagnosis – a family history of severe micrognathia in an older sibling and an ultrasound scan at 19 weeks gestation, confirming micrognathia and dysplastic ears in the foetus. A later ultrasound scan at 29 weeks showed polyhydramnios – consistent with upper airway obstruction limiting foetal swallowing of amniotic fluid, suggesting atresia, constriction or obstruction of the oropharynx (556). Prenatal diagnosis of such difficult airways will become more common as radiology techniques improve (547, 557-560).

See Appendix five for a list of devices.
Chapter 6. An audit of airway management equipment in a metropolitan region

The EXIT procedure was originally devised for reversal of tracheal occlusion performed on foetuses with severe congenital diaphragmatic hernias (561). The indications for an EXIT procedure have now expanded to include those with a variety of pathologies including foetal neck masses, thoracoomphalopagus conjoint twins, resection of congenital cystic adenomatoid malformation, congenital high airway obstruction and unilateral pulmonary agenesis (562). The key element of this technique is uterine relaxation and foetal anaesthesia with preservation of uteroplacental blood flow and gas exchange. This is usually achieved by deep maternal inhalation anaesthesia. Epidural anaesthesia, glyceryl trinitrate (GTN) infusions and foetal intramuscular neuromuscular blocking drugs have also been incorporated into the procedure. Uterine volume is maintained by constant infusion of warm electrolyte solution and delivery of only the foetal head, shoulders and, if necessary, the arms. This prevents uterine contraction, placental detachment and cord compression. Adequate uteroplacental gas exchange has been maintained for up to 66 min with this technique (562).

Orotracheal intubation by direct laryngoscopy or rigid bronchoscopy is the preferred method to secure the airway during an EXIT procedure. A few neonates have required a formal surgical tracheostomy during the EXIT procedure. Other techniques successfully employed include retrograde intubation through a tracheostomy incision (561) and laryngoscopy with a paediatric Bullard laryngoscope (Circon – ACMI, Southborough, MA, USA) (563). Because of the anatomical deformity encountered in our case, direct laryngoscopy and rigid bronchoscopy were not possible. Fibreoptic bronchoscopy has been mentioned in several algorithms (564-567), but has only been used to confirm tracheal tube placement. We successfully intubated our patient with the fibreoptic bronchoscope through an LMA, but this technique was hampered by copious amounts of amniotic fluid. Direct suctioning through the mouth cluttered the field of view. A soft catheter, placed on continuous low-pressure suction, introduced through the nose to sit in the nasopharynx, may have improved intubation conditions. The second TT tube mounted in series on the bronchoscope pushes the first into the trachea and holds it there while the LMA is removed (554). The characteristic features of dysgnathia complex, including mandibular hypoplasia or agenesis, microstomia, microglossia and ear abnormalities, present with variable degree of severity. In the severe form of agnathia, or otocephaly, there is absence or severe hypoplasia of the mandibular arch. As a consequence the external ears tend to fuse in the midline and the mouth is extremely small. Less severe forms are referred to as dysgnathia. In such forms the ears are not low set but exhibit non-contiguous lobules that are dorsal to the rest of the auricle. Middle ear anomalies can include abnormalities or absence of the ossicles. Cleft lip and palate and down-sloping palpebral fissures represent involvement of the maxilla. Occasionally hypoplasia of the zygoma is present. The oropharynx can be narrow or blind-ended with persistence of the oropharyngeal membrane, the tongue can be hypoplastic with aplasia of the anterior two-thirds and choanal atresia or stenosis may occur. These abnormalities arise from a defect in the ventral portion of the first branchial arch secondary to defective neural crest migration or proliferation. The dysgnathia complex may be associated with other malformations but neither this index case nor her older sibling had other malformations.

No commonly identifiable cause for dysgnathia has been found although there is evidence for a genetic basis (1). Teratogenic factors including salicylate (568), amidopyrine (569), and theophylline (570) have been

See Appendix five for a list of devices.
Chapter 6. An audit of airway management equipment in a metropolitan region.

We report the first two siblings with isolated dysgnathia complex to have survived infancy, providing further evidence for a genetic basis to this condition. The occurrence in two siblings of different sexes with no apparent similar anomalies in their parents may suggest an autosomal recessive pattern of inheritance. Alternatively, an autosomal dominant inheritance caused either by a phenotypically non-manifesting parent, or secondary to germ line mosaicism should also be considered. Irrespective of the exact genetic aetiology, the difference in the phenotypic severity of the condition between the siblings is an important consideration when assessing future familial cases.

Postscript

This was the first reported application of an EXIT procedure for a foetus with severe micrognathia. Since this case report, EXIT-to-airway for severe micrognathia has become a recognised indication for an EXIT procedure (117). Prior to this development, neonates born with these conditions were subject to significant risk of brain damage or death, secondary to airway obstruction.

Further genetic scrutiny since the birth of this child has resulted in a change in the diagnosis to auriculo-condylar syndrome, which includes microtia, severe micrognathia and absent ossicles (571). This change does not alter the indication for an EXIT procedure and, therefore, the airway management plan for this patient would have remained the same.

This case report was presented by invitation at the Society for Airway Management annual scientific meeting, 2011, Scottsdale, USA.
Chapter 7. A prospective randomised trial comparing supraglottic airways for flexible bronchoscopy in children


Preface

In Chapters two and three, I discussed the importance of appropriate equipment for airway management. When selecting equipment, it is important to ensure that the equipment is fit for purpose. That purpose may not be defined or intended by the manufacturer and, under these circumstances, appropriate testing should be conducted in order to establish the efficacy of the equipment. Given the critical importance of timely success in managing airways, there is a strong case for selecting equipment that is not only fit for purpose, but that is also the best in its category or class.

Flexible bronchoscopy for children at Starship Children’s Hospital is routinely performed with a general anaesthetic and a cLMA™. The infection control team recommended that the re-usable cLMA™ should be replaced with a single-use equivalent, for reasons discussed in Chapter 1.4. This recommendation was based on an assumption that a replacement single-use device would perform as well as the gold standard device. The replacement, however, caused clinical difficulty advancing the flexible bronchoscope through the single-use supraglottic airway. This problem initiated the following prospective randomised trial.

As lead author I designed this study, collected data, assisted in analysis of the results, researched the subject, wrote the first draft of the paper and supervised all subsequent revisions of the paper prior to publication.

Abstract

Objective: A prospective randomized, controlled trial was conducted comparing supraglottic airways for flexible bronchoscopy in 100 children.

Background: Paediatric flexible bronchoscopy is commonly performed using a supraglottic airway (SGA) as both a ventilation device and a conduit for flexible bronchoscopy. We observed that some disposable SGAs were associated with increased resistance to bronchoscope manipulation compared to the LMA Classic™ (cLMA™).

Methods: We compared the cLMA™ to the Ambu® Aura Once™, Portex® Soft Seal™, Boss Systems disposable silicone laryngeal mask, and LMA Unique™. We recorded the subjective resistance of the

See Appendix five for a list of devices.
bronchoscope to manipulation within the SGA by linear analogue score and measured the time to insert the bronchoscope from the proximal end of the SGA to the right upper lobe. We also scored the view of the larynx through the bronchoscope and measured SGA cuff pressures.

Results: Resistance to bronchoscope manipulation during paediatric flexible bronchoscopy was higher using polyvinyl chloride (PVC) disposable SGAs (Ambu®, Unique™ and Portex®) than the silicone re-usable cLMA™ (p<0.0001). The Unique™ and Ambu® laryngeal masks were clinically inferior to the cLMA™ at all levels of the airway (p<0.0001). The Portex® Soft Seal™ was not different above the larynx, but was significantly statistically inferior at (p<0.04) and below the larynx (p<0.006), and inferior overall (p<0.007). Boss Systems single use laryngeal mask was as effective as the cLMA™.

Conclusion: In this trial PVC single use laryngeal masks were inferior to the silicone LMA Classic™ and Boss Systems laryngeal masks for flexible bronchoscopy in children.

Trial registration. ANZCTR: ACTRN12609000586213.

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Chapter 7. A prospective randomised trial comparing supraglottic airways for flexible bronchoscopy in children

Introduction

The use of paediatric flexible bronchoscopy has steadily increased over the last two decades with numerous diagnostic and therapeutic applications (572). Anaesthesia for this procedure has evolved from predominantly local anaesthetic with sedation to general anaesthesia (573). This change was facilitated by the introduction of the Classic LMA™ (cLMA™) (LMA NZ Ltd, Lower Hutt, NZ) which functions as a conduit and ventilation device. Compared to an endotracheal tube, the cLMA™ allows passage of larger flexible bronchosopes with better images and working channels. This technique reduces anaesthesia and procedure time leading to fewer complications such as hypoxia, bleeding and laryngospasm (574). Other advantages using the cLMA™ include: minimisation of discomfort and distress for the child; dynamic visualisation of the upper airway, larynx and subglottic region during spontaneous ventilation; reduced bacteraemia rate; and decreased nasopharyngeal trauma from repeated nasal intubation (575). The cLMA™ conduit provides for passage of an adequate diameter bronchoscope for bronchoalveolar lavage (BAL), suctioning and endobronchial biopsy.

The cLMA™ is a re-usable device made of silicone and has proven to be a safe and effective airway conduit for paediatric flexible bronchoscopy (576). Single use devices are now supplied by a number of manufacturers. Inexpensive disposable SGA devices now dominate the market. They are generally made of polyvinyl chloride (PVC) with some silicone single use SGAs also available.

Theoretical advantages exist for the use of single use SGAs. First, concern about the risk of spongiform encephalopathy in 2002 prompted The Royal College of Anaesthetists (RCoA) and The Association of Anaesthetists of Great Britain and Ireland (AAGBI) to recommend the use of ‘single use devices’ where possible to minimize infection risk (178). These recommendations applied to the UK and the risk has proven to be unfounded. Second, single use SGAs are promoted as less expensive than the re-usable equivalent. This is not supported by cost analysis. Third, design features including wide conduits and open periglottic orifices, without bars, could offer favourable conditions for flexible bronchoscopy. There is no evidence to support these proposed advantages (175). Evidence supporting the safety and efficacy of single use SGAs for general anaesthesia in children is minimal (250) and there are no studies comparing the efficacy of single use PVC or silicone SGAs in paediatric bronchoscopy.

Following a change to purchase single use SGAs at our institution, we observed some single use SGAs were associated with increased resistance to bronchoscope manipulation during paediatric flexible bronchoscopy compared to the cLMA™. Based on this observation we conducted a prospective randomised controlled trial to compare the efficacy of four single use supraglottic airways to the cLMA™ during paediatric flexible bronchoscopy. Our null hypothesis was that there would be no clinical difference from the cLMA™ in their performance.

See Appendix five for a list of devices.
Chapter 7. A prospective randomised trial comparing supraglottic airways for flexible bronchoscopy in children

Methods

Clinical trial. With approval from the New Zealand Northern Y Regional Ethics Committee (approval number NTY/07/134), a prospective randomised clinical trial was conducted at Starship Children’s Health, comparing the efficacy of four single use SGAs with the cLMA™ during paediatric flexible bronchoscopy. Following written parental consent, 100 children between the ages of 4 months and 15 years, weighing 50kg or less, who were scheduled to undergo general anaesthesia for flexible bronchoscopy, were enrolled and studied. This allowed 25 comparisons for each single use SGA with the cLMA™. Exclusion criteria were: age>15 years, weight >50kg, previous difficulty with bronchoscopy, unsuitability for use of a laryngeal mask airway (as assessed by the patient’s respiratory paediatrician or anaesthetist) or family refusal.

Following enrolment, allocation according to computer generated randomization by JT was undertaken outside the clinical area by PB/KB with each child allocated to one of four single use SGA: Ambu® Aura Once™ (Ambu Australia Pty Ltd, NSW, Australia), Portex® Soft Seal™ (Smith Medical International Ltd, Kent, UK), Boss Systems single use laryngeal mask (Bosco Medical Murarrie, Qld, Australia) and LMA Unique™. Allocation and randomisation order was concealed from the enrolling respiratory paediatrician throughout and concealed from the anaesthetist until after enrolment. The single use SGA was then compared to the cLMA™ within each patient, during a single encounter. The order of use (single use SGA and cLMA™) in each patient was also randomised, with each device being used for approximately 50% of a single procedure.

Standardised general anaesthetic induction consisted of either inhalational induction using Sevoflurane or intravenous induction with Propofol. The vocal cords and upper trachea were selectively sprayed with 2% lignocaine (2 mg/kg). A rotation technique was used for SGA insertion (577). SGA cuffs were fully deflated prior to insertion and then inflated with air to the manufacturer’s specified maximum volume less 1ml. Cuff pressures were then measured with a manometer. According to local practice all cuff pressures were standardised to 20 cmH₂O and the SGA was secured in position with tape. Anaesthesia with spontaneous ventilation was maintained with Sevoflurane and Propofol. Patient monitoring was consistent with the Australian and New Zealand College of Anaesthetists (ANZCA) guidelines, and included blood pressure, ECG, end tidal carbon dioxide and pulse oximetry monitoring. The respiratory paediatrician chose a suitably sized Olympus LFV video bronchoscope (Olympus Optical Co, Tokyo, Japan) and corresponding bronchoscopy elbow.

Primary outcomes. Resistance to manipulation of the flexible bronchoscope was subjectively scored by the respiratory paediatrician at three levels; above the vocal cords, at the vocal cords and below the vocal cords, with a subjective score of overall ease of use. These were recorded individually on a 10cm line. Bronchoscopists were instructed that half way on the line should be considered normal and marks on the line approaching zero indicated high resistance and less ease of use, and marks approaching 10cm indicated low

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Chapter 7. A prospective randomised trial comparing supraglottic airways for flexible bronchoscopy in children

resistance and greater ease of use. To establish a quantitative measure of ease of use, time required to pass the bronchoscope from the bronchoscopy elbow into the right upper lobe bronchus was recorded for each SGA under standardised conditions. According to local practice neither the bronchoscope nor the bronchoscopy elbow were initially lubricated. If safe advancement of the bronchoscope was not possible due to resistance within the airway, the technique was modified by lubricating the bronchoscope and the SGA was scored again for each modification. If the SGA failed completely, despite modification, it was abandoned and the other SGA was used to complete the procedure.

Secondary outcomes. Two laryngeal views were measured from the distal SGA. First, the bronchoscopic view of the glottis with the bronchoscope in the neutral position (reflecting the angle at which an intubation device would approach during blind intubation via the laryngeal mask) was recorded as the ‘unmanipulated view’. Second, the best ‘manipulated view’ was recorded, using the directional capabilities of the bronchoscope, (reflecting the view relevant for flexible bronchoscope intubation of the trachea via the SGA). The glottic view was scored using the percentage of glottis opening (POGO) score (578). A POGO score of zero was deemed unacceptable. Measurement of the SGA cuff pressure was also undertaken.

Statistical analysis. The study was powered to detect half a standard deviation difference between the four groups with 80% power and a significance level of 5%. Mean difference in score from the reference cLMA™ was calculated for each single-use SGA at levels above, and below the vocal cords. Mean difference in overall score, from the cLMA™, was also recorded for attempted bronchoscopy without lubrication of the bronchoscope. Chi-square analysis was used to test categorical variables for differences between groups. A p-value of < 0.05 was considered significant.

Results

Demographic data. One hundred children (54 males) were successfully studied over a fifteen month period with a median age of 4 years (interquartile range 2 to 7) and median weight 18 kg (interquartile range 13 to 25). Overall 10 procedures used SGA size 1.5, 51 used SGA size 2, 21 used SGA size 2.5, and 18 used SGA size 3. The indications for bronchoscopy and bronchoalveolar lavage (BAL) included 68 investigations of infection in those with chronic disease (including cystic fibrosis, bronchiectasis, interstitial lung disease and recurrent lower respiratory tract infections), acute infection or new chest x-ray changes in 10, problematic asthma, wheeze or unexplained tachypnoea in 5, cough in 6, airway anomalies in 5, congenital lung anomalies in 3, and haemoptysis in 3. Co-morbidities were recorded in 88 patients which included chronic lung disease in 34, asthma in 10, cardiac anomalies in 6, underlying immunodeficiency in 5, neurological disorders (including

See Appendix five for a list of devices.
Chapter 7. A prospective randomised trial comparing supraglottic airways for flexible bronchoscopy in children gastro-oesophageal reflux and aspiration) in 6, prematurity (born less than 32 weeks gestation) in 4, and airway anomalies or post thoracic surgery in 6.

Clinical trial. The incidence of impossible bronchoscopy through the SGA on first attempt without lubrication occurred in 29/200 (15%), and second attempt with lubrication occurred in 4/200 (2%) and is shown in Table 7.1.

<table>
<thead>
<tr>
<th></th>
<th>1st attempt</th>
<th>2nd attempt $\chi^2=16.33$, $p=0.0026$</th>
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<tbody>
<tr>
<td>Classic (n=100)</td>
<td>1/100</td>
<td>0/100</td>
</tr>
<tr>
<td>Ambu (n=25)</td>
<td>12/25</td>
<td>3/25</td>
</tr>
<tr>
<td>Boss (n=25)</td>
<td>0/25</td>
<td>0/25</td>
</tr>
<tr>
<td>Portex (n=25)</td>
<td>3/25</td>
<td>0/25</td>
</tr>
<tr>
<td>Unique (n=25)</td>
<td>13/25</td>
<td>1/25</td>
</tr>
</tbody>
</table>

There was a significant difference in the failure rate of the SGAs with failure rates being notably higher in the Ambu® Aura Once™ and LMA Unique™. In this study the features of impossible bronchoscopy included an inability to manipulate and progress the bronchoscope due to excessive resistance. This was without risk to the patient or the equipment.

See Appendix five for a list of devices.
Chapter 7. A prospective randomised trial comparing supraglottic airways for flexible bronchoscopy in children

### Table 7.2 Effect* of LMA (compared to Classic) after controlling for randomization effect of order

<table>
<thead>
<tr>
<th></th>
<th>Above cords (χ²=22.39, p&lt;0.0001)</th>
<th>At Cords (χ²=20.23, p&lt;0.0001)</th>
<th>Below cords (χ²=11.85, p&lt;0.0001)</th>
<th>Overall (χ²=14.75, p&lt;0.0001)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classic†</td>
<td>46.8 (4.6)</td>
<td>45.6 (5.4)</td>
<td>46.1 (7.5)</td>
<td>46.5 (8.2)</td>
</tr>
<tr>
<td>Ambu</td>
<td>-13.5 (p&lt;0.0001)</td>
<td>-11.8 (p&lt;0.0001)</td>
<td>-12.5 (p&lt;0.0001)</td>
<td>-14.1 (p&lt;0.0001)</td>
</tr>
<tr>
<td>Boss</td>
<td>-2.2 (p=0.30)</td>
<td>2.9 (p=0.15)</td>
<td>1.8 (p=0.42)</td>
<td>2.5 (p=0.30)</td>
</tr>
<tr>
<td>Portex</td>
<td>-2.9 (p=0.18)</td>
<td>-5.1 (p=0.01)</td>
<td>-6.8 (p=0.005)</td>
<td>-6.8 (p=0.0066)</td>
</tr>
<tr>
<td>Unique</td>
<td>-19.1 (p&lt;0.0001)</td>
<td>-17.9 (p&lt;0.0001)</td>
<td>-15.4 (p&lt;0.0001)</td>
<td>-18.3 (p&lt;0.0001)</td>
</tr>
<tr>
<td>Order effect</td>
<td>0.1 (p=0.93)</td>
<td>0.9 (p=0.50)</td>
<td>-0.8 (p=0.62)</td>
<td>0.0 (p=0.99)</td>
</tr>
</tbody>
</table>

* Analysis based only on successful procedures, effect size is change in score in comparison to the Classic.
† Figures for Classic are mean (s.d) score

Subjective scores of first attempt flexible bronchoscope resistance through the SGA, using a 10cm line technique, are shown in Table 7.2. Zero scores from failed attempts were excluded from analysis. Ambu® and Unique™ were inferior at all levels, reflected in the inferior overall score, and these were statistically significant. The Portex® LM was scored as statistically inferior below the larynx and in its overall score compared to the cLMA™. The Boss LM was not shown to be different from the cLMA™ at any level of the airway or overall. The order in which the two SGAs were tested did not affect the results. An analysis including the additional data from second attempts following a failed attempt without lubrication produced similar results to those for first attempt data. There were no cases in which both SGAs failed completely.

The time to introduce the bronchoscope from the bronchoscopy elbow to the right upper lobe of the lung was used as an objective measure of bronchoscope resistance. The Unique™ took 10.2 seconds longer than the cLMA™ (22.5 seconds) when controlled for operator variation. Times were slightly faster with the Portex® Soft Seal™ and Boss Systems than with the control cLMA™ (Table 7.3), however these differences were not statistically significant.

See Appendix five for a list of devices.
Table 7.3 Difference in time from reference (cLMA™), in seconds, for bronchoscopy from swivel connector to the right upper lobe.

<table>
<thead>
<tr>
<th>Device</th>
<th>Time (F=2.22, p&lt;0.14)</th>
<th>Time *(F=2.21, p&lt;0.07)</th>
</tr>
</thead>
<tbody>
<tr>
<td>cLMA™ b</td>
<td>22.5 s (1.8)</td>
<td>Reference</td>
</tr>
<tr>
<td>Ambu®</td>
<td>0.6 (p=0.89)</td>
<td>2.51 (p=0.58)</td>
</tr>
<tr>
<td>Boss</td>
<td>-3.4 (p=0.29)</td>
<td>-5.2 (p=0.12)</td>
</tr>
<tr>
<td>Portex®</td>
<td>-1.9 (p=0.57)</td>
<td>-1.5 (p=0.67)</td>
</tr>
<tr>
<td>Unique™</td>
<td>7.8 (p=0.08)</td>
<td>10.2 (p=0.03)</td>
</tr>
<tr>
<td>Order effect</td>
<td>-3.3 (p=0.14) (for second)</td>
<td>-3.4 (p=0.13) (for second)</td>
</tr>
</tbody>
</table>

* Controlled for order, bronchoscopist, age group, LMA size, indication. No significant effect was found for any of the variables controlled for. **Figure for cLMA™ are mean (SD) times.

POGO scores revealed a significant difference between the five SGAs for unmanipulated views, but not for manipulated views (Table 7.4). All single use SGAs except Portex® Soft Seal™ were significantly less likely to produce POGO scores of zero than the cLMA™ in the unmanipulated view. With bronchoscope manipulation, no statistically significant difference was found.

The maximum cuff inflation volumes for the SGAs resulted in excessive cuff pressures (>100 cmH₂O), as measured by a cuff manometer, in 87.8% (173/197) (Table 7.4).

See Appendix five for a list of devices.
Chapter 7. A prospective randomised trial comparing supraglottic airways for flexible bronchoscopy in children

Table 7.4 Odds ratios (95% CI) associated with secondary outcomes by LMA

<table>
<thead>
<tr>
<th>Cuff pressure&gt;100</th>
<th>Unmanipulated Pogo &gt;50 ($\chi^2=30.00$, p&lt;0.0001)</th>
<th>Unmanipulated Pogo &gt;75 ($\chi^2=28.03$, p&lt;0.0001)</th>
<th>Manipulated Pogo&gt;75 ($\chi^2=10.44$, p=0.03)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classic†</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Ambu</td>
<td>1.05 (0.40,2.78)</td>
<td>9.72 (3.63,26.02)</td>
<td>12.27 (3.68,40.90)</td>
</tr>
<tr>
<td>Boss</td>
<td>9.80 (1.27,75.88)</td>
<td>1.73 (0.59,5.03)</td>
<td>0.77 (0.09,6.88)</td>
</tr>
<tr>
<td>Portex</td>
<td>0.32 (0.13,0.79)</td>
<td>0.78 (0.21,2.95)</td>
<td>1.67 (0.30,9.20)</td>
</tr>
<tr>
<td>Unique</td>
<td>0.61 (0.25,1.52)</td>
<td>3.91 (1.47,10.41)</td>
<td>1.67 (0.30,9.20)</td>
</tr>
</tbody>
</table>

† Classic is the reference group and hence OR=1, in comparison an odds ratio >1 implies an increased risk of the LMA having the secondary outcome and an odds ratio <1 a decreased risk.

In the total 200 episodes of SGA use, morbidity included 8 episodes of desaturation below 80%, an additional 4 episodes of desaturation below 65%, 8 episodes of laryngospasm, 3 of bronchospasm and 11 episodes of obstruction of the SGA by the epiglottis or other airway structure. All desaturations of less than 65% SaO$_2$ occurred with the first SGA; two cases related to laryngospasm and two had underlying severe bronchiectasis and bronchiolitis obliterans with oxygen dependence pre-operatively or SaO$_2$<95% in room air. Of the 34 separate adverse events, 19 (56%) were associated with SGA sizes 1.5 and 2 complications related more to the size than the types of SGA (Table 7.5 and Table 7.6).

Table 7.5 Morbidity by size of SGA.

<table>
<thead>
<tr>
<th>SGA size</th>
<th>Morbidity/number of uses*</th>
<th>Percentage morbidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5</td>
<td>6/20</td>
<td>30%</td>
</tr>
<tr>
<td>2</td>
<td>13/102</td>
<td>12.8%</td>
</tr>
<tr>
<td>2.5</td>
<td>4/42</td>
<td>9.5%</td>
</tr>
<tr>
<td>3</td>
<td>1/36</td>
<td>2.7%</td>
</tr>
</tbody>
</table>

*Individual SGA’s only scored once despite having 2 associated morbidities (i.e. laryngospasm and oxygen desaturation)

See Appendix five for a list of devices.
Table 7.6 Morbidity by type of supraglottic airway (SGA).

<table>
<thead>
<tr>
<th>Morbidity variables</th>
<th>Number of incidents</th>
<th>cLMA™</th>
<th>Portex</th>
<th>Unique</th>
<th>Boss</th>
<th>Ambu</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desaturation &lt;80%</td>
<td>8/200</td>
<td>5/100</td>
<td>0/25</td>
<td>1/25</td>
<td>0/25</td>
<td>2/25</td>
</tr>
<tr>
<td>Desaturation &lt;65%</td>
<td>4/200</td>
<td>1/100</td>
<td>0/25</td>
<td>1/25</td>
<td>0/25</td>
<td>2/25</td>
</tr>
<tr>
<td>Laryngospasm</td>
<td>8/200</td>
<td>3/100</td>
<td>0/25</td>
<td>1/25</td>
<td>1/25</td>
<td>3/25</td>
</tr>
<tr>
<td>Bronchospasm*</td>
<td>3/200</td>
<td>2/100</td>
<td>0/25</td>
<td>1/25</td>
<td>0/25</td>
<td>0/25</td>
</tr>
<tr>
<td>Obstruction of SGA</td>
<td>11/200</td>
<td>9/100</td>
<td>1/25</td>
<td>0/25</td>
<td>1/25</td>
<td>0/25</td>
</tr>
</tbody>
</table>

cLMA™, LMA Classic™

Discussion

This trial found that the PVC Ambu® Aura Once™, Portex Soft Seal™ and LMA Unique™ were inferior conduits for flexible bronchoscopy in children when compared to the cLMA™ based on the ability to manipulate the bronchoscope within the airway. The Boss Systems laryngeal mask was equivalent to the cLMA™ with both these silicone devices performing well. The PVC single use laryngeal masks in this study did not provide suitable conditions for flexible bronchoscopy in children.

Several design features of the chosen SGAs may have contributed to our results. First, the materials used to manufacture the SGAs in this trial could have contributed to the results. It appears that silicon devices (Boss Systems laryngeal mask and cLMA™) were superior conduits for flexible bronchoscopy in children compared to PVC SGAs (Ambu® Aura Once™, Portex Soft Seal™ and LMA Unique™). This finding warrants further investigation. Second, the internal diameter of SGAs differs but these variations were not related to the ability to manipulate the bronchoscope. Third, the presence or absence of epiglottic bars did not prove to be a factor in our results. The Ambu® Aura Once™ and Portex® Soft Seal® do not have epiglottic bars. However, the Ambu® Aura Once™ had an equivalent performance of bronchoscope manipulation to the LMA Unique™, which does have epiglottic bars. Fourth, the correct anatomical positioning of the SGA is a theoretical prerequisite for successful flexible bronchoscopy. We assessed laryngeal view through the bronchoscope using the POGO score (578). Other studies have also examined laryngeal view through a flexible bronchoscope and SGA in paediatric patients. In a study of 100 patients, Rowbottom et al found 17% of patients had partial airway obstruction based on fibreoptic examination, and 2% had clinically severe airway obstruction (579). In a study of 350 children von Ungern-Sternberg found good or adequate ventilation conditions in all patients, but an incomplete view of the glottis through a flexible bronchoscope occurred in up to 50% of cases with smaller single use SGAs being associated with poorer views (580). In our study 5.5% of SGA insertions were associated with clinically severe airway obstruction which required readjustment of the SGA. The Ambu®

See Appendix five for a list of devices.
Chapter 7. A prospective randomised trial comparing supraglottic airways for flexible bronchoscopy in children

Aura Once™ provided the best POGO scores which could be attributable to its pre-formed curve. This improved laryngeal view, however, did not translate into improved bronchoscope intubation. We found a poor correlation between POGO scores and overall subjective flexible bronchoscope manipulation scores and objective measurement of times to the right upper lobe. A POGO score of 0 does not necessarily represent clinically severe airway obstruction. Finally, the use of lubrication on the bronchoscope and the bronchoscopy elbow did decrease the incidence of bronchoscopy failure on the second attempt but the same trend continued with failures for the LMA Unique™ and Ambu® Aura Once™.

There are some limitations to this study. This trial involved a selection of four single use SGAs. These devices were chosen because they were available to our hospital in a range of sizes suitable for our patient population. Our clinical experience indicated that these single use SGAs did function adequately as ventilation devices for routine paediatric anaesthesia. Indeed this has been confirmed for the Ambu® Aura Once™ (581), Portex® Soft Seal® (582), and LMA Unique™ (583). We accept that there are other products available, both with and without safety data, which we did not include in our trial, and we cannot comment about the efficacy of these devices for flexible bronchoscopy. There also may have been an issue with complete operator blinding. Clearly once randomization had taken place, the anaesthetist was not blinded to the SGAs used. The respiratory paediatricians had not been party to the selection of the SGAs to be trialled and the similarities and differences were deliberately not discussed prior to the trial. There were a number of paediatricians involved in the study. If one individual had an issue with a particular type of SGA previously, it may have been possible to recall the markings specific to the SGA biasing the assessment of a later use. However the four SGAs were distributed randomly between the four respiratory paediatricians over a one year trial and so this would have been a very small effect. Finally, our results for resistance to bronchoscope manipulation will have been affected by the exclusion of failures from the chi-square analysis (Table 7.1 and Table 7.2). The decision to exclude them was made to prevent zero score distortion which may have exaggerated inferiority of the inferior single use SGAs. This means reducing the apparent inferiority of these single use SGAs as presented in Table 7.1. Despite this, inferiority is well demonstrated. The second attempt scores of those which initially failed are also shown in Table 7.1. These results may potentially disadvantage the scores of those obtained without lubricant as they may have scored better using lubricant. Despite this, the inferior single use SGAs remained significantly inferior to the single use SGAs which succeeded on first attempt.

It is important to establish that any new product is fit for purpose. This fundamental information is essential for informed purchasing prior to safe and effective use. Generic single use SGAs are currently manufactured by a number of companies. Many of these companies do not publish LM specifications leaving the majority of generic designs without safety and efficacy profiles. Also, the designs of single use SGAs frequently change preventing generalisation of results to all generic laryngeal masks. For example, the single use silicone Boss Systems laryngeal mask used in our trial is no longer available and has been replaced with another design. A scheme to guide prospective purchasers has been described (244). Laryngeal masks should comply with the appropriate recognized standard (259). This new ISO Standard does not specifically mention specialised applications such as flexible bronchoscopy, other than requiring dimensional disclosure which assists the
Chapter 7. A prospective randomised trial comparing supraglottic airways for flexible bronchoscopy in children

operator to match the appropriate size flexible bronchoscope or endotracheal tube with the laryngeal mask. The cLMA™ serves well as the “gold standard” paediatric supraglottic airway. Available literature supports the cLMA™ as a safe effective ventilation device for children over 10kg (584) and for flexible bronchoscopy (574). Any new product should also perform at least as well as a recognized “gold standard”. Complication rates increase with sizes 1 and 1.5 cLMA™s in the under 10kg group (580, 585-587), and our results are consistent with these findings. The results of this study have anaesthetic implications for diagnostic flexible bronchoscopy procedures, and fibreoptic and blind endotracheal intubation procedures (209, 554) if SGAs are utilised.

In summary, the PVC single use laryngeal masks studied were found to be significantly inferior to the silicone LMA Classic™ and the Boss single use silicone laryngeal masks. Careful consideration should apply when selecting appropriate SGAs for flexible bronchoscopy procedures.

Postscript

Specific indications for airway devices often require specific equipment. In these circumstances, the equipment should be tested for optimum performance and compared to equivalent devices; and this information should be published. There are now large numbers of devices which range in quality and performance. Small design changes can make a very significant difference to performance. The DAS ADEPT study has addressed this issue and proposes placing the responsibility with the manufacturer to provide evidence and performance data (195).

See Appendix five for a list of devices.
Chapter 8. Failure to ventilate with supraglottic airways after drowning


Preface

Airway management equipment should be fit for purpose. Medical devices are invariably accompanied by manufacturers’ instructions which define the safe use of the device and the scope of that use. Recent cases have been reported where anaesthetists have been unaware of the correct use of airway management equipment, with tragic outcomes. This case report is an example of equipment being used outside the scope of the manufacturers’ instructions. A physiological explanation can account for this failure.

As first author, I researched and wrote this case report.

Abstract

We report the failure of an i-gel® and an Ambu® AuraOnce™ supraglottic airway (SGA) to ventilate a drowning victim. Failure was attributed to changes in lung physiology following submersion and inhalation of water that may have required ventilation pressures up to 40 cmH₂O to treat the victim’s hypoxaemia. The ease of use and rapid insertion of SGAs without interrupting CPR has prompted recommendations for their use during resuscitation. The relatively low leak pressures attainable from many SGAs, however, may cause inadequate lung ventilation and entrainment of air into the stomach when these devices are used in people who are being rescued from drowning.

See Appendix five for a list of devices.
Introduction

When managing a person who is being rescued from drowning, early treatment of hypoxaemia is imperative. Early rescue breathing or positive pressure ventilation, ideally with oxygen, increases survival (588, 589). Recommended airway management for drowning victims includes mouth to mouth resuscitation, bag-valve-mask ventilation, endotracheal ventilation or an emergency airway adjunct such as a laryngeal mask, King Tube®, Combitube™ or cricothyroidotomy (590). In the event of cardiopulmonary arrest, the European Resuscitation Council Guidelines recommend airway protection, ideally with a cuffed endotracheal tube. The guideline notes the limitations of supraglottic airway devices in the presence of reduced pulmonary compliance (591). Supraglottic airways (SGAs) are suggested as an alternative to tracheal intubation during resuscitation after drowning (590). We could find no reports of SGAs use during drowning resuscitation.

Case Report

This case report was approved for reporting by the Northern X Regional Ethics Committee. A 25 year old male, of approximately 90 kg, was retrieved from the sea by an inflatable rescue boat and returned to shore in an unresponsive, non-breathing and pulseless state. Lifeguards commenced resuscitation on the beach including cardiac massage and bag-valve-mask ventilation. An automated external defibrillator (AED) confirmed asystole. The patient was noted to have significant gastric distension, and poor chest expansion despite two person bag-valve-mask ventilation using 100% oxygen with a disposable Laerdal II™ resuscitator.

An experienced resuscitation expert (JW) inserted a lubricated size 4 i-gel® (Intersurgical, Wokingham, Berkshire, UK) without stopping chest compressions. A suction catheter with suction was not available. Ventilation through the i-gel® was very difficult and chest movement was not visible. Inflation pressures could not be measured. The i-gel® was removed and replaced with bag-valve-mask ventilation by JW. Adequate chest movement without an audible leak was restored with a double “C-E grip” combined with a head tilt/jaw thrust manoeuvre. An oropharyngeal airway was not used. There was no evidence of vomit or regurgitation.

After 30 minutes of cardiopulmonary resuscitation (CPR), paramedics arrived by helicopter and ambulance and advice was given to insert a size 5 Ambu® AuraOnce™ Disposable Laryngeal Mask (Ambu, Ballerup, Denmark) (215). This device also proved to be unsuccessful with inadequate chest movement, and was therefore removed. Bag-valve-mask ventilation was resumed successfully for a further 10 minutes at which time resuscitation efforts were terminated.

The patient had been previously fit and well. A post-mortem was not conducted. The Coroner ruled that drowning was the cause of death.

See Appendix five for a list of devices.
Discussion

Some supraglottic airway devices may be unsuitable for drowning victims because they do not allow high pressure positive ventilation. Leakage pressures are low in relation to those pressures required to overcome airway resistance (Table 8.1).

Table 8.1 In vivo cuff pressures and airway leak pressures for supraglottic airways

<table>
<thead>
<tr>
<th>Device</th>
<th>Cuff volume ml</th>
<th>Cuff pressure cmH₂O</th>
<th>Airway leak pressure cmH₂O</th>
</tr>
</thead>
<tbody>
<tr>
<td>i-gel (592)</td>
<td>NA</td>
<td>NA</td>
<td>19.3*</td>
</tr>
<tr>
<td>Solus LMA (592)</td>
<td>Max. allowable volume for size</td>
<td>60</td>
<td>22.6*</td>
</tr>
<tr>
<td>AuraOnce (593)</td>
<td>Max. allowable volume for size</td>
<td>24*</td>
<td>24*</td>
</tr>
<tr>
<td>ProSeal LMA (594)</td>
<td>20</td>
<td>60</td>
<td>25*</td>
</tr>
<tr>
<td>Laryngeal Tube S</td>
<td>70</td>
<td>65</td>
<td>28*</td>
</tr>
<tr>
<td>(594)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combitube (594)</td>
<td>75</td>
<td>250</td>
<td>34*</td>
</tr>
</tbody>
</table>

Data is given as mean *, median ‡, standard deviation §, [interquartile range], and (range).

The pathophysiological sequence for a drowning victim following submersion involves breath holding then laryngospasm followed by water aspiration. Lung compliance has been shown to decrease by up to 66% within 5 minutes of relatively small quantities (1-3 ml/kg) of lung sea water inhalation in experimental animals. This fall in compliance has been attributed to widespread closure of terminal airways, compounded by a variable increase in non–elastic resistance caused by fluid and foam blocking the airways (595). The resulting uncorrected hypoxaemia leads to cardiac arrest. Safe positive pressure ventilation is required to overcome this high lung resistance. It is estimated that following inhalation of water and the rapid drop in lung compliance, ventilation pressures of 3 to 10 times the pressures required before the introduction of fluid into the lungs, are required to maintain the same tidal volumes (595). A maximum inflation pressure of 40 cmH₂O is recommended for normal lungs, based on flow volume loops (596), which is an appropriate normal upper limit when considering the drowning victim may have a mixture of closed and open airways. Transpulmonary pressures in excess of 80 cmH₂O risk complications such as interstitial emphysema and air embolism (597).

See Appendix five for a list of devices.
Correct anatomical location, cuff pressure and size of the SGA will affect airway leak pressures. Airway leak pressures are measured by fixing the fresh gas flow to 3 L min\(^{-1}\), adjusting the expiratory valve of the breathing circle to 40 cmH\(_2\)O and recording the airway pressure at equilibrium. Relatively low leak pressures for the i-gel® (19.3, SD 7.1 cmH\(_2\)O) (592) and the Ambu® AuraOnce™ (24.1, SD 5.44 cmH\(_2\)O) (598) may explain the inadequate lung ventilation we experienced when attempting to ventilate our drowning victim with both SGAs. It is also possible that a suboptimal fit of the SGAs occurred after insertion by relatively inexperienced users of these devices, especially during resuscitation.

The use of SGAs in drowning victims has not been described. The i-gel® is a disposable SGA made of thermoplastic elastomer, with a gastric drainage tube and a bite block. The i-gel® is indicated by the manufacturers for “securing and maintaining a patent airway in routine and emergency anaesthetics of fasted patients, during spontaneous or intermittent positive pressure ventilation, and during resuscitation of the unconscious patient, by personnel who are suitably trained and experienced in the use of airway management techniques and devices” (85). Several case series confirm the successful use of the i-gel® during elective anaesthesia, and it has been suggested that it may have a place during resuscitation (599), however, reservations have been expressed concerning unsatisfactory performance of the i-gel® in the pre-hospital setting (600). The Ambu® AuraOnce™ Disposable Laryngeal Mask is intended for use in fasted patients as an alternative to a facemask during routine and emergency anaesthetic procedures (215). There are no reports of i-gel or Ambu® AuraOnce™ use for resuscitation in drowning victims.

A range of ventilation techniques has been suggested for victims of drowning. Tracheal intubation has the advantage of providing a clear secure airway with positive pressure ventilation in the presence of low lung compliance and high airway resistance. The disadvantages of this technique during pre-hospital resuscitation include the risk of unrecognized oesophageal intubation, tube displacement and prolonged intubation attempts interrupting CPR. The ease of use and rapid insertion of SGAs without interrupting CPR has prompted recommendations for their use during resuscitation (601). This case report suggests that SGAs are unsuitable for resuscitation of drowning victims.

See Appendix five for a list of devices.
Postscript

The indication for SGAs in victims of drowning cannot be proven by randomised controlled trials and, therefore, evidence to support or reject the use of these devices in this context can only come from case reports. This case report provides the only clinical evidence, to date, concerning this subject. Currently, various countries are advocating SGAs for resuscitation during near-drowning, on the basis that it is easy for inexperienced rescuers to deploy SGAs in other resuscitation scenarios.

Surf Life Saving Great Britain has just introduced i-gel SGAs into their resuscitation packs on their beaches and Surf Life Saving Australia is planning to trial these devices before introducing them. In their discussion documents, they are aware of this case report. This is an area in which more evidence is needed and, therefore, every case should be reported.


Preface

In Chapter eight, I discussed a case involving airway equipment which failed when it was used outside its recommended scope of use. In this chapter, I outline a study of laryngoscopes which were failing because they did not comply with the minimum standards of practice. As first author, I devised the study, collected data, collated the results, researched the subject and wrote the first draft of the paper.

Abstract

Objective: The International Organisation for Standardisation (ISO) recently published an International Standard (ISO 7376:2009) which specifies illuminance levels and tests for illumination from hook-on type laryngoscopes used for intubation. A clinical study examining luminance for laryngoscopy found that 100 cd.m\(^{-2}\) was the minimum level acceptable for laryngoscopy. The purpose of this study was to measure the quality of light from laryngoscopes available for use by anaesthetists in an anaesthetic department and compare them to the ISO illuminance standard and published minimum acceptable luminance limits.

Methods: A measuring device was constructed to support each laryngoscope in a standardised manner. For 190 reusable laryngoscopes, illuminance was measured with a lux meter at the base of this device. Eighteen clinically available laryngoscopes were then examined in detail, as a snapshot study, with multiple light recordings according to the ISO Standard. We also measured the luminance provided by each laryngoscope.

Results: Only two of the 18 laryngoscopes met the minimum illuminance level of 500 lux after 10 minutes. Nine laryngoscopes provided a luminance less than 100 cd.m\(^{-2}\), which is the reported minimum required luminance for laryngoscopy. None of the 18 laryngoscopes tested complied with the ISO standard for laryngoscope light distribution.

Conclusions: Laryngoscope light should be regularly audited. Results from these audits can be used to retire or repair substandard laryngoscopes in order to maintain acceptable standards of laryngoscope light. Audit results produce tangible evidence that is useful when applying for capital expenditure. Light measurements are not easy to make. There needs to be a convenient device to reliably measure laryngoscope illumination.

See Appendix five for a list of devices.
Chapter 9. An audit of laryngoscopes and application of a new ISO standard

Introduction

Laryngoscopes are an essential tool for anaesthetists during airway management. Direct laryngoscopy depends on physical exposure and illumination of the airway. Following dissatisfaction within our department about the quality of laryngoscope light, a study to measure the illuminance of the laryngoscopes was conducted. In the absence of a commercially available device suitable for laryngoscope light measurement, we designed our own system. A follow up audit of laryngoscope light then examined the amount of light received on a surface (illuminance), the perceived brightness (luminance) of a surface lit by the laryngoscope and the distribution of the light from eighteen laryngoscopes. Criteria defined in the ISO 7376:2009 Standard (187) were used in the design of the light measurement system to standardise measurements.

Illuminance is the amount of light received on a unit area of the surface. The SI unit for illuminance is the lux (lx), and one lux is equal to one lumen per square metre (lm.m⁻²). The perception of brightness of an illuminated surface is determined by the amount of light emitted back to the viewer and is described as the luminance. The SI unit for luminance is candela per square metre (cd.m⁻²) (Figure 9.1).

Figure 9.1  The amount of light falling on an object is the illuminance. Some of this light is reflected and this makes the object visible. Luminance is a measure of the apparent brightness of the illuminated object.

• A steradian is the SI unit of solid angle. It is used to describe two dimensional angular spans in three dimensional space

Illumination of the airway during laryngoscopy is determined by the spread of light as well as the illuminance and colour of the light. These factors which determine the quality of the light are influenced by the characteristics of the bulb and the power rating. Other factors of laryngoscope design affecting light quality include the fibre bundle and its proximity to the bulb, the connection between handle and blade, the design of the distribution of light and the voltage of the power source.

See Appendix five for a list of devices.
A number of studies have sought to identify optimum illuminance and luminance (303, 602-607); however, a variety of methods, endpoints and results have made comparison difficult. The International Organization for Standardization (ISO) has now established a standard for laryngoscope light (330). Assessment of the performance of the laryngoscopes was according to this ISO 7376:2009 Standard. Luminance measurements from the same laryngoscopes were recorded in order to draw a comparison with a previously reported minimum luminance requirement for laryngoscopy undertaken by Skilton et al (606). In their study of luminance, 10 consultant anaesthetists, using a variable light output laryngoscope, determined that 100 cd.m\(^{-2}\) is the minimum luminance required for direct laryngoscopy in elective adult patients.

Figure 9.2 Lux meter and customised 80 mm diameter cylinder containing lux sensor at the base, light absorbing black satin lining and slit for laryngoscope blade.
Chapter 9. An audit of laryngoscopes and application of a new ISO standard

Figure 9.3 Modified lux sensor showing laryngoscope blade resting on needle spacer 20mm from the sensor surface.

Methods

This study conformed to the audit requirements of the Northern Regional Ethics Committee. Institutional permission was granted prior to the study.

A prototype apparatus was constructed with the dual purpose of controlling ambient and scattered light, and reliably positioning the laryngoscope tip 20 mm (the ISO 7376 standard distance) from the illuminance probe surface. The apparatus consisted of a hollow 80 mm diameter plastic cylinder fitted over the illuminance probe, into which the laryngoscope blade was inserted (Figure 9.2). A lengthwise slot accommodated the laryngoscope handle. An internal horizontal needle provided a depth stop to position the laryngoscope 20 mm from the probe and allow manipulation of the laryngoscope to best illuminate the probe (Figure 9.3) A lining of black velvet cloth minimised light reflections and scatter. A Tektronix J16 Digital Photometer with J6511 Cosine Corrected Illuminance Probe (Tektronix Inc. Beaverton, OR, USA) was used for all illuminance readings. A current calibration certificate (B1) indicated +/-3% accuracy. Light recordings were conducted in a dark room and ambient light was measured.

A pilot study, at Starship Children’s Health, of 190 reusable laryngoscopes, from 16 clinical workstations (including 6 operating rooms and 10 off the floor sites), was conducted in one evening. The sample comprised 43 laryngoscope handles and 192 laryngoscope blades. One hundred and thirty three (133) were ‘bulb in handle’ type, 57 were ‘bulb in blade’ type. Two blades were incompatible with the handles available. Each handle was typically used for 4 to 5 different blades, although this varied depending on compatibility. The

See Appendix five for a list of devices.
Chapter 9. An audit of laryngoscopes and application of a new ISO standard

selection of blade sizes and styles from each workstation was highly variable. The predominant brands of handle and blade were Heine, KaWe, Karl Storz and Welch Allyn.

Following this pilot study of 190 laryngoscopes, a smaller sample of eighteen laryngoscopes was examined in greater detail using the ISO 7376:2009 Standard (330) and a minimum luminance (606) was recorded. The audit of eighteen laryngoscopes was conducted as a ‘snapshot’ of equipment available on a particular day. Three laryngoscopes were found ready for use on each workstation of six operating rooms. Only these laryngoscopes were assessed. Shelf stock and stock undergoing cleaning were not included in the audit. Lux measurements were recorded before and after a 10 minute interval during which the laryngoscopes remained running. Each laryngoscope was measured three times on each occasion and mean values were calculated.

The ISO 7376:2009 Standard (330) describes limits for the distribution of light spread on paper 20 mm from the tip of a laryngoscope blade measured in a dark room. Using optical bench equipment, each laryngoscope was mounted in a stand and clamp and then precisely positioned with the tip 20mm from a pre-marked reference point on the paper screen. Marks were made by the authors on the reverse side of the white translucent paper at the illuminated edge according to limits described by the ISO 7376:2009 Standard (330). Light distribution measurements were based on mean lux levels from each laryngoscope blade with a standard handle and a xenon bulb connected to a variable voltage supply (Powertech Systems Equipment Corp. Hacienda Heights, California, USA.) as described by Scholz (326). It was then possible to measure light distribution from each of the 18 laryngoscope blades in the audit while maintaining a constant mean lux level for each laryngoscope. This method is used as a measure of light distribution and indirectly as a measure of illumination.

Luminance measurements were made using a Photo Research® PR® 650 Telespectrophotometer with a MS-75 attachment allowing focus as close as 35 cm. This device has a spectral range of 380-780nm and luminance accuracy of +/-2% of calculated luminance at correlated colour temperature of 2865K and an operating temperature of 23°C. The telespectrophotometer was positioned on the same side of the paper as the laryngoscope and at an angle of 45 degrees to the direction of illumination. Luminance of the central 1 degree area of the white paper screen was recorded with three measurements for each laryngoscope and mean values were calculated.

Following the audit, substandard laryngoscopes were removed from service and replaced with reusable, rechargeable, light emitting diode (LED) bulb-in-handle laryngoscopes. Illuminance and luminance measurements were recorded from one new laryngoscope (Macintosh size 3). Five anaesthetists from our department were involved in a limited survey and were asked to use a 10cm Visual Analogue Scale to measure their responses to the following two questions:-

1. What do you think about the suitability of the new laryngoscope light for laryngoscopy?

See Appendix five for a list of devices.
2. With respect to the laryngoscope light, how do you rate the new laryngoscopes compared to the old laryngoscopes?

The left and right ends of the visual analogue scales were labelled “Inadequate” and “Perfect” and “Worse” and “Better” respectively.

**Results**

In our pilot study of 190 laryngoscopes, the range of illuminance was 0 lux to 4789 lux (median illuminance was 345 lux, with an interquartile range of 170 lux to 605 lux). All 18 laryngoscopes in the audit were of the reusable type and consisted of hook-on blades to handles with an internal battery power source. In all laryngoscopes the power source connected to a clear xenon bulb in the handle and light was conducted through an optical bundle in the blade. The sizes, designs, manufacturers and distances of the light bundle to the blade tip are summarised in Table 9.1. There were no records of laryngoscope age or the number of cleaning, disinfection or sterilization cycles each component had been previously subjected to.

*Illuminance.* The initial median illuminance measurement for our audited laryngoscopes was 228 lux (interquartile range (IQR) 101-447). The median illuminance after 10 minutes had reduced to 148 lux (IQR 9-218). The median drop after 10 minutes was 88 lux (IQR 26 -153). Only 1 laryngoscope, with a mean illuminance of 534 lux at 10 minutes, met the ISO Standard minimum of 500 lux (Table 9.). Ambient light in the dark room where measurement took place was 1 lux. The mean light measurements from one of our new laryngoscopes were 4500 lux, decreasing to 3723 lux after 10 minutes, with luminance of 2195 cd.m⁻².

*Light distribution.* Measurement of light distribution onto white translucent paper, which was a test for illumination in the resting position, showed that all 18 laryngoscopes had light distributions within the vertical limit of the ISO standard, but none within the lateral limits. These results appear in Table 9.3.

*Luminance.* Luminance measurements when the laryngoscope was first turned on recorded a median of 92 cd.m⁻² (IQR 44-177), however, nine laryngoscopes did not reach the recommended mean of 100 cd.m⁻² reported by Skilton (606)

*Subjective rating of laryngoscope performance.* Subjective approval of the new laryngoscopes was 85% (range 78-92%, n=5), and rating of the new compared to the old laryngoscopes was also 85% (range 72-100%, n=5).

See Appendix five for a list of devices.
Table 9.1  Characteristics of the audited laryngoscopes (brands include Welch Allyn (WA), Karl Storz (KS), KaWe (KW)).

<table>
<thead>
<tr>
<th>Laryngoscope Style</th>
<th>Size</th>
<th>Bundle to tip distance (mm)</th>
<th>Blade brand</th>
<th>Handle brand</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Emac</td>
<td>1</td>
<td>WA</td>
<td>KW</td>
</tr>
<tr>
<td>2</td>
<td>Emac</td>
<td>3</td>
<td>WA</td>
<td>KW</td>
</tr>
<tr>
<td>3</td>
<td>Miller</td>
<td>1</td>
<td>KW</td>
<td>WA</td>
</tr>
<tr>
<td>4</td>
<td>Miller</td>
<td>2</td>
<td>KS</td>
<td>WA</td>
</tr>
<tr>
<td>5</td>
<td>Miller</td>
<td>1</td>
<td>KW</td>
<td>KW</td>
</tr>
<tr>
<td>6</td>
<td>Emac</td>
<td>1</td>
<td>WA</td>
<td>WA</td>
</tr>
<tr>
<td>7</td>
<td>Miller</td>
<td>1</td>
<td>WA</td>
<td>WA</td>
</tr>
<tr>
<td>8</td>
<td>Emac</td>
<td>3</td>
<td>WA</td>
<td>WA</td>
</tr>
<tr>
<td>9</td>
<td>Emac</td>
<td>2</td>
<td>KW</td>
<td>WA</td>
</tr>
<tr>
<td>10</td>
<td>Miller</td>
<td>0</td>
<td>KW</td>
<td>WA</td>
</tr>
<tr>
<td>11</td>
<td>Emac</td>
<td>2</td>
<td>KW</td>
<td>KW</td>
</tr>
<tr>
<td>12</td>
<td>Emac</td>
<td>3</td>
<td>WA</td>
<td>WA</td>
</tr>
<tr>
<td>13</td>
<td>Emac</td>
<td>2</td>
<td>KW</td>
<td>KW</td>
</tr>
<tr>
<td>14</td>
<td>Emac</td>
<td>1</td>
<td>WA</td>
<td>WA</td>
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<td>15</td>
<td>Miller</td>
<td>1</td>
<td>KW</td>
<td>WA</td>
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<td>16</td>
<td>Emac</td>
<td>3</td>
<td>WA</td>
<td>WA</td>
</tr>
<tr>
<td>17</td>
<td>Emac</td>
<td>2</td>
<td>WA</td>
<td>KW</td>
</tr>
<tr>
<td>18</td>
<td>Miller</td>
<td>1</td>
<td>KW</td>
<td>KW</td>
</tr>
</tbody>
</table>

See Appendix five for a list of devices.
Table 9.2   Illuminance and luminance recordings for 18 laryngoscopes.

<table>
<thead>
<tr>
<th>Laryngoscope</th>
<th>Mean (SD) illuminance (lux) (lm.m(^{-2}))</th>
<th>Mean (SD) illuminance after 10 minutes (lux)</th>
<th>Mean (SD) luminance (cd.m(^{-2}))</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>233 (81)</td>
<td>136 (10)</td>
<td>132 (49)</td>
</tr>
<tr>
<td>2</td>
<td>61 (9)</td>
<td>40 (5)</td>
<td>13 (1)</td>
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<tr>
<td>3</td>
<td>81 (16)</td>
<td>9 (0)</td>
<td>23 (16)</td>
</tr>
<tr>
<td>4</td>
<td>483 (171)</td>
<td>160 (17)</td>
<td>68 (26)</td>
</tr>
<tr>
<td>5</td>
<td>101 (38)</td>
<td>5 (2)</td>
<td>61 (28)</td>
</tr>
<tr>
<td>6</td>
<td>235 (116)</td>
<td>215 (33)</td>
<td>188 (25)</td>
</tr>
<tr>
<td>7</td>
<td>70 (14)</td>
<td>44 (1)</td>
<td>26 (4)</td>
</tr>
<tr>
<td>8</td>
<td>618 (54)</td>
<td>457 (19)</td>
<td>290 (32)</td>
</tr>
<tr>
<td>9</td>
<td>650 (82)</td>
<td>534 (9)</td>
<td>275 (36)</td>
</tr>
<tr>
<td>10</td>
<td>493 (23)</td>
<td>324 (26)</td>
<td>278 (54)</td>
</tr>
<tr>
<td>11</td>
<td>88 (33)</td>
<td>52 (5)</td>
<td>8 (6)</td>
</tr>
<tr>
<td>12</td>
<td>195 (72)</td>
<td>193 (16)</td>
<td>111 (51)</td>
</tr>
<tr>
<td>13</td>
<td>123 (29)</td>
<td>91 (2)</td>
<td>44 (8)</td>
</tr>
<tr>
<td>14</td>
<td>371 (25)</td>
<td>218 (23)</td>
<td>177 (13)</td>
</tr>
<tr>
<td>15</td>
<td>350 (45)</td>
<td>270 (9)</td>
<td>124 (49)</td>
</tr>
<tr>
<td>16</td>
<td>447 (63)</td>
<td>94 (2)</td>
<td>128 (8)</td>
</tr>
<tr>
<td>17</td>
<td>225 (19)</td>
<td>98 (6)</td>
<td>55 (23)</td>
</tr>
<tr>
<td>18</td>
<td>127 (108)</td>
<td>177 (16)</td>
<td>72 (44)</td>
</tr>
</tbody>
</table>
Table 9.3  Distribution of laryngoscope light in comparison with the ISO standard. Laryngoscope measurements which meet the standard are recorded in bold.

<table>
<thead>
<tr>
<th>Laryngoscope identifier</th>
<th>Illuminance at 20mm from tip (lux)</th>
<th>Upper range [ISO standard &lt;3mm]</th>
<th>Total vertical range [ISO standard 30-80mm]</th>
<th>Right to centre [ISO standard 25-50mm]</th>
<th>Left to centre [ISO standard 25-50mm]</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>233</td>
<td>7</td>
<td>32</td>
<td>23</td>
<td>15</td>
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<td>2</td>
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<td>127</td>
<td>3</td>
<td>37</td>
<td>36</td>
<td>16</td>
</tr>
</tbody>
</table>

Laryngoscope measurements that meet the standard are recorded in bold.

See Appendix five for a list of devices.
Chapter 9. An audit of laryngoscopes and application of a new ISO standard

Discussion

Laryngoscope light characteristics in our audit were substandard compared with ISO requirements and with a minimum acceptable luminance level. The results were consistent with our clinical impression. This is the first laryngoscope light audit conducted according to the new International Organisation for Standardisation, ISO 7376: 2009 (330). Audited laryngoscopes had poor illuminance after 10 minutes of use, and the distributions of light were below the recommended margins. Luminance measurements showed that fifty percent of our audited laryngoscopes were below 100 cd.m$^{-2}$, which is the minimum luminance accepted for laryngoscopy (606).

Poor laryngoscope light can be attributed to several causes including deterioration of light bundles after excessive sterilisation cycles (602, 608). Our laryngoscopes included multiple mismatching of handles and blades from different manufacturers causing poor connections. Our handle power supplies were fitted with non-rechargeable alkaline batteries which tend to discharge at a slow steady rate. Our technicians regularly replace batteries. The bulbs were all clear, xenon and located in the handles. No records were available to confirm the age and sterilisation history of individual laryngoscopes, and hence it was impossible to ascertain which components had exceeded recommended limits.

Laryngoscope components deteriorate with use. Bucx (602) reported light from fibrelight laryngoscopes deteriorated 86.5% after 300 treatment cycles using thermal sterilisation at 134°C. The damage was less after machine washing and disinfection at 90°C with 34.6% reduction in light intensity. The ISO 7376: 2009 Standard states that illumination shall exceed 500 lux for at least 10 minutes after the number of cleaning and disinfection or sterilisation cycles specified by the manufacturer have been performed. For example, Storz report a 30% drop in their laryngoscope blade light after 300 autoclave cycles and they recommend replacement of laryngoscopes after 1000 cycles. The audit revealed a significant drop in illumination after 10 minutes of use indicating that 17 out of 18 laryngoscopes had exceeded their useful life or required new batteries. The poor standard of light found in most of our laryngoscopes had been tolerated by the anaesthetists for several months. Since this deterioration is relatively insidious, reusable laryngoscope use should be tracked and light measurements recorded. This checking of performance should involve all components of light generation.

Minimum light levels required for direct laryngoscopy have now been clearly defined, along with standardised methods of testing. This standardisation will aid future research and allow studies to be compared. Assessment of laryngoscope compliance with the illuminance standard of 500 lux after 10 minutes continuous operation requires the availability of a modified lux meter such as the system we used in our study. Devices to record these measurements are not readily available. A prototype portable laryngoscope light intensity measurement apparatus has been described by Brousseau; however, it is designed to position the blade tip 10 mm from the lux meter (609), whereas the ISO Standard specifies positioning the laryngoscope tip 20mm from the illuminance probe surface.

See Appendix five for a list of devices.
The relationship between laryngoscope light and clinical performance at direct laryngoscopy has not been established. In a manikin study involving 50 anaesthetists, the majority of participants considered 700 lux laryngoscope illuminance to be too bright. These anaesthetists indicated that they could tolerate relatively low levels of illumination for simple laryngoscopy, but suggested that a brighter light would be desirable for a difficult intubation with highest optimum level of 610 lux and lowest optimum of 16 lux reported (605). It should be emphasised that these subjective assessments were conducted on a child manikin and did not assess performance during a difficult clinical laryngoscopy. Another manikin study with thirty six emergency medicine staff was designed to test the effect of different levels of laryngoscope illuminance on intubation time. This study found that different laryngoscope light intensity (50, 200 and 600 lux) did not affect intubation time; however, failure by the authors to specify the distance of the laryngoscope tip from the lux meter prevents validation of this experiment (610). In a clinical audit reported by Milne, eleven laryngoscopes were rejected by anaesthetists because of inadequate light (611). The mean illumination of these laryngoscopes was 597±160 lux (range 360–850 lux), but the light measurements were recorded from a device which held the laryngoscope tip 10 mm from the lux meter (609), and therefore these findings cannot be compared with our results or the ISO standard.

A clinical study by Skilton of 10 anaesthetists established that the minimum acceptable brightness of laryngoscope light for direct laryngoscopy was a luminance of 100 cd.m\(^{-2}\). This subjective study also found that 15% of their ‘bulb on blade’ and 33% of ‘bulb on handle’ laryngoscopes were substandard (606). Crosby performed a similar study using Skilton’s luminance cut-off. This showed a similarly poor outcome, with 15% of ‘bulb on blade’ and 92% of ‘bulb on handle’ laryngoscopes substandard (603). Unfortunately, studies which measure luminance cannot be directly compared with the ISO standard, which specifies illuminance. Our study measured both illuminance and luminance and recorded a median luminance of 92 cd.m\(^{-2}\) (IQR 44-177) with nine of our laryngoscopes not reaching a mean of 100 cd.m\(^{-2}\). Luminance is the product of illuminance and reflectance of the visualized surface. In the absence of a measured or specified reflectance, luminance cannot be related to illuminance.

As a result of this audit, substandard equipment was removed from service and replaced with new rechargeable light emitting diode (LED) laryngoscope handles and compatible blades from the same manufacturer. New equipment was individually identified with a view to track cleaning and sterilisation cycles, and audit processes were introduced according to ISO and manufacturers’ standards.

See Appendix five for a list of devices.
Postscript

This audit was conducted in response to complaints from anaesthetists about the poor quality of some laryngoscopes in their department. In order to define this problem, we designed an objective method to measure laryngoscope performance and used a standard to compare our results. The result of this audit was presented to hospital management who subsequently authorized new replacement laryngoscopes. This is an example of the value of an audit.

The use of the ISO 7376:2009 Standard for laryngoscope illuminance was an essential part of this audit. Future studies could investigate the relationship between laryngoscope illumination and visual acuity during laryngoscopy.

See Appendix five for a list of devices.
Chapter 10. Visual acuity during direct laryngoscopy at different illuminance levels


Preface

In chapter nine, I discussed an audit of laryngoscopes which were in clinical use. Measurements of laryngoscope illuminance were compared to the ISO 7376:2009 Standard for laryngoscope illuminance. No objective evidence was found to support the minimum level of illuminance described in the Standard. The study in this chapter was designed to objectively investigate the relationship between laryngoscope light and visual acuity during laryngoscopy.

As first author, I devised the study, collected data, assisted in the analysis of the results, collaborated in researching the subject, wrote the first draft of the paper and supervised subsequent revisions of the paper, prior to publication.

Abstract

Background: Adequate light is essential for vision during direct laryngoscopy. The ISO 7376:2009 Standard specifies the minimum illuminance for laryngoscopes. No studies have objectively examined the relationship between laryngoscope illumination and visual acuity during laryngoscopy.

Methods: The near visual performance of 50 anaesthetists was measured during direct laryngoscopy using near vision charts located at the larynx of four manikins. A variable voltage supply adjusted the illuminance from the laryngoscope to 50, 200, 700 and 2000 lux. Participants also rated their experience regarding brightness of the laryngoscope, clarity of view, visual performance, suitability and adequacy of the light, before proceeding to the next manikin with a different light level. The distance visual performance of the participants was also measured using standard letter acuity wall charts at the same light levels.

Results: Visual acuity in manikins and on wall charts was associated with an increasing lux level (p<0.0001). Visual acuity was lower at 50 and 200 lux compared to 700 lux by significantly greater than the clinically discernible 0.1 logMAR. No statistically significant improvement in visual acuity occurred when illuminance was increased to 2000 lux. The mean (standard deviation) logMAR scores at the four chosen lux levels on the manikin charts were: 50 lux 0.05 (0.13), 200 lux 0.06 (0.10), 700 lux -0.05 (0.11), 2000 lux -0.07 (0.11). This result was unaffected by age, seniority, sub-specialty, history of difficulty focusing, or use of lenses for laryngoscopy. Subjective rating of laryngoscope brightness favoured 2000 lux for clarity of view, suitability of the light for laryngoscopy and visual performance. The average observation distance for direct laryngoscopy was 32 cm.

See Appendix five for a list of devices.
Conclusions: Visual acuity improves as the laryngoscope illuminance increases up to 700 lux. No statistically significant improvement was measured by increasing the illuminance up to 2000 lux. Subjectively, anaesthetists favor illuminance of 2000 lux for direct laryngoscopy.

See Appendix five for a list of devices.
Introduction

Direct laryngoscopy by an experienced practitioner is usually an easy procedure; however restricted or difficult intubations (612) demand optimum conditions for a successful outcome, including an optimum laryngoscope light. Difficult intubations are not always predictable (45), and therefore laryngoscopes with an optimum light should be available at all times (150, 202). Maintenance of laryngoscopes requires regular audit, measurement of laryngoscope light and knowledge of optimum illumination. Difficulty measuring laryngoscope light and intermittent audit practices mean that laryngoscopes are often used with substandard light (458).

Several studies have examined laryngoscope light (303, 326, 458, 602-607) and some have made subjective assessments of minimum or optimum light characteristics for laryngoscopy (326, 602-606). The International Organization for Standardization has published a standard (ISO 7376:2009) specifying illuminance levels and tests for illumination from hook-on type laryngoscopes. Although this standard specifies that laryngoscope illumination shall exceed 500 lux for at least 10 minutes of use, the optimum level is not defined, nor is objective evidence provided for this minimum standard. The purpose of this study was to investigate the optimum laryngoscope illuminance for direct laryngoscopy by measuring the visual acuity and subjective assessment of 50 anaesthetists during direct laryngoscopy on a manikin using four levels of laryngoscope illuminance.

Methods

Approval for this study was obtained from the Northern X Regional Ethics Committee and written informed consent was gained from participants. Fifty practicing anaesthetists, from a range of backgrounds and specialties, with at least two years’ experience in direct laryngoscopy, were recruited for the trial from a tertiary hospital. The participant’s age, sex, years of experience, specialist interest, visual history, any previous visual difficulty during laryngoscopy and the use of lenses during laryngoscopy were recorded.

All participants were screened for contrast vision using a Pelli-Robson chart (Appendix 1) to ensure that no participants had poor contrast sensitivity which would have affected the investigation. Wall charts were then used for measurement of distance visual acuity (Appendix 1). Finally, near charts were used to measure visual acuity during the laryngoscopy procedure. These near charts were placed into the larynx of each manikin at a plane approximating that of the vocal cords (Figure 10.1). Different versions of the charts were used to minimize learning effects.
Chapter 10. Visual acuity during direct laryngoscopy at different illuminance levels

Figure 10.1 Trimmed Sloan near vision chart located at the larynx of a manikin illuminated by a red filtered laryngoscope light.

During measurements, participants began reading each acuity chart at the smallest letter size where they could correctly read all the letters on the line. Every letter read correctly on a lower line was counted in the measurement of their acuity score, which was then converted to logMAR (\log_{10} \text{minimum angle resolved}) using the method of Bailey et al (613) (Appendix 2). In this study, the logMAR values were converted using a linear transformation formula to the more intuitive VAR scale \[\text{Visual Acuity Rating} = 100 - (50 \times \text{logMAR})\] (Appendix 2). This conversion was used as it transforms the skewed MAR score to an approximately normal distribution. Research has shown that logMAR is the appropriate scale for statistical analysis of measures of visual acuity (614, 615). On the logMAR scale normal acuity (20/20) is 0.0 log (minutes of arc) and each additional letter read reduces the score by 0.02. On the VAR scale normal acuity (20/20) is 100 and each additional letter read increases the score by 1. Four levels of ambient light (50, 200, 700 and 2000 lux) were used and participants were first tested on wall charts and then near charts in manikins at each of these ambient light levels. The order of light level was randomized with a brief rest period between each recording while light levels were adjusted and calibrated with a lux meter.

As the visual tasks of laryngoscopy \textit{in vivo} involve detection of variations in red tissue colour and contrast, we used red illumination for the acuity charts that approximated the red colour of the manikin airway and the human airway. The use of a red filter in this study also minimizes the change in spectral composition that accompanies an increase in supply voltage. Normal changes in battery charge are likely to produce similar spectral changes.

Four manikins with normal anatomical airways were placed on adjustable tables to allow for varying height of the participants. The distance from each individual participant’s eyes to the plane of the near visual acuity card (vocal cord plane) was used to calculate the near visual acuity measurements. The light produced by the laryngoscope was adjusted and calibrated with a lux meter between each manikin to generate one of the four lux levels (50, 200, 700 and 2000 lux) measured as specified in the current ISO 7376:2009 Standard.
Participants were instructed to perform direct laryngoscopy according to their normal practice in order to access and read the near vision charts located in the larynx of the manikin. This task usually took less than 30 seconds but never more than one minute.

After acuity measurement at each manikin, the participant was asked to rate their subjective experience on a 10 centimetre line for each of the five different variables: brightness of the laryngoscope, clarity of view, suitability of the light for laryngoscopy, adequacy of the light to perform laryngoscopy, and the participant’s subjective perception of their visual performance using this light. The left and right ends of the visual analogue scales were labelled for each question. These questions and the visual analogue scale appear in Table 10.1.

Statistics. Visual acuity was analysed using generalised linear models, with the logMAR score used as a continuous outcome. All predictive factors were analysed as categorical variables; hence the parameter estimate (95% CI) shows the difference in logMAR score between each category and the defined reference group. Models were fitted using Proc GLM in SAS v9.1 (SAS Institute, NC, USA). The subjective scores were analysed using paired t-tests (the pair based on the individual anaesthetists) describing the mean and standard deviations. For subjective measurements, comparisons were carried out with the lux level of 2000 so as to determine whether lower light levels were considered by the anaesthetists to be inferior to the brightest light. For objective measures, we assessed differences with the 700 lux level as the comparative group, as this was considered at the time of designing the study to be the minimum light level. Statistical significance was defined at the 5% level.

Results

Fifty anaesthetists participated in this study (33 male and 17 female). The median age was 42 years (inter-quartile range [IQR] 34 - 49), with 12.5 median years of experience (IQR 7 - 22): 37 were consultants, 13 were registrars and 13 practiced paediatric anaesthesiology. Twelve participants reported a history of difficulty focusing and 29 used contact lenses or eye glasses for laryngoscopy and distance vision. The Pelli-Robson recordings were all 1.65 indicating normal contrast sensitivity.
Table 10.1 Subjective opinion of visual performance during laryngoscopy at varying laryngoscope illuminances made using a visual analogue scale (VAS). Questions and limits of 10 centimeter lines used to assess subjective opinion of visual performance during laryngoscopy at varying laryngoscope illuminances.

1. Please rate the brightness of this laryngoscope; 0 = too dim, 5 = perfect, 10 = too bright.
2. Please rate the clarity of your view; 0 = inadequate, 10 = perfect.
3. Please rate the suitability of this light for laryngoscopy; 0 = unsuitable, 10 = perfect.
4. Please rate the adequacy of the laryngoscope light to perform laryngoscopy; 0 = excessively dim, 5 = perfect, 10 = excessively bright.
5. Please rate your visual performance for laryngoscopy under the conditions at this station; 0 = inadequate, 10 = perfect.

<table>
<thead>
<tr>
<th>Laryngoscope illuminance (Lux)</th>
<th>Brightness rating</th>
<th>Clarity of view</th>
<th>Suitability of light</th>
<th>Adequacy of light</th>
<th>Visual performance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td>50</td>
<td>2.85 (1.20)</td>
<td>3.46 (2.03)</td>
<td>2.73 (1.91)</td>
<td>3.02 (1.18)</td>
<td>3.62 (2.06)</td>
</tr>
<tr>
<td></td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>200</td>
<td>1.88 (1.20)</td>
<td>4.88 (2.15)</td>
<td>4.22 (2.26)</td>
<td>2.14 (1.19)</td>
<td>4.89 (2.35)</td>
</tr>
<tr>
<td></td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td></td>
</tr>
<tr>
<td>700</td>
<td>0.72 (0.67)</td>
<td>6.56 (1.70)</td>
<td>6.18 (1.96)</td>
<td>0.87 (0.82)</td>
<td>6.53 (2.00)</td>
</tr>
<tr>
<td></td>
<td>p=0.39</td>
<td>p=0.005</td>
<td>p=0.014</td>
<td>p=0.13</td>
<td></td>
</tr>
<tr>
<td>2000</td>
<td>0.85 (0.90)</td>
<td>7.30 (1.62)</td>
<td>7.01 (2.07)</td>
<td>0.63 (0.79)</td>
<td>7.11 (1.86)</td>
</tr>
</tbody>
</table>

1 Scale rated with perfect in the middle of the scale. The numbers in columns 1 and 4 (brightness and adequacy) represent the mean distance of the points which deviate in either direction from the perfect point, which is in the center of the VAS.

2 Scale rated with perfect at the right of the scale. The reported mean in columns 2, 3 and 5 (clarity, suitability and performance), is the mean distance of the VAS.

Statistical significance was defined as p < 0.05. The p-value is in comparison to 2000 lux.
Table 10.2 Mean change in Log MAR score (95% CI) with four lux levels and potential confounding factors.

<table>
<thead>
<tr>
<th></th>
<th>Univariable change</th>
<th>Multivariable* change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>p=0.79</td>
<td>p=0.09</td>
</tr>
<tr>
<td>&lt;40</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>40+</td>
<td>-0.003 (-0.029, 0.022)</td>
<td>0.025 (-0.004, 0.053)</td>
</tr>
<tr>
<td>Subspecialty</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paediatric</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Adult</td>
<td>0.008 (-0.019, 0.035)</td>
<td>0.007 (-0.015, 0.029)</td>
</tr>
<tr>
<td>Seniority</td>
<td>p=0.09</td>
<td>p=0.01</td>
</tr>
<tr>
<td>Consultant</td>
<td>-0.024 (-0.053, 0.004)</td>
<td>-0.043 (-0.075, -0.011)</td>
</tr>
<tr>
<td>Registrar</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>History of difficulty focusing</td>
<td>p=0.13</td>
<td>p=0.08</td>
</tr>
<tr>
<td>Yes</td>
<td>-0.022 (-0.051, 0.007)</td>
<td>-0.022 (-0.045, 0.002)</td>
</tr>
<tr>
<td>No</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Lenses for laryngoscopy</td>
<td>p=0.85</td>
<td>p=0.51</td>
</tr>
<tr>
<td>Yes</td>
<td>0.002 (-0.023, 0.028)</td>
<td>0.007 (-0.014, 0.028)</td>
</tr>
<tr>
<td>No</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Lux level</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>50</td>
<td>0.095 (0.063, 0.127)</td>
<td>0.095 (0.067, 0.123)</td>
</tr>
<tr>
<td>200</td>
<td>0.111 (0.079, 0.143)</td>
<td>0.111 (0.083, 0.139)</td>
</tr>
<tr>
<td>700</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>2000</td>
<td>-0.014 (-0.046, 0.018)</td>
<td>-0.014 (-0.042, 0.014)</td>
</tr>
<tr>
<td>Wall chart or Manikin</td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
</tr>
<tr>
<td>Chart</td>
<td>Reference</td>
<td>Reference</td>
</tr>
<tr>
<td>Manikin</td>
<td>0.10 (0.077,0.123)</td>
<td>0.10 (0.080, 0.120)</td>
</tr>
</tbody>
</table>

* Controls for all variables shown in table. Statistical significance was defined as p < 0.05
### Table 10.3 Multivariable* associations of factors related to logMAR score at 700 and 2000 lux and tests of within subject effects

<table>
<thead>
<tr>
<th></th>
<th>700 lux</th>
<th>2000 lux</th>
<th>p-value for within subject effect†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lux level</strong></td>
<td></td>
<td></td>
<td>0.20</td>
</tr>
<tr>
<td>Age</td>
<td>p=0.36</td>
<td>p=0.94</td>
<td>0.19</td>
</tr>
<tr>
<td>&lt;40</td>
<td>Reference</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>40+</td>
<td>0.024 (-0.028, 0.077)</td>
<td>-0.002 (-0.052, 0.056)</td>
<td></td>
</tr>
<tr>
<td><strong>Subspecialty</strong></td>
<td></td>
<td></td>
<td>0.50</td>
</tr>
<tr>
<td>Paediatric</td>
<td>p=0.57</td>
<td>p=0.89</td>
<td>0.50</td>
</tr>
<tr>
<td>Adult</td>
<td>0.012 (-0.029, 0.052)</td>
<td>0.002 (-0.039, 0.045)</td>
<td></td>
</tr>
<tr>
<td><strong>Seniority</strong></td>
<td></td>
<td></td>
<td>0.32</td>
</tr>
<tr>
<td>Consultant</td>
<td>p=0.16</td>
<td>p=0.45</td>
<td>0.32</td>
</tr>
<tr>
<td>Registrar</td>
<td>-0.041 (-0.100, 0.017)</td>
<td>-0.023 (-0.083, 0.037)</td>
<td></td>
</tr>
<tr>
<td><strong>History of difficulty focusing</strong></td>
<td>p=0.07</td>
<td>p=0.27</td>
<td>0.26</td>
</tr>
<tr>
<td>Yes</td>
<td>-0.040 (-0.084, 0.003)</td>
<td>-0.025 (-0.069, 0.020)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Reference</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td><strong>Lenses for laryngoscopy</strong></td>
<td>p=0.74</td>
<td>p=0.63</td>
<td>0.76</td>
</tr>
<tr>
<td>Yes</td>
<td>-0.006 (-0.044, 0.032)</td>
<td>-0.009 (-0.048, 0.030)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Reference</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td><strong>Wall chart or Manikin</strong></td>
<td>p&lt;0.0001</td>
<td>p&lt;0.0001</td>
<td>0.79</td>
</tr>
<tr>
<td>Chart</td>
<td>Reference</td>
<td>Reference</td>
<td></td>
</tr>
<tr>
<td>Manikin</td>
<td>0.127 (0.090,0.164)</td>
<td>0.124 (0.087,0.162)</td>
<td></td>
</tr>
</tbody>
</table>

* Controls for all variables shown in table. Statistical significance was defined as p < 0.05

† Analysis carried out using the repeated option in Proc GLM in SAS with the logMAR scores at 700 and 2000 lux as the repeated measure and the variables list in the table included as co-variates in a multivariable model.

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Chapter 10. Visual acuity during direct laryngoscopy at different illuminance levels

Figure 10.2  Comparison of laryngoscope illumination levels, measured in lux, and visual acuity, measured by Visual Acuity Rating (VAR) or LogMAR score on (A) a wall chart and (B) a near chart in a manikin. Note, VAR 100 = 20/20 vision and VAR 85 = 20/40 vision. In the box and whisker plot of visual acuity from 50 anaesthetists, the bottom of the box represents the lower quartile, the top represents the upper quartile, the line across the box the median, the ends of the whiskers represent the maximum observation within the lower and upper quartiles ±1.5 times the inter-quartile range and the dots represent outlying values. Seven hundred lux was used as the reference point for analysis. Significant difference was found for 50 and 200 lux, but no difference was found for 2000 lux on both wall and manikin charts (see Table 10.1 for statistical results). A: Visual acuity results from the wall charts measured at four different levels of illumination (50, 200, 700 and 2000 lux). B: Visual acuity results from the near charts located in the larynx of the manikin measured at four different levels of illumination.

LogMAR= the logarithm of the minimum angle of resolution
Lux=SI unit for illuminance, VAR=Visual acuity rating

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The effect of illuminance on visual acuity using the wall charts and the manikin charts appears in Table 10.2 and Figure 10.2. The mean (standard deviation) logMAR scores at the four chosen lux levels on the manikin charts were: 50 lux 0.05 (0.13), 200 lux 0.06 (0.10), 700 lux -0.05 (0.11), 2000 lux -0.07 (0.11). Using 700 lux as a reference, visual acuities at 50 and 200 lux were statistically significantly worse; visual acuities at 2000 lux, however, were not statistically significantly better (Table 10.2). We additionally carried out a Dunnet’s correction to the analysis of lux levels. The levels of significance of the 50 and 200 lux levels compared to 700 lux were both p<0.0001. The result comparing 2000 to 700 lux became less significant as would be expected (p=0.39 to p=0.72). We further analysed the differences between 700 and 2000 lux using the repeated option in proc GLM to allow for the correlation between scores (Pearson correlation r=0.87). This continued to show no difference between logMAR scores at 700 and 2000 lux and additionally there were no differences in relation to any of the other factors controlled for, thus the lack of difference was generalisable across the whole group of anaesthetists (Table 10.3).

In multivariable analysis controlling for seniority, sub-specialty (adult and paediatric anaesthesiology), history of difficulty focusing and use of lenses for laryngoscopy, visual acuity of participants was significantly better on the wall charts than the manikin charts by an average of 0.1 log minutes of arc or one line (5 letters) on the letter chart (p<0.0001) (Table 10.2). The focal distance during laryngoscopy on the manikins had a mean distance of 32 cm [IQR, 26-44]. Measurements of filtered and non-filtered laryngoscope light reflected from the walls of the manikin larynges showed that any differences in luminance or colour were less than the measurement accuracy of the light meters.

Participants’ subjective opinion of light conditions during laryngoscopy is shown in Table 10.1. When asked to rate the subjective opinion of visual performance during laryngoscopy, at 50, 200 and 700 lux compared to 2000 lux, participants favoured 2000 lux for clarity of view, suitability of the light for laryngoscopy and visual performance.

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Discussion

The visual acuity of fifty anaesthetists was measured during laryngoscopy in manikins at four levels of laryngoscope light. Visual acuity improved between 50, 200 and 700 lux illuminance. No significant improvement in visual acuity was achieved by increasing laryngoscope illuminance from 700 to 2000 lux. Despite this objective result, anaesthetists favoured laryngoscopy at 2000 lux for the subjective measures of clarity of view, suitability of the light for laryngoscopy and visual performance.

The effect of laryngoscope light on visual acuity during direct laryngoscopy has not been previously measured. Previous studies have subjectively examined the relationship between laryngoscope light and performance at direct laryngoscopy (326, 602-606). A study performed on a child manikin involved subjective assessment by 50 anaesthetists to determine minimum and optimum levels of illuminance (605). In that study, the observers tolerated low levels of illumination for simple laryngoscopy, with a range of optimum levels reported from 16 lux to 610 lux, but preferred a brighter light for difficult laryngoscopy. The majority of those anaesthetists also considered that 700 lux was too bright for a halogen (78%) and xenon (54%) bulb respectively. This contrasts with our subjective findings where anaesthetists favoured 2000 lux illumination.

In order to create an objective measurement of visual acuity during direct laryngoscopy, the near test charts were placed inside the manikin. This added the mechanical processes of laryngoscopy to the visual process of reading an acuity chart. When the laryngoscopy task was combined with the near visual testing, a significant loss (0.1 log minutes of arc or one line of 5 letters on an acuity chart) in visual acuity was found compared with distance visual acuity testing. It is unlikely that the anaesthetists became fatigued during the task of reading the near acuity chart because the procedure was completed in less than one minute. Direct laryngoscopy is a monocular task (616), and our measurements of near visual performance in the manikins would also have been monocular. Our visual acuity testing on the wall charts did not test for monocular vision, but it has been shown that the average improvement with binocular viewing compared to best eye monocular vision, measured on the same charts used in our study, is only 0.02 log minutes of arc (1 letter on the acuity chart) (617). Therefore, the change to monocular viewing could explain only 20% of the performance loss during laryngoscopy. The remainder of the loss can only be explained by the fact that the near reading had to be accomplished when a competing task (laryngoscopy) was performed, and by the closer near viewing distance. The variable near viewing distances chosen by the anaesthetists, were accounted for in the calculation of near visual acuity and are not the cause of the difference observed.

It is important for anaesthetists to understand the visual demands of near tasks such as direct laryngoscopy. The median near observation distance of 32 cm, found in our study, is less than the normal 40 cm near working distance expected for everyday tasks indicating that direct laryngoscopy is a very demanding near vision task. Corrective lenses could be needed at an earlier age for this closer distance and lenses specifically for laryngoscopy should be stronger than ordinary corrective lenses for reading. As the 32 cm observation distance is closer than conventional reading distances, older anaesthetists should alert their eye care practitioner so that reading glasses can be prescribed to suit the close observation distance of direct laryngoscopy. Accurate focus

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is important for all the procedural tasks anaesthetists need to perform and for this reason we chose near visual acuity as a test of visual performance during direct laryngoscopy (618). Recommended illuminance levels for office tasks vary depending on difficulty, with higher illuminances being recommended for more demanding tasks. A value of 500 lux is specified for office work by the IESNA Office Lighting Committee Illuminance Selection, Illuminating Engineering Society of North America 2004. Our study was not designed to investigate other potentially important aspects of laryngoscopy performance such as contrast vision. Calibrated contrast sensitivity tests are difficult to manufacture and clinical tests of near contrast sensitivity are not commercially available.

This was a non-clinical study that would not have been possible to conduct in a clinical environment. Our study could be criticized for not using the 500 lux setting recommended in the current ISO 7376:2009 Standard. However, at the time that we conducted our study, the draft ISO Standard (ISO TC 121/SC 2, N813) was in effect, which specified a minimum illumination of 700 lux for laryngoscopes. This draft standard has been withdrawn and replaced with the current ISO 7376:2009 Standard. Although the difference between 500 and 700 lux seems large, visual perception is logarithmic, not linear, and the difference between the two levels is better represented by the difference between 2.7 log (lux) and 2.85 log (lux). Compared with the range of illuminances used in this study (1.7 - 3.3 log (lux)), a change of 0.15 log (lux) is not large.

The optimum laryngoscope light level is reached when best visual acuity is achieved and remains at this level over a range of increasing luminances. A 700 lux illumination level gives very good distance acuity (mean logMAR = -0.12, mean VAR = 106) and good near acuity (mean logMAR = 0.01, mean VAR = 99.5). An increase in light level to 2000 lux gives virtually unchanged distance acuity (mean logMAR = -0.13, mean VAR = 106.5) and unchanged near acuity (mean logMAR = -0.01, mean VAR = 100.5). Our results show that improvements in visual acuity with increasing illuminance become asymptotic around 700 lux (Figure 10.2). A future study could define the minimum illumination for laryngoscopy by examining how acuity is altered as illuminance is reduced from 700 to 200 lux. Laboratory research has shown that an observer can readily perceive the change in image quality that accompanies a change in acuity of one line (logMAR 0.1) therefore the statistically significant logMAR differences found in this study (50 and 200 lux compared to 700 lux) will also apply in clinical situations (619). The difference seen between 700 and 2000 lux was the equivalent of less than one line and this is not clinically important. The subjective preference for 2000 lux may be explained by the fact that higher luminance reduces pupil size which may improve acuity by increasing depth of focus and minimizing the effect of any focus errors (620).

This is the first study to objectively measure visual performance during direct laryngoscopy. The results may help improve the international standards for laryngoscope light. The results may highlight the importance of appropriate light during near vision tasks such as direct laryngoscopy. Progressive visualization of anatomical landmarks is important during direct laryngoscopy (621). Structures such as the epiglottis, which can be bypassed, distorted by abnormal anatomy and pathology, or masked against adjacent mucosa, need to be demarcated and carefully identified. Under adverse conditions, exposure and identification of the larynx is

See Appendix five for a list of devices.
dependent on the best optical conditions, including optimum illumination. A greater appreciation of how to optimize a view of the larynx could help decrease failed intubation and airway morbidity.

Appendix 1. Methods

Contrast vision was measured using a Pelli Robson contrast sensitivity chart (Precision Vision®, La Salle, Illinois, USA). The Pelli Robson chart was viewed from a distance of 1 meter at an ambient room light level of 200 lux.

Four levels of ambient light (50, 200, 700 and 2000 lux) were used in this study. All participants had their distance visual acuity measured using Original series ETDRS (early treatment diabetic retinopathy study, Precision Vision®, La Salle, Illinois, USA) visual acuity charts. Four different ETDRS charts were used to remove the effects of memorizing. The acuity wall charts were illuminated by a portable slide projector. The required illuminance levels were achieved for every measurement by adjusting the distance of the projector from the charts until the required level of ambient light was achieved, as measured with a lux meter.

To examine the effect of differing laryngoscope light levels on visual acuity during laryngoscopy, the study utilized four TruCorp AirSim® manikins (TruCorp Ltd, Belfast, Northern Ireland). The observers used a size 3 fiberoptic xenon bulb Macintosh laryngoscope (Karl Storz Endoscope, Tuttlingen, Germany) attached via the handle to a variable voltage supply (Powertech Systems Equipment Corp. Hacienda Heights, CA, USA) (326). The four illuminance (lux) levels chosen (50, 200, 700 and 2000 lux) reflected current international data on minimum and optimum laryngoscope illuminance at the time of the study design (326, 605). Near visual acuity during laryngoscopy was measured with Sloan pocket size near vision charts (Precision Vision® Original series ETDRS chart). These charts are designed to allow near visual acuity to be determined for the range of near viewing distances used in this study. They were modified by trimming the chart border so that they would fit into the larynx of each manikin at a plane approximating that of the vocal cords (Figure 10.1).

The red filter colour was determined using luminance and reflectance measurements gathered from the larynges of the study manikins and then corroborated using a human patient. These measurements indicated that a 35% transmittance red filter (Rosco Laboratories Inc., Stamford CT, USA) was needed in the light pathway of the study laryngoscope. The color measurements for the manikins and a human subject were made with a Photo Research® PR® 650 Telespectrophotometer (Photo Research, Inc, Chatsworth, CA, USA) with an MS-75 attachment, allowing focus as close as 0.35m. The light source used was a xenon bulb set to an illuminance of 700 lux. The in vivo measurements were taken from a consented patient during a general anaesthetic. The Telespectrophotometer has a spectral range of 380-780 nm and luminance accuracy of +/-2% of calculated luminance at correlated colour temperature of 2865K and an operating temperature of 23°C.

The anaesthetists performing laryngoscopy were allowed a brief settling period after which a line from their right eye to the right corner of the manikin’s mouth was measured. This was added to a premeasured distance.

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from the manikin’s mouth to the Sloan pocket size near vision chart in the larynx (11 cm). The participant then performed laryngoscopy on each manikin, with the purpose of identifying and reading the Sloan near chart. Letter by letter scoring of near visual acuity was performed in an identical manner to the distance visual acuity assessments. Near logMAR acuity was calculated from the total viewing distance and the size of the smallest letters read. The ambient light level was 320 lux during near visual acuity reading.

The red filtered light produced by the laryngoscope was adjusted between each manikin using the Powertech variable voltage supply to generate one of the four lux levels (50, 200, 700 and 2000 lux) measured at a distance of 20mm from the tip of the blade as specified in ISO 7376. Light levels were presented in a random order using computer generated randomization (GraphPad Software®, Inc, La Jolla, California, USA). The laryngoscope light was calibrated between each assessment using a modified Tektronix J16 Digital Photometer with a J6511 Cosine Corrected Illuminance Probe (Tektronix Inc. Beaverton, OR, USA). A current calibration certificate (B1) for the Photometer indicated +/-3% accuracy. The probe was located at the base of a custom built 80mm plastic cylinder lined with black velvet cloth to reduce light reflection and scatter, and was designed with a longitudinal slot to accommodate the laryngoscope handle (458). A horizontal needle was positioned inside the cylinder 20mm above the illuminance probe to act as a depth stop to standardize the distance from the laryngoscope blade tip to the probe as defined in ISO 7376. Ambient light during laryngoscope calibration was 1 lux.

Appendix 2. Glossary of terms

Illuminance (E): Illuminance is the amount of light falling on, or illuminating, a unit surface area. The SI unit for illuminance is the lux (lx), and one lux is equal to one lumen per square meter (lm.m⁻²).

Luminance (L): Luminance is the apparent brightness of an illuminated surface and is the product of illuminance (E) and reflectance (r) of the visual surface taking direction into account. The SI unit for luminance is candela per square meter (cd.m⁻²). The relationship between luminance and illuminance is calculated by the formula \[ L = r \cdot E / \pi. \]

Snellen notation and visual acuity (VA). Target recognition tasks such as letters presented on Snellen or more modern charts such as the ETDRS (early treatment diabetic retinopathy study), Sloan or Bailey-Lovie charts are commonly used for visual acuity measurements. The measurement of letter acuity involves recording the smallest line of letters that a subject can identify on a graduated chart. Visual acuity (VA) can be recorded clinically in Snellen notation according to the familiar notation VA = D’/D where D’ is the viewing distance and D is the distance from which the letter would need to be observed for the letter detail (the stroke width) to subtend 1 minute of arc at the eye (or the letter height to subtend 5 minutes of arc at the eye). Modern charts are used as these control letter spacing and letter difficulty much more rigorously than older “Snellen” charts.

See Appendix five for a list of devices.
Chapter 10. Visual acuity during direct laryngoscopy at different illuminance levels

**Minimum angle of resolution (MAR).** In clinical research Snellen notation is not favoured, as statistical analyses are difficult to apply. Instead visual acuity is specified as the minimum angle that the letter detail subtends at the eye when the letter can just be recognized. This angle is the minimum angle of resolution (MAR) and is the reciprocal of the Snellen fraction. The logarithm of the minimum angle of resolution (logMAR) is used for statistical purposes as it is a normally distributed continuous variable.

**Visual acuity rating (VAR).** In this study the logMAR values are converted using a linear transformation formula to the more intuitive VAR scale [Visual Acuity Rating = 100 - (50 X logMAR)]. On the Visual Acuity Rating (VAR) scale an acuity of 6/6 (20/20) is 0.0 logMAR and 100 units VAR. For each letter smaller than 6/6 that is identified, the VAR increases by 1. Therefore a VAR of 105 is recorded (logMAR = -0.10) when all five of the letters on the next smallest line from 6/6 (=6/4.8, 20/16) are read correctly. A VAR of 85 is recorded where 15 letters (3 lines) are lost from 6/6 and the acuity is 6/12 (20/40) (logMAR=0.30) (622).

**Postscript**

I presented this study at the New Zealand Society of Anaesthetists annual scientific meeting, held in Auckland, 16\(^{th}\) November 2012 and was awarded Winner of the John Ritchie Prize for the best original scientific presentation.

The study highlights the importance of appropriate light during direct laryngoscopy and suggests ways in which practitioners can improve intubating conditions by improving light and optimizing corrective lenses for near vision tasks. A future study could define the minimum illumination for laryngoscopy by examining changes in acuity as illuminance is reduced from 700 to 200 lux. A comparative study of optical conditions during direct and video laryngoscopy could also help explain how to improve intubating conditions.

See Appendix five for a list of devices.
Chapter 11. Parker Flex-Tip or standard tracheal tube for percutaneous emergency airway access? A prospective randomised trial.


Preface

Preceding chapters have discussed the suitability of airway equipment for clinical use. The importance of equipment being fit for purpose has been considered, and the use of equipment outside the scope of manufacturers’ recommendations has also been discussed. In this chapter, I present a trial which examined the use of two different tracheal tubes in an unconventional application.

Various options are available to secure percutaneous emergency airway access during a “cannot intubate, cannot ventilate” (CICV) situation. The scalpel bougie technique is popular for a number of reasons: the equipment is readily available; the technique is relatively easy to learn and can be completed quickly; and it has a relatively low complication rate. The end result is a cuffed tracheal tube which is suitable for standard ventilation with a self-inflating bag or an anaesthetic circuit. This technique is taught and practised during our routine airway course. An observation during one of those courses inspired this study.

As first author, I devised this study, collected data, assisted with analysis of the results, researched the subject, wrote the first draft of the paper and supervised all revisions prior to publication of the paper.

Abstract

Background: Percutaneous emergency airway access (PEAA) can be established utilizing a scalpel, bougie and cuffed tracheal tube. The study compared the Parker Flex-Tip tracheal tube to a standard tracheal tube for PEAA in cadavers. We hypothesized that a standard tracheal tube would be more likely to advance over a bougie into the trachea during a PEAA procedure than a Parker Flex-Tip tracheal tube.

Methods: Three anaesthetists performed a PEAA procedure with a scalpel, bougie and cuffed tracheal tube, 12 times each. Recorded times included: loading the tracheal tube onto the bougie and advancing the tube over the bougie to the skin, advancing the tube through the skin into the trachea, and completion of the whole procedure. Subjective opinion regarding the ease of tube insertion was recorded by visual analogue scoring.

Results: Subjective opinion, overall time and time to complete each component of the procedure were not significantly affected by the type of tube used. The mean time for three novice anaesthetists to complete PEAA

See Appendix five for a list of devices.
on a cadaver was 37.5 (8.8) seconds, after one hour of training. In two of the 12 cadavers, the cricothyroid membrane could not be palpated or located with the scalpel.

Conclusion: The Parker Flex-Tip tube and a standard tracheal tube perform equally well during percutaneous emergency airway access procedures on adult cadavers.

See Appendix five for a list of devices.
Introduction

Percutaneous Emergency Airway Access (PEAA) is indicated whenever ventilation by facemask, supraglottic airway device or tracheal intubation cannot maintain acceptable levels of oxygenation. Several techniques have been described to manage the “cannot intubate, cannot oxygenate,” scenario including the rapid four-step surgical cricothyroidotomy. The original description of this technique by Brofeldt included a size 20 scalpel, a tracheal hook with a large radius, and a cuffed tracheostomy tube (623). A variation of this technique has since been described by Morris et al without the tracheal hook, utilizing a scalpel, a bougie and a standard tracheal tube (624). In an adult, the cricothyroid membrane is first identified and then a transverse stab incision is performed through overlying tissue and the cricothyroid membrane, using a size 20 scalpel. The scalpel is rotated 90 degrees to form a triangular shaped pocket through which a bougie is then introduced and advanced down the trachea. Finally, a size 6.0 mm internal diameter (ID) cuffed tracheal tube is railroaded over the bougie using a rotating action, and a secure airway is established after removal of the bougie. This method has been called the scalpel bougie technique by Heard et al and includes the option of re-oxygenation through the Frova intubating introducer (Cook® Medical, Bloomington, Indiana, USA) prior to tube insertion (134).

Tracheal tube diameter and design affects tracheal intubation success rates for oral and nasal intubation. Although the diameter of the tracheal tube has been considered for adult rapid four-step surgical cricothyroidotomy (625), a comparison of tube tip design has not been previously investigated. We have previously observed that during training for emergency tracheotomy in anaesthetized pigs the Parker Flex-Tip tube occasionally everts at the edge of the tracheal wall prior to tube insertion. Our observation inspired this randomized controlled trial.

The Parker Flex-Tip tracheal tube has a soft hemispherical curved bevel tip and was designed to reduce trauma during oral and nasal intubation. The tip of the Parker Flex-Tip tube reduces the gap between the inside of the tube and the bougie, thereby reducing the chance of impingement on the larynx. Therefore, there is a theoretical advantage of advancing the Parker Flex-Tip tube over a bougie during PEAA. This advantage could theoretically be undermined by impingement due to eversion of the soft tube tip on the tissue margins of the narrow cricothyroidotomy or tracheotomy incision.

We hypothesized that a standard tracheal tube would be more likely than a Parker Flex-Tip tracheal tube to advance over a bougie into the trachea during a PEAA procedure. The aim of this study was to compare the efficacy of a Parker Flex-Tip tube to a standard tracheal tube for percutaneous emergency airway access in adult cadavers. The primary endpoint was the time taken to pass the tube through pretracheal tissue.

See Appendix five for a list of devices.
Chapter 11. Parker Flex-Tip or standard tracheal tube for percutaneous emergency airway access? A prospective randomised trial.

Methods

Approval was obtained from the Northern X Regional Ethics Committee (NTX/11/EXP/241), registration was completed with the Australian and New Zealand Clinical Trials Registry (ANZCTR: ACTRN12611001121954) and written informed consent was gained from each of the participating anaesthetists. Nine female and three male adult preserved human cadavers were used in this study and their age, gender, weight and neck circumference appear in Table 11.1.

One female and two male consultant anaesthetists, aged 41, 37 and 36 years, responded to a departmental advertisement for study participants. Inclusion criteria required consultant anaesthetists less than 45 years of age and 10 years after residency (435), with no prior experience performing PEAA or attendance at PEAA training during the last two years. Participants attended a preliminary one hour didactic and manikin based training session to familiarize them with PEAA techniques including the scalpel bougie technique. A video of the scalpel bougie technique was also shown (626).

The two tracheal tubes used were the Parker Flex-Tip™, 6.0 mm ID, 8.2 mm OD, high volume low pressure cuff tube (Parker Medical, Englewood, CO, USA) and the Mallinckrodt™ Hi-Lo™, 6.0 mm ID, 8.2 mm OD, high volume low pressure cuff tube (Covidien, Mansfield, MA, USA). A Frova intubating introducer was used for all intubations (14 French catheter, 65 cm long, 3.0 mm ID, recommended for placement of tracheal tubes with internal diameters \( \geq 6.0 \) mm) (Cook® Medical, Bloomington, Indiana, USA) (Figure 11.1).

Anaesthetist, cadaver and type of tracheal tube were all randomized by a statistician (JT). The first procedure on each cadaver was a cricothyroidotomy, and then two percutaneous tracheotomy procedures were performed below the cricothyroid incision, using the same PEAA technique. Anaesthetists were asked to conduct the technique as if it were an emergency and were video recorded performing the procedure. The cadavers were positioned with their necks extended as much as possible. All necessary equipment required for the procedure was immediately available, and an assistant handed equipment to the participant as required. A new tracheal tube was used for each procedure. It was not possible to blind the anaesthetist to the tube tip design because the tube had to be loaded onto the bougie by the anaesthetist; the anaesthetists were not told, however, that the tubes were being studied.

Each procedure was timed by stopwatch from the beginning of neck palpation until the first inflation of a self-inflating bag. Video recordings were analysed and segments of the procedure were timed using an on-screen digital timer on the recordings. Times were measured for loading of the tracheal tube onto the bougie and advancing it to the skin, and also advancing the tracheal tube from the skin down the trachea. Times were measured and compared for bougie and tracheal tube availability for oxygenation. Tracheal intubation was confirmed by direct anatomical inspection.

See Appendix five for a list of devices.
Following each procedure, the participants completed a questionnaire using a 100 mm Visual Analogue Scale (VAS) to measure their responses to the following instruction: Please rate the ease of tracheal tube insertion off the bougie during this procedure.

The left and right ends of the visual analogue scales were labelled “Very easy” and “Very difficult” respectively.

Statistical analysis was carried out using t-tests to determine differences in time between the Parker Flex-Tip tubes and standard tracheal tubes. Statistical significance was defined as \( p<0.05 \). Our sample was a sample of convenience. The trial was only possible due to the availability of cadavers usually used for teaching purposes. Our design using 12 cadavers three times each gave a sample of 18 attempts with each tube. With 80% power at the 5% level of significance, this allowed us to detect a difference of 0.962 s.d. for differences in times between the two groups.

**Results**

A tracheal tube was successfully guided over the bougie and through the surgical incision in 34 of 36 attempts. In two cadavers, the cricothyroid membrane could not be palpated or located with the scalpel, and the procedure was abandoned after 3 minutes 45 seconds and 2 min 22 sec respectively. These two cadavers (1 and 4) had been randomly allocated a Parker Flex-Tip and a standard tracheal tube. They had short thick necks with circumferences of 44 cm and 42 cm (Table 11.1).
### Table 11.1  Characteristics of cadavers including age, gender and neck circumference.

<table>
<thead>
<tr>
<th>Cadaver</th>
<th>Age</th>
<th>Gender</th>
<th>Neck Circumference (centimeters)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>71</td>
<td>F</td>
<td>44</td>
</tr>
<tr>
<td>2</td>
<td>88</td>
<td>M</td>
<td>35</td>
</tr>
<tr>
<td>3</td>
<td>99</td>
<td>F</td>
<td>27</td>
</tr>
<tr>
<td>4</td>
<td>60</td>
<td>F</td>
<td>42</td>
</tr>
<tr>
<td>5</td>
<td>78</td>
<td>M</td>
<td>37</td>
</tr>
<tr>
<td>6</td>
<td>84</td>
<td>F</td>
<td>36.5</td>
</tr>
<tr>
<td>7</td>
<td>72</td>
<td>M</td>
<td>37.5</td>
</tr>
<tr>
<td>8</td>
<td>73</td>
<td>F</td>
<td>35.5</td>
</tr>
<tr>
<td>9</td>
<td>91</td>
<td>F</td>
<td>34.5</td>
</tr>
<tr>
<td>10</td>
<td>83</td>
<td>F</td>
<td>36</td>
</tr>
<tr>
<td>11</td>
<td>81</td>
<td>F</td>
<td>33</td>
</tr>
<tr>
<td>12</td>
<td>96</td>
<td>F</td>
<td>30</td>
</tr>
</tbody>
</table>

See Appendix five for a list of devices.
Chapter 11. Parker Flex-Tip or standard tracheal tube for percutaneous emergency airway access? A prospective randomised trial.

Figure 11.1 The Parker Flex-Tip tube (right) has a soft hemispherical curved bevel which creates a smaller gap between the tube and the Frova bougie than the standard tracheal tube (left).

See Appendix five for a list of devices.
Two successful tracheotomy procedures were subsequently performed on these two cadavers.

Five video recordings of tracheotomies failed and a sixth recording was incomplete leaving 28 complete recordings. The mean times and subjective VAS score for the procedure appear in Table 11.2.

Table 11.2 Timed events and subjective visual analogue scale (VAS) for the percutaneous emergency airway access (PEAA) technique

<table>
<thead>
<tr>
<th>Timed events</th>
<th>Total times</th>
<th>Parker Flex-Tip™</th>
<th>Standard tube</th>
<th>T (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>seconds</td>
<td>seconds</td>
<td>seconds</td>
<td></td>
</tr>
<tr>
<td>Time between bougie and TT access for ventilation</td>
<td>12.8 (2.7)  n = 28</td>
<td>3.6 (1.4) n = 14</td>
<td>3.5 (0.9) n = 14</td>
<td>-0.3 (0.76)</td>
</tr>
<tr>
<td>TT load (TT starting to load until TT contacts skin)</td>
<td></td>
<td>3.6 (1.4) n = 14</td>
<td>3.5 (0.9) n = 14</td>
<td>-0.3 (0.76)</td>
</tr>
<tr>
<td>Time to advance TT from skin incision into trachea</td>
<td>4.8 (1.3) n = 14</td>
<td>5.4 (2.0) n = 14</td>
<td>5.2 (2.0) n = 14</td>
<td>0.8 (0.4)</td>
</tr>
<tr>
<td>Stop watch time for total procedure</td>
<td>37.5 (8.8) n = 34</td>
<td>36.8 (8.8) n = 17</td>
<td>38.2 (9.0) n = 17</td>
<td>0.4 (0.7)</td>
</tr>
<tr>
<td>Subjective VAS score for ease of intubation (mm)</td>
<td>24.5 (16.7) n = 17</td>
<td>18.5 (13.5) n = 17</td>
<td>18.5 (13.5) n = 17</td>
<td>-1.2 (0.3)</td>
</tr>
</tbody>
</table>

TT, Tracheal tube; SD, standard deviation.

We did not find any difference in any of the times that involved comparison of Parker Flex-Tip tube or standard tracheal tube. After one hour of training, three novice anaesthetists were able to complete PEAA in a cadaver using a scalpel, bougie and tracheal tube in a mean time of 37.5 (8.8) seconds.
Discussion

The time and ease of placement of a Parker Flex-Tip and a standard tracheal tube over a bougie during a PEAA procedure were compared. The overall time to complete these procedures was not affected by the type of tracheal tube used. When examining the time to load the tube onto the bougie and advance it to the skin, and the time to advance the tube over the bougie from the skin down the trachea, there was no significant difference between each tube. The differences seen were well below those able to be detected by our sample size and not considered to be of any clinical significance. There were no examples of severe tube impingement at the tissue margin for either tube. There was no subjective difference between the ease of inserting a standard tracheal tube or a Parker Flex-Tip tube off a bougie during a surgical tracheotomy.

Several studies have examined the impact of tracheal tube design on intubation success during oral and nasal intubation (352, 353, 355, 627). The factors which can influence intubation success include tube diameter, the relative distance between a bougie or a flexible bronchoscope and the inside of the tube, material used by the manufacturer, tube flexibility and tip design. Decreasing tracheal tube diameter can improve intubation success. A size 6 cuffed Shiley tracheostomy tube was originally proposed for the rapid four-step surgical cricothyroidotomy (623). This 6.0 mm internal diameter (ID) tube has an 11 mm outside diameter (OD) and a distal length of 49 mm, and therefore has a shorter length, larger outside diameter and surface flanges which restrict the length of intubation compared to a size 6.0 mm ID tracheal tube (8.2 mm OD) (624, 628, 629). In a cadaver study of standard surgical cricothyroidotomy with cephalad tracheal hook retraction, compared to the rapid four-step technique using caudal tracheal hook retraction, it was found that there was no significant difference in tubes passing with internal diameters of 6.0, 7.0, 7.5 and 8.0 mm (625). From an anatomical point of view, dimensions of the adult cricothyroid membrane limit the maximum outside diameter of a tracheal tube to 8.0 mm (157). The outside diameter of the bougie and the internal diameter of the tracheal tube are also important variables for intubation success. A size 6.0 mm ID tracheal tube is the minimum diameter suitable for the Frova 14 F intubating introducer. This combination has the advantage of providing the minimum gap between the inside of the tracheal tube and the outer surface of the bougie. This gap can be further reduced by the tip design of the Parker Flex-Tip tube. The Parker Flex-Tip tube has been shown to cause less bleeding during nasal intubation and improve intubation success over oral tube exchangers and flexible fibreoptic bronchoscopes, due to its soft hemispherical curved bevel tip which minimizes the gap between bougie and tube (355, 630, 631).

The rapid four-step surgical cricothyroidotomy was designed for its speed and simplicity. This method is easy to learn, has been successfully used clinically, and uses airway equipment which is readily available (624). The procedure can be completed in 30 seconds, which is one third of the time required for the standard surgical cricothyroidotomy technique (632). The three novice anaesthetists in our study were able to perform the procedure in mean time of 37.5 (8.8) seconds (Table 11.2), after one hour of training. If anatomical landmarks cannot be rapidly palpated, such as in obese patients, the neck should be incised with a longitudinal midline incision in order to internally palpate and clearly identify laryngeal cartilages before making a horizontal incision.
incision through the cricothyroid membrane (623, 632). Percutaneous palpation of the cricothyroid membrane is time-consuming, and is associated with a low success rate (44). Preoperative identification and marking of the cricothyroid membrane could shorten this time and improve the success rate.

The type of bougie selected should be suitably rigid, such as the Frova, to allow manipulation through the tissue and provide support for the tracheal tube. The 14 F Frova bougie has a 3.0 mm ID lumen which can be attached to an oxygen source with Rapifit® adapters for either jet ventilation or low pressure ventilation. This connector can also be used to confirm correct tube placement by capnography (633) or oesophageal bulb (332). We found that ventilation of oxygen through the Frova could have occurred 12.8 (2.7) seconds earlier than ventilation through the tracheal tube (Table 11.2), however, this time did not include the time to locate, attach and set up a suitable ventilation device. The benefits of slightly earlier oxygenation using this technique need to be balanced by the potential risks. The incorrect use of a high-pressure oxygen source for re-oxygenation through an airway exchange catheter can cause barotrauma leading to fatal consequences (634). It is essential not to advance the bougie or the tracheal tube beyond the carina, and these devices should be held or secured in order to prevent migration beyond or out of the trachea (635). Caution is also required during volume ventilation to maintain a patent airway for the egress of gas and to prevent over-vigorous insufflation of oxygen. The risks associated with using airway exchange catheters are discussed in the Difficult Airway Society Guidelines for the management of tracheal extubation (336).

In this study, we included both cricothyroidotomy and tracheotomy because the aim of the study was to measure the time to advance a tracheal tube through pretracheal tissue. The characteristics of the overlying tissue at the cricoid or upper tracheal level are very similar in terms of advancing a tracheal tube; and, in a study of adult cadavers by Holmes et al of standard surgical cricothyroidotomy and rapid four step cricothyroidotomy, inadvertent tracheotomies were relatively common, all between the cricoid cartilage and the first tracheal ring (632). In some clinical circumstances, such as paediatrics (140), a tracheotomy is preferable to a cricothyroidotomy. Needle cricothyroidotomy in a child under the age of five is technically challenging because of the difficulty identifying surface landmarks. In neonates, the larynx is prone to injury during cricothyroidotomy (157, 399). Percutaneous emergency airway access (PEAA) is the common clinical goal for surgical cricothyroidotomy and tracheotomy.

There are limitations to this study. The cadavers were not examined for signs of airway trauma after each procedure because this was not the aim of the study. Several studies have found a higher incidence of major complications associated with the rapid four step technique compared to the standard cricothyroidotomy technique (625, 632, 636). Complications included complete transection of the cricoid cartilage, fracture of the cricoid cartilage and puncture of the posterior trachea and anterior oesophagus (632). Using preserved cadavers as our experimental model, the procedures were not affected by bleeding, which would occur in a clinical situation (80, 637). In a clinical series of 24 successful “scalpel-finger-tube” techniques, significant bleeding occurred in four cases, all of which were managed conservatively and successfully (638). We did not visualize tracheal intubation by endoscopy during the procedure. Direct anatomical confirmation of tracheal intubation

See Appendix five for a list of devices.
was performed from the pre-dissected thorax when difficulty was encountered passing the tracheal tube over
the bougie. The tracheal tube was found to be in the trachea in every instance.

The principal finding of this study is that the Parker Flex-Tip tube can be advanced over a bougie during a
percutaneous emergency airway access as effectively as a standard tracheal tube. Based on these results, we
therefore conclude that the Parker Flex-Tip tube is a satisfactory alternative to a standard tracheal tube during
percutaneous emergency airway access procedures.

Postscript

This study established that standard or Parker Flex tip tracheal tubes can be used for scalpel bougie techniques
to secure the airway during CICV.

A secondary finding of this study was that three novice anaesthetists, with no previous experience performing
cricothyroidotomy, were able to complete this procedure successfully in an average time of 37 seconds, after
one hour of training. There were two failures in cadavers with thick necks greater than 40 cm in diameter.

This technique satisfies many of the criteria described by Smith et al for an ideal cricothyroidotomy technique
and is worthy of further research (130). The belief that anaesthetists are unfamiliar with scalpels and, therefore,
are unlikely to perform scalpel techniques in a CICV crisis, needs further investigation (see Chapter 1.3).

See Appendix five for a list of devices.
Chapter 12. Experimental adaptation of the Enk Oxygen Flow Modulator for potential paediatric use


Preface

Considerable emphasis is placed on cricothyroidotomy, whereas emergency ventilation techniques have received relatively little attention. In the previous chapter, a scalpel bougie technique was studied. The benefit of inserting a cuffed tracheal tube was discussed in terms of protecting against aspiration and avoiding the risk of barotrauma associated with transtracheal jet ventilation.

The study in this chapter was designed to establish the efficacy of flow-regulated, volume ventilation with the Enk oxygen flow modulator, after cannula cricothyroidotomy. Important information was discovered concerning the appropriate use of this device, particularly for paediatric patients.

As first author, I collaborated in the design of the study, collected and analysed the results, researched the subject, wrote the first draft of the paper and supervised revisions of the paper prior to publication.

Abstract

Aim: A bench study of the Enk oxygen flow modulator (Enk OFM) was conducted to test its performance and potential use in paediatric patients using the Advanced Paediatric Life Support (APLS) guidelines.

Background: The Enk OFM is a preassembled emergency transtracheal ventilation device.

Methods: The Enk OFM was connected to two sources of oxygen: firstly, to a Precision Medical® flowmeter and secondly, to an Aestiva® anaesthetic machine axillary flowmeter. Testing was performed on standard cannulae of 20, 18 and 16 gauge calibre and also a 7.5 cm 15 G Emergency Transtracheal Airway Catheter (Cook® Medical). Serial hole occlusion of the Enk OFM was applied and the resulting flow rates were measured by a RespiCal™ Timeter®.

Results: Oxygen flow was best controlled by occluding all holes of the Enk OFM and incrementally increasing oxygen flow by the flowmeter with an initial setting of 1 litre/minute/year of age. Contrary to the original description of this device (Anesth Analg 1998; 86: 203S), sequential occlusion of the five side holes does not

See Appendix five for a list of devices.
lead to a significant exponential increase in gas flow. Incomplete occlusion of the Enk OFM provided insufficient and unpredictable flow.

Conclusion: The Enk OFM should be fully occluded for inspiration with flow rates set at 1 L/min/year of age and adjusted to effect. These flow rates are consistent with the APLS recommendations. Flows above 15 L/min are potentially dangerous and the Enk OFM fails to perform as an on-off device. Flowmeter settings of less than 1 L/min risk no flow. Cannulae of at least 18 G should be used for optimal flow.

See Appendix five for a list of devices.
Chapter 12. Experimental adaptation of the Enk Oxygen Flow Modulator for potential paediatric use

Introduction

Cannula cricothyroidotomy with TTJV or surgical cricothyroidotomy is recommended by all current airway guidelines to manage the “cannot intubate, cannot ventilate” (CICV) situation in adults (203, 205-207, 231, 639, 640). Difficulty identifying the cricothyroid membrane, because of small anatomical dimensions, precludes surgical cricothyroidotomy in neonates, infants and small children. Italian guidelines for management of the difficult paediatric airway include the mandatory availability of 15G cricothyroid puncture needles for cricothyroid ventilation (209). Ventilation through small cannulae requires a high pressure gas source to overcome high resistance. Pressure regulated volume ventilation by an injector allows control of driving pressures to suit different age groups. However, such devices in the presence of small lung volumes can deliver high tidal volumes with potentially dangerous airway pressures (402). Flow adjusted volume ventilation may be more predictable and intuitive when dealing with smaller lung volumes and high system resistance caused by smaller cannulae.

The Enk oxygen flow modulator (Cook®Medical Inc, Bloomington, USA) is a disposable, preassembled transtracheal ventilation device (Figure 12.1). It consists of a length of oxygen tubing, a short non-compliant tube with five finger holes and a side syringe connector for nebulising drugs. A distal luer fitting allows connection to standard intravenous cannulae and the Patil 15G 5.0cm or 7.5cm cricothyroidotomy cannula. The Enk OFM was originally described for adult use with oxygen flows of at least 15 L/min using serial hole occlusion to increase cannula flow (641). There have been no reports of its use in paediatrics, however, studies comparing the Enk OFM and the Manujet III™ (VBM® Medizintechnik, GmbH, Sulz, Germany) in

Figure 12.1 The Enk oxygen flow modulator

See Appendix five for a list of devices.
Chapter 12. Experimental adaptation of the Enk Oxygen Flow Modulator for potential paediatric use

anaesthetized 20-30 kg pigs have been published showing comparable pulmonary resuscitation with both devices (146, 147).

Paediatric CICV data remains limited. The Advanced Paediatric Life Support (APLS) guidelines (395) recommend setting oxygen flow at 1 L/min/year of age through a Y-connector. The Y-connector is then occluded for one second to assess chest movement. Gas flow is then titrated if required at 1 L/min increments to effect. A rate of 12 breaths per minute with an inspiratory to expiratory ratio of 1:4 is then applied. These recommendations appear reasonable but lack reference or apparent validation. Our bench study was undertaken to evaluate the performance of the Enk OFM and to develop guidelines for its use in the paediatric population.

Methods

Age appropriate weights from the local paediatric population were sought from a data bank concerning children presenting for anaesthesia within our hospital. These age and weight data pairs were retrieved from the Injectable Drug Administration and Automated Anaesthetic Record System (IDAS®, SAFERsleep™) at Starship Children’s Hospital, Auckland, New Zealand, using an automatic program. The data pairs were displayed as a scatter plot to allow identification of grossly outlying results and these were manually confirmed or corrected by reviewing the patient’s electronic notes. These data were then divided into age blocks of less than 1 month, 1-3 months, 3-6 months, 6-12 months and then yearly groups. Weights from each group were averaged. Each year block included patients from the day of their birthday until the day before their next birthday. These data are presented in Table 12.1. These weights were used to estimate weight based tidal volumes of 7ml/kg. These estimated tidal volumes were then compared to the one second volume calculated from the APLS 1L/min/year of age in order to assess the appropriateness of this setting.

To test the performance of the Enk OFM, the device was connected to two different oxygen sources. Firstly, it was connected to a Precision Medical® flowmeter (100L/min maximum flow, 0 to 15 L/min calibrated scale, hospital medical gas wall pressure 400 kPa), and secondly to an Aestiva® (Datex-Ohmeda, GE Healthcare, Wisconsin USA) anaesthetic machine auxiliary flowmeter (0 to 10 L/min calibrated scale, down regulated to 133 kPa (1.3 bar, 18.8 PSI)). Testing was performed on standard cannulae of 20, 18 and 16 gauge calibre and also a 7.5 cm 15 G Emergency Transtracheal Airway Catheter (Cook®Medical). In turn, they were inserted through the side of silicone tubes 10 cm long and 6 mm internal diameter. One end of the silicone tube was occluded to control for entrainment while the other end was attached to either the low flow port (0-25 L/min, 3mm ID, accuracy ± 2.0% (10 to 25 L/min), ± 4% (0.1 to 10 L/min)), or the high flow port (25-240 L/min, 6mm ID, accuracy ± 2%) of a RespiCal™ Timeter® calibration analyser (Allied Healthcare Products Inc., St. Louis, USA). The RespiCal™ Timeter® calibration analyser measures gas flow with two mass flow sensors, one for high and one for low measurements of oxygen.

Serial hole occlusion of the Enk OFM was performed over the calibrated flowmeter scale in 1 litre/minute increments and also at maximum “off the scale” flow rates for the various cannulae and pressure sources. The
Chapter 12. Experimental adaptation of the Enk Oxygen Flow Modulator for potential paediatric use

resulting flow was measured in L/min and converted to mL/sec. This allowed recorded one second volumes to be compared with tidal volume approximates based on paediatric age and weight.

**Results**

Age and weight data were collected from 12,049 IDAS® records of patients less than 16 years of age over a 12 month period. Patient weights were recorded in 6724 (56%) of the total. Mean weights and standard deviations are shown in Table 12.1. Estimated tidal volumes with predicted one second volumes, based on APLS settings, are shown in Figure 12.2.

See Appendix five for a list of devices.
Table 12.1  Age-weight figures derived from the IDAS® data base. Year groups * selected from birth day until the day before the next birthday (note partially non-linear age scale).

<table>
<thead>
<tr>
<th>Age</th>
<th>Number</th>
<th>Wt. (Kg)</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1 months</td>
<td>247</td>
<td>3.3</td>
<td>0.9</td>
</tr>
<tr>
<td>1-3 months</td>
<td>258</td>
<td>4.5</td>
<td>1.4</td>
</tr>
<tr>
<td>3-6 months</td>
<td>260</td>
<td>6.3</td>
<td>1.6</td>
</tr>
<tr>
<td>6-12 months</td>
<td>377</td>
<td>8.8</td>
<td>1.6</td>
</tr>
<tr>
<td>1 Year*</td>
<td>617</td>
<td>11.3</td>
<td>1.8</td>
</tr>
<tr>
<td>2</td>
<td>425</td>
<td>13.8</td>
<td>2.2</td>
</tr>
<tr>
<td>3</td>
<td>448</td>
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</tr>
<tr>
<td>4</td>
<td>472</td>
<td>18.6</td>
<td>3.9</td>
</tr>
<tr>
<td>5</td>
<td>436</td>
<td>21.4</td>
<td>4.5</td>
</tr>
<tr>
<td>6</td>
<td>456</td>
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<td>7</td>
<td>349</td>
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<td>330</td>
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<td>15.1</td>
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</tr>
<tr>
<td>14</td>
<td>318</td>
<td>62.2</td>
<td>18.0</td>
</tr>
<tr>
<td>15</td>
<td>124</td>
<td>61.1</td>
<td>19.7</td>
</tr>
<tr>
<td>Total</td>
<td>6724</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Chapter 12. Experimental adaptation of the Enk Oxygen Flow Modulator for potential paediatric use

Figure 12.2 Comparison of estimated tidal volumes and formula calculated one second volumes for each age group. Weight estimate tidal volumes from IDAS® data using 7ml/kg. One second volumes from APLS formula of 1 L/min/year of age and 1 L/min/year of age + 4L/min.

See Appendix five for a list of devices.
Figure 12.3 Flow through a 15 G Cook® cannula measured in mL/sec after serial occlusion of the Enk OFM with different flowmeter settings and a 400kPa pressure source.

Figure 12.4 Flow measured in mL/sec through various cannulae with full occlusion at pressures of 133 kPa and 400 kPa. Large cannulae perform well but flow plateaus with cannulae less than 18 G.

See Appendix five for a list of devices.
Chapter 12. Experimental adaptation of the Enk Oxygen Flow Modulator for potential paediatric use

Using the 400 kPa oxygen source, serial hole occlusion of the Enk OFM did not result in effective incremental flow until all five holes were occluded. Even at 15 L/min, 4 out of 5 hole occlusion only resulted in 34, 18 and 8.5 mL/sec of flow for 15G, 16G and 18G cannulae. Once all five holes of the Enk OFM were fully occluded the measured flow was effectively the same as the flow set at the flow meter for cannulae 18 G and larger, so that a 15 L/min setting produces a one second volume of 250 mL. Use of a 20 G cannula was effective until flow exceeded 13 L/min, at which point it became increasingly effort dependent for the operator and difficult to occlude all holes. Fully opening the oxygen flow meter beyond the calibrated scale resulted in excessive flows which were limited by cannula size. Full occlusion resulted in 1 second volumes of 1133, 733 and 400 mL/sec for 15, 16 and 18 G cannulae respectively with difficulty occluding the Enk OFM completely. Also, at maximum flow, the Enk OFM failed to perform as an on-off device with unoccluded continuous flows of 200, 100 and 50 ml/sec for 15, 16 and 18 G cannulae respectively. The results for the 15 G Cook® cannula are illustrated in Figure 12.3. With a fully occluded Enk OFM, measured flow approximates expected flow up to 11 L/min.

The auxillary flowmeter of the Aestiva® anaesthetic machine, which operates at a lower pressure of 133 kPa (1.3 bar,18.8 psi), produced similar flows to the 400 kPa source with the 15 G and 18 G cannulae up to the calibrated 10 L/min setting (Figure 12.4). When the 20 G cannula was used, the maximum flows were lower than the equivalent 400 kPa system flow meter settings. Increasing the flowmeter beyond the calibrated scale to maximum resulted in flows of 550, 200 and 130 mL/sec for the 15 G, 18 G and 20 G cannulae. Unlike the 400 kPa system, it was noted that back pressure caused the flowmeter to drop on occlusion and become inaccurate. For example, the maximum measured flow through an 18 G cannula at 12 L/min caused the flowmeter to drop to 8 L/min.

**Discussion**

Successful TTJV requires clinical skill, immediate availability of familiar equipment and safe technique. In the ASA Closed Claims study, TTJV resulted in an 89% incidence of subcutaneous emphysema, pneumothorax or pneumomediastinum (127). For anatomical reasons, transtracheal ventilation may be even more difficult in younger patients (399). The risk of barotrauma increases with small lung volumes requiring careful attention to delivered tidal volumes, chest expansion and adequate expiratory time. Using a lung model, Craven (402) demonstrated that the Manujet™ set at 200 kPa was capable of jetting a mean tidal volume of 1370 ml at a rate of 20/min with potentially dangerous airway pressures. Easily remembered settings for flow rates that are appropriate for the size of the patient may help prevent some of the potential complications.

Wall oxygen and oxygen cylinders provide high pressure sources at 400 kPa (4 atmospheres, 4 bar, 58.8 psi). An oxygen injector such as the Manujet III™ can be regulated from high to low pressure (400 to 50 kPa). The Enk OFM usually operates from the same high pressure source (400 kPa) and at a flow meter setting of 15 L/min can deliver 250 mL/sec through an 18 G cannula. Both of these devices require regulation for safe

See Appendix five for a list of devices.
Chapter 12. Experimental adaptation of the Enk Oxygen Flow Modulator for potential paediatric use

volume ventilation. The Enk OFM is flow-regulated by attachment to a flow meter and performs solely as an on-off device requiring occlusion of all holes for effective flow. Low frequency ventilation followed by slow low pressure exhalation is similarly important to limit barotrauma (391). Optimisation of the upper airway for expiration and close monitoring of lung deflation is essential for safe technique (642). Ideally kink-resistant cannulae should be used for transtracheal ventilation (394).

The manual occlusion of holes on the Enk OFM allows some “feel” for the pressure generated, and release of the five holes opens the device to atmospheric pressure. Caution must be used if the flow rates exceed the calibrated scale of the flow meter, as this may lead to excessive continuous flow. Flow through a cannula increases up to three times when the flowmeter increases from 15 L/min to fully open beyond its calibrated scale. Incomplete occlusion of the Enk OFM provided insufficient and unpredictable flow. This study supported full occlusion of the Enk OFM and flow adjustment by the flow meter. This is in contrast to the original description by Enk who suggested that flow could be controlled with an exponential gas flow increase caused by successive occlusion of holes with the flow meter set to at least 15 L/min.

In our study, a close correlation was found between the tidal volume predicted from the APLS formula and the age-weight estimated volumes (Figure 12.2). Using a flow of 1 L/min/year of age provides a conservative starting point for oxygenation. Increasing this flow may allow effective ventilation. Modification of the formula to 1 L/min/year of age plus 4 L/min allowed closer matching of estimated tidal volume and volume delivered (Figure 12.2). Even when using the Aestiva® auxiliary oxygen source at 133 kPa, the Enk OFM performed adequately with cannula as small as 18 G. Flow rates only deviated from calculated values when smaller cannulae or maximal settings were used. Using transtracheal ventilation in patients less than 1 year of age would be technically difficult with narrower safety margins. Flowmeter settings of less than 1 L/min risk no flow.

This bench study supports the use of the Enk OFM at flows of 1 L/min/year of age where cannulae of at least 18G are used. Larger specialized kink resistant cannulae may perform more reliably. The device should be fully occluded during insufflation and flow rates and patterns should be initially set according to the APLS recommendations and then adjusted to effect. In this study the Enk OFM did not lead to a significant exponential increase in gas flow as described by Enk (641), but functioned more as an on-off flow device.

Postscript

As a result of this study, the instruction pamphlet from the manufacturer for this device has been modified to ensure that the user is aware that all five holes need to be occluded for effective operation.

The other important discovery concerned the use of the Enk OFM in paediatrics. Appropriate ventilation is achieved by using the formula of 1 L/min/year of age. Further studies are under way to confirm these results in vivo.

See Appendix five for a list of devices.
Chapter 13. How anaesthetists in New Zealand disseminate critical airway information about patients


Preface

Once airway difficulty has been identified and the airway has been managed, proper documentation and transfer of information is essential to avoid subsequent morbidity. I close the loop in this chapter by relating back to airway assessment and the implementation of pre-planned airway strategies which were discussed in Chapters five and six. An important component of airway assessment is a careful history and examination of clinical records to discover evidence of previous airway difficulty. Good documentation is, therefore, crucial.

I designed this study and was actively involved in all aspects of the subsequent publication.

Abstract

The communication of information concerning patients with difficult airways is widely recognized as an important component in avoiding future airway management difficulties. A range of options is available to impart this information; little is known, however, about how anaesthetists follow up the identification and management of a difficult airway. In this study, 158 anaesthetists were contacted and asked to comment about how they would follow-up a number of difficult airway scenarios. This was followed by a retrospective survey of 124 patients with known difficult airways. A wide discrepancy was found between stated follow-up preferences by anaesthetists, and the actual use of options such as postoperative visits, notes in the clinical record, letters to the patient and family doctor, and entries in hospital, national and MedicAlert™ data bases. Of the patients with an airway difficulty noted on their anaesthetic record, only 14% of them also had a relevant comment on their clinical record; even fewer were referred to hospital warning systems (12%) or national (6%) and MedicAlert™ (7%) databases.

Comments from our survey were critical of multiple difficult airway databases and alert systems which are not linked and do not lead automatically to a single source of information. We suggest that a custom-designed MedicAlert™ New Zealand difficult airway/intubation registry could be established, with easy access for medical practitioners and patients. This registry could be accessed through the National Health Index (NHI) database and linked to the MedicAlert™ International registry and their nine international affiliates.

See Appendix five for a list of devices.
Chapter 13. How do anaesthetists in New Zealand disseminate critical airway information

Introduction

Any patient requiring airway management should, wherever feasible, have an airway assessment performed and recorded (4, 643). Part of that assessment includes seeking a history of previous airway difficulty. A history of previous difficult intubation is regarded as the single most important predictor of subsequent difficult laryngoscopy and intubation (12). Failure to report a difficult airway can contribute to severe complications during subsequent anaesthesia and represents a failure in professional duty (7). Reliable dissemination of critical airway information depends on an accurate report from a practitioner and dependable reporting systems. Communication of critical airway information typically occurs through comments on the anaesthetic record, notes in the patient’s record, letters to the patient and the patient’s family doctor, referrals to hospital, regional and national databases and also referral to the MedicAlert™ Foundation (644, 645). There are limitations to using each of these systems such as failure by practitioners to document in the notes, misplacement or failure to present patient letters, absent patient recall of postoperative visits and airway databases and alerts which fail to transfer information. Hence, information regarding the airway difficulty may not be readily available to a subsequent practitioner, should the patient be admitted to hospital at a later date.

Little is known about the follow-up patterns of anaesthetists who have managed patients with difficult airways. The threshold to report airway information along with the reliability of communication, have not been reported previously. The aims of this study were to: (1) establish stated referral practices of anaesthetists concerning patients with airway problems; (2) examine the reliability of these statements by following 124 patients with known difficult airways; and (3) review current mechanisms for disseminating critical airway information in New Zealand.

Methods

Approval for this study was obtained from the Northern X Regional Ethics Committee and the Auckland District Health Board Ethics Committee. Research was undertaken at Auckland City Hospital which is a tertiary referral hospital with adult and paediatric services, 1000 beds and 109 anaesthetists. The hospital draws from a capture area of 460,000 people which represents approximately 10% of the New Zealand population.

Survey of Anaesthetist Referral Patterns. Email databases for public and private practitioners in the Auckland region were searched to identify consultant anaesthetists. The only inclusion criterion was that individuals were practising consultant anaesthetists. This search found 158 consultant anaesthetists in the Auckland region. All were contacted and provided with a link to an online survey (SurveyMonkey™, Palo Alto, CA, USA). Anaesthetists were sent an email reminder after four weeks to maximize the response. The format of the survey was a series of airway scenarios, each followed by a range of referral options (Table 13.1). The scenarios were

See Appendix five for a list of devices.
based on the modified Cormack-Lehane classification (612) and a grading scale for difficult mask ventilation (71). The anaesthetists were asked for their preferred action (follow up or no follow up) for the given scenario (Table 13.2) and their opinion concerning the limitations of conveying critical airway information using open ended free text.

Retrospective Patient Record Assessment. In order to assess the reliability of referrals we examined the records of patients with difficult airways documented in anaesthetic case notes. Anaesthesia for patients treated at Auckland City Hospital is recorded using an electronic system (Injectable Drug Administration System IDAS®, SAFERsleep™, Auckland, New Zealand). These records were searched retrospectively for a 12-month period from 1st November 2009 until 31st October 2010 during which time 29,385 general anaesthetics were performed. This database does not include emergency medicine, intensive care or pre-hospital airway management. Initially a search was conducted using key words from the electronic system. Search terms included fibre, fiber, Grade 3, Grade 4, Glidescope, BMV and Bag Mask. This search found 815 records that were then scrutinized using inclusion criteria. Inclusion criteria were: (1) all Cormack Lehane (CL) Grade 4 intubations (no laryngeal structures seen), (2) all CL Grade 3b intubations (epiglottis adherent to pharynx) (612), (3) any CL Grade 3 intubations with more than three techniques and/or attempts at intubation, (4) any CL Grade 3 intubation with difficult mask ventilation (requiring oral airway/adjunct and/or two-handed technique) (71), (5) all difficult mask ventilation (regardless of CL direct laryngoscopy grade), (6) airways with noted past history of difficult intubation and/or difficult mask ventilation.

Patients who satisfied our inclusion criteria had their clinical records reviewed in a more comprehensive manner. Details of a preoperative airway assessment, intra-operative airway classification and airway management were recorded into a Microsoft® Excel data extraction form. Evidence of a postoperative visit and letter concerning a difficult airway was sought from the record and from the patient via a telephone call. The patient’s family doctor was also contacted regarding correspondence from the anaesthetist concerning the difficult airway. The hospital database, the National Health Index (NHI) database and The MedicAlert™ Foundation database were also searched using the patient’s unique NHI identifying number to find evidence of an alert.

Data management and analysis. Responses were expressed as a percentage of the total number of responses for each question except where otherwise noted. Weighted means and standard deviations of percentages were calculated when appropriate to summarize tabular data. Statistical analysis was performed using STATA 12.1 (StataCorp, College Station, TX, USA).

See Appendix five for a list of devices.
Results

One hundred and ten survey replies were received, giving a response rate of 70%. Given that this survey was conducted anonymously, we were unable to comment about the characteristics of the non-responders. Details of the survey appear in Table 13.1.

Survey of Anaesthetist Referral Patterns. A written comment on the anaesthetic record was the most common response chosen for all scenarios in the survey (97.6% of anaesthetists), followed by a postoperative visit (82.9%), and a letter sent to the patient (71.1%) (Table 13.1). Difficult and failed intubation were more likely to be considered for follow-up than impossible ventilation with easy intubation (84%) or impossible supraglottic airway insertion (77%). Impossible ventilation with impossible intubation (96%) and impossible ventilation with difficult intubation (95%), had similar ratings for follow-up to easy ventilation with failed intubation (96%) (Table 13.2). Sixty of 102 respondents stated that their dissemination of critical airway information was limited by information systems. Reasons which limit dissemination of critical airway information appear in Table 13.3.

See Appendix five for a list of devices.
Table 13.1 Anaesthetists’ preferences to follow-up seven airway scenarios. Anaesthetists (n=110) preferences for follow up options associated with seven hypothetical difficult airway scenarios. Values represent number of responses (%) unless otherwise noted. Because anaesthetists were allowed to select multiple follow up options for each scenario (i.e., follow up options are not mutually exclusive), percentages in each cell are the number of anaesthetists selecting that follow up option divided by the total number of anaesthetists who provided a response for that scenario. Abbreviations: CL–Cormack-Lehane, SGA–supraglottic airway, M&M–mortality and morbidity, SD–standard deviation.

<table>
<thead>
<tr>
<th>Airway Scenarios</th>
<th>Comment on anaesthetic record, No. (%)</th>
<th>Post-operative visit, No. (%)</th>
<th>Comment in case notes, No. (%)</th>
<th>Letter to patient, No. (%)</th>
<th>Letter to family doctor, No. (%)</th>
<th>Report to M&amp;M database, No. (%)</th>
<th>Discuss at M&amp;M meeting, No. (%)</th>
<th>Referral to Medic Alert®, No. (%)</th>
<th>Other No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficult ventilation n=80</td>
<td>75 (94)</td>
<td>53 (66)</td>
<td>32 (40)</td>
<td>39 (49)</td>
<td>20 (38)</td>
<td>19 (24)</td>
<td>31 (39)</td>
<td>11 (14)</td>
<td>14 (18)</td>
</tr>
<tr>
<td>Easy ventilation, difficult intubation with CL 3b view n=95</td>
<td>94 (99)</td>
<td>80 (84)</td>
<td>36 (38)</td>
<td>63 (66)</td>
<td>46 (48)</td>
<td>24 (26)</td>
<td>28 (30)</td>
<td>28 (30)</td>
<td>13 (14)</td>
</tr>
<tr>
<td>Easy ventilation, failed intubation n=106</td>
<td>104 (98)</td>
<td>100 (94)</td>
<td>55 (52)</td>
<td>88 (83)</td>
<td>70 (66)</td>
<td>52 (49)</td>
<td>67 (63)</td>
<td>64 (60)</td>
<td>20 (19)</td>
</tr>
<tr>
<td>Impossible ventilation, easy intubation n=90</td>
<td>87 (97)</td>
<td>71 (79)</td>
<td>42 (47)</td>
<td>56 (62)</td>
<td>43 (48)</td>
<td>32 (36)</td>
<td>53 (59)</td>
<td>28 (31)</td>
<td>14 (16)</td>
</tr>
<tr>
<td>Impossible ventilation, difficult intubation n=105</td>
<td>103 (98)</td>
<td>97 (92)</td>
<td>60 (57)</td>
<td>90 (88)</td>
<td>73 (70)</td>
<td>64 (61)</td>
<td>83 (79)</td>
<td>74 (71)</td>
<td>18 (17)</td>
</tr>
<tr>
<td>Impossible ventilation, impossible intubation n=105</td>
<td>103 (98)</td>
<td>100 (95)</td>
<td>70 (67)</td>
<td>96 (91)</td>
<td>90 (86)</td>
<td>81 (77)</td>
<td>93 (87)</td>
<td>88 (84)</td>
<td>22 (21)</td>
</tr>
<tr>
<td>Impossible SGA insertion n=78</td>
<td>77 (99)</td>
<td>47 (60)</td>
<td>39 (50)</td>
<td>35 (45)</td>
<td>25 (32)</td>
<td>24 (31)</td>
<td>33 (42)</td>
<td>18 (23)</td>
<td>16 (21)</td>
</tr>
<tr>
<td>Weighted Mean Percent (SD)</td>
<td>97.6 (1.6)</td>
<td>82.9 (13.5)</td>
<td>50.9 (10.1)</td>
<td>71.1 (18.3)</td>
<td>57.4 (19.2)</td>
<td>45.2 (20.1)</td>
<td>58.5 (21.4)</td>
<td>47.4 (26.8)</td>
<td>18.0 (2.6)</td>
</tr>
</tbody>
</table>

See Appendix five for a list of devices.
Table 13.2 Preferred follow-up action by anaesthetists for seven airway scenarios. Responses of anaesthetists (n=110) regarding follow-up for seven hypothetical difficult airway scenarios. Note that 104 (95%) anaesthetists provided an answer for every scenario. Values represent number of responses (%). Percentages are row percentages. Abbreviations: CL–Cormack-Lehane, SGA–supraglottic airway.

<table>
<thead>
<tr>
<th>Airway Scenarios</th>
<th>Follow up, No. (%)</th>
<th>No follow up, No. (%)</th>
<th>No response, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficult ventilation</td>
<td>82 (75)</td>
<td>28 (25)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Easy ventilation, difficult</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>intubation with CL 3B view</td>
<td>95 (86)</td>
<td>13 (12)</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Easy ventilation, failed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>intubation</td>
<td>106 (96)</td>
<td>1 (1)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Impossible ventilation, easy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>intubation</td>
<td>90 (82)</td>
<td>17 (15)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Impossible ventilation, difficult intubation</td>
<td>105 (95)</td>
<td>2 (2)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Impossible ventilation, impossible intubation</td>
<td>106 (96)</td>
<td>1 (1)</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Impossible SGA insertion</td>
<td>80 (73)</td>
<td>24 (22)</td>
<td>6 (5)</td>
</tr>
</tbody>
</table>

See Appendix five for a list of devices.
Table 13.3 Reasons which limit dissemination of critical airway information. Responses from 63 anaesthetists who answered the following question: “Which of the following limits your dissemination of critical airway information? (you may choose more than 1 option)”. Values represent number of responses (%).

<table>
<thead>
<tr>
<th>Limitations on the dissemination of critical airway information</th>
<th>Reason offered, Number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complex, user unfriendly, data bases</td>
<td>40 (63)</td>
</tr>
<tr>
<td>Time consuming processes</td>
<td>33 (52)</td>
</tr>
<tr>
<td>Inaccessible forms</td>
<td>31 (49)</td>
</tr>
<tr>
<td>Inaccessible morbidity/mortality forums</td>
<td>15 (24)</td>
</tr>
<tr>
<td>Disinterest</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Other</td>
<td>17 (27)</td>
</tr>
</tbody>
</table>

Retrospective Patient Record Assessment. Of the 124 patients with difficult airways identified in our audit through key words in the anaesthetic record, eighteen (14.5%) had their airway difficulty mentioned in the clinical notes, fifteen (12%) had a clinical alert within the hospital, seven (6%) appeared on the national NHI data base and nine (7%) were entered in the MedicAlert™ Foundation database. We contacted seventy three patients (59% of total) by telephone, of whom only 9 (12%) recalled a postoperative visit; five (7%) did not recall a visit on that particular occasion, but were aware of their airway difficulties from a previous anaesthetic; and eight (11%) received a letter from the anaesthetist. Ninety eight family doctors were contacted and only 10 (10%) had a letter on file regarding the patient’s airway difficulty. Further review of these patients showed that 85 (68%) had a documented preoperative airway assessment and airway difficulty was predicted in 62 patients (50%). Of those 62 cases, 39 (63%) were predicted by looking at the previous anaesthetic record, 16 (26%) by a preoperative airway assessment, six (10%) from a local database alert, and one (1%) by a patient letter and history. Of the 13 paediatric patients (age less than 16 years), one had a documented preoperative airway assessment and eight had airway difficulty predicted (one by airway assessment, six by previous anaesthetic record and one from documentation on a database) (Table 13.4).
Table 13.4  Retrospective assessment of records from 124 patients with documented difficult airways. The assessment examined the prediction and dissemination of difficult airway information.

<table>
<thead>
<tr>
<th>Follow-up options</th>
<th>Count (Percentage)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airway difficulty mentioned in the clinical notes (n=124)</td>
<td>18 (14)</td>
</tr>
<tr>
<td>Airway alert within the hospital (n=124)</td>
<td>15 (12)</td>
</tr>
<tr>
<td>Alert found on the National Health Index Medical Warning System (NHI) (n=124)</td>
<td>7 (6)</td>
</tr>
<tr>
<td>Alert found on the MedicAlert™ Foundation database (n=124)</td>
<td>9 (7)</td>
</tr>
<tr>
<td>Postoperative patient visit by the anaesthetist (n=73)</td>
<td>9 (12)</td>
</tr>
<tr>
<td>Postoperative patient visit by the anaesthetist after a previous anaesthetic (n=73)</td>
<td>5 (7)</td>
</tr>
<tr>
<td>Letter from the anaesthetist sent to the patient concerning their difficult airway (n=73)</td>
<td>8 (11)</td>
</tr>
<tr>
<td>Record of a difficult airway found with the family doctor (n=98)</td>
<td>10 (10)</td>
</tr>
</tbody>
</table>

**Difficult airway prediction**

- Documented preoperative airway assessment (n=124)                                    | 85 (68)            |
- Difficult airway predicted (n=124)                                                  | 62 (50)            |
  - Airway difficulty predicted by examining the previous anaesthetic record (n=62)      | 39 (63)            |
  - Airway difficulty predicted by preoperative airway assessment (n=62)                 | 16 (26)            |
  - Airway difficulty predicted by information on the local database (n=62)             | 6 (10)             |
  - Airway difficulty predicted by a letter from the patient (n=62)                    | 1 (1)              |

**Paediatric difficult airway prediction**

- Paediatric preoperative airway assessment (n=13)                                     | 1 (8)              |
- Paediatric difficult airway predicted (n=13)                                         | 8 (61)             |
  - Paediatric difficult airway predicted by airway assessment (n=8)                   | 1 (12)             |
  - Paediatric difficult airway predicted by previous anaesthetic record (n=8)         | 6 (75)             |
  - Paediatric difficult airway predicted by database documentation (n=8)             | 1 (12)             |

Retrospective audit of 124 patients with known difficult airways including the following criteria:- (1) all Cormack Lehane (CL) Grade 4 intubations, (2) all CL Grade 3b intubations (612), (3) any CL Grade 3 intubations with more than three techniques and/or attempts at intubation, (4) any CL Grade 3 intubation with difficult mask ventilation (requiring oral airway/adjunct and/or two-handed technique) (71), (5) all difficult mask ventilation (regardless of CL direct laryngoscopy grade), (6) airways with noted past history of difficult intubation and/or difficult mask ventilation.

See Appendix five for a list of devices.
Chapter 13. How do anaesthetists in New Zealand disseminate critical airway information

Discussion

This study reveals a wide discrepancy between stated follow-up preferences by anaesthetists concerning patients with critical airways, and the actual use of options to disseminate this information, apart from writing a comment on the anaesthetic record. A preoperative anaesthetic airway assessment is widely accepted as best practice and yet 32% of patients had no documentation of this in their anaesthetic record. Preoperative anticipation of a difficult airway occurred in 50% of patients identified with a difficult airway, and this was established by examining previous anaesthetic records (63%), assessing the patient (26%), using a database (10%) or receiving a letter (1%). The majority of anaesthetists regard the anaesthetic record as the most important method of patient follow-up and 59% agree that their dissemination of critical airway information was limited by information systems.

The results from this study are similar to those from The Fourth National Audit Project of the Royal College of Anaesthetists (RCoA) and the Difficult Airway Society (DAS) (NAP4) (114). An expert panel in that study reviewed 133 cases of major airway management complications that were related to general anaesthesia. In half of those patients (66), airway management difficulty was anticipated and 41 of the 133 patients had a history of airway problems. Dissemination of this information occurred through patient notes (32), communication to the patient (14), or communication to a family doctor (6). Failure to convey this history occurred in only two cases. Of the cases where major airway complications were not anticipated (67), it is impossible to tell how many had previous unreported difficulty.

It remains unclear which patients should be referred for dissemination of critical airway information. The stated follow-up preferences by anaesthetists in our study revealed a range of actions. Anaesthetists were more concerned about intubation difficulty than other forms of ventilation. Failed intubation with easy ventilation was more likely to be chosen for follow up (96%) than impossible ventilation with easy intubation (82%), or impossible supraglottic airway insertion (73%). Identification and documentation of ventilation difficulty by mask or SGA is important. Although complications arising from intubation represent a large proportion of airway morbidity and mortality in anaesthesia (3, 127, 418), the cause of morbidity and mortality is failure to ventilate and provide oxygenation. Ultimately, the decision to report a difficult airway rests with the medical practitioner, but reason to report should include any clinically significant threat to the maintenance of oxygenation and/or ventilation with difficult or impossible mask, SGA, or tracheal tube intubation.

Reporting mechanisms for difficult airways vary in effectiveness. The 2013 American Society of Anesthesiologists practice guidelines for management of the difficult airway recommend that a patient should be notified of their difficult airway by a written report or letter, including a summary of the airway difficulty and airway management, plus a review of the outcome of that management. It is also recommended that the patient’s surgeon or primary caregiver be informed and a bracelet or similar notification device is recommended (4). The Canadian Airway Focus Group provide similar guidance (205), including entry of

See Appendix five for a list of devices.
Chapter 13. How do anaesthetists in New Zealand disseminate critical airway information

information into the anaesthetic record, the case record and a national database. Further layers of notification can be provided by in-house difficult airway data bases and alert systems, national airway registries and the MedicAlert™ Foundation National Difficult Airway/Intubation Registry.

Entry of information into the anaesthetic record is widely accepted as essential (646), and was regarded as the most important form of communication in our survey. This entry is limited if the records cannot be accessed: for example, when patients move to another hospital and their previous notes are not readily retrievable, or where pre-hospital airway management has been conducted by first responders. Verbal communication to the patient of difficult airway information is unreliable, with one study showing only 50% recall of an anesthesiologist’s visit by patients (647). A recorded postoperative visit by the anaesthetist in our survey was infrequent (nine visits from 73 patients surveyed or 12%). Letters to the patient have been shown to be more effective, with up to 92% of patients who had received a letter concerning their airway difficulty notifying a subsequent anesthesiologist about their airway when presenting for subsequent surgery (647). However, we found only 10 out of 98 patients surveyed (10%) had received a letter. Databases are valuable, provided the information is accessible. Some countries have developed difficult airway registries, such as the United States MedicAlert™ Foundation National Difficult Airway/Intubation Registry. An ideal database maintains patient confidentiality, is patient identified, non-profit, accessible internationally and capable of disseminating critical information to medical staff and patients anywhere in the world 24 hours a day, seven days a week, in multiple languages. MedicAlert™ is the only medical information system and database that fits this description. The MedicAlert™ Foundation has 1467 New Zealand members with airway alerts. The National Health Index Medical Warning System — attached to the National Health Index (NHI) — is the main national medical database in New Zealand. However, there are issues of access within this system, and it was seen that many medical staff were not sure how to access information or upload alerts onto this database. This may account for the low uptake in our study of only seven patients out of 124 surveyed. The NHI is a free text database which is “read only”. This creates limitations because although it is easy to enter any alert, it is not possible to search the data. Also, NHI does not have a distinct Difficult Airway/Intubation Registry as part of the database.

Predicting a difficult airway before anaesthesia is a critical step towards ultimately disseminating critical airway information, but is not totally reliable (45). There are obvious advantages in avoiding unexpected and unprepared difficult airway management. The incidence of reporting a preoperative airway assessment in this study was 68%. This incidence can be improved by introducing a standardised airway assessment component to the anaesthetic record. In our study, the incidence of reporting a preoperative airway examination in paediatric patients was found to be particularly low, with only one recorded out of 13 surveyed (8%). This could be attributed to the poor understanding of risk factors associated with airway difficulty in the paediatric population (111, 648).

After recognizing the difficult airway, details of that difficulty should be documented. Templates with these details have been published, and they now appear on the Difficult Airway Society website (www.das.uk.com). This is followed by appropriate identification of the patient. Wrist bands, alert stickers in the notes, See Appendix five for a list of devices.
MedicAlert™ information service and patient identification emblems/bracelets and alert cards, such as that provided by the New Zealand Society of Anaesthetists, are some of the measures which have been used. Finally, the difficult airway information must be disseminated in order to prevent future potential problems. It is recognized that safety is increased and risk is reduced by applying a range of measures to ensure safety (646). In order to provide the most reliable distribution of this information, an international alert system is ideal, to allow for patients who might need airway management in another hospital, city or country.

This study has several limitations. First, this retrospective study was dependent on the definitions we used for identification of a difficult airway. There are currently no precise definitions of the difficult airway that are universally accepted (48). An updated report by the American Society of Anesthesiologists (ASA) Task Force on Management of the Difficult Airway, defined a difficult airway as “the clinical situation in which a conventionally trained anesthesiologist experiences difficulty with facemask ventilation of the upper airway, difficulty with tracheal intubation, or both” (4). The Task Force favours difficult airway descriptions that can be categorized or expressed as numerical values, including descriptions for difficult facemask or supraglottic airway (SGA) ventilation, difficult SGA placement, difficult laryngoscopy, difficult tracheal intubation and failed intubation (4). The ASA definition does not elaborate on the expertise of a “conventionally trained anesthesiologist” which can be variable. Difficult laryngoscopy, as described by the modified Cormack Lehane system in our survey, is not necessarily synonymous with difficult intubation. The latter depends on the skill of the operator and, possibly, the chosen technique. Patient, practitioner, equipment, chronological and pathological issues all cause variability. Similarly, there are no national, regional or universal guidelines that can be used to determine which patients should be followed up. Despite these issues, our study indicates significant under-reporting of patients with a difficult airway and we believe that this is far more serious than the concern about “crying wolf” or labelling a patient for life. The potential consequences of a false positive report of a patient with a difficult airway are far less serious than a false negative in which a difficult airway is unreported and subsequently unanticipated. An airway registry should be regarded as a chronology of patient airway management experiences, not a one-time event. It can therefore be updated as technologies and practitioners change, and as a patient's anatomy and physiology change. Second, in our survey of anaesthetists we found relatively high numbers of respondents recommending dissemination options that were not reflected in our audit of patients. This may reflect regional deficiencies in databases and could also represent a reporting bias in the survey, where respondents avoided answers that were embarrassing or professionally unacceptable. Third, the use of key words to select patients from the SAFERsleep™ electronic anaesthetic safety and record system may not have adequately balanced sensitivity and specificity, and the subsequent selection according to our inclusion criteria is susceptible to selection bias. Fourth, it is possible that postoperative visits occurred or letters were sent without documentation, however, it is unlikely that the patient or the GP also failed to recall these events. Finally, the relevance of our results outside New Zealand may be determined by local practice, information systems, and patient characteristics.

See Appendix five for a list of devices.
Chapter 13. How do anaesthetists in New Zealand disseminate critical airway information

**Conclusion**

This study reveals a clear discrepancy between the dissemination of critical airway information that Auckland anaesthetists believe should occur and the dissemination that does occur. It is the authors’ opinion that practice guidelines should be established to emphasize the importance of disseminating critical airway information and this topic should also be included in the Australian and New Zealand College of Anaesthetists (ANZCA) curriculum for registrar training. Ideally, a custom designed MedicAlert™ New Zealand difficult airway/intubation registry could be established, with easy access for medical practitioners and patients. This registry could be accessed through the National Health Index (NHI) database and linked to the MedicAlert™ International registry and their nine international affiliates.

**Postscript**

This study was presented as a poster at the Society for Airway Management annual scientific meeting in Philadelphia, USA, 2013.

As a member of the Society for Airway Management MedicAlert™ task force, I am working to introduce an airway registry in the USA. This work is directly applicable to New Zealand, where a similar venture is planned. The goal is a national airway registry which complies with the recommendations of this study. It is hoped to provide free, easy access for practitioners and patients to the MedicAlert™ International registry and their nine international affiliates.

Another improvement would be the ability to add difficult airway information to the electronic anaesthetic record. This could be achieved by introducing simple templates for each patient.

See Appendix five for a list of devices.
Chapter 14. Discussion and conclusions

This thesis includes a review of literature and presentation of research that aims to improve the quality and safety of airway management.

A review of the significant and clinically relevant literature concerning airway assessment, presented in Chapter one, confirms that there are statistical inadequacies in our current methods of airway assessment. There are opportunities to substantially improve this situation by using combined tests, by using indices such as ratio of height to thyromental distance (RHTMD), by improving test methodology and by adopting techniques such as flexible nasopharyngoscopy. Airway tests should be augmented by an airway history and understanding of risk factors for each aspect of a patient’s airway. Recent information derived from meta-analyses of national and regional data bases is providing useful information about the incidence and relative risk factors for airway management procedures.

It is now known that one of the most reliable predictors of a difficult intubation is a past history of a difficult intubation. The dissemination of critical airway information is, therefore, a key aspect of avoiding future airway complications. Chapter 14 discusses problems identified in New Zealand, including a wide discrepancy between stated follow-up preferences by anaesthetists, and the actual use of options such as postoperative visits, notes in the clinical record, letters to the patient and family doctor, and entries in hospital, national and MedicAlert™ data bases. Comments from our survey were critical of multiple difficult airway databases and alert systems which are not linked, and do not lead automatically to, a single source of information.

Two concerning issues arise from data on the subject of airway assessment. The first issue is that significant numbers of patients have no record of receiving an airway assessment prior to anaesthesia. This suggests that many anaesthetists have no pre-operative airway plan in place for their patients. Our research in New Zealand found evidence of airway assessment in 68% of anaesthetic records, but only half of the patients with a difficult airway were anticipated preoperatively. These issues need to be highlighted in airway management education programmes. Practitioners should be encouraged to take a history, examine the patient pre-operatively and look for risk factors associated with a difficult airway. This information should then be documented and accompanied by an appropriate airway management plan (4, 5).

The second issue is that evidence derived from airway assessment is often disregarded. The Danish Anaesthesia Database included 15,499 patients with a past history of either a difficult or a failed intubation. Of those with a previous difficult intubation, 24% were given a general anaesthetic for subsequent anaesthesia. Thirty percent of those with a previous failed intubation were also given a general anaesthetic for a subsequent procedure (96). Similarly, in the NAP4 study, 68% of patients had documented evidence of an airway assessment in their anaesthetic record, and preoperative anticipation of a difficult airway occurred in 50% of patients subsequently identified with a difficult airway. Despite this, 81% of anaesthetists chose to proceed with a general anaesthetic.

See Appendix five for a list of devices.
in patients identified as having a difficult airway (3). Although repeating a general anaesthetic in the face of a previous difficult airway is not necessarily doomed for failure, the likelihood of difficulty is high, particularly if the same conditions apply. This reinforces the importance of detailed documentation following the management of a difficult airway, including information about the patient positioning and specific details about the equipment used. It is hoped that, by improving our electronic record-keeping and easing reporting mechanisms, we will see an increase in the reporting of critical airway information.

Airway assessment should be followed by the formulation of an airway management plan. A case report, highlighting the importance of meticulous preparation, is described in Chapter six of this thesis. Planning for failure is a useful concept, based on the realisation that every technique and device used for airway management is associated with a failure rate, and, inevitably, alternative strategies will be required. In the case described in this report, multiple alternative airway techniques were planned and ultimately implemented. The maintenance of oxygenation throughout the delivery of this child reflects another fundamental principle of safe airway management. In clinical practice, pre-oxygenation with 100% oxygen until FEO2 exceeds 90% is a simple and safe prelude to general anaesthesia (649). Other manoeuvres, such as the reverse Trendelenburg position, the semi-seated Fowler’s position (650), nasal oxygen (651), or insufflation of oxygen via laryngoscopes (652), are all useful strategies to prolong oxygenation during the apnoea that is imposed by prolonged tracheal intubation. Another principle is to avoid trauma during airway management. Repeated intubation attempts are known causes of patient morbidity (247, 653). Practice guidelines now recommend restrictions on the number of intubation attempts and promote intelligent interpretation of each attempt to optimise and minimise the number of subsequent efforts (5). Recent airway management guidelines have reiterated the importance of incorporating these principles of safe airway management into any airway plan (4-6).

In the NAP4 study, out of 184 reported cases with severe morbidity or mortality, resulting from airway management, an expert panel decided that equipment, resources and communication factors were causal or contributory in more than 25% of cases. Issues concerning airway management equipment are the focus in Chapters seven to 12 in this thesis.

Chapter two was an audit of airway management equipment in the Auckland region. The audit revealed serious equipment deficiencies which potentially could have led to patient harm. Missing or faulty equipment, inadequate equipment and absent quality control mechanisms were all identified. As a consequence of this audit, a guideline was produced by ANZCA and a background document was published, which appears as an updated version in Chapter three of this thesis. The revision of the content, after only two years, emphasises the rapidity with which equipment and practices are changing. The general trend has been to devolve to fewer devices with increasing dependence on technology. Optical instruments, such as the video laryngoscope, are now the preferred device for difficult intubations, and supraglottic airways are also increasing in use (415). Conversely, the flexible bronchoscope appears to be used less. The proliferation of single use items raises issues of quality and efficacy. Popular opinion amongst anaesthetists has changed concerning preferred

See Appendix five for a list of devices.
equipment to manage emergency percutaneous tracheal access. This change is possibly due to the NAP4 finding which identified poor results with cannula cricothyroidotomy and transtracheal jet ventilation. This, combined with information highlighting the poor success rate of identifying the cricothyroid membrane by palpation, has led to a change in preference favouring surgical cricothyroidotomy with a scalpel (5).

The importance of airway equipment is reiterated in practice guidelines, but the exact nature of that equipment may be less important. Success with a given device is more likely to be operator dependent than a reflection of the device itself. Certain devices, such as the flexible bronchoscope, are relatively underused. A survey in New Zealand found that the average consultant anaesthetist performs only three fibreoptic intubations per year. This problem is blamed primarily on a lack of clinical cases requiring the technique and a lack of practice (223). Inexperienced leads to a lack of confidence, which may then influence clinical judgement, particularly when deciding whether to perform an awake intubation.

This raises the issue of education in airway management. Distributed learning and deliberate practice are cornerstones of skill development, but shortened working hours, decreased exposure to difficult airways and an increasing emphasis on supraglottic airways are adversely affecting the development of expertise. A possible solution to this lack of clinical experience is simulation training (417).

Conclusions

Preoperative airway assessment can be improved in many ways. Our study of the thyromental distance test concluded that the test sensitivity could be trebled by using objective measurement with a ruler or a gauge, rather than finger breadth (54).

For a foetus diagnosed antenatally with severe micrognathia, early planning of airway management is important. This concept can be extrapolated to any anticipated difficult airway. Severe micrognathia is now considered an indication for an EXIT procedure and use of a flexible bronchoscope through an LMA™ is an acceptable technique in this context (117, 654).

Equipment required for management of the difficult airway needs to be checked, in good working order and readily available. There is no magical device or technique that will be suitable for all airway problems, so a range of equipment is required. Appropriate airway equipment must be matched with procedural skill. Ideally, equipment should be chosen that has proven efficacy and is familiar to the practitioner. PS56, 2012 provides guidance on the minimum equipment needed for managing unexpected difficult airways, based on expert consensus, underpinned by the best available evidence. When selecting equipment for the difficult airway container, principles of standardisation, redundancy and a culture of safety are recommended (150, 170).

Airway management equipment should be fit for purpose; practitioners should be knowledgeable in the correct use of that equipment; manufacturers’ instructions should be followed and equipment should comply with performance standards. These fundamental requirements were examined in several studies described in this thesis.

See Appendix five for a list of devices.
In a prospective randomised controlled trial, PVC single use laryngeal mask airways were inferior to silicone cLMA™ and Boss systems laryngeal masks for flexible bronchoscopy in children. This was a specific indication and an example of the importance of equipment being fit for purpose (655).

A case report of supraglottic airways being used and failing during the resuscitation of a drowning victim is another example of using equipment when it is not fit for purpose. According to the manufacturers’ instructions, neither of the devices used in this case was recommended for this specific indication. The conclusion of the case report was that SGAs are unsuitable for resuscitation of drowning victims due to the relatively high resistance in the lungs and low leak pressures with the SGAs (197).

A culture of safety with airway equipment is recommended to ensure equipment is maintained and complies with recognised standards. An audit of laryngoscopes at our children’s hospital found that a large proportion of this equipment was sub-standard. A recommendation was sent to the hospital management to replace faulty equipment and this problem was rectified. The conclusion of the study was that laryngoscope light should be regularly audited. Results from these audits can be used to retire or repair substandard laryngoscopes in order to maintain acceptable standards of laryngoscope light. Audit results produce tangible evidence that is useful when applying for capital expenditure. Light measurements are not easy to make. There needs to be a convenient device to reliably measure laryngoscope illumination (458).

Equipment guidelines and standards are useful references to measure quality of practice. Ideally those guidelines should be based on evidence and critically evaluated on a regular basis. The International Organization for Standardization has published a standard (ISO 7376:2009) specifying illuminance levels and tests for illumination from hook-on type laryngoscopes. There was no prior objective evidence to support the minimum level of illuminance described in the standard, and no information regarding visual acuity at different levels of laryngoscope illuminance. A laboratory study, involving 50 anaesthetists using laryngoscopes at different levels of illumination, tested visual acuity during direct laryngoscopy in manikins. Visual acuity improves as the laryngoscope illuminance increases up to 700 lux. No statistically significant improvement was measured by increasing the illuminance up to 2000 lux. Subjectively, anaesthetists favour illuminance of 2000 lux for direct laryngoscopy (327).

A prospective randomised trial was conducted to test the efficacy of two tracheal tubes used during a scalpel bougie technique for percutaneous emergency airway access. The conclusion of this study was that both tubes performed equally well for this purpose. A secondary finding from this study revealed that three novice anaesthetists, after one hour of training, can perform this procedure in a cadaver with a mean completion time of 37 seconds (337).

The Enk oxygen flow modulator is a device designed for transtracheal ventilation through a cannula. A bench study established that this device is fit for purpose and adequate gas flow depends on complete occlusion of all five holes on the device during the inspiration phase. Using this device, gas flow can be regulated and,
Theoretically, adequate flows can be generated for paediatric ventilation using the APLS formula of 1L/min/year of age (144).

A review article of education for airway management concluded that education in airway management is undergoing a much-needed change. The introduction of Competency Based Medical Education and the explicit definition of airway management in the curriculum as a clinical fundamental should lead to greater formalization of airway training programmes. We can anticipate improvements in training techniques as a result of research into medical education. Trainees can expect the assessment of their competence in airway management to become much more rigorous in the near future. Regular reassessment of this competence is likely to become the norm for both trainees and qualified practitioners. These changes will affect all anaesthetists. A career-long commitment to relevant education and maintenance of skills is clearly integral to the credibility of anaesthetists’ claim to being experts in airway management (417).

The final study in this thesis considered the dissemination of critical airway information in New Zealand. The conclusion of the study was the suggestion that a custom-designed New Zealand difficult airway/intubation registry could be established, with easy access for medical practitioners and patients. This registry could be accessed through the National Health Index (NHI) database and linked to the MedicAlert™ International registry and their nine international affiliates (113). Currently an international review panel established by the Society for Airway Management is designing an American airway registry which will be linked to MedicAlert™. The result of this effort may be directly applicable to New Zealand.

Future research and directions

Since this thesis commenced, a regional guideline for equipment to manage a difficult airway during anaesthesia has been published (150). That guideline needs regular attention and updating (416). Hospitals and practitioners should be encouraged to comply with the guideline. Hospital credentialing and continuing professional development programmes are possible mechanisms to achieve this.

New airway devices require careful evaluation to ensure efficacy, quality, safety and indications. Responsibility for this task could be given to a hospital airway committee or a designated department airway expert. Decisions to purchase equipment should be based on the individual needs of each department, but should also be founded on available evidence, as defined in the DAS ADEPT study (195).

Video-laryngoscopes have become popular in the management of difficult intubations (415). They are now also being proposed for routine airway management. Evidence is emerging that some video laryngoscopes provide greater first pass success and laryngeal view in predicted difficult airways compared to direct laryngoscopy and intubation with a Macintosh laryngoscope; but intubation times are longer with video laryngoscopes (73). Research is required to define the characteristics of the ideal video laryngoscope. The relative benefits of channelled versus un-channelled devices or acutely angled blades versus standard shaped blades remains unclear. The economic and quality advantages of single use versus re-usable devices need to be investigated. Predictors of failure and complication rates with video laryngoscopes remain to be defined.

See Appendix five for a list of devices.
Further work is required for the CICV emergency. This should incorporate procedural and human factor considerations. Areas of research include prediction and prevention of CICV, optimal equipment and techniques to manage CICV for adults and children, training techniques and skill retention to manage CICV, behavioural aspects of CICV and emergency transtracheal ventilation for adults and children. Further evidence is required to establish the best rescue ventilation method for drowning victims.

Emphasis in airway management should be placed on avoiding morbidity and mortality in order to minimise the cricothyroidotomy incidence. This can be effectively achieved by following practice guidelines and attending to multiple factors, such as education, equipment, documentation and the establishment of a difficult airway response team (128).

Airway management is a core skill in anaesthesia and is now an integral part of the ANZCA curriculum which incorporates competency based medical education. Further work is required to define and measure those competencies. Assessment should be introduced using valid and reliable metrics (417).

Procedural skill training using simulation is a future opportunity to enhance current medical education. Virtual-reality simulators have the advantage of providing independent and objective assessment of performance with a wide range of learning opportunities in a patient-free environment. Ideally, simulators used for evaluation of procedural skill should be reliable, valid, cost effective, feasible and comprehensive with varying degrees of difficulty (505). Simulators require rigorous scrutiny if they are to be used for assessment in order to ensure that they are valid and reliable. The ORSIM® bronchoscopy simulator (Airway Simulation Ltd. Auckland, New Zealand) is a new flexible bronchoscopy simulator that I designed to enhance skill with the flexible bronchoscope (656). A construct validation study, using the simulator, is being prepared for publication. Future studies are planned to find appropriate metrics to objectively measure performance on the simulator.

Steps should be taken to improve the dissemination of critical airway information in New Zealand. The establishment of a national airway registry linked to MedicAlert™ would be a positive step (113). A cooperative effort between New Zealand and the Society for Airway Management is pursuing this objective.

Audits of major airway complications, such as the NAP4 study, have used various markers of airway morbidity including brain damage, emergency surgical airway and unanticipated intensive care admission (3). Currently, in New Zealand, there is no reliable reporting mechanism for critical airway management events or near misses. Efforts by the ANZCA Mortality Working Group and the tripartite Australian and New Zealand Anaesthetic Data Committee incident reporting project are laudable and should be strengthened.

Education in airway management and clinical practice guidelines depend on supporting evidence. Furthermore, changes in clinical practice ideally should be guided by research and resulting evidence. In this thesis, I have presented largely clinical research, representing an inter-related body of work which addresses the quality and safety of airway management in a multifaceted way. Many of the studies have individually influenced clinical practice. The equipment audit in Chapter two was a catalyst for a new ANZCA guideline. As a result of the case report in Chapter six, severe micrognathia diagnosed antenatally is now a recognised indication for an

See Appendix five for a list of devices.
EXIT procedure. The use of supraglottic airways to resuscitate patients who are drowning is now being reconsidered internationally as a result of the case report presented in Chapter eight. Laryngoscopes were upgraded in our department after the results of the audit from Chapter nine were presented to the hospital management. Reusable laryngeal masks were reinstituted in our department as conduits for flexible bronchoscopy following the results of our randomised controlled trial, presented in Chapter seven. Correct use of the Enk oxygen flow modulator is now described in the manufacturer’s instructions as a result of our study in Chapter 12. Work is underway to establish a New Zealand airway registry as a result of the study on dissemination of critical airway information in Chapter 13. Collectively, this work is bound by a common theme to improve the quality and safety of airway management. Publication and presentation of these results extend this theme internationally.

See Appendix five for a list of devices.
Appendices

Appendix index

1 Acknowledgements
2 Permission
3 Co-authorship forms
4 Ethics approval
5 Equipment manufacturers

Appendix 1 Acknowledgements

The following is a summary of acknowledgements, funding and competing interests for each paper included in this thesis.

Chapter 2. Airway management equipment in a metropolitan region: an audit

Co-authors, Hounsell GL, Futter ME, Anderson BJ

We gratefully acknowledge the cooperation and willing support offered by the management and staff of the hospitals involved in this audit. We also thank Dr Margot Jerram for her suggestions and constructive criticism in reviewing this manuscript. Dr Baker has received free airway equipment for research and teaching from a variety of manufacturers.

Chapter 3. Equipment to manage a difficult airway during anaesthesia

Co-authors, Flanagan BT, Greenland KB, Morris R, Owen H, Riley RH, Runciman WB, Scott DA, Segal R, Smithies WJ, Merry AF

This background document was part of a larger process to produce an ANZCA guideline for equipment to manage a difficult airway during anaesthesia (PS56, 2012). Many individuals contributed to that process and some of them are named in Chapter two. Professor Merry made a significant contribution. As chairman of the ANZCA quality and safety committee he agreed to adopt this project. He then chaired the meetings and guided the entire project through to completion including writing and editing parts of the background document. Without his contribution, this guideline would not have happened.

See Appendix five for a list of devices.
Appendices

Dr Baker has received free airway equipment for research and teaching from a number of manufacturers. We wish to thank Pauline Berryman and John Biviano for administrative support and advice and Dr Margie Cowling for her advice and contribution to the first meeting.

Chapter 4. Education in airway management

Co-authors, Weller JM, Greenland KM, Riley RH, Merry AF

We are grateful to Captain Robert Henderson, who is a psychologist and a senior Air New Zealand pilot and instructor, for his advice and knowledge during the preparation of this paper and to Dr Margot Jerram who assisted in preparing the manuscript. The study was funded solely by institutional and departmental sources. P. A. Baker has received free airway equipment for research and teaching from a variety of manufacturers. He is also the owner of Airway Simulation Ltd. which has developed the Orsim™ bronchoscopy simulator. R.H. Riley receives royalties from Oxford University Press. A.F. Merry has a financial interest in Safer Sleep LLC. No competing interests are declared by the other authors.

Chapter 5. Thyromental distance measurement – fingers don’t rule

Co-authors, Depuydt A, Thompson JMD

The authors gratefully acknowledge the help and advice received from Professor Brian J Anderson, Department of Intensive Care, Starship Children’s Health, Auckland, New Zealand and Sue Foggin, librarian, Philson Library, University of Auckland, Auckland, New Zealand.

The study was supported solely by institutional and/or departmental sources.

Chapter 6. Airway management during an EXIT procedure for a foetus with dysgnathia complex

Co-authors, Aftimos S, Anderson BJ

We wish to thank Mr Colin Barber, ENT surgeon, and the large team of professionals who were involved in the successful outcome of this case. The study was supported solely by institutional and/or departmental sources.

Chapter 7. A prospective randomized trial comparing supraglottic airways for flexible bronchoscopy in children

Co-authors, Brunette KE, Byrnes CA, Thompson JMD

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Appendices

We are grateful for the support and cooperation offered by Paediatric Respiratory Bronchoscopy Consultants Drs Elizabeth Edwards, David McNamara, Jacob Twiss and Julian Vyas and Paediatric Anaesthetists at Starship Children’s Health. This study was supported solely by institutional and/or departmental sources.

Dr Baker has received free airway equipment for research and teaching from a variety of companies including LMA PacMed. The other authors declare no conflict of interest.

Chapter 8. Failure to ventilate with supraglottic airways after drowning

Co-author, Webber JB

We are grateful to Professor Brian Anderson who reviewed this manuscript.

Dr Baker has received free airway equipment for research and teaching from a number of manufacturers including Intersurgical and Ambu. Mr Webber has no conflict of interest. This study was supported solely by institutional and/or departmental sources.


Co-authors, McQuoid S, Thompson JMD, Jacobs RJ

We are grateful to the Department of Optometry and Vision Science, University of Auckland and the Bioengineering Department of Auckland City Hospital for advice and equipment loaned for this study. Three new laryngoscopes were generously donated by Karl Storz for the study.

Dr Baker has received free airway equipment for research and teaching from a variety of manufacturers including Welch Allyn and Karl Storz. No competing interests are declared by the other authors.

Chapter 10. Visual acuity during direct laryngoscopy at different illuminance levels

Co-authors, Raos AS, Thompson JMD, Jacobs RJ

The study was funded by institutional and departmental sources and laryngoscopes were provided free of charge by Karl Storz.

We are grateful to the Department of Optometry and Vision Science, New Zealand National Eye Centre, University of Auckland and the Bioengineering Department of Auckland City Hospital for advice and equipment loaned for this study. Three new laryngoscopes were generously donated by Karl Storz for the study.

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Dr Baker has received free airway equipment for research and teaching from a variety of manufacturers including Karl Storz. No competing interests are declared by the other authors.

Chapter 11. Parker Flex-Tip or standard tracheal tube for percutaneous emergency airway access? A prospective randomised trial.

Co-authors, Fernandez TM, Hamaekers AE, Thompson JMD

The study was funded by institutional and departmental sources. We are grateful to Obex Medical Limited and Covidien New Zealand who supplied us with tracheal tubes free of charge for this study. P. A. Baker has received free airway equipment for research and teaching from a variety of manufacturers. He is also the owner of Airway Simulation Ltd. A.E. Hamaekers is a member of the medical advisory board of Ambu A/S. She has no financial interest in any company. No competing interests are declared by the other authors. We are grateful to David Churhouse from Auckland City Hospital Photography Department and Peter Riordan from the Anatomy Department, The University of Auckland.

Chapter 12. Experimental adaptation of the Enk Oxygen Flow Modulator for potential paediatric use.

Co-author, Brown AJ

This study was supported solely by institutional and/or departmental sources. Dr Baker has received free airway equipment for research and teaching from a variety of manufacturers including Cook® and VBM®.

Chapter 13. How do Anaesthetists in New Zealand disseminate critical airway information?

Co-authors, Moore CL, Hopley L, Herzer KR, Mark LJ

The New Zealand Asthma and Respiratory Society generously donated a $5000 Research Scholarship to C. L. Moore to complete this study. P. A. Baker has received free airway equipment for research and teaching from a variety of manufacturers. He is also the owner of Airway Simulation Ltd. No competing interests are declared by the other authors. The authors are grateful to Mr Andrew Wigglesworth, President and CEO, MedicAlert™ Foundation for reviewing this paper.

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See Appendix five for a list of devices.
Appendices

This form is to accompany the submission of any PhD that contains research reported in published or unpublished co-authored work. Please include one copy of this form for each co-authored work. Completed forms should be included in all copies of your thesis submitted for examination and library deposit (including digital deposit), following your thesis Acknowledgements.

Please indicate the chapters, sections, or pages of this thesis that are extracted from a co-authored work and give the title and publication details or details of submission of the co-authored work.

Nature of contribution by PhD candidate

First author data collection, analysis, writing, editing

Extent of contribution by PhD candidate (%)
80

CO-AUTHORS

<table>
<thead>
<tr>
<th>Name</th>
<th>Nature of Contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catherine Moore</td>
<td>Data collection and analysis</td>
</tr>
<tr>
<td>Kurt Herzer</td>
<td>Data analysis and manuscript preparation</td>
</tr>
</tbody>
</table>

Certification by Co-Authors

The undersigned hereby certify that:

- the above statement correctly reflects the nature and extent of the PhD candidate's contribution to this work, and the nature of the contribution of each of the co-authors; and

- in cases where the PhD candidate was the lead author of the work that the candidate wrote the text.

<table>
<thead>
<tr>
<th>Name</th>
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<th>Date</th>
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<tr>
<td>Catherine Moore</td>
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<td>25/5/13</td>
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<tr>
<td>Kurt Herzer</td>
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<td>29/5/13</td>
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<tr>
<td>Lynette Mary</td>
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<td>9/27/13</td>
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</table>

See Appendix five for a list of devices.
Appendix 4 Ethics approvals

Northern X Regional Ethics Committee
Ministry of Health
3rd Floor, Unisys Building
650 Great South Road, Penrose
Private Bag 92, 522
Wellesley Street, Auckland
Phone (09) 580 9105
Fax (09) 580 9001

14 October 2008

Dr Paul Baker
21A Ranui Road
Remuera
Auckland

Dear Paul

NTX/08/104/EXP

Testing visual acuity for laryngoscopy during various levels of illumination

Principal Investigator: Dr Paul Baker, Starship Children’s Health
Co-Investigators: Assoc Prof Robert J. Jacobs, University of Auckland
Dr Shane McQuoid, ADHB

Thank you for your application received 8 October 2008. The above study has been given ethical approval by the Deputy Chairperson of the Northern X Regional Ethics Committee under delegated authority.

Approved Documents
- Information Sheet/Consent Form (version 1)
- Data Sheet (version 1)

Please insert a date with the version number in the footer. The consent form needs to include the date of the information sheet in the first paragraph; “I have read and I understand the information sheet dated [insert date].”

Accreditation
The Committee involved in the approval of this study is accredited by the Health Research Council and is constituted and operates in accordance with the Operational Standard for Ethics Committees, April 2006.

Progress Reports
The study is approved until 14 October 2009. However, the Committee will review the approved application annually and notify the Principal Investigator if it withdraws approval. It is the Principal Investigator’s responsibility to forward a progress report covering all sites prior to ethical review of the project on 14 October 2009. The report form is available on http://www.ethicscommittees.health.govt.nz (progress reports). Please note that failure to provide a progress report may result in the withdrawal of ethical approval.

A final report is also required at the conclusion of the study.

Amendments
It is also a condition of approval that the Committee is advised of any adverse events, if the study does not commence, or the study is altered in any way, including all documentation eg advertisements, letters to prospective participants.

Please quote the above ethics committee reference number in all correspondence.

See Appendix five for a list of devices.
17 October 2011

Dr Paul Baker c/- Ms Davina McAllister
Dept of Anaesthetic & Peri Operative Medicine
Auckland City Hospital Lvl 8
Private Bag 92 024
Auckland 1142

Dear Paul

Re: Ethics ref: NTX/11/EXP/241 (please quote in all correspondence)
Study title: Prospective randomised trial comparing Parker tip and Magill tip endotracheal tubes for cricothyroidotomy. Protocol V#1, 28/9/11; PIS/Cons V#1, 28/9/11
Investigators: Dr Paul Baker (Principal), Dr John M.D. Thompson, Dr Ankie E.W. Hamaekers, Dr Thomas Fernandez
Localities: University of Auckland, Auckland DHB

Thank you for your application received with Davina’s letter on 6 October 2011. The above study has been given ethical approval by the Deputy Chairperson of the Northern X Regional Ethics Committee under delegated authority.

Approved Documents
- Protocol number [version 1, dated 28 September 2011]
- Information Sheet/Consent Form [version 1, dated 28 September 2011]

This approval is valid until 30 June 2012.

Amendments and Protocol Deviations
All significant amendments to this proposal must receive prior approval from the Committee. Significant amendments include (but are not limited to) changes to:
- the researcher responsible for the conduct of the study at a study site
- the addition of an extra study site
- the design or duration of the study
- the method of recruitment

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports
Should you wish to extend your study, please supply a Progress Report by 30 June 2012. If a progress report, or final report, is not received by that date, the file will be closed and archived. No ethical approval will then cover this study.

See Appendix five for a list of devices.
Appendices

29 February 2008

Ms Katherine Emily Jessica Young
P.O. Box 28722
Remuera, Auckland

Dear Katherine

Comparison of the effectiveness of 4 disposable supraglottic airway devices and one reusable ‘LMA classic’ for use in flexible bronchoscopy in children.

Investigators: Katherine Young, Dr Paul Baker, Dr Catherine Byrnes.
Ethics ref: NTY/07/12/134
Locations: Starship Hospital.

The above study has been given ethical approval by the Northern Y Regional Ethics Committee.

Approved Documents
- Form A. Patient Information Sheet version 2 dated 8/02/2008.
- Form B. Consent Form version 2 dated 1/02/2008
- Patient Consent Form version 2 dated 1/02/2008.

Certification
The Committee is satisfied that this study is not being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is being carried out.

Accreditation
The Committee involved in the approval of this study is accredited by the Health Research Council and operates in accordance with the Operational Standard for Ethics Committees, April 2006.

Final Report
The study is approved until 30 March 2009. A final report is required at the end of the study. The report form is available on http://www.newhealth.govt.nz/ethicscommittees and should be forwarded along with a summary of the results. If the study will not be completed as advised, please forward a progress report and an application for extension of ethical approval one month before the above date.

Requirements for SAE Reporting
The Principal Investigator will inform the Committee as soon as possible of the following:
- Any related study in another country that has stopped due to severe or unexpected adverse events
- Withdrawal from the market for any reason
- All serious adverse events occurring during the study in New Zealand which result in the investigator breaking the blinding code at the time of the SAE or which result in hospitalisation or death.
- All serious adverse events occurring during the study worldwide which are considered related to the study medicine. Where there is a data safety monitoring board in place, serious adverse events occurring outside New Zealand may be reported quarterly.

All SAE reports must be signed by the Principal Investigator and include a comment on whether he/she considers there are any ethical issues relating to this study continuing due to this adverse event. It is assumed by signing the report, the Principal Investigator has undertaken to ensure that all New Zealand investigators are made aware of the event.

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See Appendix five for a list of devices.
Dear Paul

Re: Ethics ref: NTX/10/EXP/216  (please quote in all correspondence)
Study title: A survey of effective dissemination of critical airway information in New Zealand hospitals
Investigators: Dr Paul Baker, Ms Catherine Moore

Thank you for your application received 4 November 2010. The above study has been given ethical approval by the Deputy Chairperson of the Northern X Regional Ethics Committee under delegated authority.

Approved Documents
— Protocol number [undated, received 4/11/10]
— Information Sheet/Consent Form [version 1, dated 9/11/10]
— Questionnaire [version 1, dated 9/11/10]

This approval is valid until 12 November 2011.

Amendments and Protocol Deviations
All significant amendments to this proposal must receive prior approval from the Committee.
Significant amendments include (but are not limited to) changes to:
— the researcher responsible for the conduct of the study at a study site
— the addition of an extra study site
— the design or duration of the study
— the method of recruitment

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports
Should you wish to extend your study, a Progress Report is due to the Committee by 12 November 2011. If the study is completed before due date (estimated September 2011), please forward an end of study report. The Annual/Final Report Form that should be used is available at www.ethicscommittees.health.govt.nz. Please note that if you do not provide a progress report by this date, ethical approval may be withdrawn.

See Appendix five for a list of devices.
Appendix 5 Airway devices and manufacturers (city and country of manufacture) quoted in this thesis

<table>
<thead>
<tr>
<th>Airway Device</th>
<th>Manufacturer, City, Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bullard laryngoscope®</td>
<td>ACMI Corp.; Southborough, MA, USA</td>
</tr>
<tr>
<td>UpsherScope Ultra™</td>
<td>Metropolitan Medical Inc.; Winchester, USA</td>
</tr>
<tr>
<td>GlideScope® videolaryngoscope®</td>
<td>Verathon Inc. Bothwell, WA, USA</td>
</tr>
<tr>
<td>McGrath laryngoscope®</td>
<td>Aircraft Medical; Edinburgh, UK</td>
</tr>
<tr>
<td>Airtraq®</td>
<td>Prodl, Vizcaya, Spain</td>
</tr>
<tr>
<td>Pentax-AWS system® (“AirwayScope”)</td>
<td>Pentax Corp.; Tokyo, Japan</td>
</tr>
<tr>
<td>Bonfils Retromolar Intubation Fiberscope®</td>
<td>Karl Storz Endoscopy; Tuttlingen, Germany</td>
</tr>
<tr>
<td>Berci-Kaplan DCI video laryngoscope®</td>
<td>Karl Storz Endoscopy; Tuttlingen, Germany</td>
</tr>
<tr>
<td>C-Mac video laryngoscope™</td>
<td>Karl Storz Endoscopy; Tuttlingen, Germany</td>
</tr>
<tr>
<td>Shikani Optical Stylet (S.O.S.)™</td>
<td>Clarus Medical; Minneapolis, MN, USA</td>
</tr>
<tr>
<td>Levitan FPS (First Pass Success) scope™</td>
<td>Clarus Medical; Minneapolis, MN, USA</td>
</tr>
<tr>
<td>Foley Airway Stylet®</td>
<td>Clarus Medical; Minneapolis, MN, USA</td>
</tr>
<tr>
<td>Aintree catheter™</td>
<td>Cook Critical Care; Bloomington, USA</td>
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<tr>
<td>Trachlight™</td>
<td>Laerdal Medical, Wappingers Falls, NY, USA</td>
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<td>Intubating Laryngeal Mask (Fastrach)™, C-Trach™,</td>
<td>The Laryngeal Mask Company Ltd; Maidenhead, UK</td>
</tr>
<tr>
<td>Classic LMA™, LMA Unique™, LMA Supreme ™, LMA-ProSeal™</td>
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<tr>
<td>ILMA™ reusable silicone endotracheal tube</td>
<td>Euromedical; Sungai Petani, Malaysia</td>
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<tr>
<td>Berman Oropharyngeal Airway™</td>
<td>Vital Signs; Totowa, New Jersey, USA</td>
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<td>Rusch Viewmax™ laryngoscope blade</td>
<td>Rusch Inc.; Duluth, Germany</td>
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<tr>
<td>Flexiblade™</td>
<td>Arco Medic Ltd.; Omer, Israel</td>
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<tr>
<td>Truview®</td>
<td>Truphatek, Netanya, Israel.</td>
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<tr>
<td>Cookgas Air-Q™ intubating laryngeal airway</td>
<td>Cookgas LLC; Saint Louis, MO, USA</td>
</tr>
</tbody>
</table>

See Appendix five for a list of devices.
See Appendix five for a list of devices.

See Appendix five for a list of devices.

See Appendix five for a list of devices.
References


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Lundstrom LH, Moller AM, Rosenstock C, Astrup G, Wetterslev J. High body mass index is a weak predictor for difficult and failed tracheal intubation: a cohort study of 91,332 consecutive patients scheduled for direct laryngoscopy registered in the Danish Anesthesia Database. Anesthesiology. 2009 Feb;110(2):266-74.


See Appendix five for a list of devices.
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See Appendix five for a list of devices.
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See Appendix five for a list of devices.


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References


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References


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See Appendix five for a list of devices.
References


229. See Appendix five for a list of devices.
See Appendix five for a list of devices.
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See Appendix five for a list of devices.
References


See Appendix five for a list of devices.
References


See Appendix five for a list of devices.
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References


616. Levitan RM, Higgins MS, Ochroch EA. Contrary to popular belief and traditional instruction, the larynx is sighted one eye at a time during direct laryngoscopy. Acad Emerg Med. 1998 Aug;5(8):844-6.


See Appendix five for a list of devices.
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